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Readmissions, unplanned emergency room visits, and surgical retreatment rates after anti-reflux procedures

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Summary

Introduction/Background—The choice between endoscopic injection (EI) and ureteroneocystotomy (UNC) for surgical correction of vesicoureteral reflux (VUR) is controversial.

Objective—To compare postoperative outcomes of EI versus UNC.

Study design—This study reviewed linked inpatient (SID), ambulatory surgery (SASD), and emergency department (SEDD) data from five states in the United States (2007–10) to identify pediatric patients with primary VUR undergoing EI or UNC as an initial surgical intervention. Unplanned readmissions, additional procedures, and emergency room (ER) visits were extracted. Statistical analysis was performed using multivariate logistic regression using GEE to adjust for hospital-level clustering.

Results—The study identified 2556 UNC and 1997 EI procedures. Compared with patients undergoing EI, those who underwent UNC were more likely to be younger (4.6 vs 6.0 years, $P<0.001$), male (30 vs 20%, $P<0.001$), and publicly insured (34 vs 29%, $P<0.001$). Compared with EI, UNC patients had lower rates of additional anti-reflux procedures within 12 months (25 (1.0) vs 121 (6.1%), $P<0.001$), but a higher rate of 30-day and 90-day readmissions and ER visits. On multivariate analysis, patients treated by UNC remained at higher odds of being readmitted (OR=4.45; 2.69 in 30 days; 90 days, $P<0.001$) and to have postoperative ER visits (OR=3.33; 2.26 in 30 days; 90 days, $P<0.001$); however, EI had significantly higher odds of repeat anti-reflux procedures in the subsequent year (OR=7.12, $P<0.001$).

Discussions—Endoscopic injection constituted nearly half of initial anti-reflux procedures in children. However, patients treated with UNC had significantly lower odds of requiring

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retreatment in the first year relative to those treated with EI. By contrast, patients treated with UNC had more than twice the odds of being readmitted or visiting an ER postoperatively. Although the available data were amongst the largest and most well validated, the major limitation was the retrospective nature of the administrative database. The practice setting may not be generalizable to states not included in the analysis.

Conclusions—Postoperative readmissions and ER visits were uncommon after any surgical intervention for VUR, but were more common among children undergoing UNC. The EI patients had a more than seven-fold increased risk of surgical re-treatment within 1 year.

Keywords

Vesicoureteral reflux; Surgery; Complication; Urology

Introduction

VUR is a familiar problem for the pediatric urologist, affecting approximately 1% of all children in the United States, and up to 70% of those present with febrile UTI [1]. Controversy persists over optimal management of this condition, as the understandings of its incidence, clinical course, and potential sequelae continue to evolve [2,3]. Notably, the economic impact from this condition has been found to be significant, with VUR-related charges exceeding \$100 million per annum [4]. This figure does not include the broader economic impact felt by caregivers and family members as a result of healthcare-related quality of life spillover effects inherent in pediatric care [5]. It thus stands to reason that the gross economic impact of VUR is likely even higher than that previously reported in the literature.

The majority of children with VUR do not require surgical intervention for disease resolution; these children instead experience spontaneous resolution of VUR without lasting detriment [6–8]. However, for reasons that are still unknown, VUR persists in a subset of children, potentiating risk of renal scarring and loss of kidney function [2]. A general consensus has supported the use of surgical management options in such patients with unremitting VUR and recurrent febrile UTI, with some practitioners advocating for routine consideration of initial surgical management of newly-diagnosed VUR in at-risk patients [9].

Ureteroneocystotomy (UNC) has been the foundation of surgical management of VUR since the 1960s and continues to play a prominent role in modern management algorithms. With the rich history, high efficacy, and widespread provider familiarity globally, UNC unsurprisingly forms a major cornerstone of clinical management guidelines put forth by North American and European urological advisory bodies [6,10].

