

MPI6-I4: A Phase II trial of intravesical Gemcitabine and Docetaxel (GEMDOCE) in the treatment of BCG-naïve non-muscle invasive urothelial carcinoma of the bladder

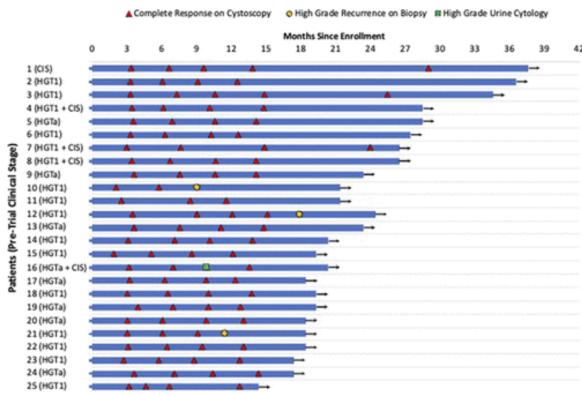
Authors: Sunil H. Patel, Andrew T. Gabrielson, Sin Chan, Deborah Schwartz, Connie Collins, Nirmish Singla, Bruce Trock, Trinity J. Bivalacqua, Noah Hahn, and Max R. Kates

Introduction: Combination intravesical Gemcitabine and Docetaxel (GemDoce) has demonstrated efficacy as a 2nd line therapy for patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). In the context of widespread BCG shortages, we performed a Phase 2 prospective trial to assess GemDoce for BCG-naïve NMIBC.

Methods: This study is a prospective single-arm open-label phase II trial for patients with BCG-naïve high risk NMIBC. Intravesical gemcitabine and docetaxel was given weekly for 6 weeks as induction followed by monthly maintenance therapy for 2 years among responders. The primary endpoint was 3-month complete response (CR), and key secondary endpoints included adverse events (AE) and I2-month CR.

Results: A total of 25 patients were enrolled between August 2020-August 2022 with median follow-up of 19.6 months. The pre-trial pathologic stages were: HGTI with CIS (n=7), HGTI without CIS (n=6), HGTa (n=9), and CIS alone (n=3) (Table I). The 3-month and I2-month CR rate was 100% and 88%, respectively (Figure I). Two patients with pre-trial HGTI had HGTI recurrences at 9 and I2 months. No patients progressed to T2 disease, underwent radical cystectomy, or had any radiographic evidence of progressive disease. Grade I AEs were common (23/25 patients) including hematuria, urinary frequency, urgency, and fatigue. Five patients (20%) experienced a Grade 3 AE including hematuria and UTI (Table 2).

Conclusions: In this single-arm phase II trial, GEMDOCE was well-tolerated with promising efficacy for patients with BCG-naïve HR NMIBC.



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Table 1. Baseline Characteristics of Study Coh	ort
Characteristic	Study Cohort (N = 25)
Age (Median [IQR]), yr	68.9 [59.9 – 73.8] yr
Male Sex (n, %)	21 (84)
Race (n, %) Caucasian African American	23 (92) 2 (8)
Smoking Status (n, %) Never Former Current	10 (40) 13 (52) 2 (8)
Pathologic Stage at Trial Entry (n, %) CIS only HGTa HGT1 HGTa with CIS HGT1 with CIS	1 (4) 7 (28) 13 (52) 1 (4) 3 (12)
Any CIS at Trial Entry (n, %) Yes No	5 (20) 20 (80)

