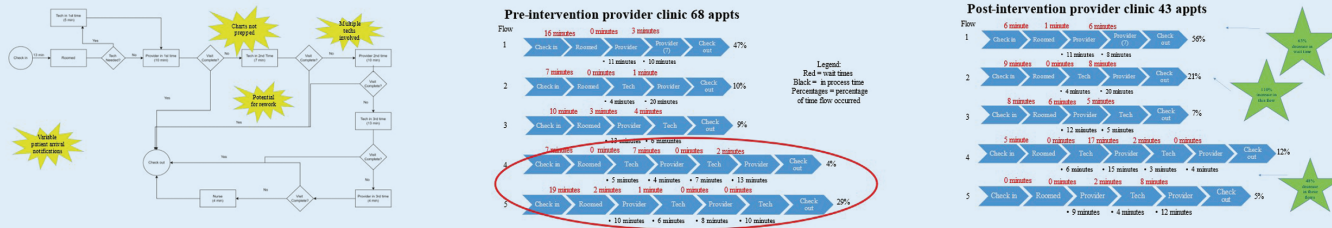




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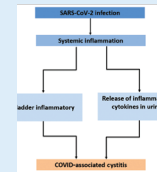
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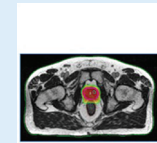
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For certain patients with HRRm mCRPC

DARE TO CHALLENGE

the treatment paradigm following progression
on prior enzalutamide or abiraterone^{1,2}

Not an actual patient.

INDICATION

LYNPARZA is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

There are no contraindications for LYNPARZA.

WARNINGS AND PRECAUTIONS

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML):

Occurred in approximately 1.5% of patients exposed to LYNPARZA monotherapy, and the majority of events had a fatal outcome. The median duration of therapy in patients who developed MDS/AML was 2 years (range: <6 months to >10 years). All of these patients had previous chemotherapy with platinum agents and/or other DNA-damaging agents, including radiotherapy.

Do not start LYNPARZA until patients have recovered from hematological toxicity caused by previous chemotherapy (\leq Grade 1). Monitor complete blood count for cytopenia at baseline and monthly thereafter for clinically significant changes during treatment. For prolonged hematological toxicities, interrupt LYNPARZA and monitor blood count weekly until recovery.

If the levels have not recovered to Grade 1 or less after 4 weeks, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics. Discontinue LYNPARZA if MDS/AML is confirmed.

Pneumonitis: Occurred in 0.8% of patients exposed to LYNPARZA monotherapy, and some cases were fatal. If patients present with new or worsening respiratory symptoms such as dyspnea, cough, and fever, or a radiological abnormality occurs, interrupt LYNPARZA treatment and initiate prompt investigation. Discontinue LYNPARZA if pneumonitis is confirmed and treat patient appropriately.

Venous Thromboembolic Events (VTE): Including severe or fatal pulmonary embolism (PE) occurred in patients treated with LYNPARZA. VTE occurred in 7% of patients with metastatic castration-resistant prostate cancer who received LYNPARZA plus androgen deprivation therapy (ADT) compared to 3.1% of patients receiving enzalutamide or abiraterone plus ADT in the PROfound study. Patients receiving LYNPARZA and ADT had a 6% incidence of pulmonary embolism compared to 0.8% of patients treated with ADT plus either enzalutamide or abiraterone. Monitor patients for signs and symptoms of venous thrombosis and pulmonary embolism, and treat as medically appropriate, which may include long-term anticoagulation as clinically indicated.

Embryo-Fetal Toxicity: Based on its mechanism of action and findings in animals, LYNPARZA can cause fetal harm. A pregnancy test is recommended for females of reproductive potential prior to initiating treatment.

Females

Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for 6 months following the last dose.

Males

Advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment and for 3 months following the last dose of LYNPARZA and to not donate sperm during this time.

ADVERSE REACTIONS—HRR Gene-mutated Metastatic Castration-Resistant Prostate Cancer

Most common adverse reactions (Grades 1-4) in $\geq 10\%$ of patients who received LYNPARZA for **PROfound** were: anemia (46%), fatigue (including asthenia) (41%), nausea (41%), decreased appetite (30%), diarrhea (21%), vomiting (18%), thrombocytopenia (12%), cough (11%), and dyspnea (10%).

Most common laboratory abnormalities (Grades 1-4) in $\geq 25\%$ of patients who received LYNPARZA for **PROfound** were: decrease in hemoglobin (98%), decrease in lymphocytes (62%), decrease in leukocytes (53%), and decrease in absolute neutrophil count (34%).

DRUG INTERACTIONS

Anticancer Agents: Clinical studies of LYNPARZA with other myelosuppressive anticancer agents, including DNA-damaging agents, indicate a potentiation and prolongation of myelosuppressive toxicity.

CYP3A Inhibitors: Avoid coadministration of strong or moderate CYP3A inhibitors when using LYNPARZA. If a strong or moderate CYP3A inhibitor must be coadministered, reduce the dose of LYNPARZA. Advise patients to avoid grapefruit, grapefruit juice, Seville oranges, and Seville orange juice during LYNPARZA treatment.

CYP3A Inducers: Avoid coadministration of strong or moderate CYP3A inducers when using LYNPARZA.

USE IN SPECIFIC POPULATIONS

Lactation: No data are available regarding the presence of olaparib in human milk, its effects on the breastfed infant or on milk production. Because of the potential for serious adverse reactions in the breastfed infant, advise a lactating woman not to breastfeed during treatment with LYNPARZA and for 1 month after receiving the final dose.

Pediatric Use: The safety and efficacy of LYNPARZA have not been established in pediatric patients.

Hepatic Impairment: No adjustment to the starting dose is required in patients with mild or moderate hepatic impairment (Child-Pugh classification A and B). There are no data in patients with severe hepatic impairment (Child-Pugh classification C).

PROfound: A phase 3 trial of LYNPARZA in mCRPC^{1,3}

- A prospective, multicenter, randomized, open-label, phase 3 trial of LYNPARZA vs investigator's choice of enzalutamide or abiraterone in patients with HRRm* mCRPC
- **KEY ELIGIBILITY CRITERIA:** metastatic castration-resistant prostate cancer; progression on prior enzalutamide or abiraterone for the treatment of metastatic prostate cancer and/or CRPC; a tumor mutation in at least 1 of 15 genes involved in the HRR pathway
- Patients were divided by mutation: **BRCA1/2 or ATM gene mutation (Cohort A [n=245]^{†,‡}) and other HRR gene mutations (Cohort B [n=142]^{†,§})**, and randomization was stratified by prior receipt of taxane chemotherapy and presence of measurable disease by RECIST 1.1
- Each cohort was randomized 2:1 to receive LYNPARZA (tablets, 300 mg per dose, twice daily) or investigator's choice of enzalutamide or abiraterone^{||}

Although patients with *PPP2R2A* gene mutations were enrolled in the trial, LYNPARZA is not indicated for the treatment of patients with this gene mutation due to unfavorable risk-benefit ratio.

*HRR gene mutations (*BRCA1*, *BRCA2*, *ATM*, *BARD1*, *BRIP1*, *CDK12*, *CHEK1*, *CHEK2*, *FANCL*, *PALB2*, *PPP2R2A*, *RAD51B*, *RAD51C*, *RAD51D*, and/or *RAD54L*) were identified by tissue-based testing using the Foundation Medicine FoundationOne® clinical trial HRR assay performed at a central laboratory. No patients were enrolled who had mutations in 2 of the 15 prespecified HRR genes: *FANCL* and *RAD51C*.

[†]Patients with co-mutations (*BRCA1*, *BRCA2*, or *ATM* plus a Cohort B gene) were assigned to Cohort A.

[‡]All patients received a GnRH analog or had prior bilateral orchiectomy.

[§]*BARD1*, *BRIP1*, *CDK12*, *CHEK1*, *CHEK2*, *FANCL*, *PALB2*, *PPP2R2A*, *RAD51B*, *RAD51C*, *RAD51D*, or *RAD54L*.

^{||}Upon radiological progression confirmed by BICR, patients randomized to enzalutamide or abiraterone were given the option to switch to LYNPARZA.

PRIMARY ENDPOINT: RADIOLOGICAL PROGRESSION-FREE SURVIVAL (rPFS)¹

LYNPARZA more than doubled median rPFS vs investigator's choice of enzalutamide or abiraterone in Cohort A

LYNPARZA median rPFS (n=162)

7.4 MONTHS

(95% CI: 6.2–9.3)

>2X median rPFS

66% relative risk reduction of disease progression or death

HR=0.34, 95% CI: 0.25–0.47, P<0.0001

Investigator's choice of enzalutamide or abiraterone median rPFS (n=83)

3.6 MONTHS

(95% CI: 1.9–3.7)

- rPFS in Cohort A was determined by BICR using RECIST version 1.1 and PCWG3 (bone) criteria
- Consistent results were observed in exploratory analyses of rPFS:
 - For patients who received or did not receive prior taxane therapy
 - For those with germline *BRCA* mutations identified using the Myriad BRACAnalysis CDx® assay compared with those with *BRCA* mutations identified using the Foundation Medicine F1CDx assay

SELECT SECONDARY ENDPOINT: OVERALL SURVIVAL (OS)^{1,3}

LYNPARZA demonstrated an OS benefit and reduced risk of death by 31% vs investigator's choice of enzalutamide or abiraterone in Cohort A

LYNPARZA median OS (n=162)

19.1 MONTHS

(95% CI: 17.4–23.4)

31% reduced risk of death

HR=0.69, 95% CI: 0.50–0.97, P=0.0175

Investigator's choice of enzalutamide or abiraterone median OS (n=83)

14.7 MONTHS

(95% CI: 11.9–18.8)

PROfound was powered to evaluate several secondary endpoints within a hierarchical statistical analysis, including: ORR in Cohort A, rPFS in Cohorts A+B, OS in Cohort A

ADDITIONAL SECONDARY ENDPOINTS^{1,3}

• **ORR in Cohort A:** LYNPARZA significantly improved confirmed ORR as assessed by BICR vs investigator's choice of enzalutamide or abiraterone for patients with measurable disease at baseline: 33% (n=28) with LYNPARZA (95% CI: 23–45, P<0.0001; n=84) vs 2% (n=1) with investigator's choice of enzalutamide or abiraterone (95% CI: 0–12, P<0.0001; n=43)

• **rPFS in Cohorts A+B:** LYNPARZA improved median rPFS as assessed by BICR vs investigator's choice of enzalutamide or abiraterone: 5.8 months median rPFS with LYNPARZA (95% CI: 5.5–7.4; n=256) vs 3.5 months median rPFS with investigator's choice of enzalutamide or abiraterone (95% CI: 2.2–3.7; n=131)

IMPORTANT SAFETY INFORMATION (CONT'D) USE IN SPECIFIC POPULATIONS (CONT'D)

Renal Impairment: No dosage modification is recommended in patients with mild renal impairment (CLcr 51-80 mL/min estimated by Cockcroft-Gault). In patients with moderate renal impairment (CLcr 31-50 mL/min), reduce the dose of LYNPARZA to 200 mg twice daily. There are no data in patients with severe renal impairment or end-stage renal disease (CLcr ≤30 mL/min).

You are encouraged to report the negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

Please see Brief Summary of Prescribing Information on the following page.

BICR=blinded independent central review; CI=confidence interval; CRPC=castration-resistant prostate cancer; FDA=US Food and Drug Administration; GnRH=gonadotropin-releasing hormone; HR=hazard ratio; HRR=homologous recombination repair; HRRm=homologous recombination repair gene-mutated; mCRPC=metastatic castration-resistant prostate cancer; ORR=objective response rate; OS=overall survival; PARPi=poly (ADP-ribose) polymerase inhibitor; PCWG3=Prostate Cancer Working Group 3; RECIST=Response Evaluation Criteria in Solid Tumors; rPFS=radiological progression-free survival.

References: 1. LYNPARZA® (olaparib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2022. 2. Teo MY, Rathkopf DE, Kantoff P. Treatment of advanced prostate cancer. *Annu Rev Med.* 2019;70:479-499. 3. de Bono J, Mateo J, Fizazi K, et al. Olaparib for metastatic castration resistant prostate cancer. *N Engl J Med.* 2020;382(22):2091-2102.

LYNPARZA® (olaparib) tablets, for oral use

Initial U.S. Approval: 2014

Brief Summary of Prescribing Information. For complete prescribing information consult official package insert.

INDICATIONS AND USAGE

HRR Gene-mutated Metastatic Castration-Resistant Prostate Cancer

Lynparza is indicated for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza [see Dosage and Administration (2.1) in the full Prescribing Information].

DOSAGE AND ADMINISTRATION

Patient Selection

Information on FDA-approved tests for the detection of genetic mutations is available at <http://www.fda.gov/companiondiagnostics>.

Select patients for treatment with Lynparza based on the presence of deleterious or suspected deleterious HRR gene mutations, including BRCA mutations, or genomic instability based on the indication, biomarker, and sample type (Table 1).

Table 1 Biomarker Testing for Patient Selection*

Indication	Biomarker	Sample type		
		Tumor	Blood	Plasma (ctDNA)
Germline or somatic HRR gene-mutated metastatic castration-resistant prostate cancer	ATMm, BRCA1m, BRCA2m, BARD1m, BRIP1m, CDK12m, CHEK1m, CHEK2m, FANCLm, PALB2m, RAD51Bm, RAD51Cm, RAD51Dm, RAD54Lm	X		
	gBRCA1m, gBRCA2m		X	
	ATMm, BRCA1m, BRCA2m			X

* Where testing fails or tissue sample is unavailable/insufficient, or when germline testing is negative, consider using an alternative test, if available.

Recommended Dosage

The recommended dosage of Lynparza is 300 mg taken orally twice daily, with or without food. If a patient misses a dose of Lynparza, instruct patient to take their next dose at its scheduled time. Instruct patients to swallow tablets whole. Do not chew, crush, dissolve, or divide tablet.

HRR Gene-mutated Metastatic Castration-Resistant Prostate Cancer
Continue treatment until disease progression or unacceptable toxicity for:

- HRR gene-mutated metastatic castration-resistant prostate cancer

Patients receiving Lynparza for mCRPC should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.

Dosage Modifications for Adverse Reactions

To manage adverse reactions, consider interruption of treatment or dose reduction. The recommended dose reduction is 250 mg taken twice daily.

If a further dose reduction is required, then reduce to 200 mg taken twice daily.

Dosage Modifications for Concomitant Use with Strong or Moderate CYP3A Inhibitors

Avoid concomitant use of strong or moderate CYP3A inhibitors with Lynparza.

If concomitant use cannot be avoided, reduce Lynparza dosage to:

- 100 mg twice daily when used concomitantly with a strong CYP3A inhibitor.
- 150 mg twice daily when used concomitantly with a moderate CYP3A inhibitor.

After the inhibitor has been discontinued for 3 to 5 elimination half-lives, resume the Lynparza dose taken prior to initiating the CYP3A inhibitor [see Drug Interactions (7.2) and Clinical Pharmacology (12.3) in the full Prescribing Information].

Dosage Modifications for Renal Impairment

Moderate Renal Impairment

In patients with moderate renal impairment (CL_{Cr} 31-50 mL/min), reduce the Lynparza dosage to 200 mg orally twice daily [see Use in Specific Populations (8.6) and Clinical Pharmacology (12.3) in the full Prescribing Information].

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Myelodysplastic Syndrome/Acute Myeloid Leukemia

Myelodysplastic syndrome (MDS)/Acute Myeloid Leukemia (AML) has occurred in patients treated with Lynparza and some cases were fatal.

In clinical studies enrolling 2901 patients with various cancers who received Lynparza as a single agent [see Adverse Reactions (6.1) in the full Prescribing Information], the cumulative incidence of MDS/AML was approximately 1.5% (43/2901). Of these, 51% (22/43) had a fatal outcome. The median duration of therapy with Lynparza in patients who developed MDS/AML was 2 years (range: < 6 months to > 10 years). All of these patients had received previous chemotherapy with platinum agents and/or other DNA damaging agents including radiotherapy.

Do not start Lynparza until patients have recovered from hematological toxicity caused by previous chemotherapy (≤ Grade 1). Monitor complete blood count for cytopenia at baseline and monthly thereafter for clinically significant changes during treatment. For prolonged hematological toxicities, interrupt Lynparza and monitor blood counts weekly until recovery. If the levels have not recovered to Grade 1 or less after 4 weeks, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics. If MDS/AML is confirmed, discontinue Lynparza.

Pneumonitis

In clinical studies enrolling 2901 patients with various cancers who received Lynparza as a single agent [see Adverse Reactions (6.1) in the full Prescribing Information], the incidence of pneumonitis, including fatal cases, was 0.8% (24/2901). If patients present with new or worsening respiratory symptoms such as dyspnea, cough and fever, or a radiological abnormality occurs, interrupt Lynparza treatment and promptly assess the source of the symptoms. If pneumonitis is confirmed, discontinue Lynparza treatment and treat the patient appropriately.

Venous Thromboembolic Events

Venous thromboembolic events (VTE), including severe or fatal pulmonary embolism (PE), occurred in patients treated with Lynparza [see Adverse Reactions (6.1) in the full Prescribing Information]. VTE occurred in 7% of patients with metastatic castration resistant prostate cancer who received Lynparza plus androgen deprivation therapy (ADT) compared to 3.1% of patients receiving enzalutamide or abiraterone plus ADT in the PROfound study. Patients receiving Lynparza and ADT had a 6% incidence of pulmonary embolism compared to 0.8% of patients treated with ADT plus either enzalutamide or abiraterone. Monitor patients for signs and symptoms of venous thrombosis and pulmonary embolism and treat as medically appropriate, which may include long-term anticoagulation as clinically indicated.

Embryo-Fetal Toxicity

Lynparza can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings in animals. In an animal reproduction study, administration of olaparib to pregnant rats during the period of organogenesis caused teratogenicity and

embryo-fetal toxicity at exposures below those in patients receiving the recommended human dose of 300 mg twice daily. Apprise pregnant women of the potential hazard to a fetus and the potential risk for loss of the pregnancy. Advise females of reproductive potential to use effective contraception during treatment and for 6 months following the last dose of Lynparza. Based on findings from genetic toxicity and animal reproduction studies, advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment and for 3 months following the last dose of Lynparza [see Use in Specific Populations (8.1, 8.3) in the full Prescribing Information].

ADVERSE REACTIONS

The following adverse reactions are discussed elsewhere in the labeling:

- Myelodysplastic Syndrome/Acute Myeloid Leukemia [see Warnings and Precautions (5.1) in the full Prescribing Information]
- Pneumonitis [see Warnings and Precautions (5.2) in the full Prescribing Information]
- Venous Thromboembolic Events [see Warnings and Precautions (5.3) in the full Prescribing Information]

Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described in the WARNINGS AND PRECAUTIONS reflect exposure to Lynparza as a single agent in 2901 patients; 2135 patients with exposure to 300 mg twice daily tablet dose including five controlled, randomized, trials (SOLO-1, SOLO-2, OlympiAD, POLO, and PROfound) and to 400 mg twice daily capsule dose in 766 patients in other trials that were pooled to conduct safety analyses. In these trials, 56% of patients were exposed for 6 months or longer and 28% were exposed for greater than one year in the Lynparza group.

In this pooled safety population, the most common adverse reactions in ≥10% of patients were nausea (60%), fatigue (55%), anemia (36%), vomiting (32%), diarrhea (24%), decreased appetite (22%), headache (16%), dysgeusia (15%), cough (15%), neutropenia (14%), dyspnea (14%), dizziness (12%), dyspepsia (12%), leukopenia (11%), and thrombocytopenia (10%).

HRR Gene-mutated Metastatic Castration-Resistant Prostate Cancer

PROfound

The safety of Lynparza as monotherapy was evaluated in patients with mCRPC and HRR gene mutations who have progressed following prior treatment with enzalutamide or abiraterone in PROfound [see Clinical Studies (14.7) in the full Prescribing Information]. This study was a randomized, open-label, multi-center study in which 386 patients received either Lynparza tablets 300 mg orally twice daily (n=256) or investigator's choice of enzalutamide or abiraterone acetate (n=130) until disease progression or unacceptable toxicity. Among patients receiving Lynparza, 62% were exposed for 6 months or longer and 20% were exposed for greater than one year.

Fatal adverse reactions occurred in 4% of patients treated with Lynparza. These included pneumonia (1.2%), cardiopulmonary failure (0.4%), aspiration pneumonia (0.4%), intestinal diverticulum (0.4%), septic shock (0.4%), Budd-Chiari Syndrome (0.4%), sudden death (0.4%), and acute cardiac failure (0.4%).

Serious adverse reactions occurred in 36% of patients receiving Lynparza. The most frequent serious adverse reactions (≥2%) were anemia (9%), pneumonia (4%), pulmonary embolism (2%), fatigue/asthenia (2%), and urinary tract infection (2%).

Dose interruptions due to an adverse reaction of any grade occurred in 45% of patients receiving Lynparza; dose reductions due to an adverse reaction occurred in 22% of Lynparza patients. The most frequent adverse reactions leading to dose interruption of Lynparza were anemia (25%) and thrombocytopenia (6%) and the most frequent adverse reaction leading to reduction of Lynparza was anemia (16%). Discontinuation due to adverse reactions occurred in 18% of Lynparza. The adverse reaction that most frequently led to discontinuation of Lynparza was anemia (7%).

Tables 16 and 17 summarize the adverse reactions and laboratory abnormalities, respectively, in patients in PROfound.

Table 16 Adverse Reactions* Reported in ≥10% of Patients in PROfound

Adverse Reactions	Lynparza tablets n=256		Enzalutamide or abiraterone n=130	
	Grades 1-4 (%)	Grades 3-4 (%)	Grades 1-4 (%)	Grades 3-4 (%)
Blood and lymphatic disorders				
Anemia ^a	46	21	15	5
Thrombocytopenia ^a	12	4	3	0
Gastrointestinal disorders				
Nausea	41	1	19	0
Diarrhea	21	1	7	0
Vomiting	18	2	12	1
General disorders and administration site conditions				
Fatigue (including asthenia)	41	3	32	5
Metabolism and nutrition disorders				
Decreased appetite	30	1	18	1
Respiratory, thoracic, and mediastinal disorders				
Cough	11	0	2	0
Dyspnea	10	2	3	0

* Graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.03

[†] Includes anemia and hemoglobin decreased

[‡] Includes platelet count decreased and thrombocytopenia

In addition, adverse reactions of clinical relevance in PROfound that occurred in <10% of patients receiving Lynparza were neutropenia (9%), VTE (7%), dizziness (7%), dysgeusia (7%), dyspepsia (7%), headache (6%), pneumonia (5%), stomatitis (5%), rash (4%), blood creatinine increase (4%), pneumonitis (2%), upper abdominal pain (2%), and hypersensitivity (1%).

Table 17 Laboratory Abnormalities Reported in ≥25% of Patients in PROfound

Laboratory Parameter*	Lynparza tablets n= 256		Enzalutamide or abiraterone n=130	
	Grades 1-4 n= 247 (%)	Grades 3-4 n=247 (%)	Grades 1-4 n=124 (%)	Grades 3-4 n=124 (%)
Decrease in hemoglobin	242 (98)	33 (13)	91 (73)	5 (4)
Decrease in lymphocytes	154 (62)	57 (23)	42 (34)	16 (13)
Decrease in leukocytes	130 (53)	9 (4)	26 (21)	0
Decrease in absolute neutrophil count	83 (34)	8 (3)	11 (9)	0

* Patients were allowed to enter clinical studies with laboratory values of CTCAE Grade 1.

[†] This number represents the safety population. The derived values in the table are based on the total number of evaluable patients for each laboratory parameter.

Postmarketing Experience

The following adverse reactions have been identified during post approval use of Lynparza. Because these reactions are reported voluntarily from a population of uncertain size, it is

not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Immune System Disorders: Hypersensitivity including angioedema.

Skin and subcutaneous tissue disorders: Erythema nodosum, rash, dermatitis.

DRUG INTERACTIONS

Use with Anticancer Agents

Clinical studies of Lynparza with other myelosuppressive anticancer agents, including DNA damaging agents, indicate a potentiation and prolongation of myelosuppressive toxicity.

Effect of Other Drugs on Lynparza

Strong and Moderate CYP3A Inhibitors

Coadministration of CYP3A inhibitors can increase olaparib concentrations, which may increase the risk for adverse reactions [see Clinical Pharmacology (12.3) in the full Prescribing Information]. Avoid coadministration of strong or moderate CYP3A inhibitors. If the strong or moderate inhibitor must be coadministered, reduce the dose of Lynparza [see Dosage and Administration (2.4) in the full Prescribing Information].

Strong and Moderate CYP3A Inducers

Concomitant use with a strong or moderate CYP3A inducer decreased olaparib exposure, which may reduce Lynparza efficacy [see Clinical Pharmacology (12.3) in the full Prescribing Information]. Avoid coadministration of strong or moderate CYP3A inducers.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on findings in animals and its mechanism of action [see Clinical Pharmacology (12.1) in the full Prescribing Information], Lynparza can cause fetal harm when administered to a pregnant woman. There are no available data on Lynparza use in pregnant women to inform the drug-associated risk. In an animal reproduction study, the administration of olaparib to pregnant rats during the period of organogenesis caused teratogenicity and embryo-fetal toxicity at exposures below those in patients receiving the recommended human dose of 300 mg twice daily (see Data). Apprise pregnant women of the potential hazard to the fetus and the potential risk for loss of the pregnancy.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. The estimated background risk in the U.S. general population of major birth defects is 2-4%; and the risk for spontaneous abortion is approximately 15-20% in clinically recognized pregnancies.

Data

Animal Data

In a fertility and early embryonic development study in female rats, olaparib was administered orally for 14 days before mating through to Day 6 of pregnancy, which resulted in increased post-implantation loss at a dose level of 15 mg/kg/day (with maternal systemic exposures approximately 7% of the human exposure (AUC_{0-24h}) at the recommended dose).

In an embryo-fetal development study, pregnant rats received oral doses of 0.05 and 0.5 mg/kg/day olaparib during the period of organogenesis. A dose of 0.5 mg/kg/day (with maternal systemic exposures approximately 0.18% of human exposure (AUC_{0-24h}) at the recommended dose) caused embryo-fetal toxicities including increased post-implantation loss and major malformations of the eyes (anophthalmia, microphthalmia), vertebrae/ribs (extra rib or ossification center; fused or absent neural arches, ribs, and sternbrae), skull (fused exoccipital), and diaphragm (hernia). Additional abnormalities or variants included incomplete or absent ossification (vertebrae/sternbrae, ribs, limbs) and other findings in the vertebrae/sternbrae, pelvic girdle, lung, thymus, liver, ureter, and umbilical artery. Some findings noted above in the eyes, ribs, and ureter were observed at a dose of 0.05 mg/kg/day olaparib at lower incidence.

Lactation

Risk Summary

No data are available regarding the presence of olaparib in human milk, or on its effects on the breastfed infant or on milk production. Because of the potential for serious adverse reactions in the breastfed infants from Lynparza, advise a lactating woman not to breastfeed during treatment with Lynparza and for one month after receiving the last dose.

Females and Males of Reproductive Potential

Pregnancy Testing

Recommend pregnancy testing for females of reproductive potential prior to initiating treatment with Lynparza.

Contraception

Females

Lynparza can cause fetal harm when administered to a pregnant woman [see Use in Specific Populations (8.1) in the full Prescribing Information]. Advise females of reproductive potential to use effective contraception during treatment with Lynparza and for at least 6 months following the last dose.

Males

Based on findings in genetic toxicity and animal reproduction studies, advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment and for 3 months following the last dose of Lynparza. Advise male patients not to donate sperm during therapy and for 3 months following the last dose of Lynparza [see Use in Specific Populations (8.1) and Nonclinical Toxicology (13.1) in the full Prescribing Information].

Pediatric Use

Safety and effectiveness of Lynparza have not been established in pediatric patients.

Geriatric Use

Of the 2901 patients with advanced solid tumors who received Lynparza as a single agent, 680 (23%) patients were aged ≥65 years, and this included 206 (7%) patients who were aged ≥75 years. Thirteen (0.4%) patients were aged ≥85 years.

Of the 535 patients with advanced solid tumors who received Lynparza tablets 300 mg orally twice daily in combination with bevacizumab, 204 (38%) patients were aged ≥65 years, and this included 31 (6%) patients who were aged ≥75 years.

No overall differences in the safety or effectiveness of Lynparza were observed between these patients and younger patients.

Renal Impairment

No dosage modification is recommended in patients with mild renal impairment (CL_{Cr} 51 to 80 mL/min estimated by Cockcroft-Gault). Reduce Lynparza dosage to 200 mg twice daily in patients with moderate renal impairment (CL_{Cr} 31 to 50 mL/min) [see Dosage and Administration (2.5) in the full Prescribing Information]. There are no data in patients with severe renal impairment or end-stage disease (CL_{Cr} ≤30 mL/min) [see Clinical Pharmacology (12.3) in the full Prescribing Information].

Hepatic Impairment

No adjustment to the starting dose is required in patients with mild or moderate hepatic impairment (Child-Pugh classification A and B). There are no data in patients with severe hepatic impairment (Child-Pugh classification C) [see Clinical Pharmacology (12.3) in the full Prescribing Information].

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Fighting Frustration: Using Lean Methodology to Improve Workflows

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Urologists continue to experience burnout at an alarming rate. The more recent census data show 36% of urologists are experiencing burnout. Further, the gender gap has vastly widened, with women experiencing burnout growing from 35% to 49% from 2016 to 2021, compared to 36% to 35% in men.¹ Burnout is associated with substance abuse, depression, and physician suicide.^{2,3} Expectedly, these conditions are associated with providing decreased quality of care, worse patient satisfaction, and increased adverse events.⁴ Interestingly, the 2020 AUA Census results show lack of time as a substantial barrier to professional success and the 2021 Census shows 75% of men and 95% of women experience conflict between work and personal responsibilities.^{5,6} We can use the application of lean methodology to aid in efficient workflows to enhance timeliness.

The use of lean methodology has been shown to reduce waste and streamline processes.⁷ In the recent AUA webinar we discussed the correct environment for quality improvement (QI) and how the right culture fosters an attitude toward continuous improvement. We also discussed the proper QI process, which includes choosing the right process, communicating with key stakeholders, constructing a current state process map, constructing an ideal state process map, constructing a future state process map, implementing a Plan Do Study Act (PDSA) cycle, standardizing the process, and auditing the process. The webinar went into each of these in further detail. Afterward, we demonstrated the QI process in a urology clinic. The clinic was felt to be functioning inefficiently. Time studies were done to examine the clinic flow. These flows were found to be erratic and not standardized (Figures 1 and 2). Five different workflows existed, with the highly inefficient flows occurring 33% of the time.

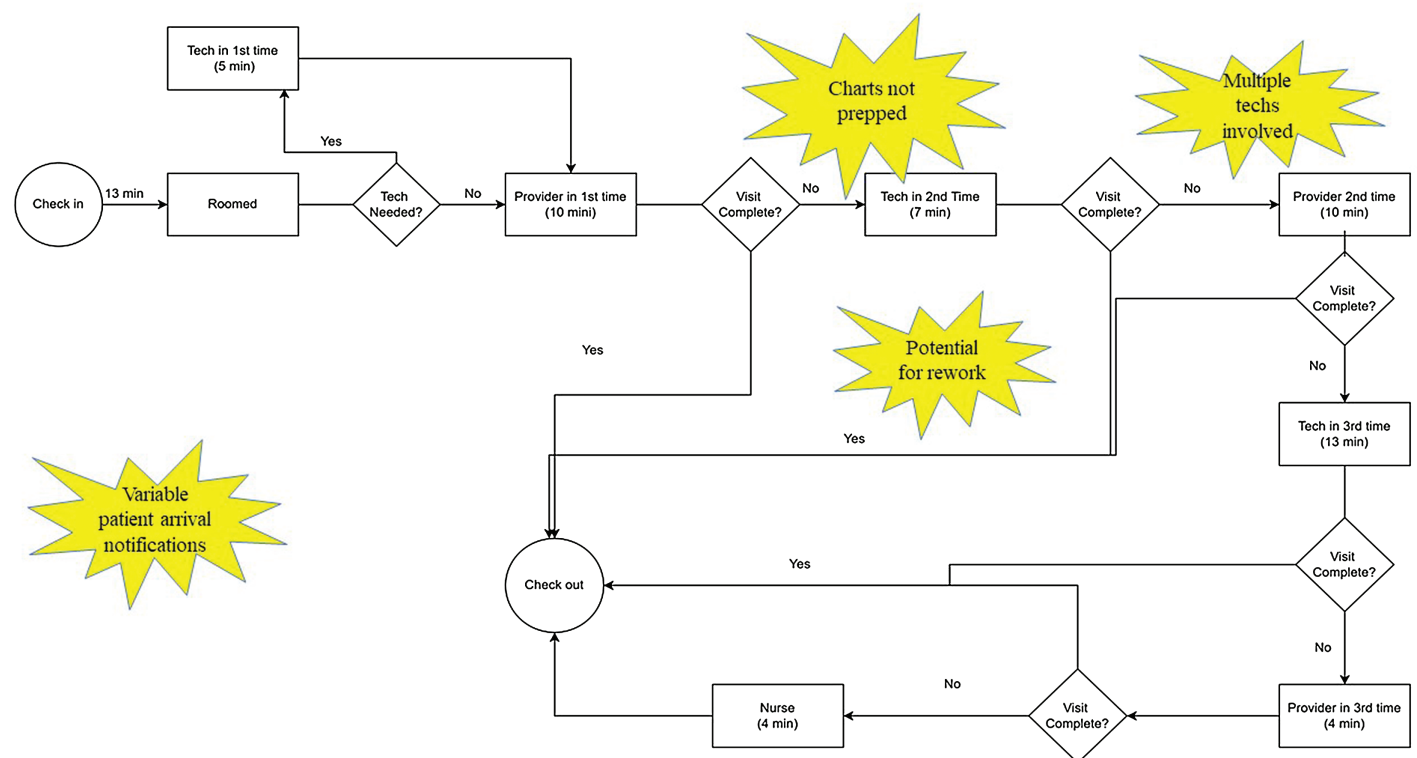


Figure 1. Current state process map.

Patient wait times were 15 minutes, and total appointment time was 36 minutes. The current process did not have the charts prepped, so no one knew if the patients needed attention prior to the physician visit, such as a urinalysis or post-void residual. This created substantial rework, with the patients going in

to see the provider and then out to see the medical assistant and then back in to see the provider. Multiple medical assistants were involved in 1 patient's care, often with the medical assistants being unaware of what the other medical assistants might have already done for the patient. This, again, created substantial re-

work. These issues were identified through studying the process.