However, significant advances in technology over the past 20 years have altered the treatment landscape, making transurethral endoscopic injection (EI) of dextranomer/hyaluronic acid copolymer and other bulking agents a viable and increasingly common alternative treatment modality [11]. Although Matouschek et al. demonstrated the viability of EI for this purpose in 1981, limitations in endoscopic technology, questions about the efficacy and long-term safety of various bulking agents, and rise in use of antibiotic

prophylaxis have limited widespread adoption in pediatric practice [12]. Endoscopic injection use increased dramatically following the Food and Drug Administration's approval of dextranomer/hyaluronic acid copolymer for use in the United States in 2001 [13], although more recent data have shown decreasing use of EI over time [14]. The minimally invasive nature of EI, its low procedure-associated morbidity, and shorter operative and recovery times have made this approach an appealing alternative to UNC for parents and pediatric providers. Industry marketing and generous research support have further incentivized its use [15].

Given substantial differences in invasiveness, cost, intra/postoperative characteristics, and likelihood of success, it is unsurprising that much controversy remains over which modality is preferable. With increasing efforts to improve care quality and optimize cost management, a clearer understanding of the merits of available treatment modalities is needed.

The objective of the present study was to characterize differences in procedure frequency, postoperative readmissions and emergency room (ER) visits, and re-treatment rates for pediatric (< 18 years) VUR patients who underwent initial intervention with UNC or EI between 2007–10, as captured in the State Ambulatory Surgery and Service Databases (SASD) [16], State Emergency Department Databases (SEDD) [17], and State Inpatient Databases (SID) [18].

Patients and methods

Data source

The present study analyzed SASD, SEDD and SID, which are all-payer databases from the Healthcare Cost and Utilization Project, a collaborative data enterprise effort sponsored by the Agency for Healthcare Research and Quality (AHRQ). Analysis was limited to 2007–10 for the states of California, Florida, North Carolina, Utah, and 2008–10 for New York, due to data completeness and availability.

State Ambulatory Surgery and Service Databases include annual, state-specific encounter-level data for ambulatory surgeries and may also include various types of outpatient services such as observation stays, lithotripsy, radiation therapy, imaging, chemotherapy, and labor and delivery. State Emergency Department Databases are an annual, encounter-level set of databases cataloguing ER visits to hospital-affiliated emergency departments that do not result in admissions. State Inpatient Databases include annual, state-specific encounter-level inpatient data, and encompass about 97% of all hospital discharges in the United States. Using Healthcare Cost and Utilization Project (HCUP) supplemental variables for revisit analysis, SASD, SEDD, and SID can be linked to track sequential visits for individual patients in each setting within the timeframe [19]. Per standard AHRQ requirements, reporting of any events occurring in <15 patients was restricted.

Patient selection

Pediatric VUR patients (age < 18 years) undergoing EI or UNC, defined by International Classification of Diseases Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology (CPT) codes. Patients with secondary VUR were excluded,

specifically those with neurogenic bladder, ureterocele, megaureter, PUV, bladder exstrophy, kidney transplant, or prune belly syndrome (please see Appendices 1 and 2 for all inclusion/exclusion codes). Additionally, patients were excluded who had received complex or laparoscopic index anti-reflux surgery (CPT codes 50783, 50785, 50947 and 50948). Those specific CPT codes were not excluded in the subsequent additional procedures.

Outcome selection

The primary outcomes were subsequent inpatient admission and ER visit within 30 and 90 days, respectively, of the initial procedure, in addition to additional anti-reflux procedure (EI or UNC) performed within 365 days of the initial procedure. All diagnoses were extracted and genitourinary (GU)-related diagnoses were selected according to HCUP Clinical Classification Software (CCS) to exclude subsequent encounters unlikely to be related to anti-reflux procedures [20].

