Podium Session 1: Endourology, BPH

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POD 1.1

A multicenter, randomized controlled trial of ambulatory vs. inpatient percutaneous nephrolithotomy

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Introduction: Ambulatory percutaneous nephrolithotomy (PCNL) has been proposed as a means to speed patient recovery, decrease hospital stay time, and decrease cost compared to inpatient PCNL. Studies evaluating ambulatory PCNL have used highly selective selection criteria that preclude the vast majority of PCNL candidates. The goal of our study was to perform a high-quality, randomized, controlled trial of ambulatory vs. inpatient PCNL in a representative patient population, including those with large stones (>4 cm), BMI >30, and ASA >2.

Methods: This was a multicentre, non-inferiority, randomized, controlled trial of ambulatory vs. inpatient PCNL at University of Manitoba and University of California, San Francisco. Patients were randomized prior to surgery stratified for ASA, BMI, stone size, and study site. Primary outcomes were complication and readmission rates within four weeks of surgery. Secondary outcomes were stone-free rate (CT scan four weeks after surgery), quality of life (using WisQOL), and return to work time.

Results: Of 70 patients (35 ambulatory and 35 inpatient), mean age was 71, 48% were BMI >30, 41% were ASA 3/4, and 31% had stone size >4 cm. Tract size was similar between ambulatory group (16 French 60%, 30 French 40%) and inpatient group (16 French 57%, 30 French 43%; p=1). There was no difference in our primary outcome of complication rate between those who underwent ambulatory (3%) and inpatient PCNL (9%, p=0.61). Readmission rate within four weeks was not different between the ambulatory (3%) and inpatient group (3%, p=1). Stone-free rate was not different between the ambulatory (71%) and inpatient group (74%, p=1). The mean recovery time in hospital after surgery was 2–3 hours in the ambulatory group vs. one day in the inpatient group. The rate of patients who were able to return to work within one week was not different between the ambulatory group (89%) vs. the inpatient group (80%, p=0.5). In those randomized to the ambulatory group, three (9%) required crossover to the inpatient group. Reasons for this were surgical for one patient (small infundibular tear that the surgeon wanted to monitor overnight), and anesthesia-related for the remaining two patients (obstructive sleep apnea monitoring, elevated potassium monitoring).

Conclusions: Ambulatory PCNL has similar complication rates, stone-free rates, and readmission rates compared to those who undergo inpatient PCNL. Our results support the use of ambulatory PCNL in patients with BMI >30, ASA >2, and stone size >4 cm who have typically been excluded from consideration for ambulatory PCNL in the past.

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POD 1.2

Break Wave™ lithotripsy for urolithiasis: Results of the first-in-human, international, multicenter clinical trial

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Introduction: Break Wave lithotripsy is a new, non-invasive technology for the treatment of urolithiasis that can be performed with little to no anesthesia, potentially allowing stone treatment in non-operative settings. This study reports safety, efficacy, and anesthesia requirements from a first-in-human, prospective, multicenter, open-label, single-arm clinical trial (NCT03811171) using the SonoMotion (San Mateo, CA) Break Wave device.

Methods: Forty-four patients with ureteral or renal stones were treated across five North American centers (U.S./Canada) between August 2019 and February 2022. Patients were recruited and treated in the operating room, office/clinic, or emergency department (ED). Thirty minutes of Break Wave therapy was delivered under continuous ultrasonography targeting. Varying therapy dose levels up to 8 MPa of acoustic pressure were administered, and safety, effectiveness, and anesthesia requirements were assessed to establish optimal dose settings. The efficacy objective was stone-free rate or fragments ≤4 mm assessed via non-contrast CT at 8–12 weeks by an independent radiologist. Patients were followed for 90 days, with all adverse events (AEs) recorded.

Results: Target stones were in typical locations and sizes (Table 1), with 59% renal (n=26) and 41% in the distal ureter (DU) (n=18). No serious AEs, hematomas, cardiac arrhythmias, or sepsis occurred at any dose level. Overall, 86% of subjects received either no medication (50%) or minor analgesia (36%) (e.g., ketorolac 15–30 mg). All patients completed the procedure. Stone fragmentation occurred in 88% of cases, with 70% of subjects being completely stone-free or with fragments ≤4 mm on CT. The retreatment rate was 7% within 90 days with either SWL or URS. The optimal dose setting was identified and delivered to 36/44 patients. Of these 36 patients, 75% had fragments ≤4 mm and 58% were completely stone-free; 71% of lower pole patients (n=14) had fragments ≤4 mm, with 29% stone-free, and 89% of DU patients (n=18) were completely stone-free.

Conclusions: Break Wave lithotripsy appears to be a safe and effective non-invasive stone therapy requiring little to no anesthesia. It is potentially suitable for non-operative environments, such as the office or ED, and is being evaluated in ongoing trials.