	Patient Groups									
	Grade 1	Grade 2	Grade 3	Grade 4 or 5						
Total reported adverse events	28	17	7	0						
No. of specific events (%)										
Hematuria	2 (8)	2 (8)	1 (4)	-						
Dysuria/Suprapubic pain/UTI	2 (8)	6 (24)	2 (8)	-						
Urinary frequency/urgency	3 (12)	1 (4)	-	-						
Nausea/Vomiting/GI symptoms	3 (12)	2 (8)	-	-						
Fatigue	6 (24)	2 (8)	-	-						
Gait disturbance	1 (4)	-	-	-						
Vasovagal syncope	1 (4)	-	1 (4)	-						
Tremor	2 (8)	-	-	-						
Headache	1 (4)	-	1 (4)	-						
Vision changes/retinopathy	3 (12)	-	-	-						
Respiratory Infection (including COVID-19)	4 (16)	1 (4)	1 (4)	-						
Thrombocytopenia/Leukopenia	-	1 (4)	1 (4)	-						
Altered Mental Status	-	1 (4)	-	-						
Skin or Mucosal Rashes or Lesions	-	1 (4)	-	-						
No. of patients reporting 1+ adverse event by grade	20 (80)	11 (44)	5 (20)	0 (0)						
No. of patients reporting any adverse event (%)	23 (92)									
No. of patients not receiving complete induction due to intolerance (%)	1 (4)									
No. of patients in which side effects affected treatment schedule (%)		3	(12)							

MP20-I9: Bipolar Enucleation of the Prostate (BipolEP) versus Transurethral Resection of the Prostate: A Prospective Randomized Controlled Non-Inferiority Trial

Authors: Maximilian Pallauf, Christian Ramesmayer, Michael Abenhardt, Maximilian Horetzky, Hubert Grießner, Lukas Oberhammer, Martin Drerup, Thomas R. W. Herrmann, Lukas Lusuardi, and Thomas Kunit

Introduction: Endoscopic enucleation (EEP) is the preferred surgical technique for treating men with moderate-to-severe lower urinary tract symptoms (LUTS) and a large prostate (>80 mL) and an accepted alternative to transurethral resection (TURP) for mid-sized glands (30-80 mL). More recently, a treatment-specific electrode was developed to facilitate EEP using bipolar current (BipolEP). This prospective randomized controlled trial tests the non-inferiority of BipolEP compared with TURP for prostates sized 50-140 mL.

Methods: We prospectively included men scheduled for surgical treatment of LUTS due to benign prostatic enlargement. We included men with an international prostate symptom score (IPSS) of \geq 15, an IPSS quality-of-life score (IPSS-QoL) \geq 3, and a peak flow rate (Qmax) of <15 ml/sec. or the inability to void following urinary retention. We randomized patients 1:1 for TURP vs. BipolEP and followed them for 12 months postoperatively. The key primary endpoint was the non-inferiority of BipolEP compared with TURP in the 12-month IPSS. According to the study protocol, the predefined non-inferiority range was 3, and the estimated sample size per treatment arm was 31. The key secondary endpoint was the superiority of BipolEP compared with TURP in resected prostate tissue per surgery-minute. We recorded complications to compare the safety of the procedures.

Results: We included 81 men, 41 TURP, and 40 BipolEP. At enrollment, the median prostate size was 79 mL (95%CI 60-95), the median PSA was 5.1 ng/ml (95%CI 2.6-8.2), the median IPSS was 21 (95%CI 16.5-24), and



the median Qmax was 7.6 ml/sec. (95%Cl 6-10.7); baseline characteristics did not differ between the treatment arms. 67 men (TURP 34, BipolEP 33) completed the 12-month follow-up. The median IPSS was 5 (95%Cl 3-7) in the TURP arm and 5 (95%Cl 3-9) in the BipolEP arm. BipolEP was tested to be non-inferior (intention-to-treat and per-protocol analyses; p<0.05). BipolEP resected more prostate tissue per surgery-minute than TURP (median g/min. 0.5 95%Cl 0.4-0.7 vs. 0.4 95%Cl 0.3-0.6; p=0.04). At 12 months, we recorded at least one complication in 43% of the TURP arm and 61% of the BioplEP arm (p=0.1). 27% of TURP complications were major (Clavien Dindo \geq IIIB), but only 1 (4.5%) in the BipolEP arm was (p=0.1).