The next steps were to design interventions to ease these inefficient flows. The team decided to assign each provider to a medical assistant for the day. This way the

→ Continued on page 7

Pre-intervention provider clinic 68 appts

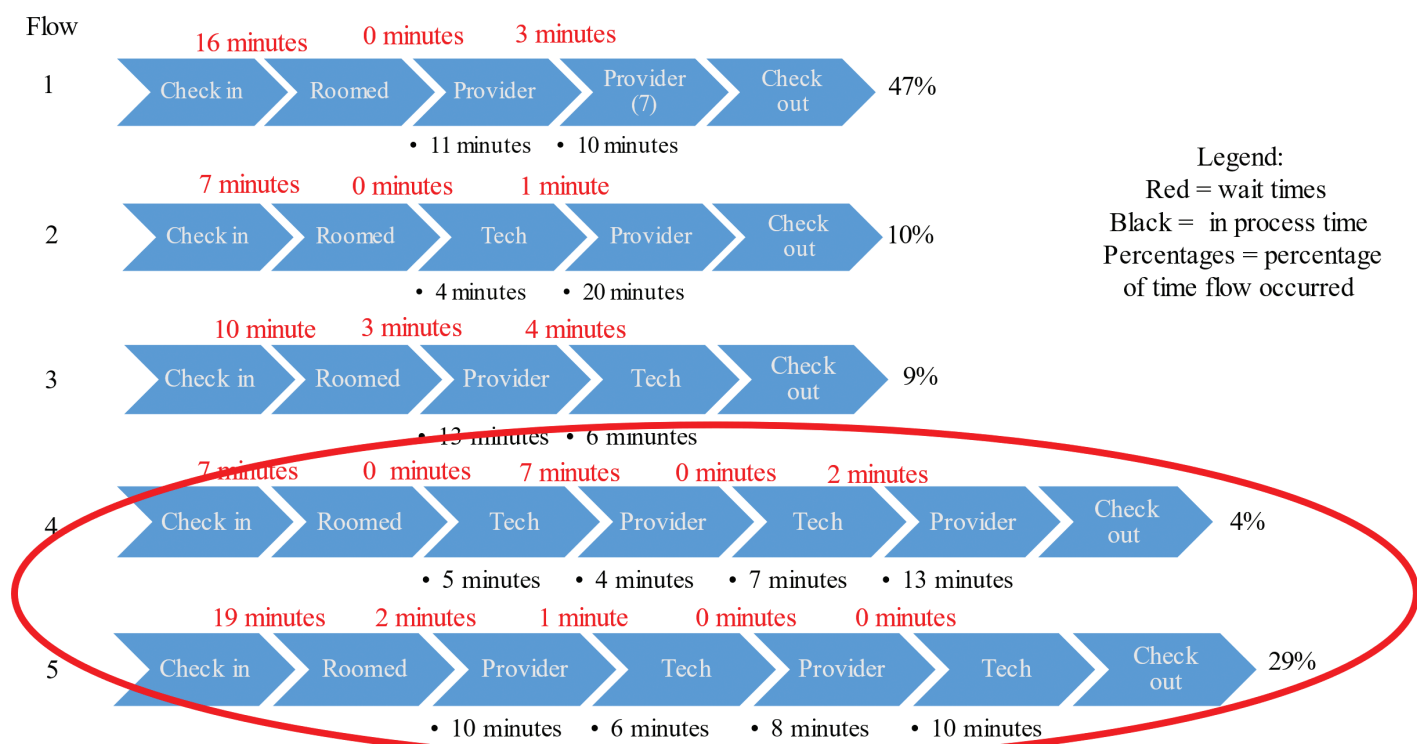


Figure 2. Description of pre-intervention patient flows with times.

AUA TAKE 5

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1

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3

The AUA is now accepting nominations for the 2023 Early-Career Investigators Workshop (ECIW), to be held October 19-21, 2023 at AUA Headquarters in Linthicum, MD. Foster your career development in urological research and receive an in-depth, hands-on tutorial on successful grant writing. Learn more and submit your nomination today!

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4

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5

At our inaugural *Urology Practice*® (UPJ) Editors' Workshop, listen to our Editors give advice on how to submit a strong paper for publication consideration in UPJ. Drs Gina Badalato, Mark Edney, Kevin Koo, and Rena Malik discuss what makes *Urology Practice*® the destination journal for your paper. The editors share priority topic areas for submission, give advice on how to submit a sound paper, and discuss common pitfalls to avoid.

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FIGHTING FRUSTRATION: USING LEAN METHODOLOGY

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Post-intervention provider clinic 43 appts

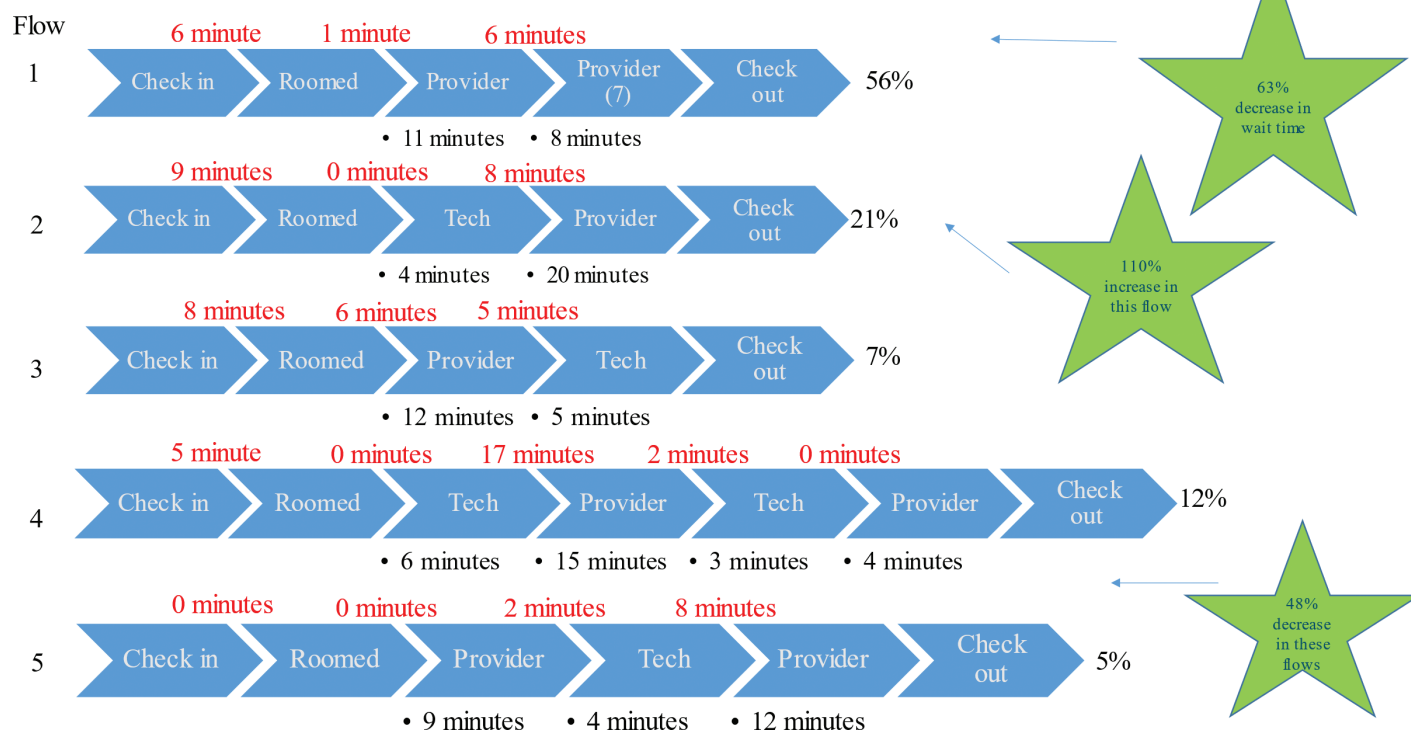


Figure 3. Description of post-intervention patient flows with times.

provider knew exactly with whom to speak if a medical assistant was needed to participate in the patient’s care. The medical assistants also prepped the charts prior to the start of clinic so they had an idea of who would need their assistance. The medical assistant and the provider would then huddle prior to the start of clinic to validate which patients needed items such as a urinalysis or post-void residual. The team then studied the process

again. After the PDSA cycle, substantial improvements were seen. A 48% decrease was seen in the most inefficient flows. The new process resulted in a 63% decrease in wait times in the more efficient flows. Overall, 6 minutes per appointment were saved, equating to 1.6 hours per day (Figure 3). This created a less chaotic clinic environment and allowed staff to have needed daily breaks, which greatly improved morale.

Utilization of QI methodology can help address some of the frustrations contributing to burnout, such as lack of time and work/personal conflict, by easing inefficiencies. Further, the QI tools will continue to be of importance as we focus on improving health care value. Those interested in learning how to develop improvement actions will benefit from learning how to utilize these tools. The full manuscript is referenced here.⁸ ■

“Utilization of QI methodology can help address some of the frustrations contributing to burnout, such as lack of time and work/personal conflict, by easing inefficiencies.”

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Antibiotic Stewardship in Urological Procedures: Are Prophylactic Recommendations Appropriate?

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Despite antimicrobial prophylaxis, transurethral procedures still carry a significant risk of postoperative urinary tract infection.^{1,2} To guide urologists, the AUA has developed a best practice statement looking at perioperative antimicrobial prophylaxis,³ with the current recommendations offering a single dose of trimethoprim-sulfamethoxazole (TMP-SMX)

or a first- or second-generation cephalosporin as the first-choice prophylaxis for most transurethral procedures. Second-line choices include amoxicillin/clavulanate or an aminoglycoside with or without ampicillin. There is an important caveat in this best practice statement, that urologists should turn to their local antibiograms when selecting a preferred regimen.

The best practice statement was initially written in 2008 (reviewed in 2011)⁴ and updated in 2019.³ After reviewing the new recommendations, we promptly changed our practice to use of TMP-SMX or cefazolin

in most cases. Serendipitously, around the same time, we received an email from our hospital infection control, which contained updated antibiograms. We were surprised to find that for *Escherichia coli* (the most common cause of post-transurethral procedure infection^{2,5}), our hospital didn’t report first-generation cephalosporin (second-generation was approximately 90%) susceptibility and that TMP-SMX susceptibility was less than 80%. We began to change our regimen for transurethral procedures (we use ceftriaxone in the absence of positive culture data) and began to consider whether there

was a better universal first-line choice for prophylaxis for transurethral procedures.

We analyzed national trends in antimicrobial resistance by evaluating antibiograms from 40 states, 22 of which provided state-level data.⁶ We focused on looking at *E. coli*, *Klebsiella* spp, methicillin-sensitive *Staphylococcus aureus*, and *Proteus mirabilis* as these are commonly identified agents of post-procedural infection. We focused on susceptibility patterns for antibiotics typically used for antimicrobial

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ANTIBIOTIC STEWARDSHIP IN UROLOGICAL PROCEDURES

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prophylaxis or for the treatment of urinary tract infection. These antibiotics included first-generation cephalosporins, third-generation cephalosporins, TMP-SMX, fluoroquinolones, penicillin combinations, and aminoglycosides. We were able to determine that there is high variability from state to state in the susceptibility to these antibiotics, and that both TMP-SMX and first-generation cephalosporins had poor coverage in many states. Figure 1 illustrates both the comparatively low effectiveness of TMP-SMX and first-generation cephalosporins, as well as the high variability in susceptibility from state to state. Given this, we found it improbable that there could be a nationwide relatively narrow-spectrum choice that would provide excellent coverage. So with this conclusion, the next step was to evaluate variability within a single state to determine if more regional/local guidelines would be appropriate.

Our home state of Missouri was used to test the next hypothesis—that there would be a good statewide choice that would provide high-level coverage across the state. We were able to obtain antibiogram data from 38 different hospitals across

Missouri.⁷ The same common pathogens were used and antimicrobial susceptibilities were reviewed. There was a lot of variability in susceptibility across the state (Figure 2), with limited correlation among hospital characteristics and susceptibility. Several antibiotics, including aminoglycosides and third-generation cephalosporins, outperformed both TMP-SMX and first-generation cephalosporins in most settings.

Putting the nationwide and state-level analysis together, there does not appear to be a universally optimal relatively narrow-spectrum antimicrobial at any level. We recommend that urologists use their individual hospital antibiograms when choosing antimicrobial prophylaxis. In the absence of a local antibiogram, we would recommend that urologists consider antimicrobials that appear to have higher coverage on average, such as third-generation cephalosporins or aminoglycosides (or even ertapenem), as opposed to the current AUA recommendation of TMP-SMX or a first-generation cephalosporin. While not directly evaluated in transurethral procedures, similar action in colorectal surgery decreased infections without

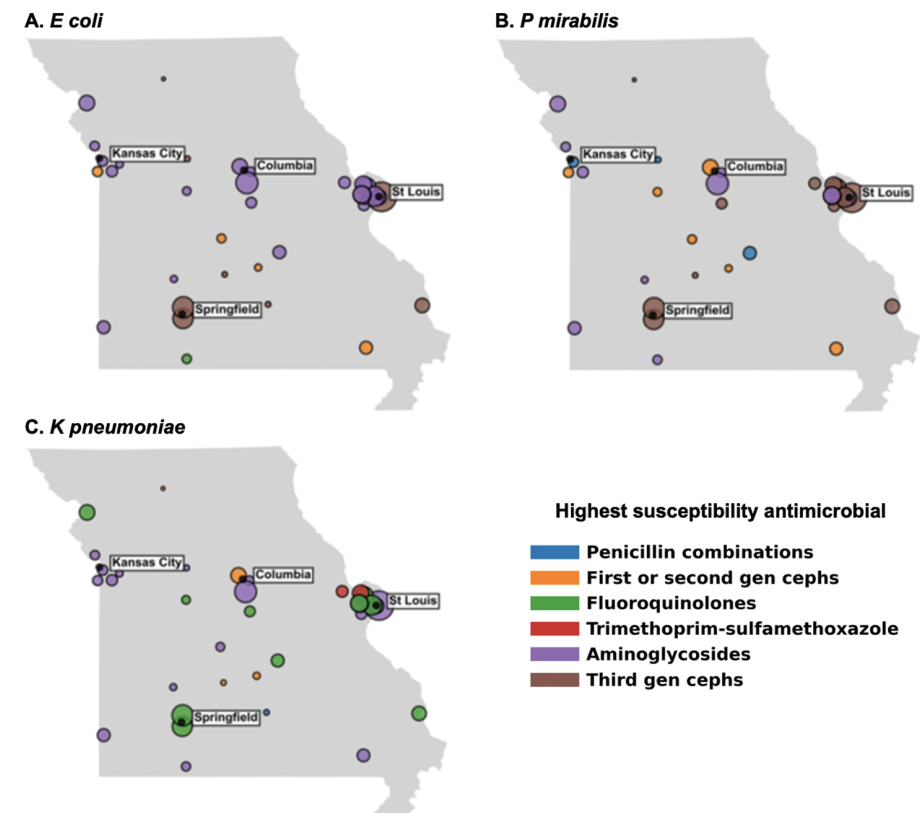


Figure 2. Antibiotic susceptibility for common urinary tract pathogens across a single state. gen cepts indicates generation cephalosporins. Reprinted with permission from Wright CC et al. *Urology*. 2023;10.1016/j.urology.2023.02.020.⁷

increasing antimicrobial resistance.^{8,9}

As many studies do, these studies have led to many more questions and potential areas of focus when considering antimicrobial prophylaxis recommendations. As noted in both the national and state-level studies, there were several locations in which data were missing or otherwise unobtainable even after several attempts. We would next seek to determine whether (1) physicians (urologists) know where to turn within their hospitals to locate this antimicrobial data, (2) urologists have used their local data to make treatment decisions or chose prophylaxis based upon AUA recommendations, and (3) changes in antimicrobial prophylaxis agent based on local antibiograms improve postoperative infections and complication rates.

Although antimicrobial perioperative antibiotic administration is standardized and even part of time-out procedures in the operating room, the choice of antibiotic has not been fully evaluated. Given the fluidity of antimicrobial susceptibility (both spatially and temporally), designing a good trial of this will require creativity or the use of very-broad-spectrum agents. Transurethral procedures are very common and postoperative in-

fection rates are high relative to other surgeries. Therefore, while challenging, this area is ripe for improvement with the potential to impact a great number of patients. ■

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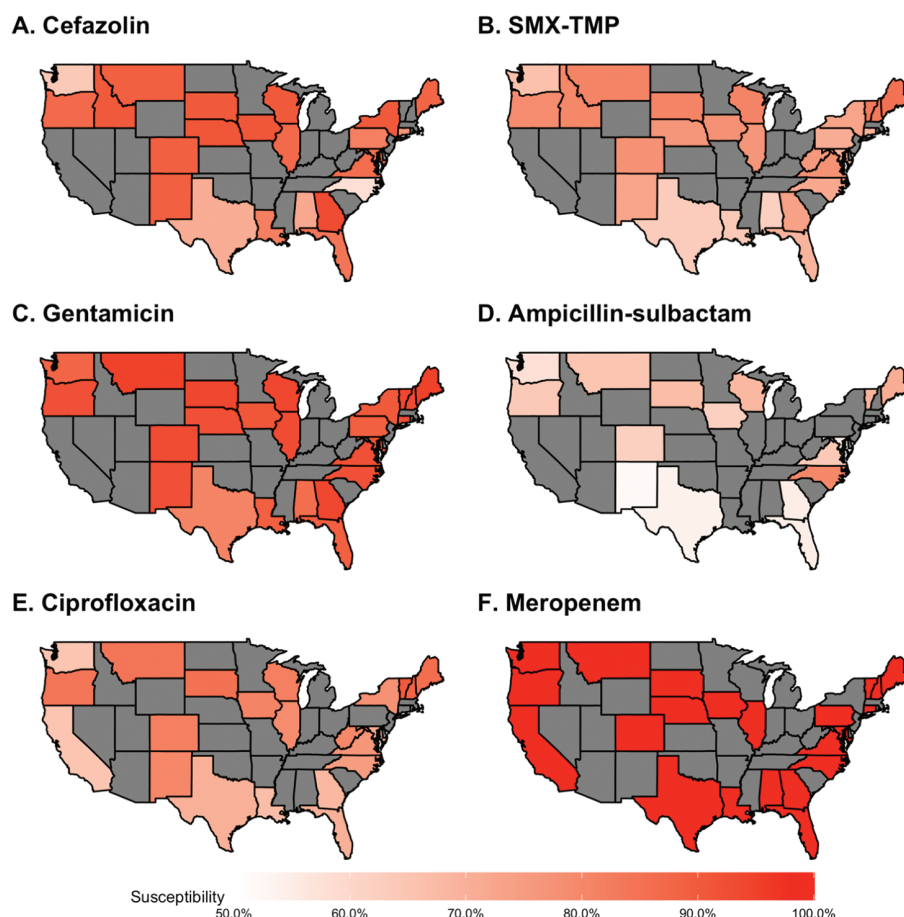


Figure 1. Antibiotic susceptibility for typical urinary tract pathogens. SMX-TMP indicates sulfamethoxazole-trimethoprim.

Complex Overactive Bladder

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Overactive bladder syndrome (OAB) is poorly understood and comprises several lower urinary tract symptoms. Identifying patients suffering with OAB is deceptively simple, given the broadly encompassing symptoms within the syndrome. However, a lack of a clear understanding of the pathophysiology, reliable diagnostic criteria, and targeted therapies make OAB complex to manage.

Idiopathic OAB is a diagnosis of exclusion with urgency being the central symptom, which is a subjective bladder sensation.¹ The symptomatology of OAB differs from person to person. Urgency and urgency incontinence have many phenotypes, with some patients having random urine leaking without any strong sensation, whereas others are leaking with known triggers such as running water or keys in the door, and others only in route to the toilet. Some have small volume leaks, whereas others completely flood and empty the bladder involuntarily. Urgency also has many variants, with constant urgency, urgency only when full, urgency sensed in the urethra only, post-void urgency, and many more. The only routinely used categorization of the condition is dry vs wet OAB, and it is not known if wet and dry OAB are different conditions or represent a spectrum of severity. Do these different symptoms have different etiologies?

Further complicating the diagnosis and management of OAB is that routine diagnostic testing may not reveal any abnormalities. For example, there are no pathognomonic findings on urodynamics (UDS), with a normal study being relatively common, especially among women,² and urodynamic parameters not correlating with symptom severity, scores on symptom scores, or response to medical therapy.³

The etiology and pathophysiology of OAB remain elusive, perhaps a sign there may not be one unifying explanation for OAB. Proposed pathophysiology ranges from afferent or efferent nerve dysfunction, detrusor muscle or mucosal disease,

or is it the central nervous system? Occult neurological dysfunction may be an explanation, especially among those patients who respond poorly to standard therapy.⁴

It is not surprising that this population, treated like a homogeneous condition, responds to treatments in a heterogeneous way with a large variability in treatment outcome, but little to help with treatment planning except through patient-centered shared decision-making.⁵ Better phenotyping for the clear purpose of offering more tailored therapy is greatly needed.⁶ A frail patient with difficulty mobilizing, having urgency incontinence going from sitting to standing is clearly different from the younger patient with constant urgency and small volume voiding days and night. The Symptoms of the Lower Urinary Tract Research Network is focusing solely on patients with urgency in their current recruitment to the study with hopes of better phenotyping to add on to the already refined clusters⁷ of symptoms and will be focusing on many of the abovementioned symptoms.

Conservative therapies such as urge suppression, timed voiding, and fluid/bladder irritant management remain mainstays in treatment, but other than a voiding diary that reveals excess fluid intake to target,⁸ there is scarce guidance. Often overlooked, however, is that these better habits must be continued even after moving on to second- or third-line therapy. A common cause of third-line therapy failures in my clinical practice are patients going back to old habits and having worsening OAB that appears perplexing until a voiding diary and history are completed.

The clinical equipoise between pharmacological treatment options makes treatment of OAB preference sensitive,⁵ meaning many oral agents with no clear superior regimen for symptom relief with all the long-acting agents improving symptoms similarly, and therapy is more often chosen for the favorable side effect profile or cost. There has been nascent work to predict response to anticholinergics using machine learning algorithms, but these tools have not been widely adopted.⁹ Given the likely hetero-

geneous nature of OAB, it would seem logical to at a minimum try both an antimuscarinic and beta3-agonists given their different receptor profile. While research has not produced other viable oral therapies, clearly these are needed since current options are limited and many do not wish to proceed to advanced treatment.

It is a logical solution to progress to third-line therapies with percutaneous tibial nerve stimulation, sacral neuromodulation, or botulinum toxin when oral agents fail. Unfortunately, just as there is equipoise with pharmacotherapy, there remains no testing or clear patient factor that will guide choices of third-line therapies since there is equivocal or absent data on effectiveness between options.¹⁰ Again, barring comorbid conditions such as fecal incontinence or incomplete bladder emptying on top of OAB where neuromodulation can have dual benefits, this is a preference-sensitive decision. As such, decision-making often rests on avoidance of side effects or complications.

The biggest dilemma facing clinicians is how to proceed when third-line agents fail. It is easy to simply try whatever third-line agent that has not been tried as the next step, but data are sparse on the effectiveness of this strategy and chances of success diminish with each failed attempt.¹¹ UDS is often employed, more to rule out other pathology such as stress incontinence or poor compliance, but there are still no clear UDS findings encouraging one modality over the other.⁶ In my clinical practice, repeating UDS is best utilized to uncover other missed diagnoses such as stress incontinence or bladder outflow obstruction.

The diagnosis and management of overactive bladder syndrome are complex; research has not identified a unifying pathophysiology, nor has diagnostic testing led to reliable patterns that can guide treatment. Nascent research has focused on phenotyping OAB, identifying predictors of treatment outcomes, and improved decision-making by incorporating these into shared decision-making. Each step presents an open opportunity for additional research. One thing is certain, we should strive for

“Nascent research has focused on phenotyping OAB, identifying predictors of treatment outcomes, and improved decision-making by incorporating these into shared decision-making.”

up-front and clear communication with patients regarding OAB as a poorly understood and chronic syndrome, with interventions designed to mitigate symptoms, rather than to “treat or resolve” an underlying condition. This may help reinforce the multimodal symptom management strategy that may cycle through treatments throughout the life course. ■

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Update on the Management of Malignant Ureteral Obstruction

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Malignant ureteral obstruction (MUO) is a common condition for urologists to manage. MUO may result from obstruction of a primary urothelial tumor, direct invasion from a nonurological malignancy, or compression from a tumor or metastatic lesion. Patients may present with renal colic, mild and nonspecific symptoms, or may be asymptomatic. With the latter, the obstruction is identified through abnormal laboratory findings or hydronephrosis incidentally found on imaging. In addition to pain, MUO may compromise renal function and lead to renal failure.

MUO is associated with unfavorable oncologic prognosis with patients typically having a life expectancy of less than 1 year.¹ Individualized prognosis and end of life or quality of life goals must be considered when deciding whether to intervene with ureteral decompression given that treatment-related side effects can lead to significant decreases in quality of life. Cordeiro et al developed a prognostic model for survival after palliative urinary diversion in MUO.² They found that greater than 4 events related to malignant dissemination (eg, number of metastasis, ascites, pleural effusion) and ECOG (Eastern Cooperative Oncology Group) performance status ≥ 2 were associated with shorter survival. Median 1-year survival rates were 44.9%, 15.5%, and 7.1% in patients with 0, 1, and 2 of these identified factors, respectively. In the absence of symptoms, observation alone is a very reasonable option for some patients pursuing a palliative approach that optimizes their quality of life. However, even in those with a noncurable diagnosis, ureteral decompression may relieve symptoms or preserve renal function, permitting palliative chemotherapy that may otherwise be contraindicated.

Upper tract decompression can

be carried out through several approaches. Cystoscopy with retrograde double-J stenting (DJS) is often the initial management for MUO, but it has limitations. First, in the setting of complete obstruction or altered anatomy, such as with bulky pelvic and retroperitoneal tumors, it may be impossible to advance a wire and stent across the obstruction. Furthermore, traditional DJS composed of polyurethane, silicone, or polymers may fail to provide long-term drainage in almost half of patients with MUO.^{3,4} A DJS may also fail from encrustation, migration, patient intolerance, or recurrent infections. Additionally, some polymer stents have a 3- to 4-month dwell time, which necessitates frequent exchanges negatively impacting quality of life. If a DJS fails, placement of tandem ureteral stents (TUSs) is another option. With this approach 2 DJSs are placed side by side. A recent study showed a stent failure rate of 13% with TUSs.⁵ TUSs still have potential drawbacks including still frequent exchanges and increased cost through use of the additional stent.

To better withstand external compressive forces, metallic stents have been developed. The Resonance stent is a 6F DJS constructed of coiled cobalt-chromium-nickel-molybdenum alloy (MP35N). It has an approved dwell time of up to 12 months and is designed to resist encrustation. Stent failure rate has been reported at 33%.⁶ Reducing the number of stent exchange procedures may improve quality of life and be more cost-effective. In our experience, these stents have been more likely to migrate compared with traditional DJS. This can lead to discomfort and malfunction of the stent. Other metallic stent options not available in the United States include the thermo-expandable metal alloy spiral stent (Memokath 051) and the self-expandable metallic mesh stent (UVENTA).

A reinforced silicone stent is

also available in the U.S. The Stenostent is a 12F reinforced silicone stent, which tapers to 8F at the coils with a dwell of up to 12 months. In a laboratory model, reinforced stents were shown to be more resistant to extrinsic compression compared to conventional polymer DJS designs.⁷ The wider 12F diameter of the stent can make it difficult to place in stent-naïve patients. We have generally used it in the setting of failure of a standard DJS. Other reinforced tumor stents are also available outside of the U.S. market.

Placement of a percutaneous nephrostomy (PCN) is traditionally the next step when stenting is not successful, not tolerated, or in stent failure. It should also be considered initially in patients needing urgent decompression in the setting of infection. In certain circumstances, patients may prefer PCN over ureteral stenting, and all patients should be counseled on the risks and benefits of PCN and ureteral stent prior to intervention. Advantages of PCN include maximized drainage, ability to be placed under local anesthesia, and easier monitoring of urine output and tube function. Disadvantages include ongoing need for 3-month exchanges and risk of infection, renal complications, and tube dislodgment, and patients actively anticoagulated may not be candidates. Also, the need for external urine collection can have quality of life consequences from impaired physical activity and sleep to negative effects on body image especially in a population likely to have experience with other external drainage or access tubes over the course of their oncologic care. A recent study showed that there were similar negative quality of life effects with both TUS and PCN placement, although patients who had been treated with both preferred TUS over PCN.⁸

Another diversion that can be used in the setting of MUO is permanent subcutaneous pyelovesical bypass. The Detour extra-anatomical urinary diversion is a reinforced silicone-lined tube that is tunneled subcutaneously from the renal collecting system to the bladder, bypassing the ureter. Although more invasive than DJS or PCN, subcutaneous bypass is intended to be permanent, obviating the need for exchange procedures required with the former. In a long-term assessment of 28 patients, the system was in and functioning in 94%, 71%, and 62% of patients at 1, 2, and 3 years, respectively.⁹

In conclusion, MUO can be managed with DJS, tandem ureteral stents, reinforced stents, metallic stents, PCN tubes, or extra-anatomical urinary diversion. All have potential downsides, so quality of life effects of each option, frequency of exchanges, and cost of exchange procedures should be taken into consideration. The indication for decompression should be weighed against goals of care and perceived benefits of decompression, such as ability to receive treatment such as chemotherapy or palliation of symptoms related to obstruction. ■

In conclusion, MUO can be managed with DJS, tandem ureteral stents, reinforced stents, metallic stents, PCN tubes, or extra-anatomical urinary diversion. All have potential downsides, so quality of life effects of each option, frequency of exchanges, and cost of exchange procedures should be taken into consideration. The indication for decompression should be weighed against goals of care and perceived benefits of decompression, such as ability to receive treatment such as chemotherapy or palliation of symptoms related to obstruction. ■

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Wearable Technology in Urology: Trendy Fashion or Here to Stay?

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Introduction

Wearable devices are ubiquitous. Over 30%–45% of U.S. adults use wearable devices, and their use is predicted to grow by 24.7% annually to create a U.S. market of \$139.35 billion by 2026.¹ The popularity of wearable devices has translated to their use in health care. Wearables allow clinicians to remotely monitor patients, resulting in reduced physician visits and improved health outcomes.² Insurance companies now offer wearable devices to promote healthy lifestyles, and have even offered incentives on the basis of targets. These devices have particular promise in the perioperative setting, where physical activity, sleep, and health trends can be monitored at a time when complications and readmissions remain at their highest. Additionally, wearable devices have shown potential in the field of urology, with 82% of patients reporting they would incorporate these devices into their urological treatment.³ Herein, we outline some of the current uses of wearable devices in urology.

Prostate Cancer

Wearable devices have been used successfully in prostate cancer patients. A study examining men on active surveillance showed that the Fitbit is able to track step counts.⁴ Furthermore, patients are accepting of the technology. The Fitbit was worn 98% of the time and 90.6% of patients were satisfied with the Fitbit. Wearable devices have also been used to provide insights into recovery after prostatectomy. In 2018, the team at Mayo Clinic Rochester utilized a Fitbit to track step counts and sleep in patients undergoing radical prostatectomy.⁵ The device was well received by patients and the authors found a significant decrease in steps taken postoperatively, but no difference in minutes slept or nighttime awakenings.

Bladder Cancer

In a prospective single-center study, authors at Cedars-Sinai examined if wearable monitors could predict length of stay after

major surgery.⁶ Patients, including those undergoing robotic cystectomy, wore a Fitbit on postoperative day (POD) 0 until discharge. The authors found that step count on POD1 was linearly associat-

ed with a decreased probability of prolonged length of stay up to 1,000 steps. Wearable monitors were shown to be an inexpensive

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WEARABLE TECHNOLOGY IN UROLOGY

→ Continued from page 11

platform to determine daily step counts. The authors proposed that wearables should be considered a “sixth vital sign” for health care teams.

In another prospective single-center study, a wearable monitor was used to track the physical activity and sleep habits of patients in the radical cystectomy perioperative period.⁷ The authors found that radical cystectomy patients had no differences in sleep throughout the perioperative period. However, there was a 50% decrease in moderate intensity exercise at POD30. These authors argue that wearable monitors can track objective measures of recovery after radical cystectomy and should be implemented into future cystectomy studies.

Men’s Health

Men’s sexual health represents an emerging field for wearable devices. The HuMOVE (Human

Movement) device is an electronic patch worn on a man’s back that tracks movement during sexual intercourse. The device allows physicians to evaluate for premature or delayed ejaculation through analysis of movement during intercourse. Although the device was validated to accurately measure intravaginal ejaculation latency and sexual performance,⁸ the device is not yet commercially available.

A variety of other male sexual health wearables have been introduced, although literature on their efficacy is lacking. FirmTech is a penile ring recently introduced at the 2022 Sexual Medicine Society of North America meeting. It is an electronic penile ring that syncs with a patient’s smartphone to measure the number, duration, and firmness of one’s erection. It can also be used to monitor nocturnal penile tumescence. Data can be uploaded to share with clinicians. The MOR device is a wearable

electrode placed on the perineum to delay premature ejaculation. The device syncs to one’s smartphone so that neuromodulation can be adjusted during intercourse to delay ejaculation. Data from the efficacy study, DELAID, has not been published, although the manufacturer is aiming for commercial release in 2023.

Urinary Incontinence

Multiple companies have developed wearable ultrasonic bladder monitors to reduce rates of urinary incontinence. The SENS-U is an ultrasound device designed for the pediatric population and worn on the lower abdomen. It continuously estimates bladder volume and notifies the user when their bladder is full via vibrations or phone notification. The device also serves as an automatic voiding diary that can be shared with clinicians. It has been validated against urodynamic testing as an accurate tool for determining bladder volume. DFree is another wearable bladder ultrasound that works similarly to SENS-U but is designed for adults.

Nephrolithiasis

Maintaining adequate hydration is a cornerstone of kidney stone prevention. As a result, multiple studies have investigated the use of a smart water bottle to increase fluid intake. The HidrateSpark is a water bottle that syncs to one’s smartphone to record fluid intake and reminds patients to stay hydrated. Initial studies show that the HidrateSpark is successful in increasing 24-hour urine volumes (1.37 L vs 0.79 L).⁹ A large multicenter trial is currently underway, which aims to enroll 1,642 participants to determine if the HidrateSpark leads to changes in symptomatic stone episodes and urine output.¹⁰

Fashion Trends

Adoption of any new technology follows a well-established “S curve,” in which various barriers to adoption must be overcome. Similarly, wearables in urology must address multiple issues until their

widespread utilization. Patients often do not wear or charge their devices. The accuracy and reliability of wearables might not be proven until additional large-scale trials are performed. Cost considerations and reimbursement pose additional hurdles. The tracking of personal information also presents a multitude of privacy concerns. Finally, urologists must be careful to ensure that wearables do not devolve into what electronic health records have become: a seemingly unending array of data points contributing to physician burnout. Before large-scale integration of wearables, ask yourself, how will you manage an increasing number of inbox messages filled with blood pressure measurements, step counts, and post-void residuals? What is the clinical utility of this data, and will physicians be liable for these results? Until all these challenges are met, we are likely to see wearable technology in urology come and go. ■

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OFFICE & SURGICAL TECHNOLOGIES

ChatGPT: A Time-saving Companion for Physicians

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Background

Over the last decade, there has been a growing interest in the use of artificial intelligence (AI) to streamline health care delivery and this technology is now being applied to areas that were previously thought to be only the jurisdiction of human experts. One AI technology that has caught the attention of the medical community and lay public alike is OpenAI's large language model (LLM)-based chatbot ChatGPT

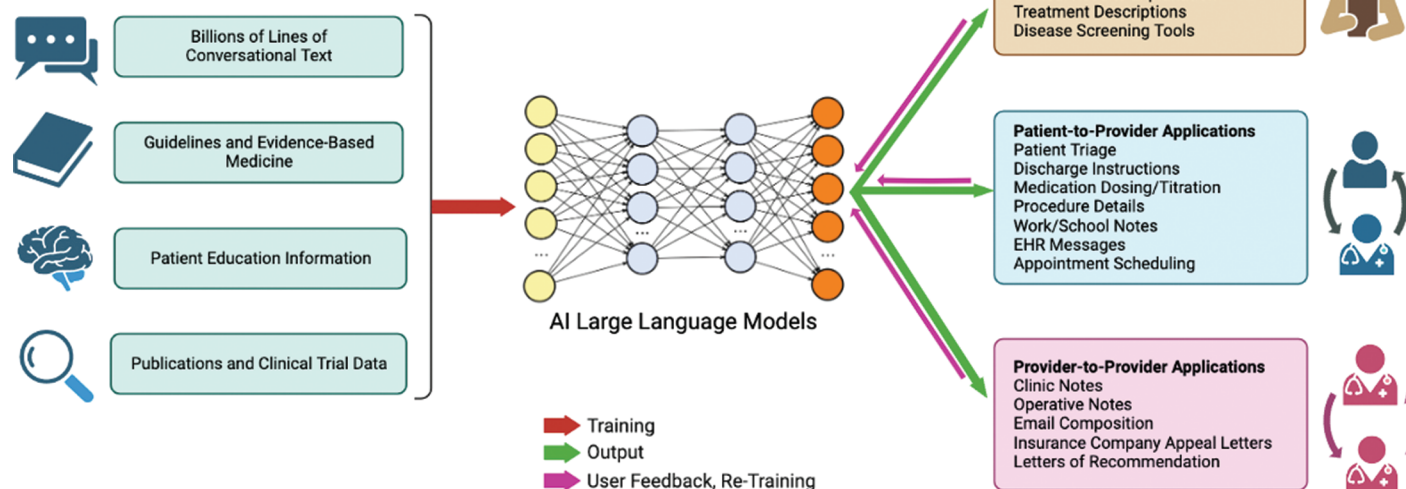


Figure 2. The future of generative artificial intelligence in health care. EHR indicates electronic health record.