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POD 1.2. Table 1. Patient demographics & results

	Characteristics N=44
Mean age ± SD (years)	50±14
Gender	32 male (73%)
Body mass index ± SD (kg/m^2)	28±5
Stone size Mean ± SD (mm) Range	 6.1±1.5 3–9
Stone density (HU) Mean ± SD Range	 847±238 450–1346
Skin-to-stone distance by CT Range (cm)	 7.6–16
Laterality	Right: 20 (45%) Left: 24 (55%)
Stone location	Upper pole: 1 Interpolar: 6 Lower pole: 17 Renal pelvis/ureteropelvic junction: 2 Distal ureter: 18
Overall stone fragmentation rate	88% (38/43)
Overall success rate (stone-free or ≤4 mm on CT)	70% (30/43)
Optimal dose setting with frags ≤4 mm on CT	75% (27/36)
Optimal dose setting: Completely stone free	58% (21/36)
Optimal dose setting: Lower pole patients with frags ≤4 mm on CT	71% (10/14)
Optimal dose setting: Lower pole patients completely stone-free	29% (4/14)
Optimal dose setting: Distal ureteral stones completely stone-free	89% (16/18)

POD 1.3

Superior outcomes with patient-chosen music during cystoscopy compared to classical and no music: A randomized control trial

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Introduction: Classical music is known to alleviate pain and anxiety during cystoscopy but the impact of patient-chosen music remains unclear. This study compared the effects of patient-chosen music, classical music, and no music on patient outcomes during cystoscopy.

Methods: In a prospective, randomized control study, 161 male and female patients undergoing outpatient flexible cystoscopy between June 2022 and January 2024 were randomly allocated to one of three groups: patient-chosen music (n=56), classical music (n=53), or no music (n=52). In the patient-chosen music group, individuals were given the opportunity to select their desired songs prior to cystoscopy. We used the State-Trait Anxiety Inventory (STAI) to measure anxiety (scored 20–80), where State STAI (STAI-S) assesses 'in-the-moment' anxiety levels. Visual Analog Scales (VAS) scored from 0–10 to one decimal place were administered following cystoscopy to measure pelvic pain, pelvic discomfort, satisfaction, and willingness to repeat the procedure. Two-way analysis of covariance (ANCOVA), controlling for baseline anxiety, compared mean post-cystoscopy STAI-S, delta STAI-S (post-procedure minus pre-procedure STAI-S score), and VAS scores among groups, followed by Tukey's post-hoc tests to compare outcomes between groups (α=0.05).

Results: Significant differences were observed in VAS scores for pelvic pain ($F(2, 154)=15.68$, $p<0.001$), pelvic discomfort ($F(2, 154)=24.84$, $p<0.001$), satisfaction ($F(2, 154)=15.70$, $p<0.001$), and willingness to repeat the procedure ($F(2, 154)=25.81$, $p<0.001$) among the groups, with no significant findings for post-cystoscopy STAI-S and Delta STAI-S. Post-hoc tests showed patient-chosen music significantly reduced pelvic pain and pelvic discomfort compared to both the classical music group (pain mean difference (MD)=-0.99, p=0.0023; discomfort MD=-1.44, p<0.001) and the no music group (pain MD=-1.57, p<0.001; discomfort MD=-2.32, p<0.001). Patient-chosen music also significantly increased satisfaction and willingness to repeat compared to both the classical music group (satisfaction MD=1.01, p<0.001; repeat MD=0.70, p=0.0011) and no music group (satisfaction MD=1.49, p<0.001; repeat MD=1.36, p<0.001). Classical music did not significantly differ from no music in pelvic pain (MD=-0.58, p=0.13) but marginally reduced pelvic discomfort (MD=-0.88, p=0.036).

Conclusions: Patient-chosen music during flexible cystoscopy is associated with a significant reduction in pelvic pain and discomfort, in addition to significantly improving patient satisfaction and willingness to repeat the procedure compared to classical music and no music.

POD 1.4

Dietary risk factors for kidney stones among the Canadian population: Implications for dietary counselling and prevention

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Introduction: Previous population-based research has shown that diet contributes significantly to kidney stone formation. Specific dietary risk factors have been identified, and guidelines for preventing kidney stone recurrences have been developed. In the context of the increasing incidence of kidney stones, we aimed to assess the percentage of the population who are eating an at-risk diet for kidney stones and to understand the baseline diet for future counselling.

Methods: The 2015 Canadian Community Health Survey, a national cross-sectional instrument administered by Statistics Canada and Health Canada, was queried. Intake of relevant nutrients was compared to dietary risk factors for kidney stone formation. Factors associated with nutrient intake were analyzed in a multivariable regression.