Conclusions: We confirmed the non-inferiority of BipolEP compared with TURP for improving LUTS, and we proved the efficiency and safety of BipolEP. Longer follow-up is needed to assess whether the increased tissue removal results in a more sustained improvement of symptoms.

MP33-I2: Industry Payments to Urologists in 2022: Descriptive Analysis of the Open Payments Program Database

Authors: Joseph Cheaib, Zhuo Su, Zeyad Hammadeh, Bruce J. Trock, and Misop Han

Introduction: Financial incentives may influence physician decision-making. The Open Payments Program (OPP) from the Centers for Medicare and Medicaid Services (CMS) now mandates medical device and pharmaceutical manufacturers to publicly report such incentives given to physicians. The OPP Payments fall under 3 main categories: general payments, research payments, and physician ownership/investment interest. This study aims to describe all open payments made to urologists in 2022.

Methods: All urologists in the US who received at least one payment in the OPP database in 2022 were included. Urologists were identified when the principal investigator reported their practicing specialty as urology. Descriptive analyses of payments by type, sex, and industry payer were performed.

Results: Open payments totaling \$149,287,170 were made to 8,063 (62.2%) urologists in 2022. Research payments (\$96,270,845) were the largest category, followed by general payments (\$30,853,188) and then ownership (\$22,163,137) (Table I). The median payment to urologists in 2022 was \$524, and the highest-paid urologist received a total of \$8,354,885 (6% of all payments). Notably, top 10 urologists received 26% of all payments. Almost all urologists in this cohort (99%) received general payments; over 50% of these general payments were non-continuing medical education-related compensations. 38 urologists (0.47% of all urologists receiving payments) accepted payments of all 3 categories, receiving a total of \$29 million (20% of all payments made to urologists). Boston Scientific and Urovant Sciences contributed the biggest number of individual payments, while Merck contributed the largest total amount (\$32.6M) (Table 2).

Conclusions: Disproportionate amount of industry payments were made with 0.1% of urologists receiving 26% of the total payments in 2022. Research payments are the largest industry payment category to urologists. Further studies are warranted to better understand the nature of this industry-urologist relationship and its impact on physician decision making.