Statistical analysis

Predictor variables were *a priori* selected based on biologic plausibility and/or demonstrated associations in the literature. Covariates included in the final model included age, gender, insurance payer (public vs private), van Walraven comorbidity score, treatment year, treatment modality (EI vs UNC), and the effect of center-specific clustering. Instead of stretching the multivariate model with the entire set of the Elixhauser comorbidity index with 30 variables, it was decided to utilize the van Walraven comorbidity score, which is a validated scoring system developed from the Elixhauser comorbidity index [21]

Bivariate analyses were performed to compare patient demographics and hospital-level characteristics of EI and UNC patients. The Chi-Squared test, Fisher's exact test, or Kruskal-Wallis test were used, as appropriate based on data characteristics and distribution. Statistical analysis was performed using multivariate regression using GEE with logit link to account for hospital-level clustering.

Multiple sensitivity analyses were performed: all models were fitted by additionally adjusting for race, and the interaction between surgery performed and year.

An alpha of 0.05 and 95% confidence intervals (95% CI) were used as criteria for statistical significance. All analyses were performed using SAS 9.4 (SAS Institute, Cary, NC).

Results

Demographics

A total of 2556 UNC and 1997 EI procedures were identified (Table 1). Mean patient age at the time of the procedure was 5.2 ± 3.7 years. Males constituted 25.3% of the overall cohort.

Compared with patients who underwent EI, UNC patients were on average younger (4.6 vs 6.0 years, $P < 0.001$), male (29.9 vs 19.5%, $P < 0.001$), Caucasian (55.1 vs 43.2%, $P < 0.001$), and publicly insured (34.2 vs 28.6%, $P < 0.001$). Endoscopic injection was used more frequently than UNC in California and Florida; UNC was more commonly employed than EI in New York and Utah.

Readmissions, unplanned emergency room visits, and additional anti-reflux procedures

Table 2 details the 30-day and 90-day GU-related readmissions, ER visits, and 365-day additional anti-reflux procedures for patients undergoing UNC and EI. Compared with EI patients, the odds of additional anti-reflux procedures within 12 months were 0.15 for UNC patients (121, 6.1% in EI vs 25, 1.0% in UNC, OR=0.15, $P<0.001$). The majority of additional anti-reflux procedures followed EI.

Ureteroneocystostomy was associated with a higher rate of 30-day GU-related readmissions (123, 4.8% vs 21, 1.1%, OR=4.76, $P<0.001$), 90-day GU-related readmissions (268, 10.5% vs 76, 3.8%, OR=2.96, $P=0.001$), 30-day GU-related ER visits (103, 4.0% vs 26, 1.3%, OR=3.18, $P<0.001$), and 90-day GU-related ER visit (148, 5.8% vs 55, 2.8%, OR=2.17, $P<0.001$).

Bivariate and multivariate analyses are detailed in Table 3. After adjusting for age, gender, insurance status, van Walraven comorbidity score, treatment year, and hospital clustering (with GEE), patients treated by UNC demonstrated significantly higher odds of readmission (OR=4.45 in 30 days, $P<0.001$; OR=2.69 in 90 days, $P<0.001$) and required unplanned postoperative ER visits (OR=3.33 in 30 days, $P<0.001$; OR=2.26 in 90 days, $P<0.001$) compared to patients that received EI as index anti-reflux surgery. In contrast, patients treated by EI continued to demonstrate a more than seven-fold increased odds of repeating anti-reflux procedures (OR=7.13, $P<0.001$).

None of the sensitivity analyses yielded significant deviation from original analysis.

Discussion

It is believed that this is one of the largest contemporary studies investigating the comparative effectiveness analysis of current urologic practice patterns using SASD, SEDD, and SID, which are large, well-validated linked state databases. In the analysis of 4553 operative encounters, EI constituted nearly half of initial anti-reflux procedures in children. However, patients treated with EI were at more than seven-fold increased odds of requiring re-treatment in the first year relative to those treated with UNC. By contrast, patients treated with the latter were more than twice as likely to be readmitted or visit an ER postoperatively. Adjusting for potential confounding variables, patients treated with EI were 7.12 times more likely to undergo additional procedures than those treated with UNC. Genitourinary-related (GU-related) inpatient readmissions were 4.45 and 2.69 times more common with UNC than EI at 30 days and 90 days, respectively. Likewise, 30-day and 90-day GU ER visits were 3.33 and 2.26 times more likely in the UNC cohort.