(generative pretrained transformer). ChatGPT is a natural language processing technology that can generate conversational, human-like text using a deep learning machine

learning algorithm that was trained on 175 billion tokens and has been heralded as the best AI chatbot ever released for public consumption (Figure 1).¹⁻³ ChatGPT has garnered significant attention for its ability to provide articulate responses and carry out tasks with a wide range of sophistication.

ChatGPT and other LLM-based chat AI represent a promising time-saving tool for physicians in an era with increasing administrative burdens.^{4,5} A recent study using AUA Census data found that 37% of urologists report signs of burnout, with the highest workplace dissatisfiers being electronic health record tasks and limited personal/family time.⁶ Given that the preponderance of physician writing follows predictable and templated formats, natural language processing AI such as ChatGPT can make an immediate impact on physician workflow.

We describe the strengths and weaknesses of ChatGPT and encourage physicians to utilize this technology to free up more time for face-to-face interaction with patients and alleviate burnout by aiding in routine, low-stakes compositions.

ChatGPT in Practice

Physicians can sign up to use ChatGPT through OpenAI's website (chat.openai.com) and submit

requests through its user-friendly interface.

There are numerous applications for this technology along the care continuum (Figure 2). Some specific examples include drafting emails, letters to insurance companies, patient-facing discharge or medication instructions, brainstorming research ideas, event or appointment scheduling, and designing queries for research articles.⁷ These tasks have predictable outputs that can be quickly reviewed and fine-tuned, saving considerable time in the initial writing process. Additionally, ChatGPT can recall inputs from within the same session and thus one can ask the chatbot to rephrase, reconfigure, or expand upon previous inputs. ChatGPT has demonstrated that it is able to cope with ambiguity from requests. However, to get the most out of its time-saving capabilities, it is advantageous for physicians to become acquainted with the terminology and structure of requests to get a desired output. There are several repositories (eg, EmergentMind) in which users have published prompts (some serious, some comical) and resultant outputs to guide others.⁸ Furthermore, there are tools that utilize ChatGPT's API (eg, Doximity's DocsGPT) to provide doctors with

AN Write a letter to Cigna appealing the denial of Mirabegron for a patient with overactive bladder. The denial stated "patient has not completed and failed a prior course of oxybutynin." The patient had a previous hypersensitivity to oxybutynin with hives and difficulty breathing.

Dear Cigna Appeals Department,

I am writing to appeal the denial of Mirabegron for my patient, [Patient's Name], who suffers from overactive bladder. The denial cited that [Patient's Name] has not completed and failed a prior course of oxybutynin. However, [Patient's Name] had a previous hypersensitivity to oxybutynin with hives and difficulty breathing, making it impossible for [Patient's Name] to complete the course.

As you are aware, overactive bladder is a debilitating condition that severely impacts a patient's quality of life. In the case of [Patient's Name], their symptoms have significantly impacted their ability to perform daily activities and maintain a normal lifestyle. Mirabegron is an FDA-approved medication for the treatment of overactive bladder and has been proven to be a safe and effective alternative for patients who have an intolerance or hypersensitivity to oxybutynin.

In addition to the hypersensitivity reaction, [Patient's Name] has consulted with several healthcare providers, all of whom have recommended Mirabegron as the appropriate course of treatment. Moreover, as per the FDA's guidelines, patients who have an intolerance to oxybutynin are not required to complete a course of the medication before trying other treatments.

I strongly urge you to reconsider the denial of Mirabegron for [Patient's Name] and cover the cost of this medication. This decision will significantly impact the quality of life of [Patient's Name] and their ability to manage their overactive bladder symptoms.

Thank you for your prompt attention to this matter.

Sincerely,
[Your Name]

Figure 1. Sample prompt to create an appeals letter in ChatGPT, with sample output.

CHATGPT: A TIME-SAVING COMPANION FOR PHYSICIANS

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premade prompts for clinical care purposes.⁹

Limitations of ChatGPT

Physicians should be cognizant of ChatGPT's numerous limitations. Since ChatGPT is trained using text obtained from the Internet, its outputs are prone to bias and inconsistencies.¹⁰ ChatGPT does not exhibit indecisiveness and may cite publications that do not exist or make factually inaccurate statements with certainty. As evidenced by events that have occurred following its beta integration with Bing, ChatGPT is also prone to hallucination—generation of meaningless (and sometimes unsettling) answers based on bugs in the algorithm.¹¹ At best, it can function as a starting point for low-value written content from which one can revise.

ChatGPT currently does not scrape the Internet for new data, so any output that it provides will be based on information that it learned prior to 2021. ChatGPT and other LLMs are not HIPAA (Health Insurance Portability and Accountability Act of 1996) or GDPR (General Data Protection Regulation) compliant. Physicians should not

enter protected health information.

ChatGPT is currently free to use during times of low traffic to their website with full capabilities. For some users, the \$20 monthly subscription, which provides faster responses, availability during high traffic times, and earlier access to new features as they become available, may be a valuable investment.

Although ChatGPT is being used to streamline researcher workflows including the brainstorming of research ideas, literature review, and peer review, there has been increasing use of this technology in the drafting of manuscripts. *JAMA Network, Science, Nature*, the World Association of Medical Editors, and the Committee on Publication Ethics have issued statements prohibiting the listing of AI as an author because "AI cannot take responsibility for submitted work ... or assert presence or absence of conflicts of interest."¹²⁻¹⁴ Researchers who use AI tools in manuscript writing must disclose this in the methods or acknowledgments of the paper. Several groups have designed software that can detect AI-generated content, and in the future, there will likely be a watermark embedded in all AI-generat-

ed content to ensure transparency of its origin.

Conclusions

When taken together, ChatGPT can be an essential time-saving companion for physicians by streamlining low-complexity tasks. Although there are many limitations to ChatGPT and other LLMs, this technology is rapidly improving and will become increasingly utilized in the health care setting. In an era in which electronic health record tasks and administrative burdens are a lead driver of burnout, now is as good a time as any to embrace AI's time-saving potential. ■

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RADIOLOGY CORNER

Pediatric Bladder Neck Mass

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Clinical Case

A 21-month-old circumcised boy presented to the outpatient clinic for evaluation after a febrile urinary tract infection. Six weeks prior, he presented to an outside emergency room with a fever of 104.9°F and a febrile seizure. He was transferred to a local children's hospital and admitted. The patient tested positive for rhino/enterovirus and respiratory syncytial virus. He clinically improved and was

discharged. However, he continued to have lower-grade fevers and a voided urine specimen was obtained. This revealed positive leukocyte esterase and he was treated for a urinary tract infection due to abnormal test results. He was then referred to urology, where renal/bladder ultrasound was obtained and revealed a 1.5-cm nonmobile echogenic bladder mass at the posterior bladder near bladder neck region (Figure 1, A and B). There was no upper tract dilation observed on ultrasound.

The patient was brought to the operating room for further characterization of this bladder mass. On cystoscopy, a white, smooth

botryoidal lesion projected into the bladder on a broad stalk based at the bladder neck. Due to the broad base and mobile intravesical component, loop resection was not deemed safe or effective. The base of the tumor was biopsied. Biopsy pathology showed no evidence of malignancy and was suggestive of but not diagnostic for fibroepithelial polyp (FEP). The patient returned to the operating room days later and repeat attempts for transurethral excision were performed with holmium laser at the tumor base. Due to the bulbous and mobile intravesical component, visualization was limited and open excision of the residual tumor was performed

(Figure 2). Final pathology of the excised tumor confirmed an FEP. His postoperative course has been uncomplicated, with no evidence of recurrence on ultrasound or observed voiding symptoms with 6 months of follow-up.

Discussion

Pediatric bladder masses are highly uncommon and, with the exception of bladder/prostate rhabdomyosarcoma, are typically benign.¹⁻⁵ Typical clinical presentations include dysuria, hematuria, urinary frequency, obstructive

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PEDIATRIC BLADDER NECK MASS

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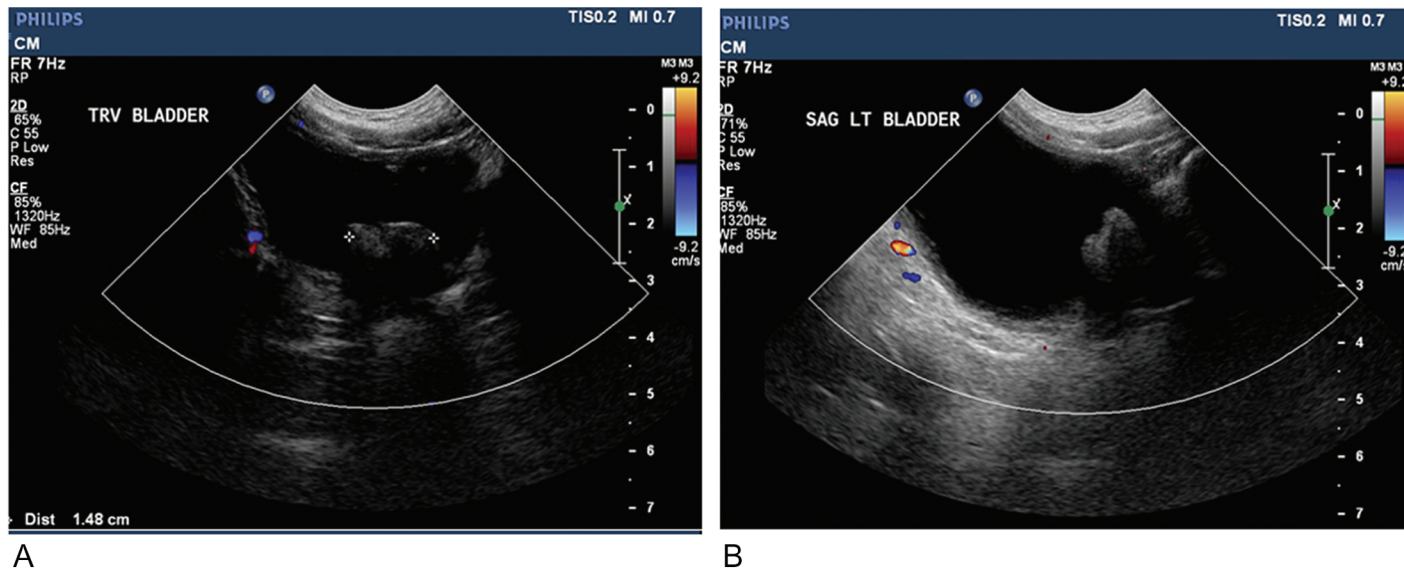


Figure 1. A, Transverse ultrasound image of 1.5-cm echogenic nonmobile lesion along the posterior bladder wall. B, Longitudinal ultrasound image of 1.5-cm echogenic nonmobile lesion at bladder neck.

symptoms, or lower abdominal pain, although they can be incidentally found as well. Ultrasound is the most common initial imaging modality, but voiding cystourethrogram can aid in diagnosis as well.^{1,5} Evaluation with a full bladder is important with ultrasonography to ensure a more thorough evaluation. However, ultrasound and other imaging studies cannot reliably predict bladder mass pathology in this population, and tissue diagnosis via biopsy or excision is required.

The differential for pediatric bladder masses includes rhabdomyosarcoma, urothelial carcinoma, inflammatory myofibroblastic tumors, nephrogenic adenoma, and FEP, among others.¹⁻⁴ Tissue sampling is critical for ruling out rhabdomyosarcoma, which is often unresectable at presentation, and multimodal therapy is employed in an organ-sparing strategy.² Urothelial carcinoma, the most common bladder tumor in adults, is exceedingly rare and, when present, is typically noninvasive and low grade.³



Figure 2. Gross photograph of the fibroepithelial polyp excised from bladder neck.

FEPs are rare, male-predominant, benign tumors of mesodermal origin, occurring at all levels of the urinary tract from the renal calyces to the anterior urethra.⁵⁻⁸ Across all age groups, FEPs are most frequently identified in the upper ureter or renal pelvis, while in children, FEPs are more likely to be located in the male posterior urethra and can result in bladder outlet obstruction.⁷ Boys with urethral FEPs typically present with hematuria, intermittent obstructive voiding complaints, and urinary retention. In girls, where reported cases are sparse, the most common presentation is an interlabial mass.⁸

Depending on the location, FEP size, and the size of the patient, they can be amenable to transurethral resection with either electrocautery or laser. However, large FEPs may require cystotomy to remove the specimen. If resected at the base of the stalk, recurrence is rare. There is debate about surveillance for recurrence. Ultrasound may be sufficient as use of cystoscopy in pediatric patients generally requires general anesthesia. ■

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“Across all age groups, FEPs are most frequently identified in the upper ureter or renal pelvis, while in children, FEPs are more likely to be located in the male posterior urethra and can result in bladder outlet obstruction.”

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Single-port Surgery: Creating New Opportunities in Robotic Surgery

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The dream of single-incision surgery has been on the mind of surgeons since the inception of laparoscopic surgery. Laparoendoscopic single-site surgery was the first culmination of this technology but came with many challenges that limited its broad appeal and use. The da Vinci SP (single port) Robotic Platform was then introduced in 2018, revolutionizing the landscape of single-incision surgery. The platform enabled multi-articulating arms alongside a camera through a single incision with the same technology platform urologists were already accustomed to with the da Vinci MP (multiport) Xi Robotic Platform.

As one of the first 10 institutions in the country to adopt the SP robot, our team witnessed the growth and astounding evolution of the platform. In the early days

“The SP robot can perform even the most complex cases in urological surgery. For patients undergoing radical cystectomy, we place a 3-cm incision at the umbilicus. We also utilize NOTES (natural orifice transluminal endoscopic surgery) principles to place the second trocar used for stapling at the vaginal cuff in female patients.”

of the SP platform, surgeons tried to imitate the same methods used with the MP platform to limited avail. Early cases used a metal trocar placed directly in the body as currently employed with the Xi. This approach resulted in limited mobility from the restricted working distance of the SP robot. To address this problem, we quickly transitioned to a floating dock system utilizing an Alexis retractor and GelPort mini. This enabled the trocar to sit outside the body and remain movable throughout the case, resulting in enhanced flexibility within the working space. da Vinci was quick to respond to the needs of urologists and introduced the da Vinci SP access port kit, which worked seamlessly with the SP robot and had further advantages over the GelPort mini, including built-in additional instrument trocar sites.

Throughout the following years, the SP platform continued to evolve rapidly and enabled surgeons to utilize new techniques and reintroduce approaches that were previously too early for their time. One good example is the SP robotic-assisted laparoscopic prostatectomy (RALP). The first cases of SP RALPs at our institution were done intraperitoneally in the same manner as performing MP RALP. Quickly, we realized the benefits of an extraperitoneal RALP, which has now become the standard SP approach to RALP across the country. In the most extensive series of SP RALP patients, we have reported the benefits of this approach, such as reduced pain requirements.¹ We had previously performed extraperitoneal RALP more than 10 years ago with the MP platform but quickly returned to a transperitoneal approach as the lateral arms often pierced the peritoneum, nullifying the benefits or making the case impossible. The SP platform has brought back the extraperitoneal approach and its many benefits. With regard to RALPs, the SP system continues to evolve. Aminsharifi et al reported other approaches enabled with the SP platform, including transvesical



Figure 1. Incision used for the single-port Ahmed modification. This incision is used to enable concomitant transperitoneal and retroperitoneal surgery for kidney cases, upper tract reconstruction, and adrenal cases.

RALP and transperineal RALP.²

The SP platform has also transformed how our team completes partial nephrectomies. MP partial nephrectomies are typically done transperitoneally, with few surgeons utilizing a retroperitoneal approach because the MP robots have limited ability to work in the small space of the retroperitoneum. One key advantage of the SP platform is to work in small areas. Given this fact, early on, we began performing SP partial nephrectomies transperitoneally using incisions placed either at the umbilicus or the pelvic brim to improve cosmesis.³ These approaches mimicked the MP approach with little change or benefit. For the extraperitoneal approach, we initially docked the robot subcostally at the level of the kidney. But this approach often led to patients developing a bulge at the incision site, likely due to the extended incision disrupting

the nerve supply to the intercostal muscles. Therefore, we sought a new approach that would utilize the unique abilities of the SP platform. This led to the introduction of the single-port Ahmed modification (SPAM) approach to retroperitoneal surgeries. In this approach, we placed the incision two-thirds of the distance to the anterior superior iliac spine from the umbilicus (Figure 1). This unique approach changed our practice and enabled us to often perform retroperitoneal and transperitoneal surgery within the same case and same patient as needed. This incision also aligned with the SP robot's ability to move longitudinally and enabled the hilum to be placed in line with the trocar (Figure 2). This allowed easy access to the hilum for the surgeon and assistant. The SPAM approach has become the de facto standard at our institution and is becoming widely adopted elsewhere. It has many advantages, and we are undergoing a prospective review of the SPAM procedure to better understand the feasibility and reproducibility of this approach for SP partial nephrectomies and other retroperitoneal surgery, including but not limited to adrenalectomy, radical nephrectomy, and upper tract reconstruction.^{4,5}

The SP robot can perform even the most complex cases in urological surgery. For patients undergoing radical cystectomy, we place a 3-cm incision at the umbilicus. We also utilize NOTES (natural orifice

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Figure 2. Intraoperative picture of single-port Ahmed modification incision with single-port robot docked in place with the da Vinci SP access port kit.

SINGLE-PORT SURGERY: CREATING NEW OPPORTUNITIES

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transluminal endoscopic surgery) principles to place the second trocar used for stapling at the vaginal cuff in female patients. Thus, this approach combines the SP platform and NOTES to enable truly single-incision surgery for cystectomy. It is a sight to behold the first time one sees a radical cystectomy with neobladder creation being performed through a 3-cm barely visible incision at the umbilicus. We have published the largest series to date regarding SP radical cystectomy and have found reduced opioid requirements and faster return of bowel function with the SPAM approach.⁶ This is just one example of

how SP surgery is changing the field.

The SP platform also enables novel approaches to old surgeries. For example, simple prostatectomies are now often performed transvesically. The robot is docked directly in the bladder, and the bladder is insufflated, thus limiting bleeding and allowing for excellent visualization. This approach combined with a circumferential closure of the prostatic defect has enabled same-day discharge of patients undergoing SP simple prostatectomies. At our institution, the transvesical approach has also enabled new methods to perform cross-trigonal reimplant, ureteral reimplantation, colovesical

fistula repair, and vesicovaginal fistula repair.

When the SP platform was first introduced, there were many naysayers about its benefits and broad adoption. As the SP platform has grown and evolved, it has become abundantly clear that the SP platform has a place alongside the MP platform. The SP platform has enabled new incisions, new approaches, and reinvigorated long-forgotten surgeries. The evolution of the da Vinci SP platform has just started and more exciting developments are on the horizon. ■

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COVID and COVID-associated Cystitis

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Pandemic: First Wave

During the first wave of COVID-19 pandemic in early 2020, New York City and Detroit were epicenters with high numbers of cases and death. We'd like to share with you our story of how we embarked on a research project during the darkest days of the pandemic and came to uncover the disease COVID-associated cystitis (CAC).

Dr Nivedita Dhar: "My husband and I are both physicians at the Detroit Medical Center. Strangely, in the first quarter of 2020, I was asked to consult pa-

tients with active or recovering COVID-19 with new onset, only after COVID-19 infection, of severe lower urinary symptoms (LUTS). I knew COVID-19 was affecting various organs and I began to wonder if it could affect the bladder. But how could I find out, as most everything at the Detroit Medical Center, including elective surgery and urology research, were shut down?"

Dr Sina Mehraban-Far, 2nd year urology resident at Wayne State University: "It is hard to believe that I am a pandemic generation physician. Finishing medical school in New York and starting my urology residency during the pandemic in 2021, I have seen the impact of COVID on patients and medical education, as well as delivery of care. So when Dr Dhar asked me if I was interested in working on a COVID urology research project I said, 'Sign Me Up!'"

Dr Michael Chancellor, Professor of Urology, Director of the Aikens Research Center, Corewell Health Beaumont University Hospital: "My wife is a physician who specializes in public health, and I remember Ginny on New Year's Eve 2019 saying to me, 'Michael, there is a serious outbreak in Wuhan, China that you need to learn about. It is going to be big,

"It is hard to believe that I am a pandemic generation physician."

and it is coming here. You need to prepare for it and get N95 masks.' After my initial skepticism I started reading everything about COVID-19, like pretty much every health care provider in the world. I wanted to contribute but felt powerless, as most patient care and urology research was shut down. Then I started reading about cytokine storm and I had an idea, so I called Nivedita.

"I discussed with Nivedita that as cytokine storm is key to COVID-19 lethality, and that given one of our top research priorities in our lab at Beaumont Research Institute is focused on detecting urine cytokines for the diagnosis of interstitial cystitis, then we may be able to detect elevated cytokines in the urine of COVID-19 patients. I asked if she and her husband would be interested in a collaboration to collect urine in COVID patients for us to analyze for cytokines. Nivedita say yes and then told me she has been seeing urology consults of COVID patients

with de novo LUTS, and wondered if I agreed with her that COVID-19 could affect the bladder. I said yes and that I also have been hypothesizing that COVID inflammation and cytokines in the urine can cause cystitis. We got off the phone and got moving, obtained IRB approval, and embarked on collection of urine from COVID-19 patients."

We want to acknowledge that before publication of our work, Mumm and colleagues from Italy were the first to report increased urinary frequency in COVID-19 patients.¹ Mumm et al first observed increased urinary frequency in 7 males out of 57 patients admitted to their COVID-19 wards. These patients reported an average of 13.7 urinary voids per day on the day of admission and 11.6 on day 5.

Cystitis After COVID

In our initial report, we followed patients after their hospitalization from COVID-19 recovery and had a confirmed positive SARS-CoV-2 molecular diagnostic test.² Thirty-nine COVID-19-positive patients, including 7 females and 32 males, developed de novo urinary symptoms without urinary tract

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COVID AND COVID-ASSOCIATED CYSTITIS

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“It was concerning that all 40 patients who had persistent urinary symptoms after 2 years were over the age of 65. We know COVID-19 hit the elderly the hardest and more research is needed on CAC in older Americans.”

infection. Median length of stay was 10 days (range 5-30). All 39 patients completed the symptom score survey. All the patients had urge incontinence and 87% had 5 or more episodes of nocturia.

At the 2021 virtual AUA and in a subsequent publication,³ we reported the first study to assess pathophysiology of CAC. We hypothesized that CAC is caused by increased inflammatory cytokines that are released into the urine and/or expressed in the

Table. Outcomes Assessment⁵

Classification (n)	Baseline (10-14 wk)		Follow-up (21-28 mo)	
	OAB Symptom Score, median (range)	QoL Score, median (range)	OAB Symptom Score, median (range)	QoL Score, median (range)
New symptoms (n=250) ^a	18 (12-21)	19 (16-24)	9 (4-21)	9 (7-20)
Worsening symptoms (n=100) ^b	19 (17-21)	20 (19-20)	13 (5-21)	14 (6-20)
Female (n=140) ^b	18 (15-21)	19 (16-21)	8 (4-21)	7 (6-22)
Male (n=210) ^a	18 (12-20)	19 (16-20)	7 (5-20)	8 (6-23)

Abbreviations: OAB, overactive bladder; QoL, quality of life.

^aThirty patients lost to follow-up^bTen patients lost to follow-up.

bladder (see Figure).⁴ Health care providers caring for COVID-19 patients should be aware of CAC, and de novo urinary symptoms should be included in the symptoms complex associated with COVID-19.

COVID Cystitis: Long Term

At the 2023 AUA meeting in Chicago, Dr Mehraban-Far presented the moderated poster “MP74-13 Long-term Outcomes of COVID-19 Associated Cystitis (CAC).”⁵ A total of 350 patients were identified with the diagnosis of CAC, of which 71% were newly

diagnosed, and 29% with worsening overactive bladder symptoms 10-14 weeks after hospitalization with COVID-19 and followed for 21 to 28 months (see Table). No differences were noted among improvements in symptoms between females and males.

Dr Dhar reported, “We feel this study is important because it is the first long-term follow-up of patients who developed CAC and assessed the prognosis of CAC in long COVID. We found that after 21-28 months, only 13% of patients had persistent LUTS. Patients with long COVID and CAC may be reassured that symptoms resolve in the vast majority of cases and that supportive and reversible treatment should be recommended. So please hold off on neuromodulation or botulinum toxin injection. It was concerning that all 40 patients who had persistent urinary symptoms after 2 years were over the age of 65. We know COVID-19 hit the elderly the hardest and more research is needed on CAC in older Americans.”

Upon reflection of what has transpired since the beginning of the pandemic, Dr Chancellor recounted, “It was so depressing during the first wave of the pandemic being unable to help. Then an opportunity to connect urology research and COVID-19 appeared. I am grateful to the students, residents, fellows, nurses, scientists, and clinicians who came together,

“Health care providers caring for COVID-19 patients should be aware of CAC, and de novo urinary symptoms should be included in the symptoms complex associated with COVID-19.”

and thank God that nobody got sick collecting the urine samples. We have heard from many urologists from across the nation and around the world who told us that they have also seen CAC patients and found our research and just wanted to reach out. We thank you for sharing your stories.” ■

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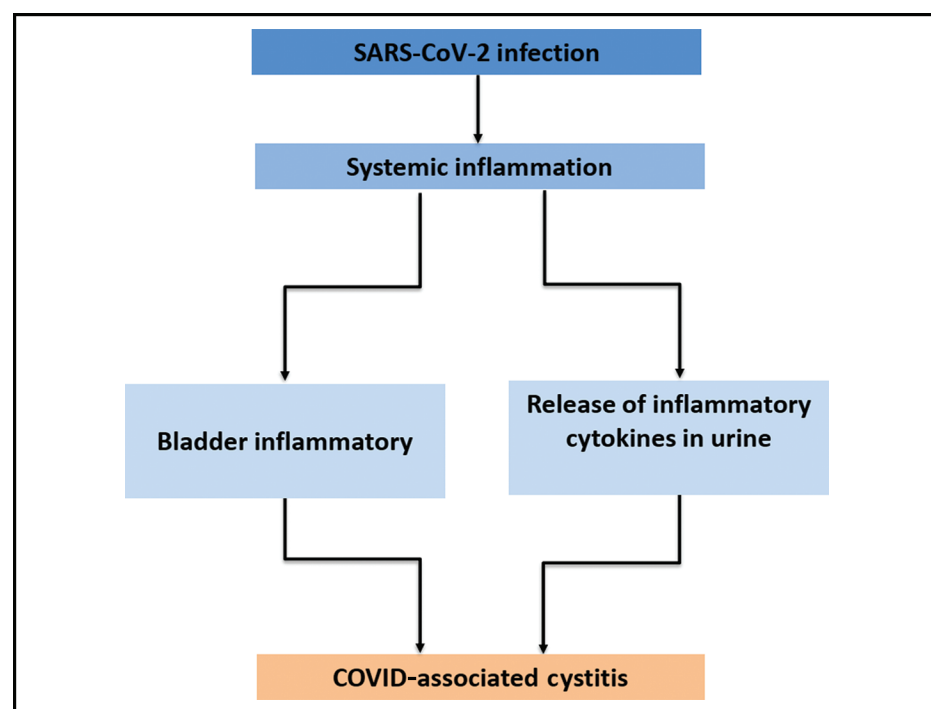


Figure. Hypothesis for COVID-associated cystitis.

Hormonal Therapy for Men Undergoing Definitive Radiation for Prostate Cancer

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Radiation therapy (RT) plus castration-inducing hormonal therapy (HT) is widely accepted as a standard treatment approach for localized prostate cancer (PCa). However, use of HT with definitive RT is highly variable in real-world practice, given its significant adverse impacts on quality of life.¹ Thus, the selection of appropriate patients and the appropriate duration for HT remains controversial. Herein, we discuss the role of HT as a component of the up-front treatment of intact PCa with RT.

The MARCAP meta-analysis pooled data from 10,853 patients at 12 centers and found that adding HT to RT in the form of androgen deprivation therapy (ADT) improved metastasis-free survival (HR: 0.83 [0.77-0.89]) in men undergoing definitive RT for PCa, as did prolongation of adjuvant ADT (HR: 0.84 [0.78-0.91]) irrespective of RT dose, patient age, or National Comprehensive Cancer Network (NCCN) risk group.² This suggests that even in the modern era of RT dose intensification, there appears to be a relative benefit to adding any duration of ADT to RT for most men with localized PCa. However, the absolute benefit of ADT diverges for intermediate-risk (IR) vs high-risk patients, with a calculated number needed to treat in order to avert 1 distant metastasis (DM) event at 10 years of 8.4 (95% CI: 6.0-13.8) for high-risk patients compared to 18.0 (95% CI: 12.7-30.7) for IR patients.

Among IR patients, ADT may be most beneficial for patients with unfavorable IR (UIR) disease, whereas men with favorable IR (FIR) disease might reasonably be spared ADT given the potentially minimal absolute benefit.³ If ADT is chosen for IR disease, multiple studies have demonstrated that the ideal duration of ADT that balances oncologic

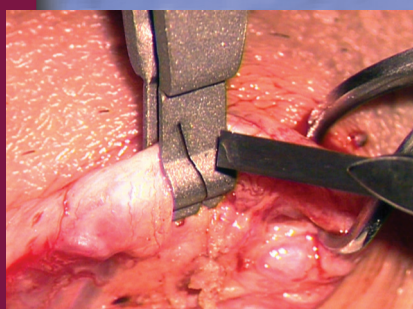
outcomes and quality of life in IR patients is between 4-6 months, with longer durations failing to improve biochemical progression and event-free survival.^{4,5} RTOG 9408 was

the only study to demonstrate an overall survival (OS) advantage for IR patients (HR: 1.17, $P = .03$, 62% vs 57%)⁶, but this study employed a lower dose of RT (66.6 Gy) than

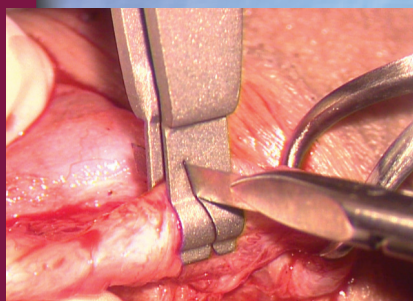
would be standardly utilized today, potentially inflating the benefits of ADT in their cohort.

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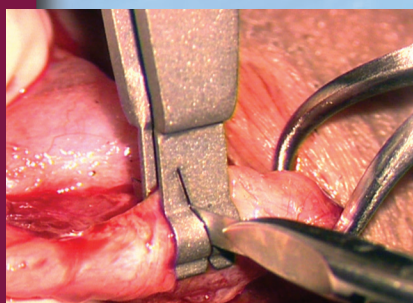
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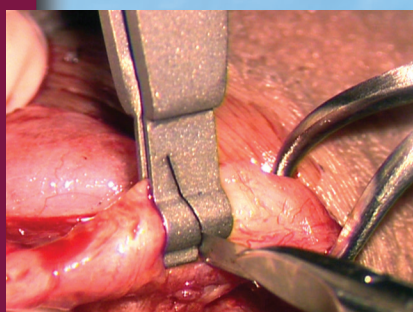
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HORMONAL THERAPY FOR MEN UNDERGOING DEFINITIVE RADIATION

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The timing of short-term ADT also remains an important question, with recent data favoring a greater proportion of ADT in the adjuvant vs the neoadjuvant setting. In the SANDSTORM analysis,⁷ when comparing concurrent/adjuvant ADT to neoadjuvant/concurrent ADT, metastasis-free survival (MFS; HR 0.65 [0.54-0.79], corresponding to a 10-year benefit of 8%), DM (HR 0.52 [0.33-0.82]), prostate cancer-specific mortality (HR 0.3 [0.16-0.54]), and OS (HR 0.69 [0.57-0.83]) were all improved with a concurrent/adjuvant approach, though these benefits were reserved for men receiving prostate-only RT and not recapitulated in men who also received whole pelvis RT.

Ongoing clinical trials seek to harness precision medicine platforms to identify IR patients who may benefit from de-escalation to RT alone vs those who benefit from treatment escalation with intensified ADT. For example, NRG GU010/GUIDANCE (NCT05050084) will risk-stratify 2,050 UIR patients using The Decipher Prostate Cancer Test. Patients with a Decipher score <0.4 are randomized to RT alone or RT with 6 months of ADT with a primary endpoint of DM. A separate randomization for men with Decipher score >0.4 will determine if patients should undergo an intensified regimen of RT plus 6 months of ADT along with a second-generation antiandrogen, darolutamide, or standard-of-care RT with 6 months of ADT alone, with MFS as the primary endpoint. An artificial-intelligence-derived digital pathology-based biomarker has also garnered recent excitement following validation of its ability to predict the benefit of ADT in cohort of IR patients enrolled on RTOG 9408.⁸ However, until such biomarkers can be prospectively validated, candidates for omission of ADT without significant compromise in oncologic outcomes are likely best identified by NCCN risk group classification, with omission preferred for FIR patients and 4-6 months of concurrent/adjuvant ADT preferred for UIR patients.