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		Number of payments	Number of physicians	Total	tal value	Median		USD a	f Highest Paid	Males	Total	45	5.6	rdian	Females	Total	a s	Median
lesearch		manual or payments	manuser on projections		an variou	*****		Physic		mare.	Total		-	-	renaes	Total		-
	Total	8,329	486	5	96,270,845	5	25,369	\$	7,305,691	437(89.9)	5	94,965,	32 5	27,110	49(10.1)	5	1,305,31	2 5 16,50
	Independent Pls	280	77	5	827,795	\$	2,620	5	155,645	63(81.8)	\$	788,	00 \$	2,748	14(18.2)	\$	39,56	4 \$ 2,18
	Hospital Pls	995	110	5	8,694,970	5	20,260	5	2,515,758	98(89.1)	5	8,426,		19,408	12(11.9)	\$	268,73	7 \$ 22,60
	Non-covered entities Pis	7,054	370	5	86,748,080	5	28,113	\$	7,269,894	338(91.3)	\$	85,751,	199 \$	29,564	32(8.7)	5	996,58	5 16,90
General																		
0.1.7.7	Urologists	185,825	8,006	5	30,853,188	5	474	\$	2,367,283	6,973(87.1)	\$	28,704,	21 5	484	1,033 (12.9)	\$	2,148,66	7 5 40
	All physicians	7,524,670	395,771	5	2,185,382,188	5	298	5	133,688,000	268,681(67.89)	\$	1,954,002,	97 \$	239	127,090(32.11)	\$:	231,379,19	5 14
Ownership																		
	Urologists	298	279	5	22,163,137	5	35,673	\$	3,796,200	254 (91)	\$	21,266,	27 \$	35,673	25-(9)	\$	896,53	0 \$ 35,70
	All physicians	3,515	3,211	5	1,001,653,644	\$	9,000	5	260,062,608	2,630 (81.9)	\$	977,088,	160 5	15,325	581 (18.1)	\$	24,564,88	4 5
Total Industry	Payments.																	
	All Urologists	294,452	8,063	5	149,287,170	\$	534	5	8,354,885	7,024(87.1)	\$	144,936,0	81 5	538	1,039(12.9)	5	4,350,48	9 5 43
industry pay	ments stratified by the to	p 20 manufacturers /	/GPOs reporting payme	ents	to urologists													
Submitting	nanufacturer/SPO		Total USD.M (% of total	9	Numb	er of pay	ments (% of total	1	Max payment value	Number	of phy	dicians	dedian	payment (IQR)	%.research	25.0	general 5	ownership
Merck Sharp	& Dohme LLC		32.6 (22)		3,771	(2)		5	2,804,29	0 1,670			0.39 (7	7	98.5%		1.5%	
Pfizer Inc.			28.2 (190			mirra.												
Printer inst.			warm fresh		9,909	(5)		5	236,36	4 2,275			1 (576)	1	98.3%	- 93	1.7%	
	uc		12.7 (9)		540 (0	5-5		5	236,36- 1,462,61) (5,262)	98.3%		3%	97%
Sn Holdings	LLC earch & Development LLC					0.3)		\$ \$		7 226				(5,262)		3		
Sn Holdings Janssen Rese			12.7 (9)		540 (0	(1)		5 5 5	1,462,61	7 226 8 119			,050 (3 ,905 (4	(5,262)		8	3%	97%
Sn Holdings Janssen Resi Applied Med	earch & Development LLC		12.7 (9) 8.06 (5)		540 (0 1,494	(1) (0)		5 5 5 5	1,462,61° 475,90	7 226 8 119 0 6			,050 (3 ,905 (4	15,262) 1.377) 1 (1,000,658)	99%		3% 1%	97%
Sn Holdings Janssen Resi Applied Med Boston Scien	earch & Development U.C dical Corporation stific Corporation		12.7 (9) 8.06 (5) 5.55 (4)		540 (0 1,494 6 (0.0	(1) (0) (2) (7)		5 5 5 5 5	1,462,61 475,90 3,796,20	7 226 8 119 0 6 1 3,532			,050 (3 ,905 (4 51,648	15,262) 1.377) 1 (1,000,658) 106)	99%		3% 1%	97%
Sn Holdings Janosen Resi Applied Med Boston Scier Urovant Scie	earch & Development U.C dical Corporation stific Corporation		12.7 (9) 8.06 (5) 5.55 (4) 5.34 (4)		540 (0 1,494 6 (0.0 13,04	0.3) (1) (03) 2 (7) 3 (7)		\$ \$ \$ \$ \$	1,462,61 475,90 3,796,20 431,94	7 226 8 119 0 6 1 3,532 3 2,877			,050 (1 ,905 (4 51,648 6.56 (1	15,262) 1.377) 1(1,000,658) 106)	99%		3% 1% -	97% 100%
Sn Holdings Janosen Resi Applied Med Boston Scier Urovant Scie Sanofi and G	earch & Development LLC fical Corporation etific Corporation ences Inc.		12.7 (9) 8.06 (5) 5.55 (4) 5.34 (4) 4,62 (3)		540 (0 1,494 6 (0.0 13,04 13,42	(1) (2) (3) (0) 2 (7) 3 (7) (2)		\$ 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	1,462,61* 475,90 1,796,20 431,94 124,85	7 226 8 119 0 6 1 3,532 3 2,877 0 263			,050 (3 ,905 (4 151,648 16.56 (1 17.93 (9	15,262) 1,377) 1 (1,000,658) 1,06) 0 1,03)	99% 20% 84%		3% 1% - 80% 16%	97% 100%
Sn Holdings Janosen Resi Applied Med Boston Scier Urovant Scie Sanofi and G	earch & Development LLC dical Corporation stific Corporation ences Inc. lienzyme US Companies aceuticals Inc.		12.7 (9) 8.06 (5) 5.55 (4) 5.34 (4) 4,62 (3) 4.43 (3)		540 (0 1,494 6 (0.0 13,04 13,42 455 (0	(3) (3) (0) (2) (7) (3) (7) (3.2) (3.3)		\$ \$ \$ \$ \$ \$ \$ \$ \$	1,462,61 475,90 3,796,20 431,94 124,85 751,54	7 226 8 119 0 6 1 3,532 3 2,877 0 263 1 2,030			,050 (3 1,905 (4 151,648 16.56 (1 17.93 (9 15.06 (1	15,262) 1.377) 1 (1,000,658) 10 (1,000,658) 10 (1,003) 2)	99% 20% 84% 94%		3% 1% 80% 16% 6%	97% 100%
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PD20-07: Oncologic Outcomes in Patients with Variant Histologies of Upper Tract Urothelial Cancer: Results from an International Multicenter Cohort