This result demonstrated the primary limitation of UNC with its relative degree of invasiveness. Even with the technology advances, UNC, ultimately, is still an involved surgical procedure. These factors may place children who undergo UNC at higher risk for complications associated with length of sedation, hospitalization, pain, and surgical site infections. In turn, this may account for the higher rate of ER visits captured in the present analysis.

By comparison, the primary drawback of EI, as suggested by the present analysis and others, is inferior treatment efficacy compared to UNC, particularly in patients with high-grade VUR or challenging anatomy. Several studies have demonstrated widely variable VUR-free success rates following initial EI, ranging from 50–100%, with consensus estimates of 75–80% per ureter [15,22–24]. Given the need for use of general anesthesia in children undergoing EI, as well as costs associated with each procedure and repeat VCUG, the re-treatment rate for EI remains concerning.

The findings of the present study should be viewed in the context of its design limitations. The decision to use encounter data from SASD, SEDD, and SID was driven by the fact that these datasets are amongst the largest and well-validated that are available. However, as with any administrative database, the present analyses were limited by the retrospective nature of the dataset. Detailed patient-level clinical factors such as disease severity (reflux grade and laterality), prior UTI history, and bowel-bladder dysfunction were unavailable. It is therefore possible that the clinical characteristics between the two comparison groups were substantially different and thus impacted the study estimates. For example, higher readmission and ER visit rates in UNC group may have been partly due to the more severe VUR nature of this population. However, with current controversies and various treatment patterns, a definitive selection pattern or bias between those two treatment modalities has not yet been established. It was therefore chosen to present this data to reflect the ‘real-life’ data, to hopefully pique more interest in future prospective trials investigating this subject. Additionally, the present analyses relied upon accurate coding and database completeness. Although the accuracy of these particular databases is relatively high, the possibility of miscoding bias cannot be excluded. In order to minimize this limitation, HCUP databases are routinely and rigorously monitored by AHRQ for coding accuracy and, thus, it is believed in all likelihood that they represent a reasonably reliable snapshot of their respective cohorts.

The decision to utilize only a small subset of available state data – in this case from California, Florida, North Carolina, Utah and New York – was driven by the ability to track individual patients through multiple encounters over time, which was made possible by the depth of data capture by participating agencies in those states. These states further represent a diverse sample of geographic regions, demography, and socioeconomic composition and were felt to be a fair proxy for the country as a whole. However, given regional variations in healthcare practices, it is acknowledged that the reported results may not be generalizable to encounters from states not included in the sample pool. It must also be noted that certain states opted to discontinue individual patient tracking after 2010, limiting the ability to comment definitively on utilization and effectiveness trends for UNC and EI in subsequent years. Numerous other studies have continued to support usage and effectiveness rates similar to the present findings for both procedures, and it is believed that the trends reported in the present study are an accurate picture of current practice patterns.

Significantly, the dearth of highly accurate, current, and large outpatient datasets in pediatrics precluded an analysis of outpatient encounters not captured by HCUP data; notably patients who may have received unscheduled minor procedures or postoperative treatments in-office by their primary care physician, pediatric urologist, or at urgent/

specialty care centers. Although it is believed that the number of such patients excluded from the cohort from these encounters is relatively small, it remains possible that such data may alter understanding of retreatment and readmission rates, as well as economic impact. Another limitation of the present study was the restriction of capturing re-operative rates for only the first 12 months following surgery; EI is known to have an even higher failure rate over time [25], so the discrepancy of re-operative rates could become even more profound with longer follow-up. Furthermore, granular data such as timing of follow-up and choice of the follow-up imaging was unavailable. Therefore, a portion of additional procedure difference may have been driven by more frequent follow-up with VCUG in the EI population compared to patients who underwent UNC. Lastly, since only a specific time frame of data was available, a portion of the index EI or UNC may actually be repeat procedures instead of index (first) procedures.