The value of ADT plus RT in high-risk and very high-risk patients has been well-studied. Long-term ADT (LTADT) has consistent-

ly improved OS in multiple large, randomized trials,⁹⁻¹² with RTOG 9202¹³ and DART 01/05⁵ both finding that 28 months of ADT was more effective than 4 months of ADT, particularly in men with Gleason 8 disease and other high-risk factors. Several studies have also suggested that intermediate-term ADT (IT-ADT) is also superior to short-term ADT and may even be comparable to LTADT. PCS IV was designed as a superiority trial and specifically sought to compare ITADT (18 months) vs LTADT (36 months) in high-risk patients and failed to demonstrate superior OS outcomes in the LTADT arm (86% vs 91% $P = .07$) with quality of life analysis favoring ITADT.¹⁴ However, it is worth noting that lack of superiority is distinct from non-inferiority and that ADT compliance was poor in the 36-month arm, which may have driven the similar comparison. The addition of a brachytherapy boost may also factor into the calculation of ADT duration, with favorable progression-free survival rates on the ASCENDE-RT trial¹⁶ driving the recommendation for just 12 months of ADT in men who receive a brachytherapy boost as part of their high-risk RT approach. A recent retrospective analysis that incorporated data from the TROG RADAR trial and the DART 01/05 trial suggested that 12 months of ADT might be optimal for patients receiving a brachytherapy boost, while durations longer than 18 months may still offer an oncologic benefit even with dose-escalated external beam radiotherapy.¹⁵ Taken together, these data suggest patients receiving dose-escalated external beam radiotherapy should receive a minimum of 18 months of ADT (supported by high-level data), while those receiving a brachytherapy boost might be able to shorten ADT duration to 12 months (supported by lower-level data).

Finally, recent attention has also focused on the benefits of adding advanced second-generation antiandrogen therapies to standard ADT in the highest-risk patients. In a recent meta-analysis of 2 phase 3 trials from the STAMPEDE platform protocol, 1,974 high-risk patients (defined as node positive disease or the presence of two-thirds of the follow-

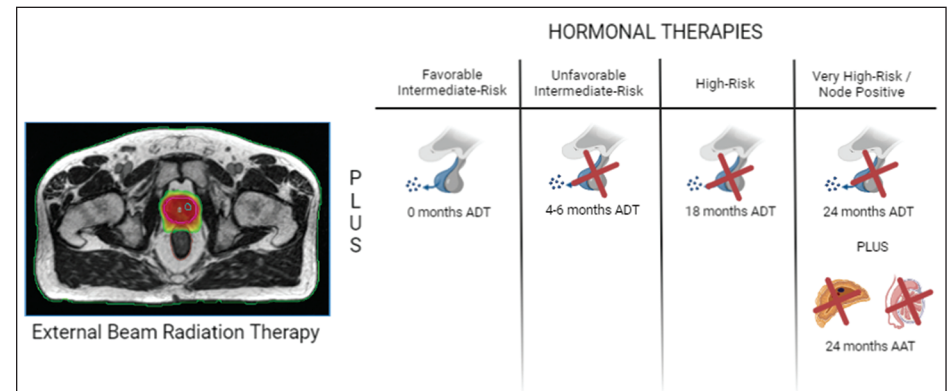


Figure. Recommendations for androgen deprivation therapy (ADT) use and duration when combined with definitive radiation therapy according to National Comprehensive Cancer Network risk group. AAT indicates antiandrogen therapy.

ing features: T3/T4 disease, Gleason score 8-10, or PSA ≥ 40) undergoing local therapy (predominately with RT) were randomized to either ADT alone (control group), ADT with abiraterone and prednisolone (intervention arm of the first trial), or ADT with abiraterone, prednisolone, and enzalutamide (intervention arm of the second trial).²⁵ At 6 years, the combination arms demonstrated improved MFS (HR: 0.53 [95% CI: 0.44-0.64 $P = .0001$], 82% vs 69%) along with improved OS, prostate cancer-specific mortality, biochemical recurrence, and progression-free survival when compared to ADT alone. Thus, HT intensification for these high-risk patients is now a category I recommendation in NCCN guidelines (see Figure).

In summary, as RT technology has improved, so too has our understanding of the appropriate patient selection, duration, and timing of HT. Genomic classifiers and digital histopathologic-based artificial intelligence platforms are poised to improve patient selection for the addition of HT to RT in the near future. ■

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Children Undergoing Bladder Augmentation: What Should the Parents Know?

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Informed consent is a process of communication between the health care provider and the patient that ultimately culminates in the authorization or refusal of a specific intervention.¹ The process involves multiple elements, including disclosure, comprehension, voluntary choice, and authorization. Physicians disclose understandable information to patients to facilitate informed choice. In the pediatric population, such decisions regarding interventions are made by the parent/guardian on behalf of their child due to young age.

Bladder augmentation (BA) is a major intra-abdominal procedure that is accompanied by risks and benefits which must be discussed prior to its performance. In pediatric BA is most frequently employed in the neurogenic bladder population, although it has been performed in pediatric patients with bladder/cloacal exstrophy and/or posterior urethral valves.² The benefits of BA in a patient with upper tract injury from medically refractory impaired bladder compliance could be viewed from the perspective of avoidance of renal replacement therapy if the hostile bladder continues unimpeded. In contrast, urinary incontinence from abnormal bladder capacity or storage characteristics is another clinical scenario where BA may be considered as part of the surgical treatment plan. The benefits of achieving urinary continence by means of surgical reconstructive procedures such as BA when medical management fails have been well documented.^{3,4}

However, these benefits of BA are inextricably linked to its post-operative risks with extended follow-up. Multiple prior single-institution studies have described a high percentage of patients who underwent BA undergoing future surgeries for a litany of augmentation-associated complications such as bladder calculi, bladder perforation, bowel obstruction, repeat BA, and even bladder cancer.^{2,5-10}

Clinical studies that quantify risk of complications over specific a time frame following BA, while accounting for patients having multiple complications and differential follow-up, are useful when counseling families prior to performing BA. Szymanski et al in a single-institution cohort of 400 patients with spina bifida reported the risk of any subsequent surgery within the first 5 years after BA occurred in 1 in 4 of their patients; however, complications continued to accumulate throughout follow-up.⁵ The risk increased to nearly 1 in 2 patients (43.9%) at 10 years and over half (57.4%) at 20 years. Schlomer and Copp using a national pediatric database described 10-year cumulative incidence ranges for the following outcomes after BA: bladder stones (13.3%-36.0%), bladder perforation (2.9%-6.4%), small-bowel obstruction (5.2%-10.3%), and reaugmentation (5.2%-13.4%).²

Bladder calculi are the most frequently reported additional surgery after BA. The mucus that is produced by the intestinal segment used in BA is theorized to be the nidus for stone formation, and daily bladder irrigations to remove the mucus have been shown to reduce the risk of bladder stone formation.^{8,9} Endoscopic procedures can be safely and effectively performed to remove the bladder stone as an alternative to open cystolithotomy, similar to non-BA patients.¹¹

Bladder perforation is a potentially lethal complication of BA and fortunately not as commonly observed as bladder calculi. Avoidance of prolonged intervals of noncatheterization can minimize the risk of bladder rupture.^{8,9} BA surgical technique can also reduce risk of bladder perforation. Utilization of a detubularized and reconfigured intestinal segment had a lower risk of bladder perforation or reaugmentation compared to non-detubularized and reconfigured segments.⁵ Bladder perforation risk was 9.6% for patients undergoing vs 23.7% for those not undergoing detubularized reconfigured ileocystoplasty. Similarly reaugmentation rate was 5.3% for patients

“Bladder calculi are the most frequently reported additional surgery after BA. The mucus that is produced by the intestinal segment used in BA is theorized to be the nidus for stone formation, and daily bladder irrigations to remove the mucus have been shown to reduce the risk of bladder stone formation.^{8,9}”

undergoing vs 15.2% for those not undergoing detubularized reconfigured ileocystoplasty.

The most concerning long-term reported complication of BA is carcinogenesis, and its causality has not been proven to place a moratorium on the procedure. Too few long-term data are available, probably because of the too low incidence and the long latency between surgery and cancer occurrence. Higuchi et al reported on 153 patients treated with BA matched 1:1 to a control group treated with intermittent catheterization based on etiology of bladder dysfunction, gender, and age.¹⁰ There was no difference in the incidence of bladder cancer in patients with BA (7 patients, 4.6%) vs controls (4 patients, 2.6%). In addition, there was no difference between the 2 groups regarding age at diagnosis, stage at diagnosis, mortality rate, or median survival.¹⁰

Lastly, in the scope of lower urinary tract reconstructive surgery performed in pediatric patients who undergo BA, a significant percentage undergo the Mitrofanoff procedure.² Creation of a continent

catehetizable channel such as the Mitrofanoff procedure carries additional risks for needing revisionary procedures for the channels.¹² These additional channel procedures only “augment” the reported risks of additional surgery compared to BA alone.

At the current time, BA despite its risks will continue to play a specific role in the surgical care of pediatric patients with complex abnormal lower urinary tract. BA is not unlike other surgical procedures with increasing complications with continuous follow-up.^{2,5} This fact makes the transition from pediatric to adult urology critical for ongoing identification of such issues after BA and mitigation of them when possible. Therefore, parents of children undergoing BA should be told by their surgeon that the future holds a lifetime need for close urological surveillance. ■

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The Value of a Pathology Rotation in Urology Residency: The University of Vermont Medical Center Experience

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Genitourinary (GU) pathology reporting and terminology continue to evolve at a rapid pace, reflecting advances in molecular diagnostic testing, continued pathology subspecialization, and as a response to new treatment algorithms/guidelines. Some examples include the recognition of new diagnostic entities in the classification of renal tumors (see Figure), the documentation of variant histology and grade heterogeneity in bladder cancer, and the need to document and recognize treatment-related changes seen in advanced prostate cancer and other GU malignancies. Interpreting and translating these complex pathology reports can be challenging and necessitate increased communication between clinicians and pathologists.

Recognizing the importance of collaboration and communication between our specialties, a required 4-week GU pathology rotation for postgraduate year 2 urology residents was created since the reestablishment of the University of Vermont Medical Center urology residency program. The goals of the rotation are to increase proficiency in understanding pathology reporting and terminology, introduce new and emerging pathology entities that are less likely to be encountered in daily practice, and provide exposure on how pathological staging of GU malignancies is derived from gross and microscopic exam. Residents also gain knowledge on how specimen acquisition and submission by urologists can impact the ability to make a diagnosis and the inherent limitations of certain specimen types.

During the rotation, urology residents spend most of their time in surgical pathology and are also exposed to cytopathology and

the microbiology lab. In surgical pathology, reviewing GU cases with an attending pathologist allows the urology resident to observe how morphological findings inform diagnostic classification and how diagnostic thresholds are established in various organ systems. Further, they have the opportunity to see the strengths and limitations of immunohistochemical stains and both observe and better understand the decision-making process in both routine and challenging cases. Pathologists share some of the diagnostic dilemmas they face in their daily practice (diagnosis of intraductal carcinoma on prostate core biopsies, grading a subset of papillary urothelial tumors, grade grouping small foci of prostate cancer, etc). In turn, urology residents review the most recent clinical guidelines and share what they know about

“Cytopathology and microbiology are also important components of the rotation. In cytopathology, terminology for the Paris System for Reporting Urinary Cytology is reviewed, and residents learn the impact of collection methods (barbotage, catheterized, voided) and common contaminants (lubricant, squamous cells, etc) on the cytomorphology of urothelial cells.”

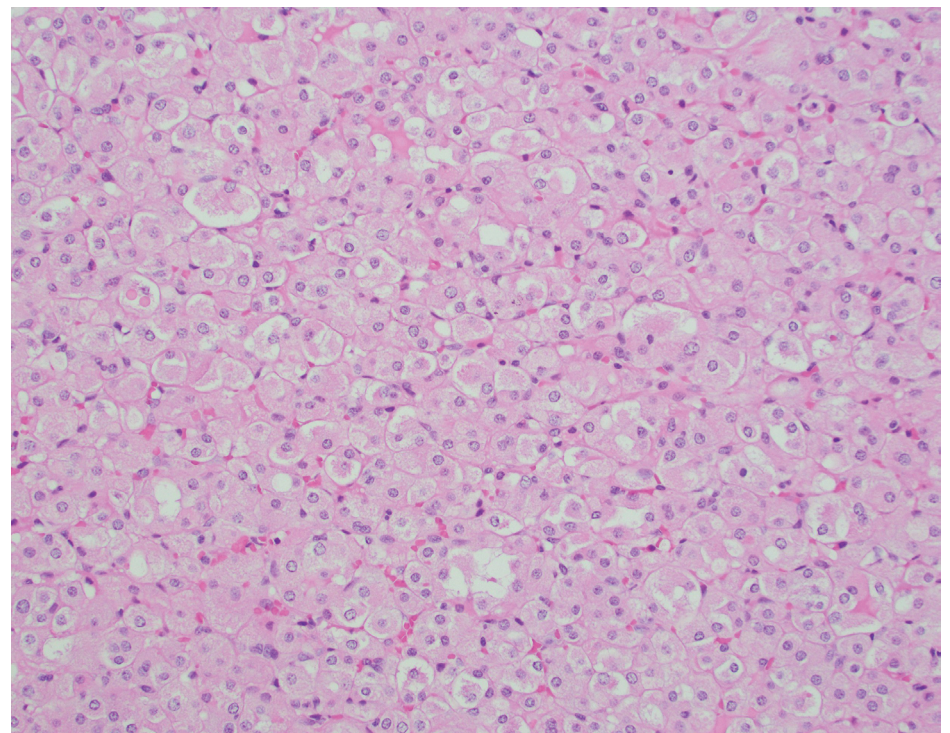


Figure. Succinate dehydrogenase-deficient renal cell carcinoma (200× magnification), a rare subtype of renal cell carcinoma officially recognized by the WHO in 2016. The diagnosis of succinate dehydrogenase-deficient renal cell carcinoma is considered an indication for genetic counseling and for testing for germline mutation in the succinate dehydrogenase genes.¹

the clinical impact of the diagnoses they see at the microscope. Finally, molecular assays and their minimal tissue requirements are discussed, which allows for basic teaching on molecular testing methodology.

Cytopathology and microbiology are also important components of the rotation. In cytopathology, terminology for the Paris System for Reporting Urinary Cytology is reviewed, and residents learn the impact of collection methods (barbotage, catheterized, voided) and common contaminants (lubricant, squamous cells, etc) on the cytomorphology of urothelial cells. Residents are often surprised to learn that collection methods, providing relevant clinical history, and the presence of contaminants can impact interpretation and results reporting in cytology, too. Similarly in microbiology, the impact of preanalytic variables and collection methods on reporting of urological culture results is emphasized. Culture growth interpretation is discussed in the context of patient history, and residents are reminded of the appropriate specimen collection methods for sexually transmitted disease testing.

Beyond providing exposure to the field of pathology, important questions and lively discussions arise during this rotation, which spark research interest. By sharing their clinical experience about the surgical management of urologic oncology cases, urology residents bring new perspectives and insight into future studies that may be informative in the study of GU disease. Afternoons are available to pursue research projects and prepare abstracts for regional and national meetings.

As pathologists, we strive to ensure that our reports are interpreted correctly, clinically actionable, and discussed with patients with a greater degree of understanding. This can only be achieved with close collaboration with our clinical colleagues. We hope that exposing both pathology and urology trainees to the importance of collaborating with peers in other specialties will strengthen their future career endeavors and benefit patient care. ■

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Hard Flaccid Syndrome Proposed to Be Secondary to Pathological Activation of a Pelvic/Pudendal-Hypogastric Reflex

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Hard flaccid syndrome, in which the penis is observed in an unwanted persistent semirigid flaccid state (Figure 1), is an acquired, persistent, painful, and bothersome sexual dysfunction that is poorly understood.¹⁻³ During physical examination, the flaccid penis is shrunken, contracted, and noncompressible, and on palpation feels hard, described by the patient as tender. Most individuals with hard flaccid syndrome are in their 20s or 30s, with multiple biopsychosocial concerns.¹⁻³ Biological complaints include penile morphometric changes such as wrinkles or indents; cold-feeling glans; decreased penile sensation, especially in the glans; urinary symptoms such as decreased force of stream; constipation; high-tone pelvic floor dysfunction; perineal and penile pain during ejaculation; and erectile dysfunction with loss

of morning erections. These symptoms often worsen when standing. From a psychosocial perspective, symptoms of hard flaccid syndrome trigger significant emotional distress manifested by anxiety, depression, decreased libido, and insomnia, and inability to maintain romantic relationships.¹⁻³

Patients with hard flaccid syndrome have presented to our sexual medicine practice with increasing frequency as patients read about this topic online. We propose that this syndrome, which presents at the level of the end organ (ie corpora cavernosa), results from excessive sympathetic activity in the hypogastric nerve leading to extreme, unrelenting erectile tissue smooth muscle contraction. This hypothesis is supported in part by the observation that intracavernosal injection of phentolamine (an α -adrenergic antagonist) temporarily resolves the hard flaccid state and induces penile erection.^{4,7} This implies that the hypogastric nerve plays a role in maintaining baseline sympathetic tone that results in the normal flaccid penile state. However, in patients with hard flaccid syndrome, the pro-

HARD FLACCID SYNDROME

Baseline flaccid state



Hard flaccid state



Figure 1. In the flaccid state, the penis normally hangs over the scrotum, is easily stretched and compressible, feels soft, and is nontender. In the hard flaccid state, the penis is drawn back to the lower abdomen "like a turtle head." The flaccid penis is shrunken, contracted, and noncompressible, and on palpation feels hard, and is described by the patient as tender.

PUDENDAL/PELVIC-HYPOGASTRIC REFLEX IN HARD FLACCID SYNDROME

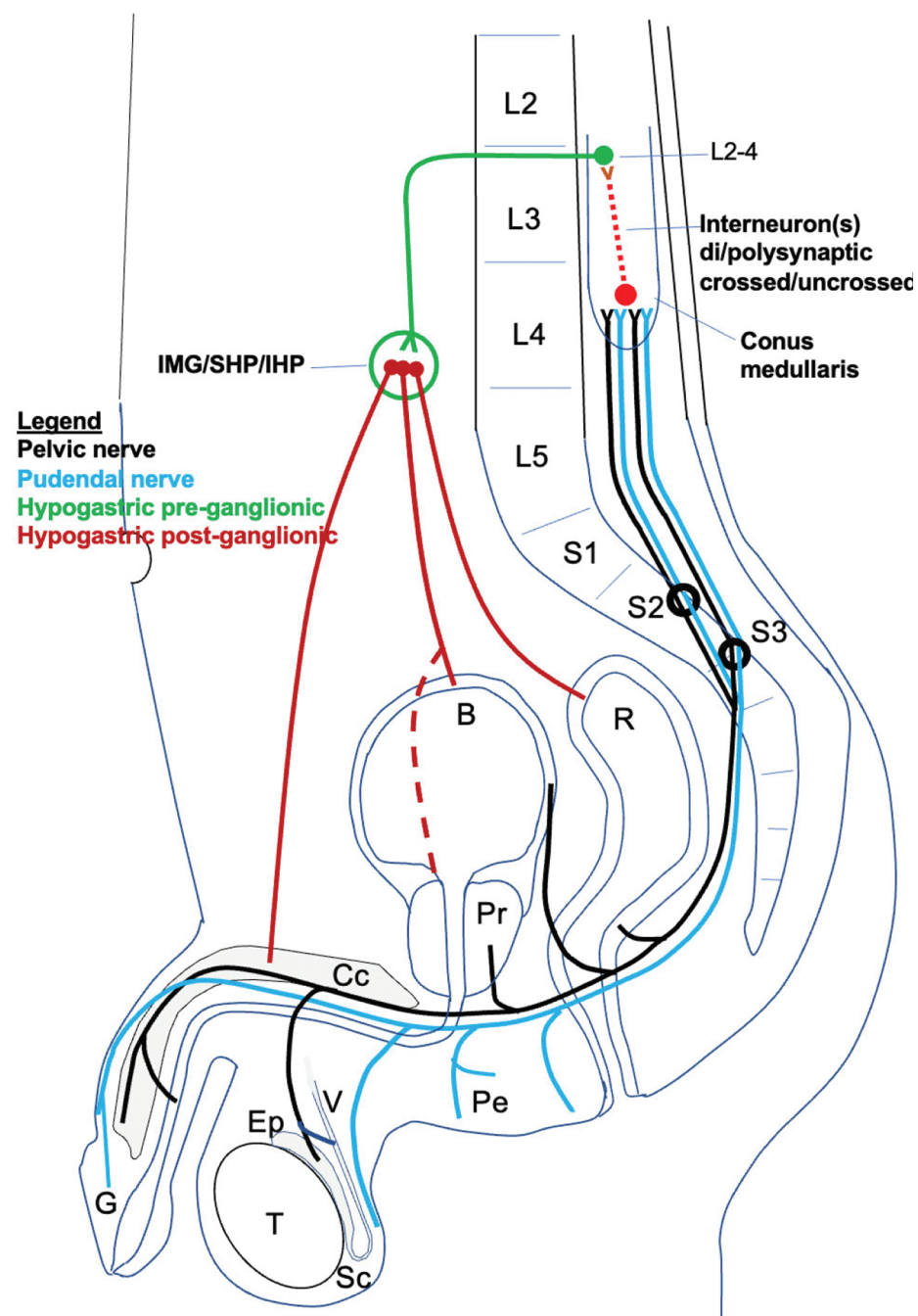


Figure 2. This pelvic/pudendal-hypogastric reflex is a somato-visceral and/or a viscerovisceral reflex. The afferent leg is the dorsal branch of the pudendal (somatic) nerve (S2, 3, 4) and/or the cavernosal branch of the pelvic (visceral) nerve (S2, 3, 4). The first synapse is at the sacral level of the spinal cord (S2-4) in the conus medullaris. The connection between the afferent and efferent limbs of this reflex is likely crossed and uncrossed, di- or poly-synaptic, rather than monosynaptic. The efferent limb (L 2-4) involves the hypogastric preganglionics that synapse in the inferior mesenteric ganglia and the superior and inferior hypogastric plexus. The hypogastric postganglionics pass to the corpora cavernosa erectile smooth muscle tissue, bladder neck, and rectum to release norepinephrine and induce contraction. B indicates bladder; Cc, corpus cavernosa; Ep, epididymis; G, glans penis; IHP, inferior hypogastric plexus; IMG, inferior mesenteric ganglia; Pe, perineum; Pr, prostate; R, rectum; Sc, scrotum; SHP, superior hypogastric plexus; T, testicle; V, vas deferens.

posed excessive sympathetic activity in the hypogastric nerve can account for many of the symptoms resulting from intense pathological smooth

muscle contraction of erectile tissue, bladder neck, and rectum (Figure 2).

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HARD FLACCID SYNDROME PROPOSED

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We propose that the penile pain associated with hard flaccid syndrome is a form of genito-pelvic dysesthesia (GPD).⁸ An expert panel assembled by the International Society for the Study of Women's Sexual Health defined the term GPD to represent an unpleasant, atypical sensation (eg, pain) in the genito-pelvic region

(eg, genitals). The advantage of using this new classification is that GPD can originate in 1 or more of 5 regions: (1) end organ, (2) pelvis/perineum, (3) cauda equina, (4) spinal cord, (5) and brain.⁸

Thus, we propose that hard flaccid syndrome is a consequence of pathological activation of a somato-visceral and/or a viscerovisceral

reflex that we term a “pelvic/pudendal-hypogastric” reflex. This reflex can be pathologically activated at multiple different anatomical sites via triggers located in regions 1-5 (Figure 3). The afferent limb of this proposed reflex is the dorsal branch of the pudendal (somatic) nerve (S2-4) that conveys penile skin sensation and/or the cavernosal branch of the pelvic (visceral) nerve (S2-4) that likely conveys intracavernosal distension pressure sensation of the rigid penile erection.⁹ The first synapse is at the sacral level of the spinal cord (S2-4) in the conus medullaris. The connection between the afferent and efferent limbs of the reflex is likely crossed and uncrossed, di- or poly-synaptic, rather than monosynaptic (W. C. De Groat, personal communication, December 16, 2022).¹⁰ The synapse with the efferent limb of the reflex (ie, the hypogastric preganglionics) is located at the lumbar level (L2-4) of the spinal cord. The hypogastric preganglionics synapse in the inferior mesenteric ganglia and the superior and inferior hypogastric plexus, while the hypogastric postganglionics pass to the corpora cavernosa erectile smooth muscle tissue, bladder neck, and rectum to release norepinephrine, thereby inducing smooth muscle contraction.

We propose that this “pelvic/pudendal-hypogastric” reflex can be pathologically activated in the following regions in the hard flaccid syndrome. For patients with re-

gion 1 (end organ) pathology, we hypothesize excess sympathetic activity occurs secondary to injury to the erect penis (during intercourse, masturbation, jelqing), and some symptom relief is obtained by downregulating sympathetic triggers using analgesics, anti-inflammatory agents, oral alpha-blocking agents (doxazosin, tamsulosin), and/or low-intensity shock wave therapy. For patients with region 2 (pelvic/perineum) pathology, excess sympathetic activity may occur secondary to pain from pudendal nerve neuropathy after blunt perineal trauma (bicycle riding, spinning, horseback riding) and/or high tone pelvic floor dysfunction. In such region 2 patients, neural inhibitory agents (pregabalin, gabapentin, amitriptyline), skeletal muscle relaxing agents (diazepam), pudendal nerve blocks, and/or pelvic floor physical therapy aid in reducing pelvic/perineal drives of increased sympathetic tone. For patients with region 3 (cauda equina) pathology, excess sympathetic activity is thought to occur secondary to sacral radiculopathy from a lumbosacral annular tear and/or sacral Tarlov cyst. In our experience, region 3 patients have a more treatment-resistant hard flaccid state. In this population, once regions 1 and 2 have been ruled out with neurogenital testing and administration of regional anesthetic agents and

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PATHOLOGICALLY ACTIVATED PUDENDAL/PELVIC-HYPOGASTRIC REFLEX IN HARD FLACCID SYNDROME BY REGION

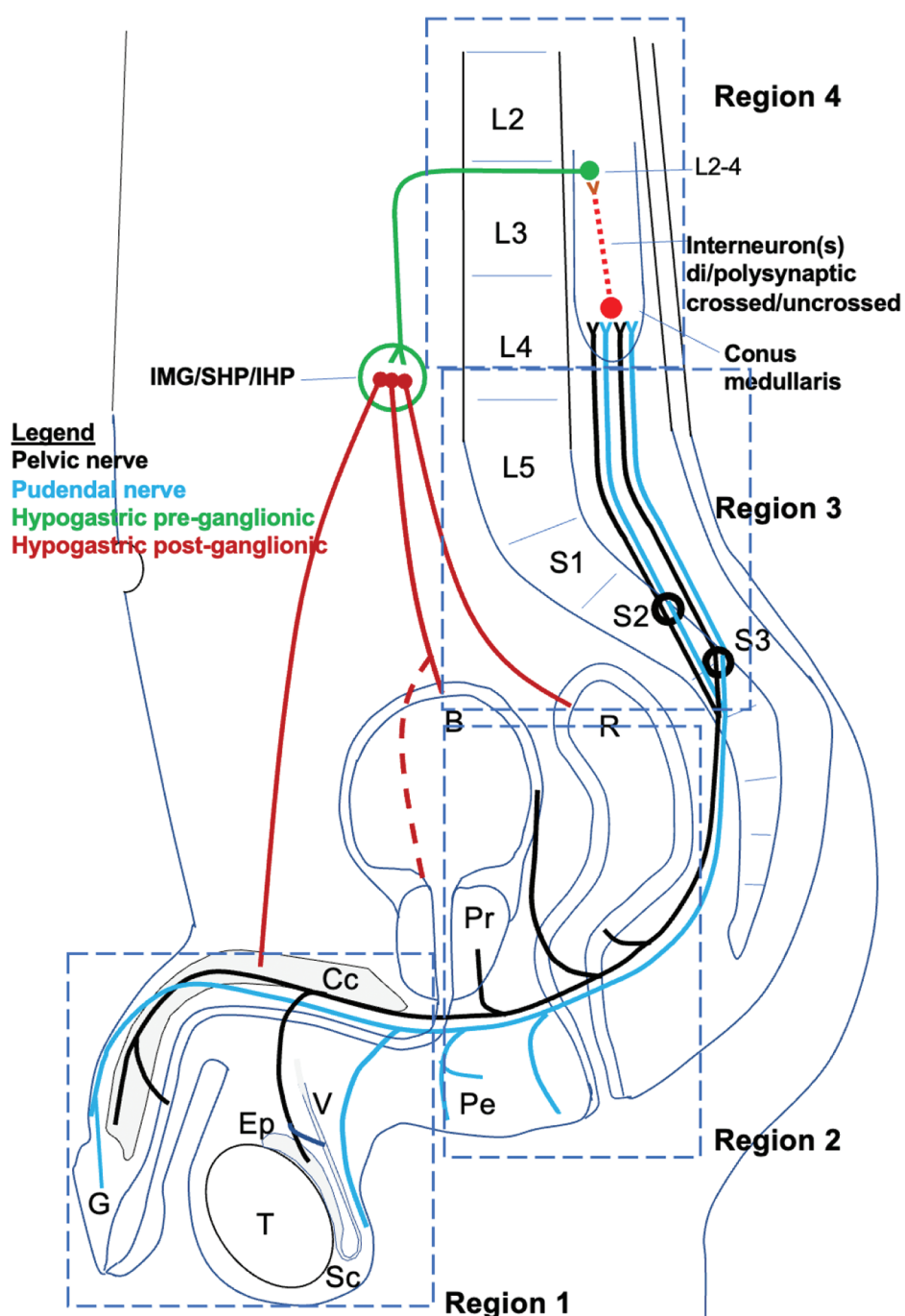


Figure 3. Hard flaccid syndrome is a consequence of pathological activation of a somato-visceral and/or a viscerovisceral reflex, for which we proposed the term, “pelvic/pudendal-hypogastric” reflex. We propose that in hard flaccid syndrome, there is pathological activation of this reflex that occurs at multiple different anatomical sites via triggers located in regions 1-5. Regions 1-4 are shown in this figure. B indicates bladder; Cc, corpus cavernosa; Ep, epididymis; G, glans penis; IHP, inferior hypogastric plexus; IMG, inferior mesenteric ganglia; Pe, perineum; Pr, prostate; R, rectum; Sc, scrotum; SHP, superior hypogastric plexus; T, testicle; V, vas deferens.

Hard flaccid syndrome from region 3 (cauda equina): L5-S1 lumbosacral annular tear-induced sacral radiculopathy

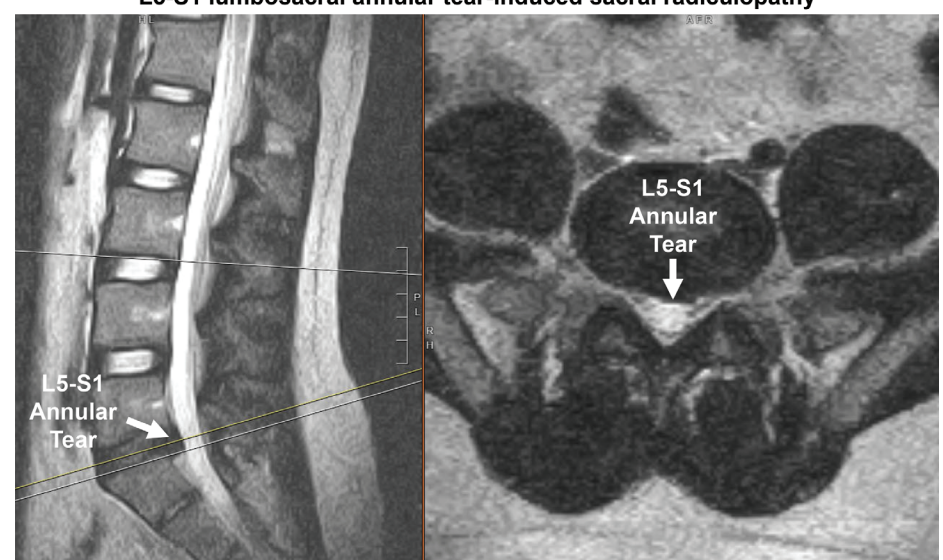


Figure 4. A patient with hard flaccid syndrome was suspected of having sacral radiculopathy triggered region 3 based on neurogenital testing and regional anesthesia testing. This lumbar MRI revealed an L5-S1 disc protrusion with annular tear.

HARD FLACCID SYNDROME PROPOSED

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lumbosacral MRIs show evidence of cauda equina pathology, patients undergo region 3 anesthesia testing.⁸ Those patients with a positive response have undergone spine surgery to resolve the sacral radiculopathy and recovered from hard flaccid syndrome.¹¹

We herein report management of an 18-year-old patient with hard flaccid syndrome. He presented to our sexual medicine facility in 2018 with a 4-month history of erectile dysfunction, depression, decreased penis/glans sensation, and hard flaccid syndrome that involved a smaller, firmer, painful flaccid penis. Conservative medical treatments, sex therapy, and pelvic floor physical therapy performed over a

4-year period yielded no improvement. When the patient revealed a history of low back pain with intermittent sciatica, sacral radiculopathy was suspected. Neurogenital testing performed in 2022 was abnormal, with a pattern consistent with cauda equina pathology.⁸ A subsequent lumbar MRI revealed an L5-S1 disc protrusion with annular tear (Figure 4). He underwent a left transforaminal epidural spinal injection and experienced a transient “much better” improvement in hard flaccid symptoms. At age 23, he underwent a left L5-S1 lumbar endoscopic interlaminar discectomy.¹¹ At 1-year follow-up, he has significantly improved erectile function, penile/glans sensation,

and reduction in hard flaccid syndrome symptoms. He is continuing both pelvic floor physical therapy and sex therapy. ■

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Dietitians in Multidisciplinary Stone Clinics: Evidence and Barriers to Their Implementation

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Nutrition is a key component of prevention for the most common types of kidney stones. The AUA Guidelines for the Medical Management of Kidney Stones include many nutrition-related recommendations, including increasing fruits and vegetables, reducing nondairy animal protein, inclusion of dietary calcium, and sodium reduction, depending on 24-hour urine chemistries and stone type (see Figure).¹ Urologists' perception of the importance of nutrition for kidney stone formers is in line with these recommendations. A 2014 study found that 82% of urologists believe nutrition advice should be given to stone formers, regardless of number of stone events. However, less than 50% of urologists report assessing dietary intake before providing nutrition recommendations, and 36% feel they have insufficient time to provide nutrition education to patients.²

Registered dietitian nutritionists (RDNs) are uniquely trained to provide both nutrition education and counseling to patients for the pre-

vention and treatment of chronic diseases. RDNs are the only health care professionals able to provide medical nutrition therapy (MNT), which includes a nutrition diagnosis and treatment plan to help patients make lifestyle changes to improve health outcomes. MNT provided by an RDN has been shown to improve outcomes related to a variety of health conditions such as chronic kidney disease.³ Conversely, nutrition education, or simply providing information, has not been shown to change behavior. In 2021, Betz et al found that higher knowledge of renal diet recommendations did not correlate with greater adherence in people with chronic kidney disease.⁴ However, counseling strategies such as motivational interviewing can induce behavior changes and improve health outcomes such as reduced hemoglobin A1c, cholesterol, and blood pressure.⁵ More research needs to be done to determine the effectiveness of MNT on kidney stone outcomes specifically.