Authors: Maximilian Pallauf, Sean A. Fletcher, Michael Rezaee, Morgan Rouprêt, Stephen A. Boorjian, Aaron M. Potretzke, Hooman Djaladat, Alireza Ghoreifi, Francesco Soria, Andrea Mari, Riccardo Campi, Zine-Eddine Khene, Eiji Kikuchi, Michael Rink, Kazutoshi Fujita, David D'Andrea, Joost L. Boormans, Guillaume Ploussard, Alberto Breda, Firas Abdollah, Jay D. Raman, Shahrokh F. Shariat, Benjamin Pradere, and Nirmish Singla

Introduction: Histologic variants (VH) of urothelial carcinoma (UC) of the lower urinary tract are associated with worse oncologic outcomes than pure UC. However, outcomes for patients with VH in the upper urinary tract are poorly described, given their rarity. We sought to elucidate the oncologic outcomes for patients with upper tract urothelial carcinoma (UTUC) with VH.

Methods: We queried an international, multicenter cohort of non-metastatic UTUC patients treated with radical nephrouterectomy (RNU). We categorized patients into pure UC (no-VH) and VH. VH was subcategorized based on the distribution of subtypes into 'squamous/glandular/trophoblastic' (VH-S) and 'other' (VH-O), comprising all other VH. We compared clinicopathologic characteristics and oncologic outcomes, including recurrence-free (RFS), cancer-specific (CSS), and overall survival (OS), among groups. We performed subanalyses matched by pathologic stage: organ-confined (OC: ≤pT2 and pN0-x) and non-organ-confined (NOC: ≥pT3 or pN1-2). Kaplan Meier methods and multivariable proportional hazards Cox regression with multivariate imputation by chained equations (MICE) for missing predictor covariates were performed to evaluate outcomes.



Results: We included 3,435 patients treated from 1985-2022 across 23 centers worldwide and identified 201 (6%) with VH. The median follow-up was 30 months (IQR 12-61). The most common VH subtype was VH-S (133/201, 66%). Neoadjuvant (12% vs. 5%, p<0.001) and adjuvant (27% vs. 13%, p<0.001) systemic therapy were more often administered in VH than in no-VH patients. Lymph node dissection was also more often performed in VH patients (54% vs. 39%, p<0.001). Patients with VH presented with more advanced pT (p<0.001) and pN (p<0.001) stage. In patients with OC disease, VH had worse RFS than no-VH (5-year RFS 58% vs. 80%, p=0.004), though CSS and OS were not significantly different. Stratified by VH subtype, VH-S exhibited similar oncologic outcomes as no-VH, but VH-O demonstrated worse stage-matched RFS (4-year RFS 39% vs. 83%, p<0.001 [OC] and 28% vs. 46%, p=0.01 [NOC]) and OS (5-year OS 45% vs. 75%, p=0.004 [OC]) compared to no-VH. VH-O independently predicted worse survival outcomes on multivariable Cox regression analyses.