Results: Data for 14 275 participants was included, of whom only 34% consumed >2 L of fluid per day and only 9.4% consumed 1000–1200 mg of dietary calcium; 53.9% consumed too much sodium but 61% of the population had the recommended protein intake. Less than 1% of the population had no dietary risk factors for developing kidney stones, while 92.2% have two or more risk factors. As seen in Table 1, fluid, sodium, calcium, and protein intake increased significantly with education level, income, and if employed (p<0.01). Participants with food insecurity were more likely to have low dietary protein and calcium but had no significant differences in sodium or fluid intake. Hypertension was associated with lower intake of fluid, sodium, calcium, and protein, while an elevated BMI was associated with increased intake of each of these (p< 0.05 for all). Osteoporosis but not dairy-free diets were associated with low calcium. Supplements were common, with 62.3% of the population taking a supplement containing vitamin C, 51.2% vitamin B6, 47.2% calcium, and 38% magnesium.

Conclusions: While only a subset of the population will develop stones, this study shows that 92.2% of the population is eating a diet that elevated the risk of stone disease. As the incidence of kidney stones increases, population-based dietary interventions should be considered. Furthermore, clinicians may use these data to understand the average diet as a starting point for questioning and counselling patients.

POD 1.4. Table 1. Association between socioeconomic status and dietary risk factors for kidney stones

Income	<$40 000	$40 000–79 999	$80 000–119 999	≥$120 000	p
Protein (≤80 g/day)	70.50%	63.80%	60.50%	59.70%	<0.01
Calcium (1–1.2 g/day)	8.70%	10.40%	11.80%	12.30%	<0.01
Sodium (≤ 2.3 g/day)	51.90%	47.70%	44.90%	45.90%	<0.01
Fluid (≥ 2.5 L/day)	16.10%	18.10%	20.50%	21.90%	<0.01
Education	<High school diploma	High school diploma	Certificate/ diploma/trade <bachelor	≥ Bachelor degree	p
Protein (≤80 g/day)	71.30%	62.20%	58.60%	56.10%	<0.01
Calcium (1–1.2 g/day)	11.70%	9.20%	10.00%	10.60%	<0.01
Sodium (≤2.3 g/day)	52.00%	46.20%	44.20%	44.90%	<0.01
Fluid (≥2.5 L/day)	9.20%	23.60%	27.50%	25.20%	<0.01
Work status	Worked	Had a job but did not work	Did not have a job	p	
Protein (≤80 g/day)	55.10%	56.90%	63.90%	<0.01	
Calcium (1–1.2 g/day)	10.20%	10.40%	8.70%	<0.01	
Sodium (≤ 2.3 g/day)	41.60%	43.40%	47.50%	<0.01	
Fluid (≥2.5 L/day)	29.10%	33.40%	19.50%	<0.01	
Food security	Food secure	Moderately food insecure	Severely food insecure	p	
Protein (≤80 g/day)	63.00%	66.70%	71.50%	<0.01	
Calcium (1–1.2 g/day)	10.90%	8.70%	7.00%	<0.01	
Sodium (≤2.3 g/day)	47.70%	48.90%	49.20%	0.552	
Fluid (≥2.5 L/day)	18.10%	18.30%	21.50%	0.134	

POD 1.5

Rez□m water vapor therapy for large-volume benign prostatic enlargement: Large, multicenter, real-world cohort

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Introduction: Open or laser prostatectomy have been the standard treatments for benign prostatic hyperplasia (BPH) of large-volume prostates ≥80 ml. Rezūm is a minimally invasive procedure to ablate benign prostatic tissue. Herein, we report the prospective, multicenter results of the largest cohort of prostates ≥80 mL treated with Rezūm.

Methods: A prospective registry was established for Rezūm therapy in Canada (2019) at two high-volume centers. We reviewed data for patients followed between April 2019 and June 2023. All patients had baseline medical and BPH history documented, along with uroflowmetry (Qmax and PVR), and validated questionnaires (IPSS, IPSS QoL, BPHII, IIEF-15, MSHQ-EjD function and bother).

Results: A total of 175 patients (mean age 68.8±8.3 years) with prostate size ≥80 ml were treated with Rezum. The median prostate volume was 105 (range 80–271) ml, 11.4% had prostate volume >150 ml, and 79.4% had a median lobe. A prior history of urinary retention was documented in 54 patients. The procedure involved an average of 14±3.6 injections and the duration was five minutes, on average (ranging from 2–13 minutes). Post-procedure catheterization was required for a mean duration of 14.3±7.7 days. IPSS reduced from a baseline score of 21.8 to 9.1, 9.3, and 10.1 at three, 12 and 24 months, respectively. IPSS QoL score improved from a baseline of 4.5 to 1.5 at 12 months and 1.4 at 24 months. Qmax improved from a mean baseline of 7.8 ml/s up to 19.7 ml/s at 12 months. BPHII improved from a baseline of 7.3 to 2.3 at 12 months, with further improvement to 1.8 at 24 months. IIEF and MSHQ showed no significant change from baseline to 12 months. Eleven (6.3%) patients noted retrograde/anejaculation and eight (4.6%) patients needed retreatment at an average followup of 18±10.6 months.