This study adds to the growing body of literature indicating substantial differences in outcomes between EI and UNC when used for primary treatment of VUR, and further supports other studies that have found UNC to have a higher likelihood of success after a single procedure, vis-à-vis EI [11,26]. Although EI use has recently plateaued somewhat, it remains used in roughly half of all anti-reflux procedures [27,28]. Given these findings, it is believed that a discussion of the merits of each approach is warranted as new clinical practice guidance.

It is, of course, important to bear in mind that interventional choice is undoubtedly multifactorial and patient/setting-specific. Either UNC or EI may be a more appropriate option for a particular child, based on institutional resources, provider proficiency, parental preferences, and local procedural costs [29,30]. Further investigations are warranted to more closely examine these factors as they pertain to VUR management choices.

Conclusion

Between 2007–10, UNC and EI were used in nearly equal numbers for the surgical management of VUR across several US states. The UNC patients were more likely to require an unplanned readmission or ED visit postoperatively, although EI patients were also more than seven-fold more likely to require a repeat anti-reflux procedure compared to those who underwent UNC.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Summary Fig.

Multivariate adjusted Odds Ratio of ureteronecystotomy compared to endoscopic injection (Using EI=1 as reference).

EI, endoscopic injection; ER, emergency room; GU, genitourinary

Table 1

Patient and hospital characteristics by procedure type.

	Endoscopic injection (N=1997)	Ureteroneocystotomy (N=2556)	Total (N=4553)	P-value
Age in years at admission				<0.001 ¹
N	1997	2556	4553	
Mean (SD)	6.0 (3.9)	4.6 (3.4)	5.2 (3.7)	
Median	6.0	4.0	5.0	
Q1, Q3	3.0, 8.0	2.0, 7.0	2.0, 7.0	
Range	(0.0–18.0)	(0.0–18.0)	(0.0–18.0)	
Patient age, by category				<0.001 ²
0–1 years, infants	195 (9.8%)	491 (19.2%)	686 (15.1%)	
1–3 years, toddlers	421 (21.1%)	688 (26.9%)	1109 (24.4%)	
3–6 years, preschoolers	519 (26.0%)	674 (26.4%)	1193 (26.2%)	
6–12 years, school-aged	752 (37.7%)	637 (24.9%)	1389 (30.5%)	
12–18 years, teens	110 (5.5%)	66 (2.6%)	176 (3.9%)	
Gender				<0.001 ²
Missing	109 (5.5%)	64 (2.5%)	173 (3.8%)	
Male	389 (19.5%)	764 (29.9%)	1153 (25.3%)	
Female	1499 (75.1%)	1728 (67.6%)	3227 (70.9%)	
Race				<0.001 ²
Missing	501 (25.1%)	339 (13.3%)	840 (18.4%)	
White	863 (43.2%)	1408 (55.1%)	2271 (49.9%)	
Black	39 (2.0%)	48 (1.9%)	87 (1.9%)	
Other	594 (29.7%)	761 (29.8%)	1355 (29.8%)	
Insurance				<0.001 ²
Public	572 (28.6%)	874 (34.2%)	1446 (31.8%)	
Private	1145 (57.3%)	1469 (57.5%)	2614 (57.4%)	
Other	280 (14.0%)	211 (8.3%)	491 (10.8%)	
Treatment year				0.158 ²
2007	399 (20.0%)	520 (20.3%)	919 (20.2%)	
2008	542 (27.1%)	708 (27.7%)	1250 (27.5%)	
2009	582 (29.1%)	672 (26.3%)	1254 (27.5%)	
2010	474 (23.7%)	656 (25.7%)	1130 (24.8%)	
Income				0.959 ²
Missing	29 (1.5%)	36 (1.4%)	65 (1.4%)	
First quartile	438 (21.9%)	549 (21.5%)	987 (21.7%)	
Second quartile	480 (24.0%)	626 (24.5%)	1106 (24.3%)	
Third quartile	496 (24.8%)	640 (25.0%)	1136 (25.0%)	
Fourth quartile	554 (27.7%)	704 (27.5%)	1258 (27.6%)	
van Walraven score				0.144 ³
–1	16 (0.8%)	35 (1.4%)	51 (1.1%)	