Conclusions: UTUC patients with VH exhibit more aggressive disease at presentation compared to pure UC. Despite the increased use of systemic therapy, certain VH subtypes demonstrate worse oncologic outcomes compared to pure UC. Further study is warranted to elucidate the biology of different UTUC VH subtypes to optimize treatment approaches.

Source of Funding: This publication was made possible by the Johns Hopkins Institute for Clinical and Translational Research (ICTR) which is funded in part by Grant Number ULI TR003098 from the National Center for Advancing Translational Sciences (NCATS) a component of the National Institute of Health (NIH), and NIH Roadmap for Medical Research. Its contents are solely the responsibility of the authors and do not necessarily represent the official view of the Johns Hopkins ICTR, NCATS or NIH.Maximilian Pallauf gratefully acknowledges the support of the Paracelsus Medical University Research and Innovation Fund (2022-FIRE-004-Pallauf)

PD37-01: Measuring Seminiferous Tubules Diameter Using High-Frequency Ultrasound In Murine Models And Men With Non-Obstructive Azoospermia And Obstructive Azoospermia

Authors: Taylor P. Kohn, Nora Haney, Amin Herati, Max Kates, and Kenneth Pienta

Introduction: For men with non-obstructive azoospermia, no imaging exists to determine if sperm is present prior to testicular sperm extraction (TESE). The objective of this pilot study is to assess whether high-frequency ultrasound (HFUS), which can differentiate structures of less than 70 μ m, is capable of distinguishing enlarged seminiferous tubules with spermatogenesis from sclerotic seminiferous tubules without spermatogenesis.

Methods: A 29 MHz HFUS (ExactVu micro-ultrasound system) was performed on 3 adult male Sprague-Dawley rats (controls), 3 three-week at pups (prepuberal), and 3 bulsulfan-treated (20 mg/kg) adult male rats. Ultrasound imaging was additionally performed in 3 fertile male controls, 3 men with microTESE-negative non-obstructive azoospermia, 3 men with TESE-positive obstructive azoospermia. Conventional ultrasound was also performed for a fertile man and man with NOA to compare resolution with HFUS. Each testicle was imaged in 3 cross-sectional frames with 30 seminiferous tubules measured in each frame using Image].

Results: A total of 3,240 tubules were measured. HFUS could distinguish individual seminiferous tubules while no distinct structures were identifiable with conventional ultrasound (Figure 1). Control adult rats had significantly larger seminiferous tubules when compared to prepubertal rats $(250\pm42~\mu m\ vs\ 139\pm26~um,$



p<0.0001, Figure 2). Busulfan-treated rats had wide range of tubule variability with some areas with larger tubules (220-350 μm) and patches with sclerotic tubules (100-170 μm). In humans, fertile men had significantly larger tubules when compared to men with microTESE-negative non-obstructive azoospermia (264±38 versus 163±32 μm , p<0.0001). Men with obstructive azoospermia had similar tubule size to men with proven fertility (241±53 versus 264±38 μm , p>0.05).

Conclusions: HFUS is able to differentiate tubule sizes in men with NOA and OA as well as regions of large tubules versus sclerotic tubules in rats treated with busulfan.

Figure 2 - Measured Tubule Diameter

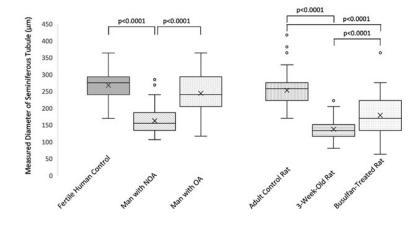
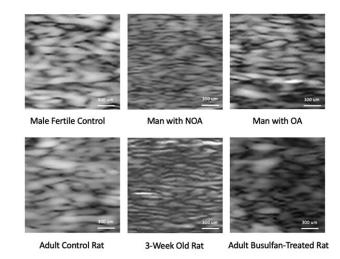
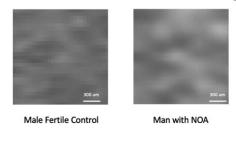