RDNs have the time and skill to properly assess a patient's current

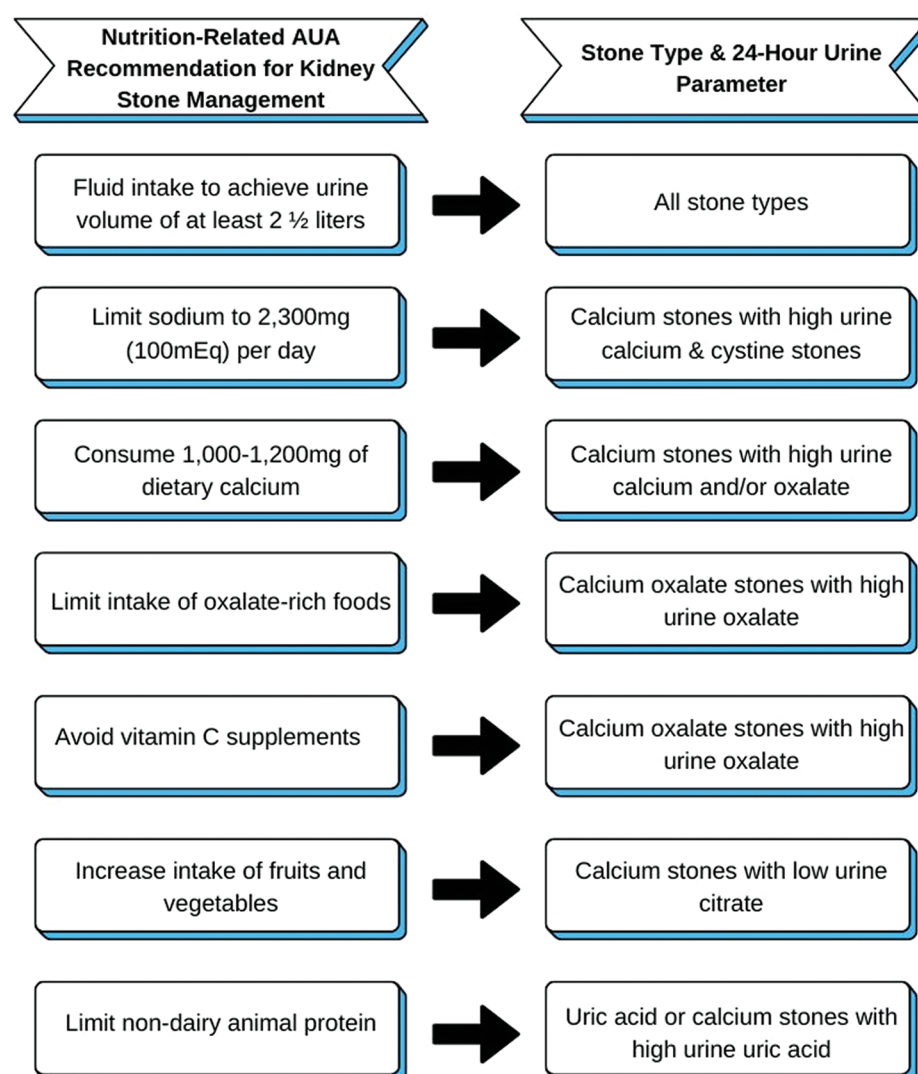


Figure. Nutrition recommendations for kidney stone management.

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DIETITIANS IN MULTIDISCIPLINARY STONE CLINICS

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“Registered dietitians are not necessarily trained in kidney stone prevention. There are no required competencies related to kidney stones in dietetic undergraduate or internship programs, as they are for disease states such as diabetes, obesity, or hypertension.”

dietary intake, identify possible lithogenic eating patterns and/or supplementation, and personalize dietary recommendations for kidney stone prevention. Although 24-hour urine testing provides valuable information about consumption of nutrients such as fluid, sodium, protein, and potassium, only 1-3 days of intake are captured. Urine tests do not provide information about foods consumed, dietary patterns, or timing of meals. RDNs can help better understand patients' long-term dietary patterns and foods consumed that contribute to nutrients of concern for kidney stone prevention to help make effective and realistic nutrition recommendations. Shared medical appointments in a kidney stone clinic that included an RDN have shown to improve 24-hour urine chemistries.⁶ In addition, RDNs can make nutrition recommendations considering a patient's entire past medical history. This is especially important as comorbid conditions with nutrition considerations such as cardiovascular disease, hypertension, chronic kidney disease, and inflammatory bowel disease are common in people with kidney stones.⁷

Nutrition misinformation about kidney stones is prevalent. A 2021

study found that 23% of YouTube videos had inaccurate claims about kidney stones, and videos with inaccurate claims had more than twice the user engagement compared to videos with accurate claims.⁷ Nutrition was a common topic covered in YouTube videos; 28% discussed prevention including diet and hydration, and dietary supplements, natural remedies, and alternative medicine were promoted in 25% of the videos.⁸ In 2018, education materials provided in the emergency department were found to be a common source of nutrition misinformation, or inappropriate for people with kidney stones.⁹ RDNs can help reeducate patients about evidence-based strategies to prevent kidney stones, and direct patients to focus on strategies relevant to them, based on 24-hour urine studies. This could help improve patient confusion and frustration surrounding nutrition recommendations for stone prevention.

Despite the benefits, many barriers exist to the inclusion of RDNs in kidney stone clinics. Kidney stones are not a covered diagnosis for MNT by the Centers for Medicare and Medicaid Services. Coverage by private insurance payers varies. Patients may be required to pay out of pocket for RDN services if they are not subsidized by the urology clinic.

Registered dietitians are not necessarily trained in kidney stone prevention. There are no required competencies related to kidney stones in dietetic undergraduate or internship programs, as they are for disease states such as diabetes, obesity, or hypertension. As a result, many RDNs will require training to competently provide nutrition recommendations for kidney stone prevention. Given the high prevalence of nephrolithiasis, the Accreditation Council for Education in Nutrition and Dietetics should consider including a competency related to nephrolithiasis for accredited programs.

Lastly, RDNs are not currently available in most urology patients. Only 23% of urologists report partnering with an RDN,² and a 2014 survey found that only 8% of RDNs

Table. Summary of Benefits and Barriers to Registered Dietitians in Kidney Stone Clinics

Benefits of Registered Dietitians in Kidney Stone Clinics	Barriers to Registered Dietitians in Kidney Stone Clinics
Nutrition is a key component of prevention for the most common types of kidney stones	Lack of/inconsistent insurance coverage of MNT for kidney stone prevention
Likely greater adherence to nutrition recommendations and more effective stone prevention	Lack of RDN training in kidney stone prevention
Assessment of current dietary patterns, foods and supplements consumed	Lack of access to dietitians in urology clinics
Comorbid health conditions considered in dietary advice	
Help correct misinformation	

“The urology community should work to increase the availability of RDNs for kidney stone patients.”

provide MNT for kidney stones as part of multidisciplinary clinic.¹⁰ A summary of the benefits and barriers to the inclusion of registered dietitians in kidney stone clinics is provided in the Table.

The urology community should work to increase the availability of RDNs for kidney stone patients. RDNs can help patients implement nutrition-related recommendations for kidney stone prevention, prevent kidney stone recurrence, and improve the health and well-being of patients. ■

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CASE REPORT

Endoscopic Treatment of a Ureteric Stone in a Paraperitoneal Ureteroinguinal Hernia

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Introduction

Modern endourology has allowed surgeons to treat stones in complex situations that would previously require a major intervention. While less invasive treatment for complex stones provides faster recovery, some cases pose complex challenges. The complexity may result from stone burden and location, patient comorbidities, anatomical characteristics, or a combination thereof. Herein we describe the diagnosis, management, and follow-up of a patient with a right ureteric stone in the context of a massive paraperitoneal ureteroinguinal hernia (UIH).

Case Presentation

A 76-year-old man with a medical history significant for hypertension, type 2 diabetes, neurogenic bladder, and a right inguinal hernia was transferred with a 12-mm ureteric stone, chills, and subjective fever. Investigations revealed a marginally elevated creatinine (150 $\mu\text{mol/L}$) and leukocytosis ($22.1 \times 10^9/\text{L}$). CT scan showed a low-lying right kidney with perinephric fat stranding and a 12-mm ureteric stone with moderate proximal hydronephrosis. Noteworthy, part of the ureter was herniated within a large right indirect inguinal hernia (Figure 1, A-F).

Management

The patient was started on broad-spectrum antibiotics, and urinary decompression was indicated and achieved with a right US-guided nephrostomy tube insertion. The patient stabilized clinically and was discharged well from the hospital.

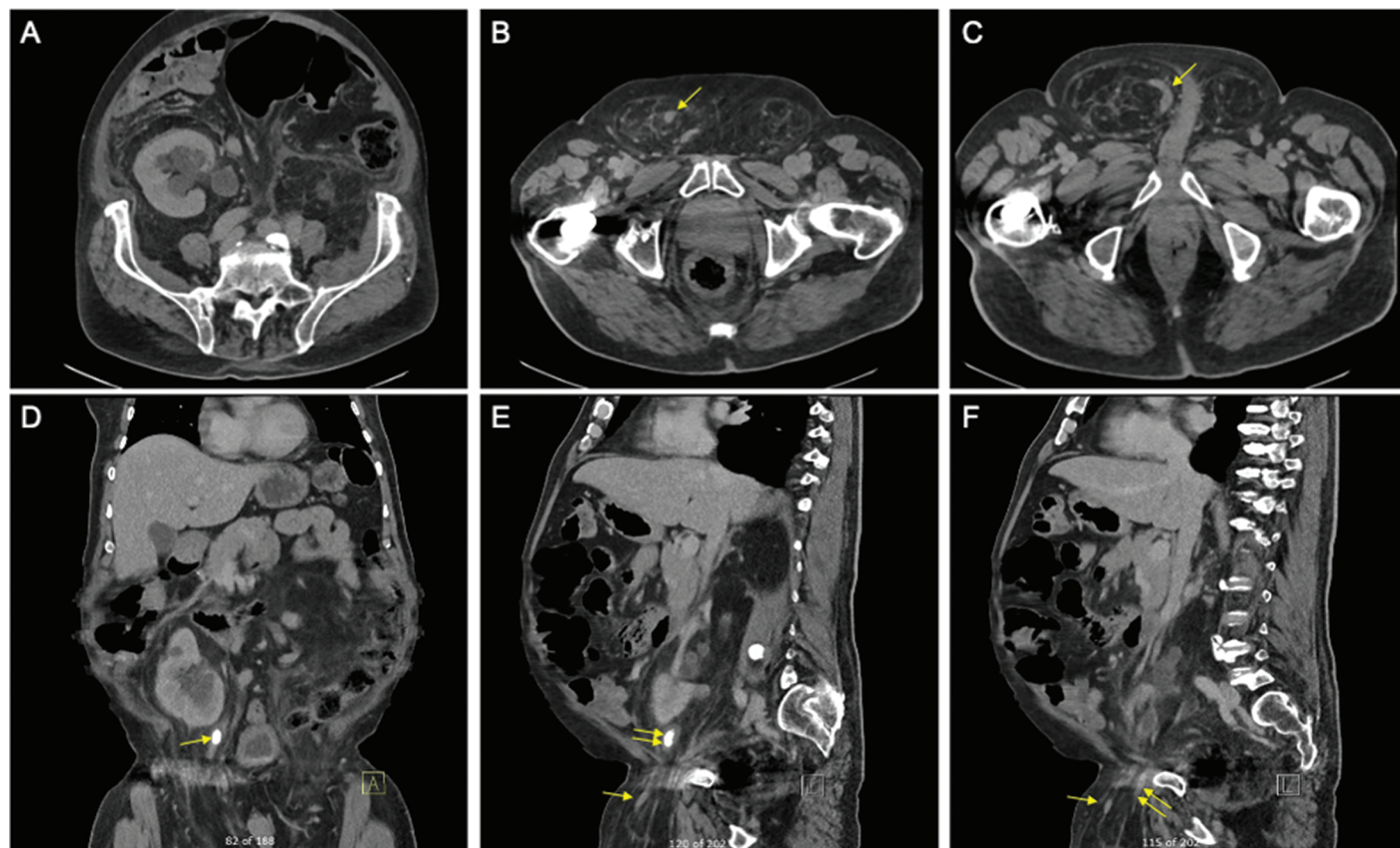


Figure 1. CT scan cross-sectional axial (A-C), coronal (D), and sagittal (E, F) images of kidney, ureters, and bladder: A, Low-lying hydronephrotic kidney with perinephric fat stranding. B, A segment of the ureter (arrow) along the inguinal hernia. C, A loop (arrow) of the herniated ureter. D, The 12-mm ureteric stone (arrow) with upstream hydronephrosis. E, The 12-mm ureteric stone (2 arrows) and the ureter through the inguinal hernia. F, The ureter going in (arrow) and out (2 arrows) the inguinal hernia.

A shared decision for ureteroscopy and laser lithotripsy was made for definitive stone treatment. At the time of cystoscopy, we were unable to identify the right ureteric orifice, and therefore a guidewire was advanced in an antegrade fashion through the nephrostomy tube to the level of the bladder. The guidewire was

extracted from the bladder with endoscopic graspers securing through-and-through access. Interestingly, fluoroscopy showed the ureter made 2 complete loops outside the bladder and into the hernia, as documented on retrograde pyelogram (Figure 2, A and B). Following dilation of the ureteral orifice, a digital flexible ure-

teroscope was backloaded over the guidewire and advanced to the level of the stone, which was then effectively fragmented with the holmium:YAG laser. A 30-cm \times 7F double-J stent was placed (Figure 2, C) and the nephrotomy tube removed.

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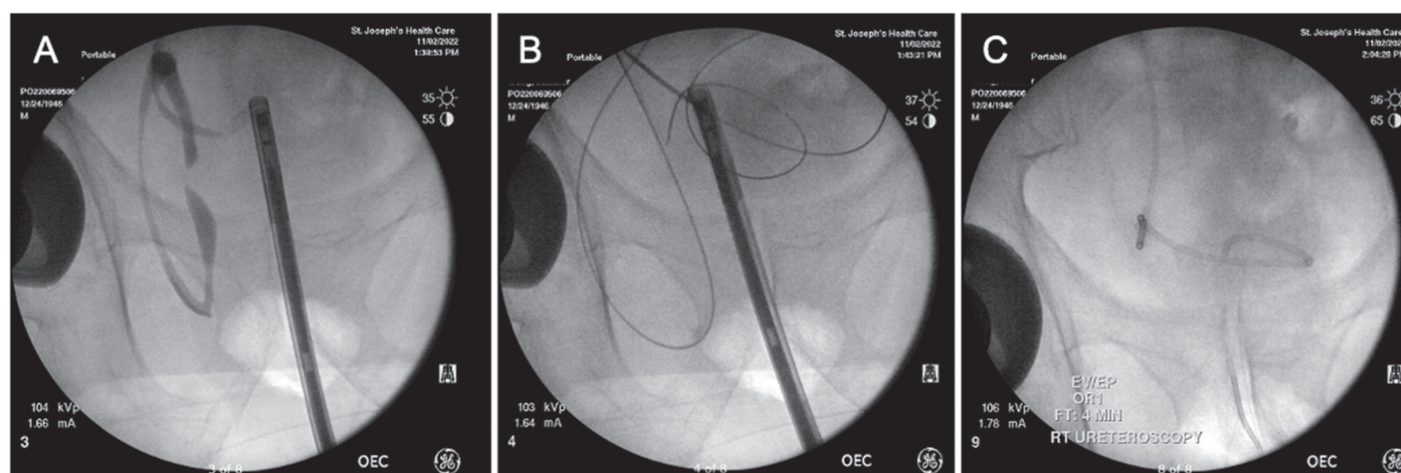


Figure 2. Fluoroscopy stills. A, Retrograde pyelogram showing the ureter looping into the inguinal hernia. B, Ureter cannulated with a guidewire demonstrating the ureter loops. C, Distal loop of the double-J ureteric stent.

ENDOSCOPIC TREATMENT OF A URETERIC STONE

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An x-ray of the kidney-ureter-bladder showed no residual fragments in follow-up, but the ureteric stent had migrated proximally and was not visible at the time of cystoscopy (Figure 3). The migrated stent was removed percutaneously by intervention radiology. Follow-up US showed improvement of the hydroureteronephrosis, and the patient was discharged from urology and referred to general surgery for hernia repair.

Discussion

Inguinal hernias can be classified as direct if they protrude through Hesselbach's triangle or otherwise as indirect. Ureter-containing hernias are rare and can be found on inguinal or femoral defects. UIHs are a unique type of indirect inguinal hernia and can be further divided as paraperitoneal and extraperitoneal. The former is the most common type (~80%) and contains a peritoneal evagination, whereas the latter contains ureter only and might additionally contain some retroperitoneal fat.¹⁻³

As paraperitoneal UIH develops a peritoneal sac, other abdominal viscera may be contained within. Thus, the ureter is pulled down into the inguinal canal along the hernia, attached to the hernia sac wall by an unusual adherent layer of posterior parietal peritoneum. As the ureter

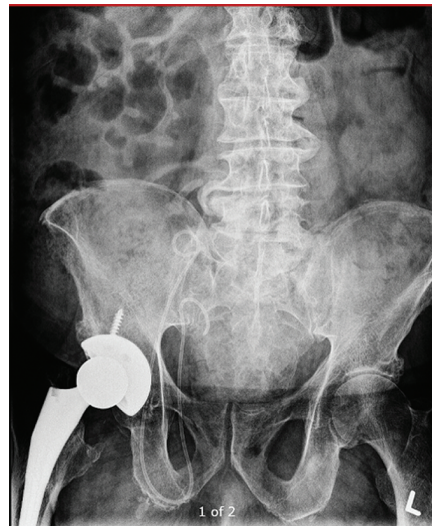


Figure 3. X-ray of kidney-ureter-bladder showing no residual fragments and the proximally migrated double-J ureteric stent along the course of the ureter in the ureteroinguinal hernia.

is a retroperitoneal structure, it is not truly within the peritoneal sac. The extraperitoneal UIH, on the other hand, lacks a peritoneal sac and the ureter protrudes solo along some retroperitoneal fat. The bladder is frequently herniated as well in one-quarter of patients. This type of UIH is mostly associated with urinary tract anomalies as ptosis of the kidney or after kidney transplant. The underlying mechanisms are not fully understood, but a congenital basis has been suggested in which the ureteric bud fails to separate from the Wolffian duct. Both the bud and the Wolffian duct are drawn down to the scrotum to form the epididymis and vas deferens.²⁻⁵

UIHs are mostly underdiagnosed until unexpectedly encountered during surgery, thus carrying a risk of ureteric injury. UIH can be asymptomatic, but otherwise may be diagnosed when associated with other conditions such a stone causing obstruction and/or urinary tract infections, hydroureteronephrosis, acute kidney injury, and lower urinary tract symptoms. A CT urogram is paramount for the diagnosis of UIH and associated conditions such as stones. Moreover, CT allows adequate surgical planning. If renal impairment is encountered, magnetic resonance imaging is a good alternative choice.^{3,4}

When urgent decompression is needed in the context of complex stone associated with a UIH, nephrostomy drainage is recommended given challenges that may be anticipated with retrograde stent insertion. In our case, the nephrostomy access also assisted in securing a guidewire to facilitate ureteroscopy. It is also recommended to perform a retrograde or antegrade pyelogram to understand the anatomy and trajectory of the ureter, and this may be facilitated by having a nephrostomy tube in. In fact, the “curlicue” or “loop the loop” sign is pathognomonic of UIH (Figure 2, A). This sign comprises the loops of the ureter vertically oriented and is seen in ureterofemoral hernias and UIHs,

as opposed to more horizontally oriented loops, which are seen in ureterosciatic hernias.⁶

Conclusion

UIHs with urinary stones are exceedingly rare. Despite being a rare situation, it is important to bear in mind that, in a patient with hydronephrosis and an ipsilateral inguinal hernia, UIH is a possible diagnosis and important to anticipate in cases where hernia repair is contemplated. Moreover, endourological management of patients with stones in the context of UIHs is feasible yet challenging, and surgeons must mind the risk of stent migration as ureteral length is typically enhanced. Nephrostomy tube placement facilitates the treatment for both retrograde and antegrade approaches. ■

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Closing the Orgasm Gap: Another Gender Disparity

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Everyone, both men and women, deserves to experience an orgasm. There are several disparities between men and women, including longevity between men and women, gender pay disparity, and orgasm disparity. The orgasm gap, or pleasure gap, is a social and physical phenomenon referring to the general inequality between men and women in terms of sexual satisfac-

tion—more specifically, the unequal frequency in the achievement of orgasm during sexual encounters.

Currently, across every demographic studied, women report the lowest frequency of reaching orgasm during sexual encounters with men. The size of the orgasm gap varies from 20% to 72%, to the disadvantage of women.¹ This report will discuss the definition and causes of orgasm disparity and suggestions for closing that gap.

Studies have found that heterosexual women have the fewest orgasms during sex, which could

come from a lack of understanding of female anatomy, the vulva, and the clitoris.²

A pleasurable and healthy sex life can't be measured purely by how many orgasms people have. Still, studies have found a considerable difference between the number of orgasms men and women experience in heterosexual relationships.

Gap Disparity

Multiple factors may contribute to the orgasm gap. The fault for the orgasm gap doesn't lie with penises

or vaginas. The fault lies primarily in cultural expectations and traditions and a lack of knowledge of what stimulations are most effective for the female partner.

From ancient times, sex has been surrounded by myths and misinformation. Since recorded history began, sexual intimacy has been relegated primarily to procreative activity. Historically, other forms of sexual intercourse, such as oral sex, anal sex, and oral clitoral stimulation, were considered

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CLOSING THE ORGASM GAP: ANOTHER GENDER DISPARITY

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immoral. We have moved beyond antiquated values, and most people openly embrace sex for pleasure and procreation.

Most people use the terms sex and intercourse interchangeably. Due to our culturally established ideas that sex is the insertion of a penis into the vagina, women are less likely to experience orgasms. Unfortunately, vaginal penetration favors male orgasms, whereas clitoral and genital arousal favors female orgasms. Clitoral stimulation and oral sex are often classified as foreplay rather than sexual experiences.

Another hangover from our puritanical past is the definition of the end of a sexual act. Traditionally, sex was associated with procreation. Sex was considered complete once the male deposited his semen into the vagina. Unfortunately, female orgasm wasn't deemed necessary because it didn't contribute to procreation. Even today, men may consider the sexual act complete after ejaculation, regardless of whether their female partners have achieved an orgasm.

There has been abundant information on the role of the penis and very little on the anatomy and physiology of the clitoris. The penis serves multiple purposes—urination, procreation, and pleasure. However, in women, all these purposes are distributed among different organs. The clitoris is the seat of ultimate female pleasure, making it key to female orgasms. Less than 10% of women can orgasm with vaginal penetration alone.³ Most women need clitoral stimulation to achieve an orgasm.

Additional causes for the existence of the orgasm gap include:

- Women are judged more harshly for wanting casual sex than men
- Sex education focuses on abstinence or procreation—not female sexual pleasure
- The lack of awareness of the clitoris's crucial role in female orgasms
- Little to no education in sexual communication, which is essential for female orgasms
- Body consciousness and lack of self-esteem can come in the way

of experiencing sexual pleasure.

Closing the Orgasm Gap

Good communication is vital when it comes to female orgasms. There are differences between women regarding what they need to orgasm—and what women need to orgasm can vary from one encounter to another. Many women are plagued by body image self-consciousness during sex, and it's impossible to have an orgasm while worrying if they are feeling fat.

Tips to help women experience orgasms:⁴

- Expect and request more oral sex and clitoral stimulation
- Increase the duration of the sexual experience
- Focus on methods to improve the overall quality of the relationship
- Discuss what you expect in bed
- Praise the sexual partner when they do something correctly
- Tactfully give instructions to the partner's do's and don'ts
- Explore new sex positions
- Explore anal stimulation
- Discuss sex fantasies
- Express love during the sexual experience

Women should teach themselves (and their partners) about clitoral stimulation. Developing an understanding of the clitoris isn't enough to achieve consistent orgasms. Women must explore their bodies to discover their erogenous zones. Women need to discover their bodies and accurately instruct their sexual partners on what they enjoy and what areas of their bodies require stimulation.

In their landmark research on sexual function and dysfunction published in 1970, Masters and Johnson also emphasized the educational direction of the partner in genital-play episodes. Their research revealed the most significant error of men is “the direct attack on the clitoral glans.” Their studies emphasized for a satisfactory sexual encounter, stimulation of the general mons area along either side of the clitoral shaft. In addition, their study of female sexual response found that the inner aspect of the

thighs and labia are erotic areas for most women.⁵

Numerous clitoral-focused sex toys have arisen to help women achieve orgasms. Clitoral sex toys focus on clitoral stimulation to help women achieve regular orgasms and bridge the orgasm gap. Clitoral vibrators are effective in delivering sonic pulses into the clitoris. These sonic pulses vibrate the entire clitoral structure, helping women achieve orgasms within minutes.

Once women understand their bodies, they can more accurately guide their partners to help achieve better orgasms.

Women's orgasms are an area where knowledge is insufficient. When penetration is involved, it's often considered the main event and mistakenly assumed to be the way that both partners should orgasm. So, to close the orgasm gap, partners must hold clitoral and erogenous zones stimulation and vaginal penetra-

tion as all-important in achieving female orgasm.

Bottom Line: It's obvious that closing the orgasm gap isn't easy—not for individual women or our culture. Still, it's well worth the effort. With enhanced understanding and communication, both men and women will be happier if sexual intimacy and orgasm are a shared event and equal for both. ■

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Observational Units for Patients With Renal Colic: Between a Rock and a Hard Place

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Introduction

Urolithiasis is a common cause of emergency department (ED) presentation, accounting for over 1 million visits and \$5 billion in health care expenditures annually in the United States.¹ Acute management in the ED requires identifying patients who require admission vs candidates for expectant management. While sepsis from obstructive pyelonephritis is a clear indication for admission and urgent decompression, poor pain control, nausea/emesis, and azotemia are more

Table 1. Summary Demographic and Clinical Data

Clinical parameter	Value
Age, mean±SD, y	51.3±13.54
% Male gender	57.7
% History of nephrolithiasis	57.6
Length of stay, mean±SD, hr	23.4±7.32
WBC count, mean±SD, cells/mm ³	11.5±3.17
SCr, mean±SD, mg/dL	1.25±0.39
Stone size, mean±SD, mm	3.87±2.49
% Proximal stone	27

Abbreviations: SCr, serum creatinine; SD, standard deviation; WBC, white blood cell.

nebulous. For these patients, continued assessment may be warranted for proper disposition, yet utilization of inpatient beds may not be the most judicious use of hospital resources.

The observation unit (OU) is an adjunct to emergency care by serving as an intermediary between hospital admission and prolonged occupation of emergency beds. Studies have demonstrated OU utilization results in comparable health outcomes to inpatient admission, while decreasing length of stay and lowering hospital costs for conditions such as acute coronary syndrome, heart failure, and obstructive pulmonary diseases.²⁻⁴ To the best of our knowledge, we provide the first examination of OU utilization for renal colic and examine clinical factors that may predict inpatient hospital admission.

Methods

A retrospective, Institutional Review Board–approved study of patients with renal colic observed in the OUs of 2 tertiary care EDs between January 2014 and December 2015 was performed to compare patients requiring admission to those discharged following OU stay. Admitting diagnoses of calculus of the kidney, calculus of the ureter, and/or renal colic (ICD-9 592.0, 590.1, and 788.0) with radiographic evidence of obstructive urolithiasis were included. Criteria for placement into the OU was at the discretion of the treating ED physician, typically with urology consultation. Clinicodemographic data including age, gender, history of urolithiasis, laboratory data, imaging findings, analgesia usage, and disposition following OU stay were examined. Average Medicare reimbursement with Diagnostic Related Group 694 and Ambulatory Payment Classification 8011 was used to estimate inpatient and outpatient costs, respectively. Fisher's exact test, Mann-Whitney *U* test, and multivariable analysis using binomial regression were utilized for statistical analysis with *P* < .05 as significant.

Results

Eighty-five patients with renal colic observed in the OU qualified for analysis. Subjects had a mean age of 51.3 years (SD 13.4) with slight male predominance (58%) and urolithiasis history in nearly half (58%; Table 1). Following OU stay, 10 patients (12%) required admission for uncontrolled pain (50%), worsening renal function (30%), fever (20%), and infection (10%). Seven admitted patients underwent intervention, including ureteral stent (n=4) or ureteroscopy (n=3). Nearly 85% of the 75 discharged patients did not return to the ED within 30 days. Of these, 23 patients had follow-up data and underwent successful surveillance or definitive therapy. Eleven (14.6%) of the discharged patients returned to the ED within 30 days, and only 6 required operative intervention.

Only serum creatinine ≥1.5 mg/dL was significantly associated with

admission (60% vs 24%, *P* = .027; Table 2). Other factors such as previous ED visit within 30 days, age, leukocytosis, stone size ≥5 mm, analgesia requirements, and proximal stone location were not associated with admission. On multivariate analysis only azotemia was significantly associated with admission. The average Medicare payment for Diagnostic Related Group 694 in fiscal year 2016 was \$5,457.80, while the equivalent payment for Ambulatory Payment Classification 8011 was \$1,813.30. Total Medicare cost savings approximated of OU utilization was \$273,982 for this cohort.

Discussion

OUs have demonstrated both safety and efficacy as well as cost savings in various clinical conditions. Madsen et al prospectively

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Table 2. Comparison Between Discharged and Admitted Observation Unit Patients

Clinical parameter	Discharged (n=75)	Admitted (n=10)	<i>P</i> value
<i>Univariate model</i>			
% Previous ED visit within 30 d	14.7	20	.65
Age, mean±SD, y	50.9±13.8	53.8±10.0	.77
% Male gender	56	70	.51
% WBC count ≥12,000 cells/mm ³	38.7	60	.30
% SCr ≥1.5 mg/dL	24	60	.027
% Stone size ≥5 mm	40	26.7	.46
% Proximal location	30.7	0	.055
Opioid density, mean±SD, mg morphine/h ^a	0.95±2.5	0.90±0.62	.23
Ketorolac density, mean±SD, mg/h ^b	2.5±4.3	2.1±0.98	.55
<i>Multivariate model</i>			
	Odds ratio	95% Confidence interval	
Age, y	0.99	0.94-1.05	.808
Gender (male referent)	0.35	0.032-3.8	.388
WBC count ≥12,000 cells/mm ³	1.6	0.37-7.1	.513
SCr ≥1.5 mg/dL	14	1.2-160	.037
Stone size ≥5 mm	4.0	0.78-20	.097

Abbreviations: ED, emergency department; SCr, serum creatinine; SD, standard deviation; WBC, white blood cell.

^aNumber = 69 for discharged and 9 for admitted.

^bNumber = 58 for discharged and 5 for admitted.

OBSERVATIONAL UNITS FOR PATIENTS WITH RENAL COLIC

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examined UO utilization for chest pain evaluation in geriatric patients and found no adverse events in those discharged, suggesting patients at high risk for readmission may be safely managed in an OU following careful patient selection.⁵ Another study demonstrated that implementation of an atrial fibrillation treatment algorithm in the OU decreased admissions without an increased risk of readmission.⁶ Similarly, our data suggest that renal colic can be safely managed in the OU. An inpatient admission for uncomplicated renal colic can cost up to 4 times that of an ED visit.⁷ A review of claims data for patients presenting to the ED with chest pain found that OUs saved \$1,535 per patient compared with inpatient admission.⁸ Similarly, when using the 2016 Centers for Medicare & Medicaid Services standard payment database, each patient differs by \$3,644.50, which represents a substantial saving to the health system overall.

We found most patients (88%)

treated in the OU avoided hospital admission, and of those admitted, 70% underwent intervention during hospital stay. Our admission rate is consistent with the 12% admission rate described in a large population study of over 3 million ED visits for upper urinary tract stones.¹ The high rate of inpatient surgical management following hospital admission from the OU in our cohort demonstrates the OU's ability to screen for patients who truly warrant inpatient management. A recent study examining >1 million ED visits for uncomplicated renal colic found that 8% of patients were admitted and only 6% required urological procedures during hospitalization.⁷ It is possible that the use of an OU could have reduced inpatient hospitalizations given the rate of nonintervention by identifying patients who may be discharged from those who would likely require intervention.

Our study, of course, is not without limitations. First, the retrospec-

tive nature and lack of criteria for OU admission increase the risk of selection bias. Second, management in the OU was not based on a specific protocol, and thus discharged patients may have undergone more efficacious treatment. Lastly, follow-up was unfortunately limited as patients were not required to seek urological care within our hospital network.

Conclusions

Our study found that most patients with renal colic observed in the OU can be discharged home without requiring admission or intervention. The OU was a useful intermediary between discharge from the ED and admission to an inpatient unit for equivocal cases and has potential to significantly decrease health care costs. Prospective studies with defined criteria for OU admission, management protocols, and adequate follow-up are needed before widespread adoption of OU utilization for acute renal colic. ■

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Conflict of Interest: None.

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AUA ADVOCACY

Seven Principles to Maximize the Impact of Your Health Policy Research

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Every year, millions of dollars and significant effort are expended in the production of health policy research that may never capture the attention of decision-makers. This is not due to a lack of quality or relevance of the research, but rather because the traditional approach to scientific publication and dissemination is not always in alignment with how policymakers and the public consume information. In this article, I will outline 7 principles that you can use to maximize the impact of your health policy research.

Principle 1. Have a dissemination-focused mindset. For many years, I have considered getting a research study published as the ultimate goal. While it is cer-

tainly an achievement to have a study published, the reality is that most articles will never be read, let alone seen by decision-makers. Policymakers and other important individuals are often bombarded with information from various sources and are unlikely to spend their time searching for your article on PubMed. It's crucial to recognize that publishing should be viewed as a starting point, not the final destination for your research. While the peer review process is important for ensuring that your study is scientifically sound, it is equally important to have a well-planned dissemination strategy to effectively communicate your work. With over 700,000 new citations added to PubMed annually, it's essential to ensure that your research is heard and understood.

“Every year, millions of dollars and significant effort are expended in the production of health policy research that may never capture the attention of decision-makers.”

Principle 2. Become a subject matter expert. In the early stages of your career, it's crucial to identify a specific area of focus in which you can establish yourself as a leading authority on a national

level. In other words, it's important to “pick a lane.” This level of expertise is necessary to enable you to confidently discuss the topic with any stakeholder who is interested in your research. Stakeholders often pose questions that are tangential to your particular study, and your breadth and depth of knowledge in the field will allow you to address those questions with ease.

Principle 3. Create a dissemination strategy based on your audience's needs. Avoid the “curse of knowledge” by presenting your ideas in a manner that is both accessible and relatable to your audience. This will help ensure that they remain interested and invested in your message. It's important to keep in mind that

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SEVEN PRINCIPLES TO MAXIMIZE THE IMPACT

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“Avoid the “curse of knowledge” by presenting your ideas in a manner that is both accessible and relatable to your audience. This will help ensure that they remain interested and invested in your message.”

policymakers may not be well versed in the specifics of your research topic, such as prostate can-

cer or virtual care. Thus, it's crucial to avoid diving into the details too quickly, as this can cause your message to become lost. Instead, take the time to walk your audience through your presentation, document, or meeting by starting at a high level and gradually working your way down to the finer points. By doing so, you can help ensure that your research is understood and valued by all.

Principle 4. Create scalable research products. It is important to convert your research article into a more readable and user-friendly format. This can be achieved through policy briefs, infographics, videos, or a tweetorial. While each research product has its own merits, you should consider creating numerous research products so that your work is widely disseminated.

Principle 5. Make ideas memorable. Chip and Dan Heath's book, “Made to Stick,” presents an acronym called “SUCCESS,” which outlines 6 strategies for making ideas memorable: Simple, Unexpected, Concrete, Credible, Emotional, and Stories. Although scientific research may not inherently possess all of these components, you can incorporate these principles into your communication strategies to effectively convey your findings. For instance, linking your research findings to a patient's personal story can be a highly compelling way to communicate your research outcomes.