	Endoscopic injection (N=1997)	Ureteroneocystotomy (N=2556)	Total (N=4553)	P-value
0	1844 (92.3%)	2331 (91.2%)	4175 (91.7%)	<0.001 ²
1	0 (0.0%)	2 (0.1%)	2 (0.0%)	
2	137 (6.9%)	188 (7.4%)	325 (7.1%)	
Hospital State				
CA	742 (37.2%)	715 (28.0%)	1457 (32.0%)	
FL	603 (30.2%)	669 (26.2%)	1272 (27.9%)	
NC	212 (10.6%)	267 (10.4%)	479 (10.5%)	
NY	377 (18.9%)	695 (27.2%)	1072 (23.5%)	
UT	63 (3.2%)	210 (8.2%)	273 (6.0%)	

¹Kruskal Wallis

²Chi-Squared

³Fisher Exact

CA, California; FL, Florida; NC, North Carolina; NY, New York; UT, Utah

Table 2

Readmissions- ER visits and additional procedures by procedure type

	EI (N=1997)	UNC (N=2556)	Total (N=4553)	p value
30-day GU readmissions(Y/N)	21 (1.1%)	123 (4.8%)	144 (3.2%)	<0.0001 ^I
90-day GU readmissions(Y/N)	76 (3.8%)	268 (10.5%)	344 (7.6%)	<0.0001 ^I
30-day GU ER readmissions (Y/N)	26 (1.3%)	103 (4.0%)	129 (2.8%)	<0.0001 ^I
90-day GU ER readmissions	55 (2.8%)	148 (5.8%)	203 (4.5%)	<0.0001 ^I
365-day additional VUR procedure (Y/N)	121 (6.1%)	25 (1.0%)	146 (3.2%)	<0.0001 ^I
UNC	*	*	15 (0.3%)	0.2071 ^I
EI	114 (5.7%)	19 (0.7%)	133 (2.9%)	<0.0001 ^I

^I Chi-Square

* Cells with less than 15 patients excluded per AHRQ guidelines

Table 3

Bivariate and multivariate analysis of the association of treatment modality and outcomes.

Outcomes	Unadjusted OR (95% CI)	Adjusted OR (95% CI) *	P-value *
30-day GU readmissions (Y/N)	4.76 (3.00–7.59)	4.45 (2.62–7.55)	<0.001
90-day GU readmissions (Y/N)	2.96 (2.28–3.85)	2.69 (1.63–4.43)	0.001
30-day GU ER visits (Y/N)	3.18 (2.06–4.91)	3.33 (2.21–5.02)	<0.001
90-day GU ER visits (Y/N)	2.17 (1.58–2.97)	2.26 (1.62–3.14)	<0.001
365-day additional procedure	0.15 (0.10–0.24)	0.14 (0.08–0.23)	<0.001
365-day additional procedure **	6.53 (4.23–10.09)	7.12 (4.25–11.93)	<0.001

* adjusted for age, gender, year of admission, insurance, comorbidity score, and hospital clustering (endoscopic injection as reference surgery)

** ureteroneocystotomy as reference surgery

ER, emergency room; GU, genitourinary; OR, odds ratio; N, no; Y, yes