Figure 1 - Representative Ultrasound Images

A) Representative High-Frequency Ultrasound Images



B) Representative Conventional Ultrasound Images



MP55-20: The effect of neonatal upper and lower urinary tract obstruction on the gastrointestinal microbiome in a murine animal model

Authors: Nora M. Haney, Kara Lombardo, Taylor P. Kohn, Charlotte Q. Wu, Max R. Kates, John P. Gearhart, and Trinity J. Bivalacqua

Introduction: The effect of congenital urinary obstruction on the gastrointestinal microbiome has not yet been characterized. The objective was to evaluate the effect of upper and lower urinary tract obstruction on the gastrointestinal microbiome in a neonatal animal model.

Methods: Male and female neonates were operated on day 3 of life. Control group (C) was sham operated. Partial left ureteral obstruction was performed in upper urinary tract obstruction group (U) via suture ligation over a wire. Partial urethral obstruction was created in lower urinary tract obstruction group (L) via modified clip applier technique. Kidney, bladder, and colonic fecal samples were obtained at the time of sacrifice. The intestinal microbiome was evaluated via 16S rRNA gene amplicon sequencing. Alpha and beta diversity, single taxa abundance, and unique indicator species analysis was performed using R Statistical Software 4.2.0 (p<0.05).

Results: At 21d post-operatively, body mass was lower in U compared to L (C: 62.8+/-3.4 g, U: 53.9 +/-3.2 g,



L: 72.7+/-5.2 g, U v L p=0.003). Stool microbiome demonstrated elevated Firmicutes:Bacteroidota ratio in L compared to U (C: 3.0, U: 2.3, L: 3.4; U vs L p=0.014). Beta diversity clustered significantly between groups (C vs L p=0.016; C vs U, p=0.004; L vs U, p=0.012). Alpha diversity was not significant between groups (Observed p=0.065, Shannon p=0.799). Relative abundance demonstrated Lactobacillus B was significantly downregulated in the U group compared to C (p=0.028) and L (p=0.033). All unique indicators of the U group came from the Lachnospirales order (Genus: Clostridium Q, p=0.013; 28-4, p=0.013; CAG81, p=0.017). One unique L indicator was an absence of a particular genus from the Firmicutes phylum (Genus: CAG302, p=0.014).

Conclusions: This is the first study of its kind to evaluate the neonatal response of the gastrointestinal microbiome to upper and lower urinary tract obstruction. There were unique genera indicators and significant beta diversity clustering in U and L groups indicating that stool microbiome plays an important role in the downstream pathology of neonatal urinary tract obstruction. The Firmicutes: Bacteriodota composition, known to play a role in obesity, was associated with weight distribution, providing evidence of a direct effect of lower urinary tract obstruction on gut metabolism. In the future, such patterns in the intestinal microbiome may be used as a prognostic model to noninvasively detect children at high risk for end stage organ damage of the genitourinary system secondary to obstructive uropathy.

Source of Funding: This work was funded by the 2021 SWIU Elisabeth Pickett Research Award

MP50-05: A Scoping Review of Financial Toxicity and Bladder Exstrophy-Epispadias Complex: The Hidden Burdens of a Major Congenital Genitourinary Anomaly

Authors: Logan Galansky, Andrew T. Gabrielson, Tony Su, Victoria Maxon, Ahmad Haffar, Alex Hirsch, Heather Di Carlo, John P. Gearhart, and Chad Crigger

Introduction: Financial toxicity (FT) is the direct and indirect costs of healthcare on patients, which can lead to financial burden, psychosocial distress, diminished quality of life, and worse clinical outcomes. While FT has been widely examined in the oncology literature, it is still an emerging topic in pediatric urology. However, the impact of FT on the well-being of patients and caregivers is salient for those managing serious chronic conditions, such as bladder exstrophy-epispadias complex (BEEC). We aimed to provide the first review of FT and BEEC literature.