Conclusions: Rezūm therapy is a safe, effective, quick, outpatient procedure in prostate glands ≥80 ml with long-term improvement in voiding function.

POD 1.6

Does intervention for non-obstructing kidney stones affect recurrent urinary tract infections? A prospective, observational cohort study from the EDGE Consortium

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Introduction: Retrospective studies evaluating surgical intervention for nephrolithiasis in patients with recurrent urinary tract infections (UTIs) report that infections resolve in approximately half of individuals after stone removal. Therefore, we sought to perform a multicenter, observational, prospective study with a comparison group to evaluate whether surgical treatment of stones is associated with a reduced risk of UTIs in patients with recurrent infections.

Methods: From November 2020–2023, patients with kidney stones and three symptomatic, culture-confirmed (100k CFU/mL) UTIs in the preceding 12 months, or two in six months, were prospectively recruited at three academic institutions (NCT#04495699). After shared decision-making, observation or sur-

gical intervention of the stone/s was performed. The primary outcome was the occurrence of UTI relapse between 30 days and six months after enrollment comparing those on observation vs. surgical intervention for kidney stones.
Results: Among 82 patients recruited, 20 opted for observation of their stones and 62 opted for surgical intervention. Followup data at six months was available for 11 observation and 37 intervention patients, with the remainder lost to followup or having data maturing. In the intervention group, 70% received their surgery; in the observation group, 18% crossed over to surgery. The intervention group in the intention-to-treat analysis was significantly more likely to be stone-free at six months (59% vs. 0%, p<0.001). At six months, 45% of patients in the observation group compared to 32% of patients in the intervention group experienced one or more UTIs (5 vs. 12, p=0.5).
Conclusions: For patients with recurrent UTIs, surgical intervention is not associated with a significantly decreased risk of UTI relapse by six months. While underpowered to detect smaller differences, our findings suggest that surgery may have less of an impact on recurrent UTIs for non-obstructing stones than previously reported.
Acknowledgements: Study data were collected and managed using REDCap electronic data capture tools hosted at Vanderbilt University Medical Center and supported by grants UL1 TR000445 from NCATS/NIH.

POD 1.6. Table 1. Comparison of patients at 6-month followup who opted for observation or intervention of their stones

	Observation (n=11)	Intervention (n=37)
Age (years, mean ± SD)	59±18	63±12
Sex		
Female	11	29 (78%)
Male	0	8 (22%)
BMI (kg/m^2, mean ± SD)	30.6±4.8	31.0±7.0
UTIs prior to study (median, range)		
6 months prior	2 (1–6)	2 (1–8)
12 months prior	4.5 (2–8)	3 (2–8)
Recurrent UTI 6 months after recruitment		
Yes	5 (45%)	12 (32%)
No	6 (55%)	25 (68%)
UTIs after 6 months for patients with recurrence (median, range)	2 (1–4)	1 (1–4)
Pathogen(s) in prior cultures (% of patients)		
E. coli	11 (100%)	21 (57%)
Proteus	0 (0%)	4 (10%)
Klebsiella	5 (45%)	8 (22%)
Pseudomonas	0 (0%)	3 (8%)
Staphylococcus	0 (0%)	2 (5%)
Enterococcus	2 (18%)	5 (14%)
Candida	0 (0%)	2 (5%)
Other	0 (0%)	6 (16%)
Staghorn		
Yes	0 (0%)	5 (14%)
No	11 (100%)	32 (86%)
Preoperative stone size (total axial diameter mm, median, Q1-Q3)	8 (3.3–12.3)	13 (9–20)
Intervention type		
URS	2 (18%)	26 (70%)
SWL	0 (0%)	0 (0%)
PCNL	0 (0%)	7 (19%)
None	9 (82%)	4 (11%)
Residual or known stone at followup		
Yes	10 (91%)	11 (30%)
No	0 (0%)	22 (59%)
Unknown	1 (9%)	4 (11%)
Unscheduled care required		
Yes	2 (18%)	13 (35%)
No	9 (82%)	24 (65%)
UTI recurrence type		
E. coli	5 (45%)	9 (75%)
Proteus	0 (0%)	1 (8%)
Klebsiella	2 (18%)	1 (8%)
Pseudomonas	0 (0%)	0 (0%)
Staphyloccocus	0 (0%)	0 (0%)
Enterococcus	1 (9%)	2 (17%)
Candida	0 (0%)	0 (0%)
Other	1 (9%)	0 (0%)
Not available	0 (0%)	3 (25%)