Principle 6. Establish distribution channels. Establishing a distribution channel for your research is crucial. One strategy is to collaborate with organizations such

as the American Urological Association. Additionally, you can create your own personal distribution list by collecting the contact information of individuals you meet at scientific meetings or through other channels. Simply request their permission to be added to your research distribution list. With time, this list will expand and grow, providing a valuable platform for disseminating your research.

Principle 7. Have faith in the compound effect. Investing consistent and sustained efforts into research dissemination over time can yield significant rewards and opportunities. Although it may not appear evident in the initial stages, after several years, you will notice that your impact will be much greater with much less effort. ■

OUT OF OFFICE

Mini Medical College

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I am grateful for the opportunity to provide an update to the original article published in the July 2021 edition of *AUANews*. For those readers who are not familiar with the program, allow me to briefly review my current role, and the Mini Medical College program.

I am a clinical urologist with administrative responsibilities for the Bon Secours Charity Health System in New York. These roles include the Administrative Director for Robotic Surgery and Director of the Bloodless Medicine Surgery Program.

I developed the Mini Medical College program in 2017. The concept behind the curriculum is to bring medical school to high school junior and senior students. The program is available for students of all racial and economic backgrounds. I do not accept any form of remuneration from the schools or students.

When the initial article was published in *AUANews*, I hosted the pro-

gram for 3 high schools located in 3 New York counties. The program has since expanded to include 2 additional high schools, for a current total of 5 high schools located within 4 New York counties. The Mini Medical College has been featured in 3 regional newspapers and several social media platforms, prompting inquiries from varying regions of the United States (see Figure).

This program is unique in that it is integrated into the schools' curriculum throughout the academic year. The classes are held onsite in the actual classroom. Students are exposed to new and exciting content that has previously been reserved for medical school students.

The program is offered to all high school juniors and seniors, and is not solely for the advanced placement or high academic achievers. There are many students who have the potential to become health care providers, but not all of them have had the same exposure or nurturing home and academic environments.

The goals of the Mini Medical

College program are to challenge the students, increase their vocabulary, teach new hand skills, and motivate them for life. If they become interested to explore the medical field—even better.

A series of 20 sessions is provided over the span of the school year. I provide a session at each school on a rotational basis. The course content is custom designed specifically for the high school student. Medical school didactics are combined with clinical practice and presented in an engaging and stimulating format.

Since last year, I have added lectures and refined course material to remain relevant. Students are encouraged to share their thoughts on the course material and to contribute their ideas. I often query students about their interests and compose presentations to align with their thoughts.

The Mini Medical College curriculum includes the following topics:

1. Health Care Career Options
2. Medical School Admission: Build a Pathway

3. Interviews: Create and Relate
4. Patient Engagement: Building Trust
5. Physical Examination
6. HIPAA (Health Insurance Portability and Accountability Act): Medical Law and Ethics
7. Learn to Interpret Chest X-rays
8. Learn to Interpret CT Scans
9. Bloodless Medicine and Surgery
10. Kidney Stone Presentation: Prevention, Management, and Treatment
11. Interpret Blood and Urine Test Results
12. COVID-19: Microbiology; Vaccines
13. Dermatology: Appearances and Pathophysiology of Rashes
14. Blunt and Penetrating Trauma: Injuries and Management
15. Medical Apps: Concept to Market
16. Robotic Surgery: Joints to Kidneys
17. Learn to Suture and Tie Knots
18. Common Illness: Definitions, Pathophysiology, Prevention, and Treatment (strokes, myocardial

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MINI MEDICAL COLLEGE

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infarction, pneumonia, vaping and lungs, appendicitis, poison ivy, and kidney stones [Part 1 and Part 2]

The schools are always amazed how the suture/knot tying sessions engage the students more than any other class. We have yet to observe any student glance at their mobile device during these classes. Throughout my own years of education, beginning with high school, student engagement was not at the core of education. A teacher/professor would present a topic for 45 to 60 minutes, and we were trained to listen and copy what was displayed on the blackboard or screen. We did not know what engagement was, nor were the classes oriented as such. However, today's high school students spend the majority of their lives constantly stimulated and engaged, whether it be on their personal mobile device or computer. The "old school" style of education is not applicable to the current high school generation. If we are to have an impact and influence the students, we must evolve teaching methods to engage them. I continue to modify the presentations to promote interactive education and encourage student involvement.

The high school students have minimal medical knowledge since the standard school curriculum is void of medical education. Therefore, students do not yet have the medical fund of knowledge to answer clinical questions. However, they are encouraged to listen, think, and discuss the possibilities. This always leads to fun and stimulating conversation.

In the Fall of 2021, I implemented a new dimension to the Mini Medical College program. I developed a clinical internship. Students are invited to accompany me during clinical office hours for a semester, and earn school credit for their initiative.

All patients are asked in advance if they approve of having a student observe their visit. The majority of patients agree. Those patients who object have their wishes respected.

The internship provides the students with the rare opportunity to observe patient-physician interaction, including the art of per-



Figure. Richard Evans, MD, a urologist with the Bon Secours Charity Health Systems, WMC Health Network, is pictured at the Chester Academy in Chester, New York, October 8, 2021. Evans started a Mini Med School and travels to various schools in the region to talk to teens about various medical careers. Reprinted with permission from Mark Vergari/The Journal News/USA Today Network.

forming a physical examination. They observe how the physician must focus on listening, and how to provide a trusted platform for the patient to be heard. The skill of asking questions is learned in real time, and how probing questions can elicit important information. They are exposed to the electronic medical record system, and observe how technology and medicine intertwine. After each patient encounter, the student and I review the highlights of the encounter and define medical vocabulary/terms.

The personal satisfaction for providing the Mini Medical College program is the appreciation expressed by the students, and school leadership. Recently, one of the high school professors forwarded me one of their high school senior's college essays. It was at this moment that I realized the true impact we can have on high school students. The essay included how her experience with the Mini Medical College made her realize how a physician can impact lives in ways she never realized before. The sense of accomplishment upon seeing my name in her college essay has been a motivating force to build and expand the program.

I encourage high schools to offer

the program to students of all backgrounds and academic achievements. The more schools that can incorporate the Mini Medical College program into their curriculum will enable us to enhance the educational experience for students of varied economic and racial backgrounds.

It is imperative that we support the effort to diversify the physician workforce. In October 2022, New York state announced it is doubling its spending to \$2.4 million on a variety of college and medical school programs. However, we must start even earlier in the education process to engage and motivate students to enter the health care field. If we leave it until the college years to motivate students to enter the medical field, it will remain a challenge to redirect students' interests.

According to the Association of American Medical Colleges (AAMC) 2022 data, there was an 18% spike in medical school applications across the United States in 2022. The COVID-19 pandemic's uneven toll in communities of color across the nation motivated many people of color striving to remedy health inequalities.

In New York, for example, more than 30% of the state's population is Black or Hispanic, but only 12% of physicians represent those demo-

graphics. Studies have revealed that people of color are healthier when treated by physicians of color.¹ The Mini Medical College program has been integral in engaging the students and allowing them to open their minds to a medical career. Waiting to influence college students to pursue the medical field might prove to be more challenging than initiating the process in high school.

My role as the course instructor has allowed me to entertain candid and frequent conversations with students of varied backgrounds. The medical field is often seen by many students as an unattainable profession and thought of as a pathway only for the wealthy and privileged students. Through these classes, they are enlightened that with hard work, sacrifice, and direction, they can compete with anyone and pursue a medical career. I provide information and options to improve their preparedness in order to realign their high school goals.

I encourage my fellow colleagues to join me in bringing medical school to high school students. Urologists have always been at the forefront of technology and continue to lead in the advancement of medical care. If we can initiate the movement to connect to high school students, others will follow our direction.

The journey starts with reaching out to just one high school, and forming a program to fulfill your personal vision. University hospital programs are in a position to provide a more vigorous curriculum by enlisting multiple providers to visit neighborhood schools. This will provide a benefit to the students, but will also help to strengthen relationships within the community.

The Mini Medical College program affords us the opportunity to be a physician, teacher, role model, and guidance counselor. The ultimate goal is to shape lives for the future—an opportunity we should not overlook or pass on to someone else to ensure the viability of the medical field.

Leadership through education—a wonderful win for everyone. ■

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MEDICAL STUDENT COLUMN

A Guide for Medical Students Without Home Residency Programs or Strong Research Opportunities

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Pursuing research as a medical student can be challenging, especially when attending a school without a residency program or strong research opportunities. However, with persistence, creativity, and networking skills, you can still make significant contributions to the field. In this essay, we will explore tips and best practices for medical students who want to pursue research despite these challenges.

1. Find a Mentor

Having a mentor is a crucial factor in the success of your research endeavors as a medical student. A mentor provides guidance, support, and resources throughout your research journey. A good mentor should have experience in the field you are interested in, including a high level of academic productivity, and be willing to invest time and energy into your growth as a researcher.¹

To find a mentor, first identify attendings in your field of interest within your institution. If you cannot find any actively conducting research, consider looking outside your institution. To do so, search for potential mentors on PubMed, Scopus, or Google Scholar, and examine their publication output. Additionally, assess their interest in mentoring by checking their previous mentoring experience, which can be determined by contacting their coauthors or checking their social media profiles, such as Twitter and Instagram.

You may need to identify multiple possible mentors and contact them sequentially as not all mentors will be able to accept new mentees. Most times, simply emailing a

principal investigator (PI) to ask for research opportunities is often not enough. Instead, try to be creative and develop or run a study, and then reach out to someone with a draft of your work asking for help to complete it. There are many research projects that can be done remotely using databases and tools, and many projects in one field can have universal applications. For example, a study on malpractice lawsuits among ophthalmology trainees² could be applied to urology trainees,³ or similarly a study on the quality of online information about a certain pathology or treatment in one field may apply to another.^{4,5} If you possess research training or experience, such as statistical analysis abilities or an MPH/MS degree, emphasize it in your communication with potential mentors. Don't become disheartened if you don't receive a response initially, as mentors often have many commitments. A polite follow-up email can serve as a gentle reminder for them to respond.

Other avenues to gain experience include participating in journal clubs, attending research meetings, or shadowing in clinic. Also, strategically utilizing a summer break during medical school may provide time to embark on independent research projects, form connections, and gain valuable experience in the field. Most students interested in research opt into doing this between the first and second years of medical school.

Once a mentor has expressed interest in accepting you as a mentee, it is important to have open communication with your mentor and to set clear expectations from the start. A mentor-mentee relationship is a 2-way partnership, and as a mentee, you should be proactive in seeking feedback and support from your mentor. Regular check-ins, updates on your progress, and an open dialogue about any challenges you may be facing will strengthen the relationship and

help ensure the success of your research project(s). Having a mentor who is also the PI of your research project is particularly beneficial, as it can streamline the process and help ensure that your project is well designed and properly executed.

2. Be a Good Mentee

As a medical student seeking a mentor, it is important to be proactive and demonstrate your dedication and commitment to the research project.⁶ Here are specific steps you can take to be a good mentee:

- Engage with previous mentees: If your potential mentor has previously mentored medical students, reach out to them and ask about their experience. These individuals can offer valuable insights into the mentor's working style and provide tips on how to be successful. Additionally, befriending previous mentees can be beneficial, as they are usually 1 to 2 years ahead of you and may be able to offer more specific guidance than your mentor, who may have graduated from medical school years ago. By networking with previous mentees, you can establish connections that may help you to identify research opportunities, and to collaborate on future projects.
- Identify ways to improve research efficiency: As a mentee, you can suggest ways to streamline the research process and increase efficiency. This could include using online tools or databases, collaborating with other researchers, adopting new research methods, or streamlining a platform (ie, create/organize a Google Drive document that contains an ongoing research project).
- Find avenues to promote research: It is important to disseminate your research findings through conferences, publications, and other channels. Work with your mentor to identify the best opportunities to share your work with others in the field.

- Regularly communicate with your mentor: Regular check-ins and updates on your progress are important for maintaining a strong mentor-mentee relationship. Keep your mentor informed of any challenges you may be facing and be open to feedback and suggestions.

- Avoid overpromising: It is not uncommon to stretch oneself thin, particularly when embarking on the research process. Refrain from committing to a project if you are unable to allocate sufficient time to it, given the extensive time investment required for research. Your prospects for future collaborations may be impacted if you are known for consistently missing deadlines and taking an extended amount of time to respond. Declining a proposition is preferable to agreeing to it and ultimately disappointing others.

Remember that a good mentor is an invaluable resource, but it is up to you as the mentee to take the initiative and make the most of the opportunity.

3. Understand the Different Types of Publications and Meetings

It is important to understand the different types of publications available to researchers. A publication is a written work that has been accepted for publication in a peer-reviewed journal. An abstract is a brief summary of a research article. Meetings are conferences or seminars where researchers can submit their abstracts, present their work, and network with other researchers.

Google Scholar displays both peer-reviewed publications and abstract publications presented at conferences. PubMed only displays peer-reviewed publications of PubMed-indexed journals. It is important to note that many journals are not indexed by PubMed.

A GUIDE FOR MEDICAL STUDENTS WITHOUT HOME RESIDENCY PROGRAMS

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Additionally, not all conferences publish abstracts that were presented. Within the realm of publications, there are different types of articles, including literature reviews, case studies, commentaries, and original research.⁷ The process of publishing research as a medical student can pose financial challenges, as many journals require payment for publication. However, some journals have taken steps to mitigate this issue. For instance, Florida medical students can consider using the Florida Medical Student Research Publications (FMSRP) channel within the *Cureus Journal of Medical Science*. This platform offers free publication opportunities, aimed at increasing authorship among medical students.

While a journal publication is a widely recognized accomplishment in the field, presenting research at meetings and conferences can also serve to establish a student's reputation and provide useful networking opportunities. Attending meetings and conferences can also incur significant expenses, such as travel and accommodation costs. Nonetheless, medical students may consider traveling in groups or seeking funding through their institution as aid. A mentor or PI can also be invaluable in guiding the student in selecting suitable journals or conferences for publication and presentation.

4. Develop a Simple Approach to Writing and Seek Feedback

As a novice in scientific writing, it is essential to be open to feedback tips given by experienced editors. One effective approach to writing a scientific manuscript is to focus on clear, concise, and well-structured writing. In the Introduction section, provide a brief background, highlight the gap in knowledge that your study aims to address, state your hypothesis, and clearly outline the objective of the study. In the Discussion section, summarize the gap in understanding addressed by the study, critically evaluate the major findings, explore additional findings and their relationship to existing literature, acknowledge the limitations of the study, discuss future research directions, and provide a clear conclusion and impact statement.

5. Take Advantage of Resources and Programs

Coursea. Coursea offers a number of online courses related to statistics and research methodology that can be helpful for medical students. Some relevant courses include "Introduction to Data Science in Python," "Data Analysis and Statistical Inference," and "Data Management and Visualization."

YouTube. YouTube can be a great resource for medical students looking to learn more about research methodology and statistics. Some channels to check out include Crash Course Statistics, StatQuest with Josh Starmer, and Khan Academy Statistics.

Twitter. Twitter has emerged as a highly effective tool for building and maintaining connections within the urology community, and its usage has surged in recent years.⁸ In addition to its networking benefits, Twitter can serve as a valuable source of information on residency programs, events, and social activities for residents.⁹ The platform has also gained popularity in other fields, including orthopedics, where it is utilized to showcase research publications, presentations, and professional achievements, as well as to stay up to date on the latest developments in the field. Overall, Twitter offers an excellent opportunity to enhance one's visibility and reputation within the medical community. Lastly, it is worth noting that certain Twitter profiles, including @Uro_Res and @UroResidency, offer regular updates on urology programs that provide research opportunities. These accounts can be beneficial resources for individuals looking to stay informed about the latest developments in the field and identify potential opportunities for professional growth.

Specific Programs for Minorities. Participating in research programs geared toward minority medical students can provide additional support and resources to help overcome the challenges of pursuing research as a medical student. These programs can provide significant opportunities to work with experienced researchers, receive mentorship, and access funding and resources that can help enhance the research process. Some programs

also provide a supportive community for minority students to network, build relationships, and share their experiences. Research programs for minority students can be found at various academic institutions and medical or public health agencies. Such programs aim to increase the representation and success of underrepresented minority students in research.

6. Do You Need to Take a Research Year?

A research year is a highly sought-after and increasingly common experience among medical students. A research year offers medical students the chance to expand their knowledge and gain a deeper understanding of their chosen field. It can also provide a unique perspective on the research process, including the planning and execution of a project, data analysis, and communication of results. A research year is also an excellent way to build a skill set in research through formal coursework. Furthermore, building relationships with mentors and experts in the field can provide students with invaluable resources and opportunities as they begin to navigate the residency process.

While many students have been accepted into urology programs without prior publications, having research experience and publications can increase the likelihood of being selected for competitive programs. A 2020 study determined that medical students accepted into top 50 urology programs had an average of 2.38 ± 4.19 PubMed publications. The study also found that 38.8% of students had no publications.¹⁰ However, the impact of the Step 1 exam transitioning to a pass/fail scoring system on research productivity's importance in the selection process remains unclear. A 2023 study identified that the pre-residency h-index, a metric that measures an author's productivity and citation impact, was strongly associated with the production of urology residents.¹¹

Ultimately, an honest mentor can help you evaluate your com-

petitiveness based on several factors, including your research experience, work ethic, and ability to work effectively as part of a team.

In conclusion, pursuing research as a medical student can be challenging, but with persistence, creativity, and effective networking, you can make a meaningful contribution to the field. Embrace the research process wholeheartedly. If you find a topic you are passionate about, you will likely find it both fulfilling and beneficial for your professional growth and your future career as a physician.

Since its inception in 2002, the Residents and Fellows Committee has represented the voice of trainee members of the AUA. The Committee's mission is to address the educational and professional needs of urology residents and fellows, and promote engagement between residents and fellows and the AUA. The Committee welcomes your input and feedback! To contact the Committee, or to inquire about ways to get more involved, please email rescommittee@AUAnet.org. ■

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FROM THE RESIDENTS & FELLOWS COMMITTEE

Fitting Wellness Into the 80-Hour Workweek

Stephanie Hanchuk, MD

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Take a moment to reflect on how much time you devote to your well-being on any given day. I imagine many of you will find it hard to think about more than 1 activity you did for yourself in the last week. With increasing professional responsibilities, it is unsurprising that many trainees find it difficult to dedicate time to personal wellness. Recent studies report high levels of burnout (75%) and depression (40%) in surgery residents.¹ Given these alarming rates, focusing on our mental and physical well-being is key.

With only so many hours in a day, we must find ways within our

demanding work schedules to cultivate our well-being. Numerous residency programs have integrated wellness into their curriculums to address this concern.² Team-based efforts are encouraged, but there is no one-size-fits-all solution. We all must identify and pursue the habits that keep us engaged, motivated, and passionate about our work.

Below are 3 evidence-based methods that can improve both mental and physical wellness. Each is designed to readily fit into a few minutes between cases, during your commute, or in the call room. I encourage you to try them out and find what works best for you—hopefully, you can take away at least 1 method to practice.

Mindfulness Meditation

How to

1. Sit up straight with your feet flat on the ground.
2. Rest your hands comfortably.
3. Close your eyes.
4. Focus on your breathing. Pay attention to each inhale and exhale.
5. Continue for 1 minute (or longer).
6. Gradually open your eyes and resume activities.

Evidence

Mindfulness meditation can reduce stress, burnout, and depression.³ These benefits have been observed even with daily, short sessions (<5 minutes).³

Diaphragmatic Breathing (4-7-8)

How to

1. Inhale through your nose for 4 counts.
2. Hold your breath for 7 counts.
3. Exhale through your mouth for 8 counts.
4. Repeat steps 1–3.

Evidence

Breathing with a low inhale-to-exhale ratio activates the parasympathetic nervous system to promote relaxation.⁴

Targeted Stretching Microbreaks

Targeted stretching microbreaks (TSMBs) are intended to be performed for 1-2 minutes and repeated at intervals of 20-40 minutes during surgery.⁵

How to

Shoulder Stretch: Shrug shoulders up, back, and down. Repeat.
Neck Stretch:

1. Tilt your head back to look up. Hold for 1 breath.
2. Tuck your chin to your chest to look down. Hold for 1 breath.
3. Repeat.

Additional instruction on operating room stretches can be

found at [ORStretch.mayoclinic.org](https://orstretch.mayoclinic.org/).⁶

Evidence

TSMB improved surgeon post-procedure joint pain without increasing operative time. Surgeons perceived improvements in both physical performance and mental focus, and a majority (87%) planned to incorporate TSMB in their practice.⁵

Like surgery, these activities require practice. Be kind to yourself and reflect on what daily exercises work best for you. We must remember that, in the words of Carl Jung, “The shoe that fits one person pinches another; there is no one recipe for living that suits all cases.”⁷

Since its inception in 2002, the Residents and Fellows Committee has represented the voice of trainee members of the AUA. The Committee’s mission is to address the educational and professional needs of urology residents and fellows, and promote engagement between residents and fellows and the AUA. The Committee welcomes your input and feedback! To contact the Committee, or to inquire about ways to get more involved, please email rescommittee@AUAnet.org. ■

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Domain-based Interviews for Residency Applicants in the Virtual Era: Ready for Primetime?

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I am not envious of today's urology residency applicant. An increasingly competitive field, combined with a plethora of residency programs, lends itself to potential decisional regret on the part of both the applicant and residency program. Moreover, many applicants who go unmatched are likely excellent candidates, yet face uncertain futures. While many repeat the process the following year, there is no guarantee of matching the second time around. The ranking process is therefore critical, as it sets the foundation for the residents' training and future professional development. For urological residency programs, the selection process should assess not only the applicants' knowledge and skills that are germane to the field, but also their ability to apply this knowledge in practical situations. In the age of rapid-fire virtual interviews, each lasting between 10 and 12 minutes, assessing a candidate's fit for a particular program may seem like an imperfect and sometimes arbitrary exercise.

While the vast majority of today's applicants are excellent candidates and each residency program has its unique strengths, the top ranked candidate may not be ideally suited for the number 1 program. Rather, a paradigm shift is unfolding where precious limited interview time is optimized so that the right candidate is matched with right program. The process should endeavor to find the best fit for both parties. This is where domain (also known as skill)-based interviews are an emerging and useful tool in the selection process of urology residency programs.

Domain-based interviews are structured and seek to assess an applicant's knowledge and skills in a specific field of study or practice. In the context of a urology residency program, a domain-based interview evaluates the applicant's knowledge and skills related to the demands and required skill set of a surgical field.

The interview consists of a set of questions that are designed to assess the applicant's knowledge and abilities in areas such as anatomy, surgical procedures, patient management, and ethical considerations. At Rutgers New Jersey Medical School, we devised 5 domains that were felt to best represent the pedigree that is generally sought:

1. Academic productivity and performance
2. Urological experiences in clerkship and interaction with specific patient populations
3. Fit for the program (generally assigned to the chief residents)
4. Interpersonal skills and conflict resolution
5. Manual dexterity skills, including hobbies, sports, instruments, etc

Each interviewer is assigned a single domain and conducts each interview by asking standardized questions related to their domain. The questions are designed to elicit information about the applicant's skill sets and their ability to apply this knowledge in practical situations. Domain-based interviews have been shown to be reliable and valid measures of knowledge and skills. The structured format of the interview, as well as the use of standardized questions, while perhaps repetitive, allows for valid response comparisons.¹ After each domain-based interview, the applicant is given a score (1.0-4.0) by the interviewer. Scores for each candidate are tallied for each domain to create a preliminary rank list.

There are several advantages of domain-based interviews. Not only do they reliably elicit an applicant's knowledge and skills in a specific domain, they do so economically and maximize precious limited interview time. In contrast, other selection methods such as open-ended interviews may duplicate questions among different interviewers within the same program that are not necessarily helpful to the ranking process. Open-ended interviews may not provide a comprehensive assessment of an applicant's knowledge and skills, as they rely on the

interviewer's subjective judgment.² Furthermore, we seek to minimize the "halo effect"—as an applicant's charm or ability to interview well compared to their peers may not necessarily predict for success in residency and beyond.³ Domain-based interviews may also compartmentalize and minimize a particular weakness in a specific domain. A candidate with a lower score in one domain may be very strong in the aggregate, and a more complete picture emerges with each domain score. The same applicant may perform poorly in an open-ended interview format, where they may be queried more narrowly and not given the opportunity to reveal their true potential as a urology trainee.

While many may find this process cold and mechanical, leaders in the field of industrial psychology have successfully utilized these methods for years. As much as we do not wish to admit, human intuition is a poor judge when compared to standardized, domain-based interview techniques.

Incredibly, research has shown that domain-based interviews are more predictive of future job performance compared to other selection methods, such as personality tests or biographical information.⁴

In addition to the reliability and validity of domain-based interviews, they are more efficient and cost-effective compared to other selection methods. The structured format of the interview allows for a more streamlined selection process, as the questions can be predetermined and easily scored. This reduces the time and resources required to assess the applicants and enables programs to efficiently make informed decisions.⁵

A secondary advantage of domain-based interviews is their ability to assess the applicant's ability to think critically and apply their knowledge in practical situations. The questions in a domain-based interview are additionally designed to assess the applicant's problem-solving abilities and to think on their feet. This is particularly important for a residency program in urology,

as the field requires not only knowledge of the subject matter but also the ability to make decisions quickly and effectively in high-pressure situations.

Lastly, domain-based interviews rely on trust among faculty. By assigning each faculty interviewer to a particular domain, there is little to no overlap in interview questions, meaning that each faculty reports their respective domain-based findings of a given applicant to the group. Unique knowledge is then gained from each interviewer during the round table discussion with their fellow faculty members, leading to a cumulative score.

Despite the advantages of domain-based interviews, it is important to acknowledge that they should not be the sole selection method used in a urology residency program. We recommend that domain-based interviews be used in conjunction with other selection methods, such as reference letters and performance evaluations, to provide a comprehensive assessment of the applicant.

Additionally, the use of multiple ranking methods can help reduce the potential for bias in the selection process and ensure that the most suitable candidates are prioritized.¹

Since introducing domain-based interviews at Rutgers New Jersey Medical School in 2021, we have successfully matched our top-ranked candidates in both cycles (number 1 and number 2 in 2021, and number 1 and number 3 in 2022). This reflects the mutual fit that emerged from our interview process, and we are confident that these residents will thrive in our program. ■

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CASE REPORT

New Approach for Monitoring Neuroendocrine Differentiation of Prostate Cancer

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Here, we present a case of persistent osteodynia and a sharp increase in neuron-specific enolase, carcinoembryonic antigen, and tissue polypeptide-specific antigen in the serum after receiving regular androgen deprivation therapy (ADT) and anti-osteoporosis treatment, following the diagnosis of prostate adenocarcinoma with a Gleason score of 5+5 by pathology and bone metastases by radionuclide bone imaging 15 months prior. ^{18}F -AIF-NOTA-octreotide positron emission tomography (PET)/CT and ^{18}F -PSMA (prostate membrane-specific antigen)-1007 PET/CT imaging were performed. We found that the uptake of octreotide and PSMA was completely different in different parts of the lesions, and the distribution of PSMA was superior to that of octreotide in most lesions, except for a lesion in the right scapula. ^{18}F -AIF-NOTA-octreotide PET/CT illustrated that octreotide distribution was significantly increased in the right scapula lesion, while ^{18}F -PSMA-1007 PET/CT showed mild uptake. Subsequent bone biopsy confirmed partial neuroendocrine differentiation of prostate cancer. Hence, the combined ligand PET/CT patterns, octreotide plus PSMA, could provide a basis for the early diagnosis of partial endocrine differentiation of prostate

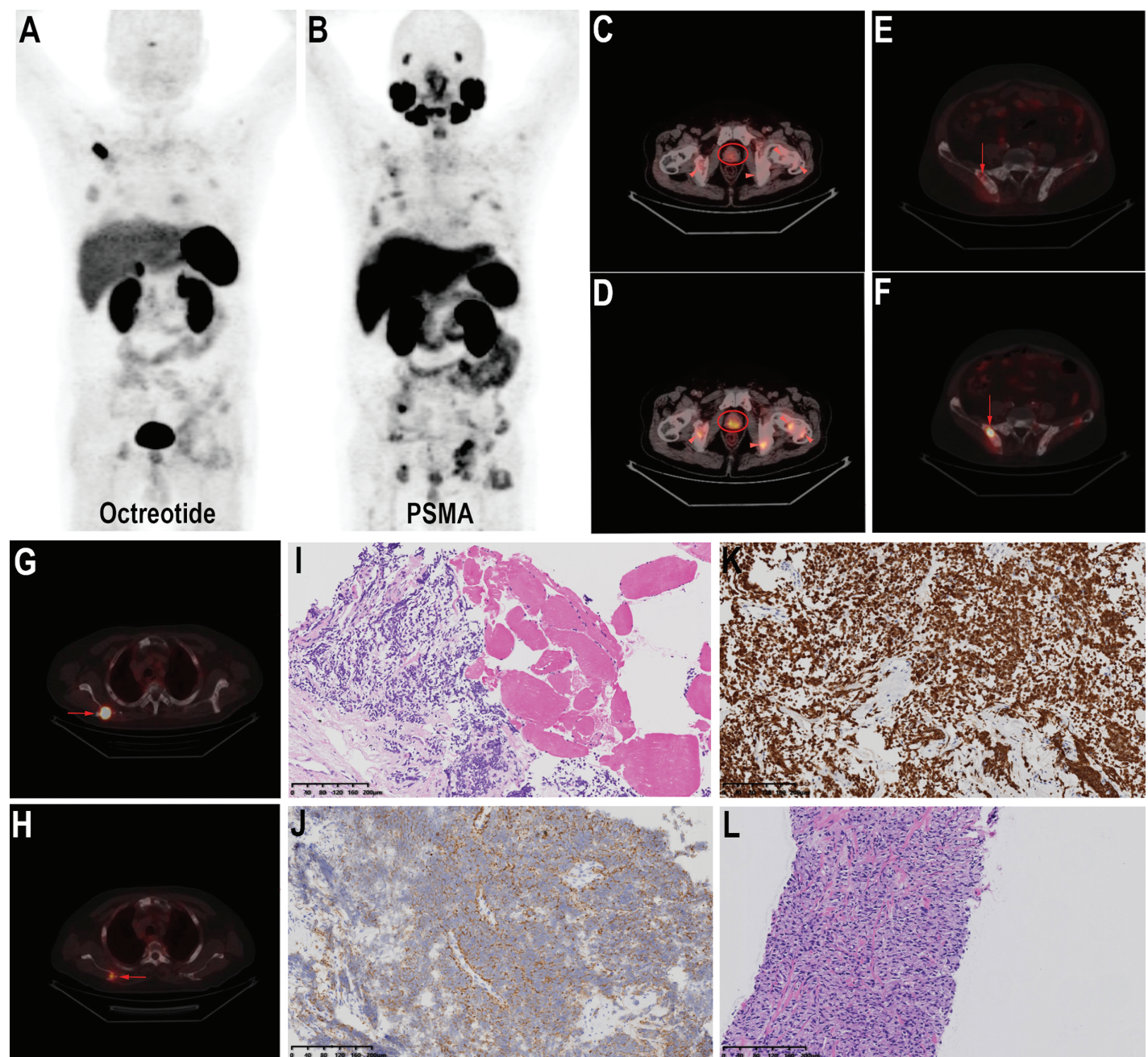


Figure. Whole-body ^{18}F -AIF-NOTA-octreotide positron emission tomography (PET)/CT (A) and ^{18}F -PSMA (prostate specific-membrane antigen)-1007 PET/CT (B). Octreotide (C) and PSMA (D) distributions in prostate (red ellipse) and bone lesions (red arrowheads). Octreotide (E) and PSMA (F) distribution in the right iliac bone (red arrow). Octreotide (G) and PSMA (H) distribution in the right scapula (red arrow). Pathological results of the right scapula: hematoxylin-eosin staining (I), and immunohistochemistry for Syn (J) and Ki-67 (K). Primary prostate biopsy pathology.

cancer, especially for patients with long-term ADT.

A 62-year-old man with initial prostate adenocarcinoma and multiple systemic bone metastases presented to our clinic after 15 months of regular hormone therapy as well as anti-osteoporosis treatment because of an excruciating bone ache and an increase in neuroendocrine tumor markers. The patient underwent both ^{18}F -AIF-NOTA-octreotide PET/CT

and ^{18}F -PSMA-1007 PET/CT scanning. Most tracer-associated lesions in bones and prostate have been identified with higher uptake patterns than liver octreotide uptake on ^{18}F -AIF-NOTA-octreotide PET/CT imaging (part A of Figure), while PSMA-associated lesions in bones and prostate were observed with lower uptake in the context of hepatic high PSMA background (part B of Figure). In general, PET/CT imaging showed that the dis-

tributions of both octreotide (part C of Figure) and PSMA (part D of Figure) were mildly increased in the prostate and bone metastases. Nevertheless, 2 bone metastases deserved our reconsideration: 1 lesion in the right iliac bone and another in the right scapula. Specifically, the lesion in the right iliac bone featured only mild octreotide uptake (maximum standard uptake value

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[SUV_{max}]=2.62; part E of Figure), but it showed significantly high PSMA uptake (SUV_{max}=9.68; part F of Figure). Although PSMA expression is decreased and the detection efficiency of tumor cells in PSMA ligand imaging is impacted after long-term, ADT,^{1,2} metastatic lesions with significant PSMA enrichment have a high probability of prostate cancer because PSMA tracer imaging is highly consistent with pathological results.³ However, octreotide distribution was significantly increased in 1 lesion of the right scapula (SUV_{max}=18.22; part G of Figure) compared with PSMA distribution on ¹⁸F-PSMA-1007 PET/CT (SUV_{max}=2.83; part H of Figure). Given that the patient presented with persistent osteodynia before the PET/CT examination accompanied by a sharp increase in

markers of neuroendocrine differentiation, including neuron-specific enolase, carcinoembryonic antigen, and tissue polypeptide-specific antigen, with the highest Gleason score (5+5), which is the only independent risk factor mediating endocrine differentiation of prostate adenocarcinoma,⁴ a bone biopsy was subsequently performed. The results of hematoxylin-eosin staining (part I of Figure) and immunohistochemistry (parts J and K of Figure) confirmed the partial neuroendocrine differentiation of prostate cancer based on the primary diagnosis (part L of Figure). Neuroendocrine differentiation of prostate adenocarcinoma is a dynamic process, and approximately 15%-20% of castration-resistant prostate cancers ultimately undergo neuroendocrine differentiation.^{5,6} Because of

the lack of effective early diagnosis, neuroendocrine prostate cancer often has a poor prognosis. The dynamic changes in PSMA and somatostatin receptor detected by whole-body ¹⁸F-PSMA-1007 PET/CT and ¹⁸F-AIF-NOTA-octreotide PET/CT may be able to manifest the process of neuroendocrine differentiation of prostate cancer. This case highlights that the dual-tracer uptake pattern with ¹⁸F-AIF-NOTA-octreotide and ¹⁸F-PSMA-1007 PET/CT explored the biological characteristics of prostate cancer cells from the expression of both somatostatin receptor and PSMA, not only effectively detecting the systemic tumor burden and precisely judging the disease stage, but also reflecting the dynamic process of neuroendocrine differentiation of prostate cancer. ■

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Impact of Robotic Radical Cystectomy on Urinary Diversion

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Introduction

Radical cystectomy with urinary diversion remains the gold standard treatment for patients with localized muscle-invasive bladder cancer and is often performed for those with bacillus Calmette-Guérin-refractory non-muscle-invasive bladder cancer. The robotic-assisted approach (RARC) has promised improvements in open radical cystectomy (ORC) complication rates, though many purported benefits lack supporting evidence. Here we review the impact of RARC on urinary diversion for radical cystectomy.