Methods: We conducted a scoping review of the literature addressing FT and BEEC using thematic search queries of the PubMed database built from unique keyword searches with MeSH terms and free text. Themes selected were quality of life, financial cost, caregiver burden, psychosocial and socioeconomic stress, and FT explicitly. All journal articles that were peer-reviewed and published in the English language were included. Given the relative paucity of BEEC literature, no restrictions were put on publication date. After abstracting the search results, two independent reviewers screened and extracted relevant articles to further evaluate for qualitative analysis.

Results: Our scoping review resulted in 296 articles related to our selected themes and BEEC. Of these articles, the quality of life theme query yielded the greatest number of overall search results (157 total), with the psychosocial and socioeconomic stress, cost, and caregiver burden queries producing 88, 38, and 13 results, respectively. The query for articles specifically analyzing FT and BEEC produced 0 results. After reviewing the selected abstracts, 45 total articles addressed the patient-level financial and psychosocial burdens of BEEC. Literature pertaining to the FT of BEEC on caregivers was particularly sparse with only 3 relevant articles included in our analysis.



Conclusions: While this scoping review revealed that studies evaluating cost and psychosocial factors related to BEEC exist, there were no articles addressing the concept of FT specifically for patients and caregivers in the BEEC community. This represents a clear gap in the literature that warrants future research to help improve support and outcomes for this patient population.

MP55-I3: Contemporary Management and Outcomes of Pediatric Patients with Low-Grade vs. High-Grade Renal Trauma

Authors: Logan Galansky, Andrew T. Gabrielson, Corey Able, and Chad Crigger

Introduction: Over the last decade, management of renal trauma has shifted to favor observation for high-grade renal trauma (HGRT) in hemodynamically stable children. We hypothesized that there has been a decrease in surgical intervention for pediatric HGRT compared to historical rates, but that HGRT continues to be managed with more aggressive intervention than low-grade renal trauma (LGRT).

Methods: A retrospective cohort study was conducted using the TriNetX database between 2012-2023. Patients < 20 years old presenting with renal trauma were queried. We used AAST grading to categorize injuries as either LGRT (I-III) or HGRT (IV-V). We analyzed evaluation and management strategies after index trauma event, including initial and subsequent surveillance imaging modality, interventions within one week of trauma, and long-term sequela outcomes from I month to 5 years.

Results: A total of 1,997 renal trauma patients were identified (526 HGRT, 1,471 LGRT). Abdominal/retroperitoneal ultrasound and multi-phase CT were used at similar rates during the index trauma between groups, but those with HGRT were more likely to have additional imaging with abdominal/pelvic plain films. The most common management strategy in both groups was observation (95% vs. 84%, p<0.01), but those with HGRT were more likely to require transfusion (37% vs. 26%, p<0.01), embolization (6% vs. 3%, p<0.01), exploratory laparotomy (6% vs. 3%, p<0.01), and/or nephrectomy (4% vs. 0%, p<0.01). For surveillance, most patients were followed with renal ultrasound. There was no difference in rates of subsequent hypertension (11% vs. 10%, p=0.5), CKD (4% vs. 3%, p=0.2), need for renal replacement therapy (1% vs. 0.5%, p=0.4), depression (4% vs. 3%, p=0.9), or anxiety (9% vs. 8%, p=0.7).

Conclusions: Historically, pediatric HGRT management included surgical intervention in as high as 36% of patients. In this contemporary cohort, we observed much lower utilization of surgical interventions for HGRT, with observation as the most common current management strategy. Although LGRT was managed almost exclusively with observation, we observed similar rates of subsequent hypertension, CKD, and psychological sequela among patients with LGRT and HGRT, suggesting that even LGRT warrants continued follow-up and psychological support.