Current Evidence: Extracorporeal Diversion

There have been 4 randomized trials to date which have evaluated

RARC vs ORC (see Table). The first 2 published trials utilized exclusively extracorporeal urinary diversion (EUD), whereby an open incision was made for urinary reconstruction after the extirpative portion of the case was completed robotically.

Bochner et al from Memorial Sloan Kettering Cancer Center (MSKCC) published their single-center randomized trial of 118 patients in 2015, providing some of the earliest level 1 evidence comparing ORC and RARC with EUD.¹ There was significantly less operative time with the open approach (329 minutes ORC vs 456 minutes RARC, $P < .001$) but less blood loss robotically (676 mL ORC vs 515 mL RARC, $P = .027$). There were no differences in patient-reported quality of life outcomes at any time point, and while there was a decrease in wound complications (14% ORC vs 3% RARC, $P = .041$), there was no difference in overall complication rates. The authors concluded that RARC failed to demonstrate the large benefit promised by prior early reports.

RAZOR was a multicenter, randomized noninferiority trial comparing ORC vs RARC with EUD.² Among 302 randomized patients, there was no significant difference in 2-year progression-free survival (RARC 72.3% vs ORC 71.6%, HR 0.94, 95% CI 0.63-1.39) or adverse events (RARC 67% vs ORC 69%, $P = .75$), indicating noninferiority of RARC. The trial did demonstrate some advantages to RARC including decreased blood loss (300 vs 700 mL, $P < .0001$) and a small decrease in hospital length of stay (6 vs 7 days, $P = .02$). ORC was associated with significantly less operative time (428 vs 361 minutes, $P = .0005$).

While the RAZOR and MSKCC trials were some of the first to demonstrate comparable oncologic outcomes and noninferiority of RARC, a key limitation to both trials was the exclusive use of EUD for reconstruction instead of intracorporeal urinary diversion (IUD), which many have argued limits the potential benefits of the robotic approach. In this context, further trials were designed to evaluate RARC with IUD.

Current Evidence: Intracorporeal Diversion

In 2022, Mastroianni et al published their single-center randomized trial of 116 patients comparing RARC with IUD vs ORC.³ The only significant differences noted by the authors were decreased blood loss and transfusion rate for the robotic approach (EBL 401 mL vs 467 mL, $P = .02$; transfusion rate 22% vs 41%, $P = .046$) and a shorter operative time open (190 vs 313 minutes, $P < .001$). While limited by sample size and its single-center nature, this study provides evidence consistent with previous trials utilizing EUD.

The iROC trial was a multicenter randomized trial comparing RARC with IUD and ORC in 317 patients.⁴ For the primary outcome, days alive and out of the hospital at 90 days, RARC demonstrated an advantage of 2 days (82 vs 80 days, $P = .01$). RARC patients had a decreased

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length of hospital stay (7 vs 8 days, $P = .05$), readmission rate (21.8% vs 32.2%, $P = .04$), wound (5.6% vs 17.3%; difference [95% CI]: -11.7 [-18.6 to -4.6]), and thromboembolic (1.9% vs 8.3%, difference [95% CI]: -6.5 [-11.4 to -1.4]) complications. Among multiple other secondary outcomes, there were some marginal improvements noted for RARC, many of which disappeared by 12 weeks. The clinical significance of the highlighted differences in this trial remains uncertain. A limited number of high-volume centers have adopted IUD in virtually all RARC cases,⁵ but there remains significant variability in surgical approach (EUD vs IUD) and diversion type across the country, and there is no level 1 evidence directly comparing EUD and IUD.⁶

Long-term Functional Outcomes

Most of the randomized trials evaluating RARC are lacking in long-term follow-up data to evaluate functional outcomes including ureteroenteric anastomotic stricture (UEAS) rates. The MSKCC group demonstrated a 9.3% increased risk of UEAS in ORC patients (95% CI 1.5%-17%, $P = .026$) in their trial cohort.⁷ However, there are conflicting reports from other large retrospective series. Some have shown no difference in UEAS by surgical approach,⁸ while others have shown increased risk of UEAS with RARC with IUD compared to ORC.⁹ Whether RARC truly has an impact of UEAS rates remains unknown, and further research in this area is warranted.

Trends in Diversion Type

Some select centers have maintained high rates of continent diversion use over time (55% of all patients in some series¹), but most published series have demonstrated declining utilization over the past several years.¹⁰ This trend is concurrent with the increasing adoption of RARC and IUD. Intracorporeal ileal conduit creation is complex and time intensive with a significant learning curve, and intracorporeal orthotopic neobladder creation compounds this complexity.¹¹ While adoption of ro-

Table. Summary of Key Randomized Trials Evaluating Robotic Cystectomy

Trial author (year)	Design and population	Intervention and outcomes	Key findings
Bochner et al ¹ (2015)	Single-center randomized trial 118 patients with Ta-T3/ N0-3/M0 bladder cancer	1:1 Randomization to RARC with EUD vs ORC Primary outcome: 90-d Clavien-Dindo grade 2-5 complications Secondary outcomes: high-grade complications, EBL, operative time, pathological outcomes, 3- and 6-mo patient-reported QOL, and total costs	<ul style="list-style-type: none"> - No difference in overall complication rate, decrease in wound complications robotic (14% ORC vs 3% RARC, $P = .041$) - Less operative time open (329 min ORC vs 456 min RARC, $P < .001$) - Less blood loss robotic (676 mL ORC vs 515 mL RARC, $P = .027$) - No difference in patient-reported QOL
Parekh et al ² (2018)	Multicenter, phase 3, randomized noninferiority trial 350 patients with T1-T4/ N0-N1/M0 bladder cancer	1:1 Randomization to RARC with EUD vs ORC Primary outcome: 2-y progression-free survival Secondary outcomes: EBL, blood transfusion, surgical margins, No. lymph nodes resected, operative time, length of hospital stay, 90-d complications, health-related QOL at 3 and 6 mo	<ul style="list-style-type: none"> - RARC noninferior for 2-y PFS (RARC 72.3% vs ORC 71.6%, $P_{\text{noninferiority}} = .001$) - RARC decreased EBL (300 vs 700 mL, $P < .0001$) and decreased hospital LOS (6 vs 7 d, $P = .02$) - ORC less operative time (428 vs 361 min, $P = .0005$) - No differences in patient-reported QOL - No difference in adverse events (RARC 67% vs ORC 69%, $P = .75$)
Mastroianni et al ³ (2022)	Single-center randomized trial 116 patients with T2-4/ N0/M0 or recurrent bacillus Calmette-Guérin-refractory NMIBC	1:1 Randomization to RARC with IUD vs ORC Primary outcome: overall perioperative transfusion rate Secondary outcomes: LOS, 30-, 90-, and 180-d complications, global costs, and 6-mo functional, oncologic, and QOL outcomes	<ul style="list-style-type: none"> - RARC with IUD had lower transfusion rate (22% RARC vs 41% ORC; $P = .046$) and lower EBL (RARC 401 mL vs ORC 467 mL; $P = .02$) - RARC with IUD longer operative time (313 min vs 190 min; $P < .001$) - RARC higher cost (€31,886 vs €20,102; $P < .001$) - No significant differences in perioperative complications, LOS, or 6-mo QOL
Catto et al ⁴ (2022)	Multicenter, phase 3, randomized trial 338 patients with Ta-T4/ N0-N1/M0 bladder cancer	1:1 Randomization to RARC with IUD vs ORC Primary outcome: days alive and out of hospital within 90 d of surgery 20 Secondary outcomes including: 90-d complications, overall survival, oncologic outcomes, and health-related QOL outcomes	<ul style="list-style-type: none"> - RARC with IUD associated with 2 more d alive and out of hospital at 90 d (82 vs 80, $P = .01$), decreased LOS (7 vs 8 d, $P = .05$), and decreased readmission rate (21.8% vs 32.2%, $P = .04$) - RARC decreased wound (5.6% vs 17.3%) and thromboembolic (1.9% vs 8.3%) complications - Some marginal early differences in QOL, physical activity, strength/stamina; no longer significant at 12 wk - No significant difference in recurrences or overall survival - RARC decreased EBL (200 mL vs 550 mL; difference 95% CI, -275.7 to -424.3) but no difference in transfusions

Abbreviations: EBL, estimated blood loss; EUD, extracorporeal urinary diversion; IUD, intracorporeal urinary diversion; LOS, length of stay; NMIBC, nonmuscle-invasive bladder cancer; ORC, open radical cystectomy; PFS, progression-free survival; QOL, quality of life; RARC, robotic-assisted radical cystectomy.

botic surgery may contribute to stable or declining rates of continent diversion use, other long-standing factors including limited resident training, centralization of cystectomy care, technical complexity, and patient factors may also be mediating this trend.

Conclusions

Utilization of RARC is increasing rapidly despite limited evidence supporting its superiority over an open approach. Randomized trials have thus far failed to demonstrate the large benefits promised by RARC. This continued adoption mirrors the increased use of the robotic platform

for radical prostatectomy and may reflect a national trend of decreasing trainee experience with complex open pelvic surgery.¹² Despite these technical advances, radical cystectomy remains a high-risk surgery, and while there is abundant interest in the promise of surgical robotics, the centralization of cystectomy care to high-volume centers with surgeons performing the procedure using their preferred technique may be more impactful on patient outcomes.¹³ As new technologies push the boundaries of surgical bladder cancer management,¹⁴ time will tell what interventions ultimately have an impact on our patients. ■

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Trends, Predictions, and Barriers in Urologists' Telemedicine Usage

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Prior to the COVID-19 pandemic, telemedicine was a budding field within medicine. The initial goals of telemedicine were to use electronic, video, and audio communication to increase access to health care in rural and underserved areas. To remotely match specialists, such as urologists, with patients who might not otherwise have access to care was the target of early telemedicine. Compounded by worsening urologist workforce shortages, the need for effective telemedicine was obvious. However, there was not widespread utilization of telemedicine to effectively render this care to large populations, nor was there broad insurance or Medicare reimbursement for telemedicine outside of limited geographic or diagnostic restrictions.¹

Of the many changes wrought by the COVID-19 pandemic, the blossoming of telemedicine usage remains one of the most consequential advances. We assessed urologists' trends in telemedicine usage by comparing AUA Census data from 2016 to 2021.² We also examined trends in urologists' predictions for future telemedicine usage and potential barriers to more widespread telemedicine adoption beyond pandemic-related social distancing mandates. We used logistic regression to assess geographic variability in telemedicine usage.

Overall, urologists' telemedicine usage rose dramatically from

pre-pandemic to 2020/2021 levels. From 2016 to 2019, reported telemedicine usage rose only from 8.5% to 11.9%. Telemedicine usage exploded to 71.5% in 2020, likely due to the pandemic, and rose even higher in 2021 to 81.3%. The 2021 AUA Census also showed that 93.3% of urologists anticipated using telemedicine in some capacity in the future (part A of Figure). These increases are reflected across all practice types examined, including private practices, institutional practices, metropolitan practices, and nonmetropolitan practices (part C of Figure). Additionally, the 2021 AUA Census data showed that almost one-quarter of all practices were using telemedicine for >10% of all encounters, a 150% increase from 2018 levels (part D of Figure).

Despite these large increases in telemedicine usage and predictions for increased use, AUA Census data also reveal that 41.0% of urologists anticipate decreased future telemedicine use and 6.7% anticipate that they will not use telemedicine at all (part B of Figure). The increases in telemedicine usage were also not uniform across practice types, as nonmetropolitan practices' adoption of telemedicine lagged behind metropolitan practices' adoption (part C of Figure). When stratified more specifically by practice type, solo practitioners' 50.7% telemedicine usage also lags behind institutional and academic adoption of telemedicine (part E of Figure). Perhaps unsurprisingly, urologists at academic centers reported the highest telemedicine usage at 92.7%, which may reflect

greater availability of resources and less concern about reimbursement. AUA Census data also revealed interesting telemedicine usage pat-

terns when stratified by geographic region as reported by AUA section.

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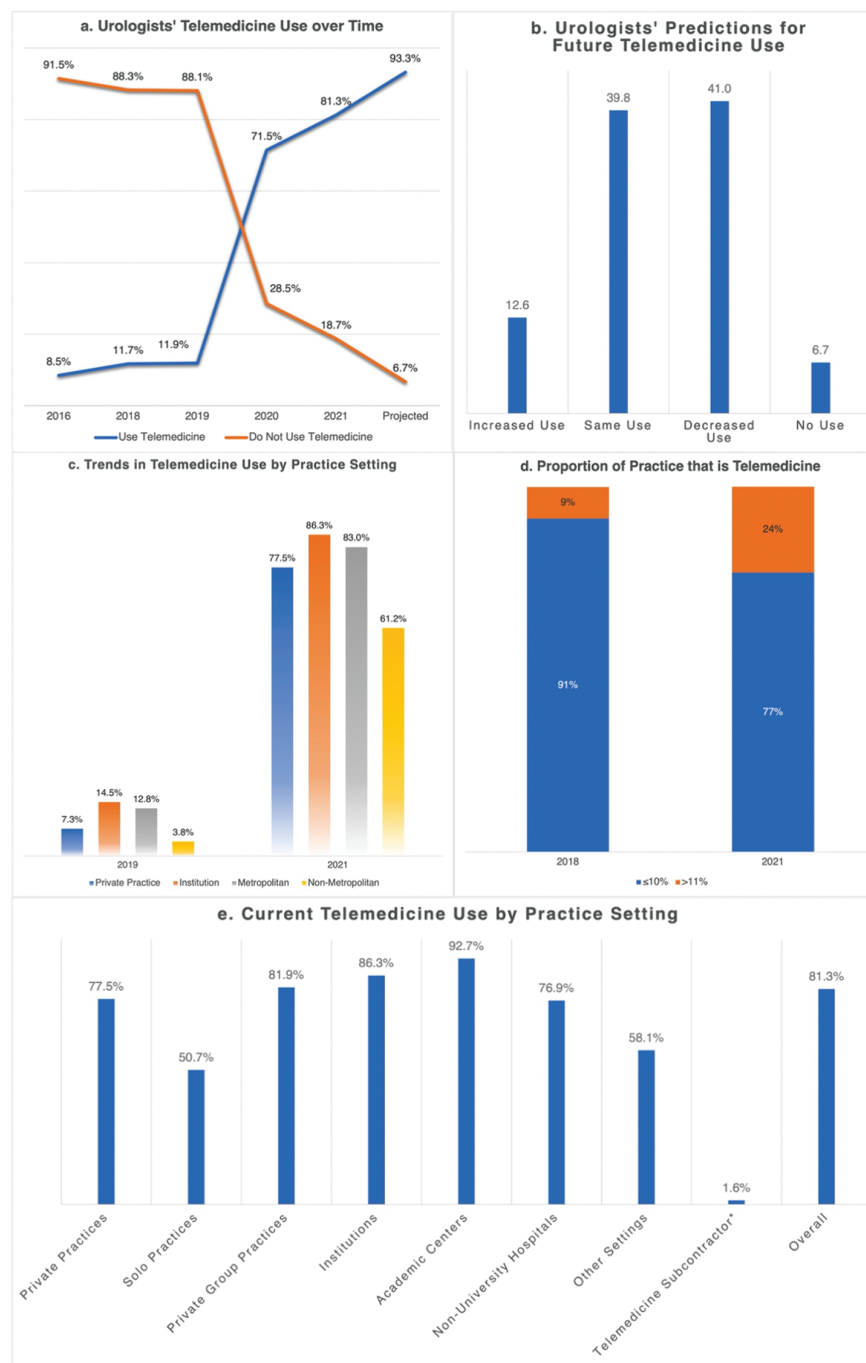


Figure. Current, past, and future telemedicine use by urologists.

TRENDS, PREDICTIONS, AND BARRIERS IN UROLOGISTS' TELEMEDICINE USAGE

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AUA Census data show that the sections with the lowest pre-pandemic telemedicine usage were the South Central, Northeastern, and New England sections (see Table). In 2020, the Northeastern section rose from the lowest usage to highest usage of telemedicine, and in 2021, New England urologists reported the highest telemedicine usage at 96.0%. The South Central section, however, did not see the same gains in telemedicine usage; urologists from this section reported the lowest telemedicine usage in both 2020 and 2021. These patterns stand in contrast to the proportion of urologists to population: the New England section, with the lowest proportion, had the highest telemedicine usage, while the South Central section, with the second lowest proportion, had the lowest telemedicine usage.

These geographic disparities in telemedicine might be mirroring the reported compensation for telemedicine: the South Central section reported the lowest percent compensation for telemedicine, and the Northeastern section, with the second lowest compensation,

Table. Telemedicine Use by American Urological Association Section

	% Urologists responding yes			Urologist: population ^b	% Compensated for telemedicine ^c	Population density ^d	Overall population
	2019	2020	2021 ^a				
South Central	8.0	60.5	68.4	3.43	87.9	67	55,534,878
Southeastern	8.4	67.2	78.3	4.11	95.6	182	75,684,646
Northeastern	6.6	86.5	80.1	5.24	88.7	166	11,631,445
Mid-Atlantic	9.6	78.7	81.7	4.12	89.9	348	32,701,897
North Central	13.2	73.8	82.9	4.73	95.2	115	52,457,878
New York	14.1	72.6	85.2	5.12	93.6	1856	19,656,411
Western	19.8	80.5	86.9	4.33	91.5	64 ^e	62,093,595
New England	8.1	79.1	96.0	3.31	92.5	368	23,089,443
United States	11.9	71.5	81.3	4.16	92.2	94	332,850,193

^a2021 Values compared to urologist:population, % compensated, and population density using regression analysis; there were no statistically significant correlations ($P > .05$).

^bPeople/mi², 2020 United States Census data.

^c2020 AUA Census data.

^dUrologists per 100,000 people, 2021 AUA Census.

^eExcluding Alaska; with Alaska population, density decreases to 41 people/mi².

saw a drop in telemedicine usage from 2020 to 2021 (see Table). Despite these interesting patterns, after comparison of urologists' telemedicine usage by AUA section to ratio of urologist to population, to percentage of urologists reporting compensation for telemedicine, and to AUA section population

density, regression analysis did not reveal any significant correlations (see Table). Thus, the variability in usage by practice type may reflect providers' concerns about telemedicine, patient-related concerns, and heterogeneity within and between AUA sections. Regarding barriers to telemedicine usage, providers specifically cited video/phone quality, patients lacking sufficient technology, and lack of high-speed internet in some areas as hurdles to widespread telemedicine utilization. Further, providers also perceived patients as preferring in-person visits likely as a result of patients' cultural familiarity with the in-person medical visits.

The use of AUA Census data to draw broad generalizations is not without limitations. AUA Census data may be skewed by recall bias and selection bias. The AUA Census does not stratify "nonmetropolitan" urologists into more meaningful categories such as practicing in small cities or rural areas. The data also are limited to video or phone telemedicine usage, and the results are not specific to whether the reported telemedicine usage is in the outpatient setting, emergency setting, or inpatient setting. Finally, the role of "telesurgery" has not been assessed, as this field remains mostly experimental in nature.

Despite dramatic increases in telemedicine usage during the COVID-19 pandemic, disparities

in usage persist both geographically and among practice types. AUA Census data do not show telemedicine being used to increase rural access, which is contrary to pre-pandemic predictions for its use. Worryingly, urologists foresee further slowing in telemedicine usage from their current levels, which may reflect equilibration to where telemedicine is efficient and economical for urologists. The anticipated decreased use likely stems from concerns about barriers to access such as connectivity/technology issues, patient preferences for in-person visits, and decreasing compensation. The AUA must continue advocating for patients by improving access to technology needed for telemedicine and for its members with goals of increasing telemedicine ease and economic viability for urologists.

Acknowledgments

We thank Raymond Fang, MSc, MASc, Director of AUA Data Management & Statistical Analysis, for his contributions. ■

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American
Urological
Association

AUA Advanced Practice Provider of the Year Award



2023

Kenneth A. Mitchell, MPAS, PA-C
Erlanger Urology- Men's Health
Chattanooga, Tennessee

Celebrating a Year as AUA President

Edward M. Messing, MD, FACS
President, AUA

As my year serving as AUA President comes to an end, I've been reflecting on my career. I've dedicated myself and my work to patient care, education, administration, leadership, and my particular passion, research. In addition to these areas, as AUA President, I focused on workforce shortage issues and diversity, equity, and inclusion initiatives. And, thanks to the hard work of the AUA staff under Mike Sheppard's leadership, the AUA Board of Directors, the committee and council chairs, and, most importantly, the AUA volunteers, we have made incredible strides in all of these areas over the last year.

Workforce Issues

The AUA Census reports that 60% of U.S. counties do not have a practicing urologist. In March, thanks to tireless advocacy from

AUA members, Senators Jacky Rosen (D-NV) and Roger Wicker (R-MS) introduced S. 705, the Specialty Physicians Advancing Rural Care (SPARC) Act. The SPARC Act establishes a loan repayment program for specialty physicians who elect to practice in a rural community for up to 6 years. In exchange, the specialists will have up to \$250,000 of their student loan debt repaid. The Act expands specialty care coverage in rural America where many Americans lack access to close and readily available specialty care.

Research

In 2022 alone, the Office of Research awarded \$1.548 million in grant funding to 48 researchers, 39% of whom are women and 27% of whom are underrepresented in medicine awardees.

In April, the AUA announced the first recipient of the Boston Scientific Medical Student Innovation Fellowship, which funds a 12-month research

project for a medical student interested in translating urology research into innovation. Strong preference is given to applicants from groups underrepresented in urology and/or projects focused on health disparities.

Additionally, the AUA recently established Innovation Nexus, the only urology-specific incubator of its kind, which hosted its inaugural event in April just prior to the AUA Annual Meeting. The event brought together startups, entrepreneurs, venture capitalists, investors, and urologists to advance urological discovery to solutions that improve patient care and save lives.

Leadership

As part of the newly launched Institute for Leadership & Business—an initiative dedicated to providing education, training, and resources to support leadership development and business acumen within the urology community—the AUA hosted the inaugural Global Residents Lead-

ership Retreat in April. The 1-day event brought together 40 residents from across the globe for a unique program dedicated to leadership training and development as well as fostering connection between residents and trainees around the world.

Diversity, Equity, and Inclusion

Last summer, the AUA announced the appointment of Larissa Bresler, MD, DABMA, as AUA's new Chief Diversity Officer and Diversity & Inclusion (D&I) Committee Chair. In the fall, the full D&I Committee was announced. It is made up of members from all 8 sections of the AUA and has the diversity of gender, race, sexual orientation, practice type, and specialty that provides the diversity of thought that is necessary to move diversity, equity, and inclusion initiatives forward. The inaugural

→ Continued on page 44

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CELEBRATING A YEAR AS AUA PRESIDENT

→ Continued from page 43

“Last summer, the AUA announced the appointment of Larissa Bresler, MD, DABMA, as AUA’s new Chief Diversity Officer and Diversity & Inclusion (D&I) Committee Chair.”

D&I Committee includes:

- Denise Asafu-Adjei, MD, MPH, Director of Male Reproductive Medicine and Assistant Professor in the Department of Urology and the Department of Public Health Sciences at Loyola University Chicago Stritch School of Medicine
- Gregory Broderick, MD, Pro-

fessor of Urology, Mayo Clinic Alix School of Medicine; Program Director, Urology Residency, Mayo Clinic Florida

- Pamela Coleman, MD, FACS, FPMRS, Associate Professor of Urology, Department of Surgery, OBGYN, Howard University School of Medicine; Interim Chief of Urology, Howard University Hospital
- Gabriela Gonzalez, MD, Urology Resident Physician, University of California, Davis
- Tomas Griebeling, MD, MPH, FACS, FGSA, AGSF, John P. Wolf 33rd Degree Masonic Distinguished Professor Urology, Department of Urology, Faculty Associate, The Landon Center on Aging, The University of Kansas School of Medicine
- Nathan Grunewald, MD, FACS, Chief Medical Innovation Officer and Urology Medical Director, Sauk Prairie Healthcare

- Lourdes Guerrios, MD, Urology Attending, Urology Section, Surgery Department, Introductory Research Program Co-Director, VA Caribbean Healthcare System; Research Program Director, Puerto Rico Trauma Center; Assistant Professor, Surgery Department, University of Puerto Rico School of Medicine
- Justin Han, MD, Assistant Professor of Urology, Hofstra-Northwell Zucker School of Medicine; Director of Male Reconstructive Urology, Smith Institute for Urology, Northwell Health; Chair for Quality in the Department of Urology, North Shore University Hospital
- Linda McIntire, MD, Urologist, MyMichigan Health; President, R. Frank Jones Urological Society
- Michelle Jo Semins, MD, Professor, West Virginia University School of Medicine; Chief,

Division of Urology, West Virginia University Wheeling Hospital

- Gjanje Smith-Mathis, MD, MPH, Staff Urologist, WakeMed Health and Hospitals
- Simone Thavaseelan, MD, Associate Professor of Surgery/Urology and Program Director of the Urology Residency, Brown University; Chief, Section of Urology, Providence VA Medical Center
- Vijaya Vemulakonda, JD, MD, Professor of Pediatric Urology, Director of Research and Residency Program Director, Division of Urology, Department of Surgery, University of Colorado School of Medicine

Looking back on the past year, it has truly been a pleasure to serve as the AUA President. We’ve accomplished much, but there is always more to do. Onward! ■

— IN THE NEXT ISSUE OF AUANEWS —

JUNE 2023 - FOCAL THERAPY FOCUS ISSUE

The Case for Focal Therapy in Intermediate-risk Prostate Cancer

Herbert Lepor, MD

Multiparametric Ultrasound and High-resolution Ultrasound for Prostate Cancer Diagnosis

Peter KF Chiu, MD; Xiaobo Wu, MD; Rafael Tourinho, MD; and Jochen Walz, MD

Comparison of Adverse Events and Quality of Life Between Focal Therapy and Whole-gland Treatment in Prostate Cancer

Ruben Olivares, MD and Tarik Benidir, MD

Focal Irreversible Electroporation for Prostate Cancer

Sean Ong, PhD; Jianliang Liu; and Nathan Lawrentschuk, PhD

Transurethral Ultrasound Ablation (TULSA) as a Promising Focal Therapy Option for Prostate Cancer

Joseph Chin, MD; Xiaosong Meng, MD; Stephen Scionti, MD; and Laurence Klotz, MD

FROM THE AUA SCIENCE & QUALITY COUNCIL

Data Research Program

Amanda C. North, MD

*Children's Hospital at Montefiore/Albert Einstein
College of Medicine, Bronx, New York*

Matthew Nielsen, MD, MS, FACS

*The University of North Carolina School of Medicine
at Chapel Hill*

The AUA Data Committee is pleased to announce a new Data Research Program that will be introduced this year. The AUA has been building a comprehensive data repository in urology that would allow researchers to conduct studies from clinical, workforce, and policy perspectives. The new AUA Data Research Program is aimed at connecting urology's research community to the vast AUA resources to encourage the broad use of AUA data, with the assistance of AUA statisticians.

The AUA Data Department gained rich experience from operating the former Data Research Grant Program from 2014 to 2018. The former grant program funded 14 projects between 2015 and 2018 when it was discontinued because of financial constraints. Funding ranged from \$25,000 to \$50,000 per study, with \$100,000 total awarded annually. This program resulted in tremendous knowledge generation, with 25 peer-reviewed publications and 28 presentations at national meetings.

The newly approved Data Research Program also is intended to stimulate the use of AUA data sources for knowledge generation and dissemination. For the inaugural cycle, a total of 6 projects (2 projects using AUA Quality [AQUA] Registry data and 4 projects using AUA Census data) will be selected and funded in the form of complimentary data access, statistician time (25 hours per Census project and 100 hours per AQUA project), and dissemination support in the amount of \$2,000 per project. This will be equivalent to an awarded value of \$10,000 per AUA Census project and \$30,000 per AQUA Registry project. The first Request for Proposal process will start in May 2023.

An overview of the timeline for

“The patient cohorts and the Census data will be linked using NPI numbers to support data research projects from both workforce and clinical perspectives. All interested investigators will have the opportunity to explore data dictionaries and data summaries online to help build their study hypotheses and research proposals.”

the AUA Data Research Program is included in the Table. The program will be repeated annually. Detailed application requirements, selection criteria, and program milestones will be available to applicants on the Data Research Program's webpage. The program is open to all AUA members, including practicing urologists, residents and fellows, and advanced practice providers.

Submitted proposals will be reviewed by a scientific review group comprising AUA Data Committee members. Dr Hung-Jui (Ray) Tan (Chair of the AQUA Subcommittee of the AUA Data Committee) will serve as the panel chairperson.

Data to be used in the AUA Data Research Program include the following:

- Practice, provider, and patient data in the AQUA Registry.

Table. Timeline for the AUA Data Research Program

Step	Description	Deadline
1	Research Datasets, including Data Dictionaries Ready	12/31/2022
2	Program Materials and Process Ready	04/01/2023
3	Scientific Review Panel Formed	04/01/2023
4	Call for Letter of Intent (LOI)	05/01/2023
5	LOIs Due	06/24/2023
6	Invitation for Full Application to Selected Project Principal Investigators	08/01/2023
7	Full Applications Due	09/21/2023
8	Notification Date	12/05/2023
9	Project Starts	01/03/2024
10	Mid-year Progress Report to the AUA	07/01/2024
11	Project Ends	12/31/2024
12	Final Project Report to the AUA	02/28/2025

- Disease-specific patient cohorts with well-documented information on initial and follow-up diagnoses, treatments, and outcomes.
 - AUA Annual Census datasets from 2014 to the most recent year.
- Starting with 5 nonmalignant urological disease cohorts (overactive bladder, BPH, stone disease, male incontinence, and erectile dysfunction), the data repository will continue to add more diseases and gradually expand to the cancer domain in the future.

The patient cohorts and the Census data will be linked using NPI numbers to support data research projects from both workforce and clinical perspectives. All interested investigators will have the opportunity to explore data dictionaries and data summaries online to help build their study hypotheses and research proposals. Once the projects are awarded, investigators will collaborate with AUA statisticians on research design, statistical analysis, and results dissemination, with valuable input and oversight from the AUA Data Research Review Panel.

The AUA Data Research Program will have several benefits for the AUA and the urology community: support the AUA's mission of advancing urology through re-

search by addressing key knowledge gaps related to urology care and workforce development; enhance the broad use of AUA data and increase AUA's visibility in knowledge generation through presentations and publications; transform clinicians to physician scientists through exposure to clinical and workforce data and the building of mentoring relationships with experts in the AUA data subcommittees; and inform policymakers, payers, the urology community, other health care providers and the public about key issues in urology care.

Awardees are expected to provide reports to the AUA and communicate their findings in scholarly venues, such as at the AUA annual meeting and in high-impact, peer-reviewed journals. Moreover, investigators must complete the proposed deliverables on time.

The goal of this new Data Research Program is not only to increase knowledge in urology but to democratize access to AUA data resources. Early career investigators and AQUA Registry participants are encouraged to apply, especially given the unprecedented access to both AUA data and AUA statisticians. ■

Long-term Pelvic Function After Symphysis Pubectomy for Urosymphyseal Fistula

Andrew C. Peterson, MD, MPH
Duke University, Durham, North Carolina

Urosymphyseal fistula in the cancer survivor was first described by Dr Jaspreet Sandhu's group at Memorial Sloan Kettering Cancer Center in 2012.¹ At that time, however, the reconstructive urology community could not grasp the implications of this potentially devastating disease process. The Duke reconstructive group described the first series of patients with fistula and concomitant bone infection and proposed an algorithmic approach to obtain cure in these patients in 2015.² Subsequently, the London group, led by Professor Mundy, validated this disease process with their cohort of patients the next year.³

The evolution of our understanding of this disease process over the last decade now has established a successful treatment algorithm for this disease, which often includes bladder removal along with the majority of the pubic symphysis and superior and inferior pubic rami bone. We now have long-term follow-up data on the quality of life in patients who have undergone these massive procedures. Resec-

“The evolution of our understanding of this disease process over the last decade now has established a successful treatment algorithm for this disease, which often includes bladder removal along with the majority of the pubic symphysis and superior and inferior pubic rami bone.”

tion can be quite drastic and often requires bone removal all the way to the acetabular joint (see Figure). Early on, surgeons had concerns about pelvic instability and we saw reports of preemptive placement of pubic symphysis metallic hardware, bridges, and cement into the resection area as well as prophylactic posterior screw placement into the sacroiliac joint in order to stabilize the pelvic rim. However, we are now learning that despite this very radical resection the adult pelvis may not be destabilized as might be expected after removing this portion of the anterior pelvic ring.

From the very beginning, our group prospectively followed the outcomes for all patients undergoing cystectomy with pubic symphysis resection for pubic bone osteomyelitis. We have learned that not only are these patients uniformly cured almost instantly of their chronic debilitating pain,⁴ but are able to return to normal functional activities after this massive operation. Additionally, many groups now have a combination of preoperative and postoperative objective and subjective data that have helped us understand the stability of the adult pelvis after these resections. These include pain scores, quality of life scores, and assessment of gait after pubic bone removal. Our group follows patient-reported pain scores obtained both pre- and postoperatively. The preoperative groups have pain scores that are significantly elevated but drop to normal (0/10) at the 1-year follow-up.⁴ Similarly, the quality of life scores as outlined in the 12-Item Short-form (SF) surveys have similar improvement. The SF-12 is a validated 12 question patient-reported outcome survey that addresses both mental functioning and physical functioning in patients.⁵ While the physical functioning score does not directly address changes in gait, it does address certain things such as being able to perform daily activities, physical activity, and strenuous exercise. We found that patients with pubic

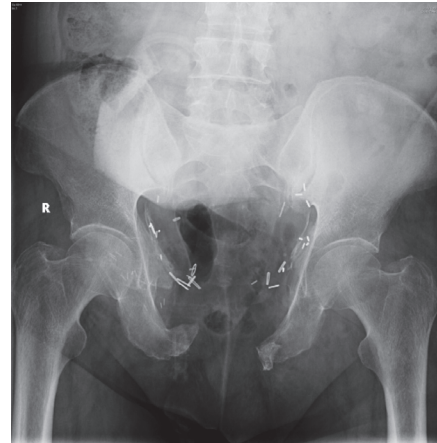


Figure. Pelvis film showing the extent of resection of the pubic symphysis and superior and inferior pubic rami with no need for posterior fixation.

symphysis fistula and osteomyelitis had significantly impaired mental and physical functioning scores prior to surgery. Uniformly, both of these scores return to normal baseline scores at 1-year follow-up after surgery.

Recently, the orthopedic literature started publishing outcomes for these patients. Shue et al followed subjective outcomes including the Numeric Pain Rating Scale and the SF-36 survey. Objective measures were also followed postoperatively, including radiographic evaluation of the distance between the 2 superior tips of the pubis on anteroposterior x-rays as well as sacroiliac joint diastasis measured by x-ray postoperatively at various time intervals. They found that the pain scores improved significantly as well as the SF-36 scores. Most interestingly, the investigators found no difference in measurements on the follow-up radiographs when analyzed postoperatively with a mean follow-up of 19 months (range 6-37).⁶ Other groups have validated these findings as well, with a recent series from 2021 reporting on 5 patients who underwent surgical resection, all regaining the ability to be fully ambulatory without the need of walking aids by 13 months.⁷

Pubic symphysis fistula with resultant osteomyelitis of the pubic bone is a potentially devastating side effect of life-saving radiation therapy given for prostate cancer.

“Pubic symphysis fistula with resultant osteomyelitis of the pubic bone is a potentially devastating side effect of life-saving radiation therapy given for prostate cancer.”

The current curative procedure often includes complete removal of the bladder and resection of the infected bone to noninfected healthy bone along with postoperative antibiotics based on the cultures from the resected bone. Despite this very large operation, the current experience indicates that patients are able to return to a normal quality of life without the threat of destabilizing the pelvis. This reinforces that there is no need for preventive internal fixation of the pelvic rim in order to potentially prevent pelvic instability down the road. ■

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VOICES

Giants in Urology: Martin K. Dineen, MD, 1952-2023

Ronald Rabinowitz, MD
AUA Historian, Linthicum, Maryland

Ralph Pennino, MD, FACS
Rochester Regional Health, New York

The urological community and the people of Haiti lost a true humanitarian on January 13, 2023. Marty Dineen was born and raised in Upstate New York, an hour and a half south of Rochester. Following his undergraduate degree at Notre Dame (ND) and medical school and urology residency at Louisiana State, Marty spent 2 years as a Fellow at Roswell Park (1985-1987). During that time, he visited Rochester numerous times, attending conferences, visiting our research labs, and observing surgery. He was always interested in organized urology and planning a lifetime career in helping patients clinically and by leadership roles in urology. We often discussed his future plans. During those 2 years, he presented at our section meetings and resident conferences. I would often see him at national AUA meetings over the years, as he became a leader in AACU (American Society of Clinical Urologists) and UROPAC, yet remained the humble person he was when I first met him more than 35 years ago. He was President of the AUA Southeastern Section 2008-2009 and President of the AACU in 2016-2017. Marty was an active member of the AUA Health Policy Council and the Board of Directors of the Urology Care Foundation. In 2016, Dr Dineen received the Distinguished Service Award from the AUA.

Following the 2010 earthquake in Haiti, I met Dr Dineen in Rochester in the office of Dr Ralph Pennino, a plastic surgeon and former Chief of Surgery at Rochester General Hospital. At that visit, Drs Dineen and Pennino, both ND grads, were discussing and planning how to assist the people of Haiti. Thirty years ago, plastic surgeons Ralph Pennino and Tim O'Connor founded InterVol, a Rochester organization that collects and repurposes medical equipment and unused medi-

cal supplies that now distributes to more than 80 countries and 65 local and national nonprofits. InterVol (www.intervol.org) collects at more than 500 locations in Rochester, Buffalo, Syracuse, and other facilities across Upstate New York. The following is Dr Pennino's experience working, volunteering, and operating with Dr Dineen.

Compelled by a beloved former ND professor, Marty and I jumped at the opportunity to help the ND Haiti program in 2008. Its mission, funded by the Gates foundation, was to eradicate lymphatic filariasis, a parasitic disease endemic to Haiti. The existing successful ND program focused on prevention, but no one was caring for the secondary effects: marked lymphedema of the legs and male scrotum resulting in huge hydroceles estimated to affect 200,000 Haitian males. In the past, Marty had actively participated in surgical mission trips, but what was needed for this new venture was a larger effort by many colleagues. Together, we planned a repeating series of surgical missions by ND grads and their colleagues from around the country. Three back-to-back-to-back complete surgical teams were scheduled to begin January 24, 2010, with over 150 patients to be treated. Twelve days prior, the massive earthquake hit Haiti. While most were trying to get out of Haiti, Marty was trying to get in—and he did. Over the next 6 months, he helped InterVol and ND recruit, coordinate, and operate with surgical teams in a donated MASH (mobile army surgical hospital)-like surgical tent. These surgical teams rotated every 8-9 days. Despite a busy practice back home, Marty traveled to Leogane, Haiti every 3-4 weeks, eventually making more than 30 trips and operating on more than 1,000 hydroceles. On the very enormous ones, I got to do the reconstructions. I never thought that I would be doing scrotoplasties at the end of my career. We developed a close relationship and called our-

selves the “Ball Busters.” Marty's efforts to help those afflicted with lymphatic filariasis also included bringing needed surgical supplies. Dr Dineen also paid local Haitian doctors, nurses, and support staff to assist with the surgery, which in turn helped support the local community. Eventually, Haiti fell out of the headlines, and the tent hospital closed. However, the need did not. Marty continued his unwavering support over the next decade.

Over the past few years, Marty and his wife Marianne have supported the building of a new school in Leogane, started by a local resident and former Haitian head of the ND Haiti program. Through their help and many others, the school has been educating more than 100 children for the past

“Despite a busy practice back home, Marty traveled to Leogane, Haiti every 3-4 weeks, eventually making more than 30 trips and operating on more than 1,000 hydroceles.”

5 years. The permanent structure is almost completed and will contain a medical clinic to support the future medical and surgical teams. Appropriately, the clinic will be named after Marty. ■

Applications Now Being Accepted for AUA Treasurer

The AUA is currently seeking a highly qualified member to fill the position of Treasurer-elect beginning May 2024. A job description along with information about compensation, time commitments and travel requirements are available online at AUAnet.org/Treasurer.

Deadline to receive applications is July 16, 2023.



American
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SPECIALTY SOCIETIES

Paradigm Shifts in the Diagnostic Pathway for Prostate Cancer in Accordance With Evolving Technology

Timothy K. O'Rourke Jr, MD

Wake Forest University School of Medicine,
Winston-Salem, North Carolina
Atrium Health Wake Forest Baptist Medical Center,
Winston-Salem, North Carolina

Parth U. Thakker, MD, MS

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Ashok K. Hemal, MD, MCh, FACS,
FRCS (Glas)

Wake Forest University School of Medicine,
Winston-Salem, North Carolina
Atrium Health Wake Forest Baptist Medical Center,
Winston-Salem, North Carolina

The diagnostic evaluation of prostate cancer (PCa) has evolved significantly in the last century. For perspective, consider this: In the early 1900s, the only modality used to screen for PCa was the digital rectal examination (DRE). Refinements in the diagnostic algorithm have vastly improved over time.

Prostate Biopsy

Transrectal ultrasound (TRUS) has permitted image-guided, systematic prostate biopsy and has been utilized in practice since the latter half of the 20th century. PSA, first implemented in clinical practice in the early 1990s, was investigated in a study at our institution in 1994, where men with PSA 4-10 ng/mL or abnormal DRE underwent TRUS-guided prostate biopsy. Volumetric analysis was obtained by ultrasound; PSA density was calculated and demonstrated to be significantly different among those with and without cancer.¹ Novel high-resolution micro-US has significantly optimized the diagnostic capabilities for PCa. The OPTIMUM trial is ongoing, which has randomized 3 cohorts into micro-US-only biopsy, MRI/micro-US "FusionVu" biopsy, and MRI/US biopsy with conventional fusion system.²

Transperineal prostate biopsy has gained traction over the last 5-10 years with advantages including lower rates of infection and, especially in larger glands, optimized anterior prostatic cancer de-

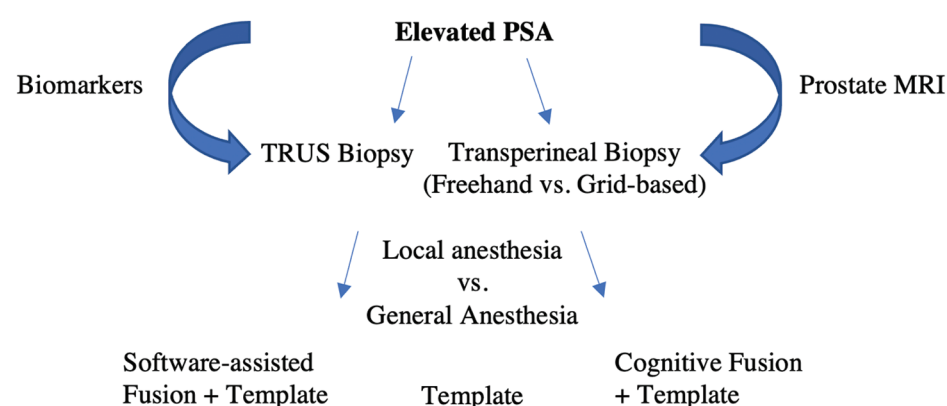


Figure. Nuances in the contemporary prostate cancer diagnostic algorithm. MRI indicates magnetic resonance imaging; PSA, prostate-specific antigen; TRUS, transrectal ultrasound-guided.

tection.³ The Figure simplifies the overarching pathways in modern prostate biopsy.

Pros for performing TRUS-guid-

“Transrectal ultrasound (TRUS) has permitted image-guided, systematic prostate biopsy and has been utilized in practice since the latter half of the 20th century. PSA, first implemented in clinical practice in the early 1990s, was investigated in a study at our institution in 1994, where men with PSA 4-10 ng/mL or abnormal DRE underwent TRUS-guided prostate biopsy.”

ed biopsy include broad familiarity among all urologists, optimized sampling of the peripheral zone, facility, efficiency, and commonality in performing under local anesthesia. The increased risk of sepsis relative to transperineal biopsy is well documented; however, this can be minimized through approaches including rectal swabs to identify antibiotic resistance, peri-procedural antibiotics, and augmented antibiotic prophylaxis at the time of biopsy. Transperineal biopsy has gained significant momentum; however, limitations include lack of familiarity with all urologists, especially with regard to comfort performing the procedure under local anesthesia, increased cost, decreased efficiency, and perhaps an increased risk of urinary retention post-biopsy.⁴ We have found that there seems to be a steeper learning curve in transperineal biopsy relative to transrectal biopsy, particularly among urology trainees. Taking all the available data, both approaches are viable and the decision to proceed will depend on clinical factors, patient-related factors, and surgeon experience. A strong niche for transperineal biopsy in our practice includes persistently elevated PSA with prior negative transrectal biopsy, large prostate with inability to access the anterior prostate via transrectal biopsy, in those with anterior lesions on

MRI to be targeted, and in confirmatory biopsy for patients who elect active surveillance for PCa 12-18 months from initial biopsy.

MRI

MRI has become an important adjunct to the workup of PCa. Studies including PROMIS and PRECISION have helped clarify the ideal utility of MRI in PCa diagnosis. In PROMIS, the concept of pre-biopsy screening MRI was evaluated and found to be of value; the authors suggested that approximately 27% of patients could defer biopsy in the setting of a negative MRI. While the sensitivity

“MRI has become an important adjunct to the workup of PCa. Studies including PROMIS and PRECISION have helped clarify the ideal utility of MRI in PCa diagnosis. In PROMIS, the concept of pre-biopsy screening MRI was evaluated and found to be of value; the authors suggested that approximately 27% of patients could defer biopsy in the setting of a negative MRI.”

PARADIGM SHIFTS IN THE DIAGNOSTIC PATHWAY

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Table. Biomarkers in the Prostate Cancer Diagnostic Algorithm

Test	Source	Patient selection	Result	Utility
4k Score	Blood	Pre-biopsy	Risk of csPCa on biopsy	Initial or repeat biopsy
PHI	Blood	Pre-biopsy	Risk of csPCa on biopsy	Initial or repeat biopsy
SelectMDx	Post-DRE urine	Pre-biopsy	Risk of csPCa on biopsy	Initial biopsy
ExoDx	Urine	Pre-biopsy	Risk of csPCa on biopsy	Initial or repeat biopsy
MIPS	Post-DRE urine	Pre-biopsy	Risk of csPCa on biopsy	Initial or repeat biopsy
PCA3	Post-DRE urine	Prior negative biopsy	Risk of csPCa on biopsy	Repeat biopsy
ConfirmMDx	Tissue	Prior negative biopsy tissue	Risk of csPCa on biopsy	Repeat biopsy
STHLM3	Serum	Pre-biopsy	Risk of detecting Gleason ≥ 7 PCa on biopsy	Initial biopsy
epiCaPture	Urine	Pre-biopsy	Risk of detecting high-risk PCa on biopsy	Initial biopsy
Decipher	Tissue	Post-biopsy	Risk of pT3 or Gleason grade 4 or N+ PCa	High-grade disease
Oncotype DX	Tissue	Post-biopsy	Risk of pT3 or Gleason grade 4 PCa	Aggressive disease
Prolaris	Tissue	Post-biopsy	PCa-specific mortality, BCR, metastasis	Aggressive disease and PCa-specific mortality
PTEN	Tissue	Post-biopsy	Risk of harboring aggressive PCa	Aggressive disease
ProMark	Tissue	Post-biopsy	Risk of pT3 or Gleason grade 4 PCa	Aggressive disease
Ki67	Tissue	Post-biopsy	Risk of BCR, metastatic disease, RFS	PCa-specific mortality

Abbreviations: BCR, biochemical recurrence; csPCa, clinically significant prostate cancer; DRE, digital rectal examination; PCa, prostate cancer; RFS, recurrence-free survival.

for detection of Grade Group 2 PCa was 88% (range 84%-91%), it is important to consider the negative predictive value was 76% (69%-82%).⁵ While a negative MRI can be reassuring to patients and urologists alike, a negative MRI should be interpreted with caution and biopsy should still be advised with shared decision-making. PRECISION demonstrated superior diagnosis of clinically significant prostate cancer (csPCa) in those who underwent MRI prior to biopsy with MRI-targeted biopsies obtained vs standard 12-core TRUS prostate biopsy. Lower rates of clinically insignificant PCa were detected via this modality and optimization of positive core identification was noted.⁶ The PRIME study (NCT04571840) has been proposed to clarify detection of csPCA with biparametric MRI (T2 weighted and diffusion weighted, no dynamic contrast enhanced [DCE]) vs standard multiparametric magnetic resonance imaging (mpMRI) to assess whether IV

contrast is required for prostate MRI. Patients will undergo standard mpMRI; however, radiologists will be blinded to the DCE phase. Biopsies in both biparametric MRI and mpMRI will undergo MRI-targeted prostate biopsies and the primary outcome will be proportion of men with csPCa. Benefits of deferring DCE would include faster MRI and risk mitigation of allergic and other contrast-related reactions.⁷

Pre-biopsy MRI in our practice is utilized primarily in patients with elevated PSA (<10 ng/mL) with negative DRE and clinical suspicion for PCa prior to biopsy. In patients with a palpable nodule and clinical concern for PCa we find it logical to proceed with transrectal prostate biopsy directly in most cases to optimize efficiency in diagnosis. We routinely favor cognitive fusion transrectal and transperineal prostate biopsy for larger lesions, predominantly peripheral zone lesions, and palpable lesions to improve diagnostic

efficiency and avoid a backlog for software-assisted MRI/US fusion. We typically reserve software-assisted grid-based transperineal fusion biopsy for patients with small anterior lesions in large prostates that would otherwise be quite challenging to localize with cognitive fusion alone. In our practice, TRUS-guided biopsy is generally performed under local anesthesia, whereas transperineal biopsy is performed under general anesthesia to optimize patient comfort.

Biomarkers

Adjunct tests including tissue, blood, and urine-based assays have been developed for clinical practice (see Table).⁸ Tissue-based tests utilize multigene footprints and can be used to risk stratify patients diagnosed with low- and intermediate-risk PCa, especially those considering additional information to decide on active surveillance or radical treatment. Head-to-head comparisons for tissue- and

blood-based tests are lacking, however, and their utility is nuanced.

Artificial Intelligence

Artificial Intelligence (AI) is developing at a swift pace. AI applications have been applied to mpMRI to assist radiologists in assigning a PI-RADS (Prostate Imaging-Reporting and Data System) score and have shown promise previously for detection of suspicious lesions in the peripheral zone.⁹ In prostate histopathology, AI models with acceptable accuracy may have a role in minimizing inter-rater variability and improving diagnostics, reducing cost, and improving efficiency.¹⁰

We have come a long way from the early days of open incisional prostate biopsy based solely on DRE. We look forward to continued technological improvements as we continue to push for optimized diagnostic precision in men at risk for PCa. ■

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SPECIALTY SOCIETIES

Management of Bladder Exstrophy: What a General Urologist Should Know

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Background

Bladder exstrophy-epispadias complex (BEEC) is a rare congenital malformation characterized by a spectrum of anatomical anomalies involving the ventral body wall, urinary tract, genitalia, pelvic organs, bony pelvis, and the muscles of the pelvic floor. The first reported repair was performed by Trendelenburg over 100 years ago.

The goals of the management of individuals with BEEC is to provide a competent reservoir (bladder) for storage of urine, prevent upper tract damage, and to provide cosmetically acceptable genitalia that permit good functional outcomes in terms of continence, sexuality, and fertility. Additionally we have to address any psychological issues that can impact their mental wellness. These goals can be collectively summed up by the Latin phrase “cura personalis,” care of the whole person (see Figure).

Epidemiology

Based on the incidence of 3.3 cases per 100,000 live births (male-to-female ratio 2:1), it is estimated that there will be approximately 120 children born with BEEC each year in the U.S. This number does not take into account the number of prenatally diagnosed fetuses with bladder exstrophy that are medically terminated. BEEC is less prevalent among the non-White race, high or low socioeconomic status, and Western geographic region. Some studies have demonstrated an association with maternal smoking and irradiation in the first trimester.

Physical Exam

The diagnosis of BEEC is based on the clinical exam of the baby and is usually made by

Goals of Holistic Care for all Patients with BEEC

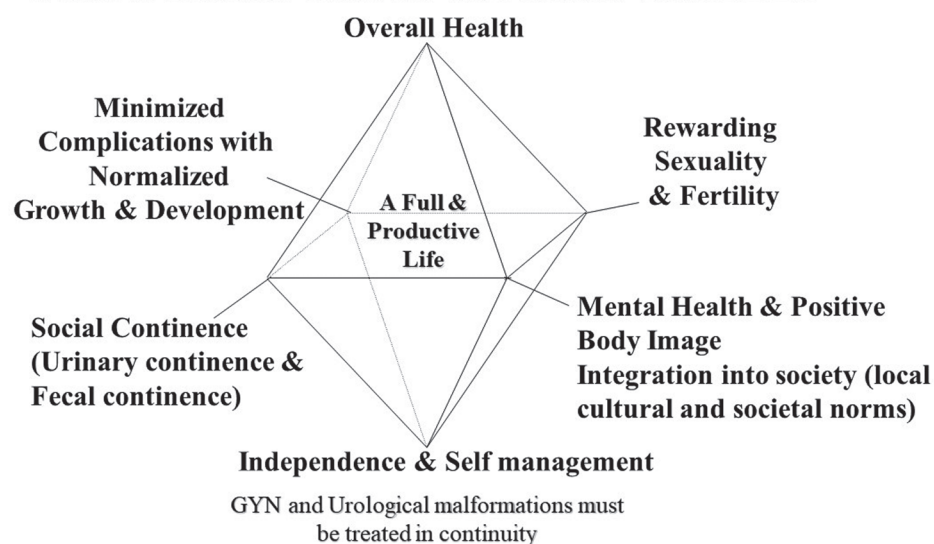


Figure. This diagram represents the long-term objectives of care for all patients with bladder exstrophy-epispadias complex (BEEC), the ultimate goal being to enable all individuals born with BEEC to live their life to their fullest potential. GYN indicates gynecologic.

the obstetrician, soon after delivery in the majority of cases. The baby will present with an infra-umbilical defect of the anterior

abdominal wall; the bladder plate protrudes through this defect and functions as part of the abdominal wall. The ureteric orifices are of-

ten visible and can be seen to be effluxing urine.

In females, the bladder plate continues as a short urethral plate that passes between the bifid clitoris. The vaginal introitus is ventrally displaced with the vagina being more horizontally oriented. In classic BEEC, uterine and vaginal duplications are uncommon, as opposed to cases of cloacal exstrophy, where these variants are much more common.

In males, the bladder plate continues as a urethral plate on the dorsum of the phallus. The phallus is short with dorsal chordee and a flat glans with divergent corpora due to the pubic diastasis. The scrotum is separated from the base of the phallus by a skin bridge. The testes are usually descended and often there are bilateral inguinal hernias present.

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Table. Some of the Conditions in the Management of Bladder Exstrophy-Epispadias Complex That Will Need to Be Proactively Addressed as These Children Grow Into Adults

Conditions that patients with BEEC present with	Management strategies
Urinary continence—reported achievement of a 2-3 h dry interval during the day and 8 h at night is the goal for these patients. Reported continence rates are currently at 20%-23% for all patients with BEEC who are voiding with native bladder function ⁴ Up to 67% of patients with BEEC who are being managed with CIC can expect to achieve continence ⁵ In instances where bladder augmentation/substitution procedures have been undertaken continence is >90%	<ul style="list-style-type: none"> Procedures that restore bladder outlet function and permit bladder cycling Use of anticholinergic medications to improve storage function CIC, usually via a catheterizable channel Bladder augmentation/urinary diversion if patient is requesting for continence
Renal injury (30% of all patients with BEEC) from UTIs, VUR (almost 100% of patients with BEEC have VUR), and elevated storage pressures	<ul style="list-style-type: none"> Address the VUR once the bladder begins to cycle Antibiotic prophylaxis until VUR is resolved Lifelong annual monitoring of BP, urine for proteinuria, and renal function assessment is critical for the health of these patients Female patients with BEEC should be monitored for higher risk of preeclampsia
Sexual function—in a self-reported survey of patients with BEEC conducted by Dr Gearhart, over 52% of patients reported engaging in penetrative intercourse. Female fertility with successful pregnancy was documented to be 25.3%. Male fertility with paternity was reported to be 23.8% ⁶	<ul style="list-style-type: none"> Early education about these issues and referral for psychological support plays an important role in assisting these patients managing these intimate issues Referral to specialists for assisted reproductive techniques when they are ready to start a family Education that while there is a slightly increased risk of having a baby with BEEC, this risk remains very low Delivery by means of a planned cesarean section is recommended
The incidence of female patients with BEEC who present with pelvic organ prolapse requiring repair is 38% ⁷	<ul style="list-style-type: none"> Early education about this condition can permit patients seeking timely care and enable optimal sexual function and fertility outcomes

Abbreviations: BEEC, bladder exstrophy-epispadias complex; BP, blood pressure; CIC, clean intermittent catheterization, UTI, urinary tract infection; VUR, vesicoureteral reflux.

MANAGEMENT OF BLADDER EXSTROPHY

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Children with BEEC will have a ventrally displaced anus due to abnormalities of the pelvic floor muscles resulting from the pubic diastasis and open book pelvis.

Preoperative Care of the Exposed Bladder

We recommend a protective covering over the bladder plate with a nonadherent film (Saran wrap) or Tegaderm. This prevents trauma by the diaper and reduces the formation of polyps. Additionally, if a plastic clamp was used to occlude the umbilical cord, we recommend removing this and using silk ties to occlude the cord; this prevents damage to the exposed bladder plate.

These patients should then be transferred to a children's hospital for ongoing care by pediatric specialists.¹

Evaluation

The diagnosis of BEEC is based on the clinical exam. Baseline assessment of complete blood count and renal function is recommended. An x-ray of kidney-ureter-bladder and/or pelvic x-rays to assess the pelvic anatomy and determine the pubic diastasis as well as a renal ultrasound are recommended imaging studies. The incidence of spinal abnormalities in BEEC is not significant as opposed to the increased incidence in cloacal exstro-

“Gone are the days of the surgical management being deemed an emergency that had to be performed within 24 hours of birth.”

phy, and so routine spinal imaging is not indicated unless indicated by an abnormal sacral exam.

The surgical treatment of BEEC is aimed at restoring the normal anatomy, functionality, and cosmesis of the involved structures. Gone are the days of surgical management being deemed an emergency that had to be performed within 24 hours of birth. This philosophy was predicated on the belief that neonatal levels of a hormone, relaxin, would avoid the need for osteotomies. We now know that there are no measureable levels of this hormone in the neonate.

We now recommend an elective closure be performed to permit the bonding of the child with their family, optimize the nutrition of the infant, and potentially allow the male infants to go through the “mini-puberty” at 3 months if a combined primary repair of BEEC is being contemplated to allow for improved healing. The additional benefit of the elective repair of BEEC is that it allows for the development of a dedicated team to be involved in the care of these patients with improved clinical outcomes as they gain more experience caring for children with BEEC and working with each other.

There are a number of reconstructive procedures that are utilized to achieve the surgical objectives; patient anatomy and surgeon preference dictate which technique is utilized:

- modern staged repair of exstrophy
- complete primary repair of exstrophy
- Kelly's radical soft tissue mobilization
- Warsaw procedure

Long-term Care and Transition to Adult Care Providers

All patients born with BEEC require and deserve lifelong care by specialists, and there are some issues that come to the forefront when they are adults. Having a transitional urology program is vital to ensure that these patients don't fall through the cracks of the U.S. health care system. See the Table for details of these conditions.

Logistical Considerations

There are approximately 120 cases delivered each year at one of the 3,207 labor and delivery hospitals in the U.S. (0.03 cases/y per birth hospital). These neonates are then transferred to one of 250 children's hospitals for specialized care (0.48 cases/y). Given the infrequent presentation of these cases, most hospitals do not develop the experience or the specialized teams required to ensure optimal care for these patients.^{1,2}

Bladder exstrophy surgery is hard to do, and it is hard to perform due to the infrequent occurrence of this condition. Annually the 120 new cases in the U.S. are managed by one of 724 pediatric urologists. On average each pediatric urologist will have to wait 6 years to be involved with 1 case of BEEC; another way of looking at this is that during a 35-year career, most pediatric urologists will have the privilege of being involved in the care of 6 patients with bladder exstrophy. Improved clinical outcomes and reductions in the overall cost of care and burden of care have been demonstrated by the creation of dedicated centers focused on the management of specific clinical conditions. We need to be more proactive in developing regional centers for the care of individuals with BEEC; in addition to improved clinical outcomes, this strategy will also ensure ongoing coaching and mentoring of clinicians involved in the care of these individuals.

“BEEC is indeed a very challenging condition with significant impact on the affected individual and their family.”

Multi-institutional collaborative networks in the care of patients with BEEC have also demonstrated significant benefits.³

Conclusions

BEEC is indeed a very challenging condition with significant impact on the affected individual and their family. Over the past few decades, significant advances have been made in the care of these patients and there have been improvements in clinical outcomes. The 2 deliverables that we still have to considerably enhance are urinary continence and phallic reconstruction for male patients. By creating regional centers of excellence for the management of BEEC, we can enable clinical teams who focus on this condition to develop the expertise to change the outcome for these individuals for whom we are all privileged to provide care. ■

“Improved clinical outcomes and reductions in the overall cost of care and burden of care have been demonstrated by the creation of dedicated centers focused on the management of specific clinical conditions.”

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UPJ INSIGHT

eConsult Provides a Novel Opportunity to Evaluate Hematuria Referrals for Medicaid Patients

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Sanchez DE, Low J, Lucas MI, et al. eConsult provides a novel opportunity to evaluate hematuria referrals for Medicaid patients in the “real-world” community. Urol Pract. 2023;10(3):236-243.

Study Need and Importance

Uninsured or low-income patients experience longer delays in hematuria evaluation and treatment. This disparity contributes to higher mortality rate from bladder cancer in underserved populations. Prior studies report that the use of eConsults increases efficiency of care in underserved populations. There is a need to understand the appropriateness and completeness of hematuria evaluation in Medicaid patients.

What We Found

Most Medicaid patients in community health systems do not receive the recommended hematuria evaluation and workup per AUA guidelines. Primary care provider evaluation for risk factor rates prior to eConsult were low (see Table). Over two-thirds of the patients were referred without a documented urinalysis with microscopy or history of gross hematuria. Most patients did not have computerized tomographic urography ordered or completed

Table. Appropriateness of Hematuria Referrals

	No (N=53)	Yes (N=53)	P value
Sex, No. (%)			.364
Male	16 (30.2)	20 (37.7)	
Female	37 (69.8)	33 (62.3)	
Face-to-face visit, No. (%)			< .001
No	35 (66.0)	12 (22.6)	
Yes	18 (34.0)	41 (77.4)	
Further baseline information/workup needed, No. (%)			.123
No	10 (18.9)	18 (34.0)	
Yes	43 (81.1)	35 (66.0)	
Medicorenal disease factors, No. (%)			.082
No	21 (47.7)	16 (41.0)	
DM/HTN	16 (36.4)	12 (30.8)	
DM/no HTN	5 (11.4)	2 (5.1)	
HTN/no DM	2 (4.5)	9 (23.1)	
Missing	9	14	
Smoking status, No. (%)			.446
Past	1 (2.9)	2 (6.2)	
Current	7 (20.0)	10 (31.2)	
Never	27 (77.1)	20 (62.5)	
Missing	18	21	
Additional urothelial risk factors count			.263
Mean (SD)	0.3 (0.5)	0.5 (0.8)	
Median (Q1-Q3)	0.0 (0.0-1.0)	0.0 (0.0-1.0)	
Minimum-maximum	0.0-2.0	0.0-2.0	
Missing	9	10	
Nonmalignant etiologies count			.365
Mean (SD)	0.4 (0.5)	0.5 (0.8)	
Median (Q1-Q3)	0.0 (0.0-1.0)	0.0 (0.0-1.0)	
Minimum-maximum	0.0-1.0	0.0-1.0	
Missing	9	9	
LUTS, No. (%)			1
No	9 (69.2)	12 (75.0)	
Yes	4 (30.8)	4 (25.0)	
Missing	40	37	
Gross hematuria, No. (%)			.005
No	15 (83.3)	7 (33.3)	
Yes	3 (16.7)	14 (66.7)	
Missing	35	32	
Weight loss, No. (%)			1
No	0 (0.0)	1 (50.0)	
Yes	1 (100.0)	1 (50.0)	
Missing	52	51	
Dysuria, No. (%)			.46
No	16 (80.0)	11 (64.7)	
Yes	4 (20.0)	6 (35.3)	
Missing	52	51	
Flank pain, No. (%)			1
No	9 (69.2)	1 (100.0)	
Yes	4 (20.0)	6 (35.3)	
Missing			
Imaging results provided, No. (%)			.856
No	26 (53.1)	29 (56.9)	
Yes	23 (46.9)	22 (43.1)	
Missing	4	2	

Abbreviations: DM, diabetes mellitus; HTN, hypertension; LUTS, lower urinary tract symptoms; Q1, first quarter; Q3, third quarter; SD, standard deviation. Bolded values indicate P value significant at < .05.

“Most Medicaid patients in community health systems do not receive the recommended hematuria evaluation and workup per AUA guidelines.”

at the time of eConsult dialogue completion, despite the 2012 AUA Guideline recommendation. Only half of all referrals were deemed appropriate based on a history of gross hematuria or ≥ 3 red blood cells/high-power field on urinalysis. Over three-quarters of the patients who met documented hematuria criteria compared to one-third of the patients who did not meet documented hematuria criteria ended in a face-to-face (FTF) urologist visit recommendation. By the conclusion of the eConsult only half of the patients were referred for an FTF visit.

Limitations

This study was conducted via retrospective data collection. Furthermore, our analysis only includes information available at the time of the original eConsult and final iterative dialogue outcome. We do not have follow-up information and cannot determine whether these patients eventually obtained the appropriate workup, imaging, or procedures.

Interpretation for Patient Care

eConsult dialogues can be used to assess quality of care and improve information dissemination of guidelines to community primary care providers. Thus, eConsults can be used as a teaching tool to improve the completeness of hematuria evaluation in underserved settings and minimize unnecessary FTF urologist referrals. ■



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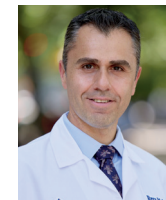
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Sarah Faris, MD
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Reza Mehrazin, MD
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Aditya Bagrodia, MD
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New England Section



Ahmed Kotb, MD
Northeastern Section



Akanksha Mehta, MD
Southeastern Section



Doreen Chung, MD
New York Section



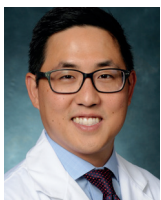
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Mid-Atlantic Section



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JU INSIGHT

Displacement of Lower Pole Stones During Retrograde Intrarenal Surgery Improves Stone-free Status

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Yaghoubian AJ, Anastos H, Khusid JA, et al. Displacement of lower pole stones during retrograde intrarenal surgery improves stone-free status: a prospective randomized controlled trial. *J Urol.* 2023;209(5):963-970.

Study Need and Importance

Retrograde intrarenal surgery (RIRS) is a mainstay in the surgical management of stone disease. Despite a plethora of technological

Table. Primary and Secondary Outcomes

	Displacement group (n=69)	In situ group (n=69)	Odds ratio	P value
Stone-free status, No./total No. (%) ^a	59/62 (95)	46/62 (74)	0.15 (0.03;0.50)	.003
Operative time, median (IQR), min	65.0 (51.0;84.0)	55.0 (34.0;82.0)	0.99 (0.98;1.01)	.11
Total laser energy used, median (IQR), kJ	2.80 (1.53;6.20)	1.84 (0.64;5.16)	0.94 (0.87;1.01)	.11
Complication (Clavien grade), No. (%)			0.48 (0.12;1.64)	.3
None	61 (88)	65 (94)		
II	7 (10)	3 (4.4)		
IIIb	0 (0)	1 (1.5)		
IVa	1 (1.5)	0 (0)		
30-Day ED visit, No. (%)	8 (12)	4 (5.8)	0.48 (0.12;1.64)	.4
30-Day hospital readmission, No. (%)	3 (4.4)	3 (4.4)	1 (0.17;6.01)	1

Abbreviations: ED, emergency department; IQR, interquartile range.

Bolded P values indicate statistical significance.

^aA total of 14 patients (7 in each group) did not receive follow-up imaging to determine stone-free status.

advancements over the last several decades, stones within the lower pole of the kidney continue to present a challenge to urologists. Indeed, lower pole stones are associated with the lowest stone-free status (SFS) of any location in the urinary tract. To avoid laser lithotripsy in the lower pole, many urologists use a basket to displace lower pole stones into a more accessible upper or interpolar calyx. We investigated whether displacing stones out of lower pole calyces would improve SFS for patients during RIRS.

What We Found

A total of 138 patients with lower pole stones were randomized to undergo RIRS with laser lithotripsy in situ or with basket displacement. Ultimately 124 patients (62 in each group) followed up for postoperative imaging. SFS was

significantly higher in the basket displacement group (95% vs 74%, $P = .003$). There were no significant differences between groups in operative time, laser energy usage, complications, emergency department visits, or hospital readmissions (see Table). Multivariate analysis showed that only study group allocation was associated with SFS ($P = .024$).

Limitations

Despite lower sensitivity for detecting residual stone fragments compared with computerized tomography, we chose to use abdominal x-ray and renal ultrasound to avoid additional costs to patients. Additionally, there was an element of procedural variability, as patients were enrolled by 2 different surgeons without standardization of certain aspects of the procedure. Despite these limitations, our data suggest that

“Moving lower pole stones into more accessible parts of the kidney maximizes SFS during RIRS.”

displacement of lower pole stones during RIRS maximizes SFS.

Interpretation for Patient Care

Moving lower pole stones into more accessible parts of the kidney maximizes SFS during RIRS. The technique is simple, safe, and requires no additional equipment costs and little additional operative time. We encourage all urologists to displace lower pole stones during RIRS to improve patient outcomes. ■



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