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Urinary Diversion during and after Pediatric Pyeloplasty: A Population Based Analysis of More than 2,000 Patients

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Abbreviations and Acronyms

FPSC = Faculty Practice Solutions Center

NT = nephrostomy tube

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Purpose: We evaluated the use and efficacy of intraoperative urinary diversion with ureteral stent or nephrostomy tube during pyeloplasty in children.

Materials and Methods: The Faculty Practice Solutions Center® national billing database was queried to identify all pediatric pyeloplasties performed from 2009 to 2012. Patient variables, surgical approach, use of intraoperative stent/nephrostomy tube and return for postoperative stent/nephrostomy tube or second pyeloplasty were obtained.

Results: A total of 2,435 children underwent open (1,792) or laparoscopic/robotic (643) pyeloplasty, with intraoperative urinary diversion rates of 45% and 83%, respectively. Comparing patients with and without an intraoperative stent/nephrostomy tube, 5.6% and 7.4%, respectively, returned to the hospital for urinary diversion. Multivariable analysis revealed no association with surgical approach, but higher surgeon volume ($p < 0.01$) and use of an intraoperative stent/nephrostomy tube ($p < 0.01$) were associated with decreased odds of requiring postoperative urinary diversion. Second pyeloplasty rate was 3.8% and was not associated with surgical approach or use of intraoperative stent/nephrostomy tube.

Conclusions: Intraoperative stent/nephrostomy tube use and increased surgeon volume were each independently associated with a significant but small decrease in risk of postoperative stent/nephrostomy tube placement. Use of an intraoperative stent/nephrostomy tube was not associated with rate of second (redo ipsilateral or contralateral metachronous) pyeloplasty.

Key Words: outcome assessment (health care), stents, ureter, ureteral obstruction, urinary diversion

SINCE the initial description of Anderson-Hynes pyeloplasty as a stentless procedure in 1949,¹ there has been ongoing debate regarding the use of upper urinary tract diversion during pyeloplasty.² Current options that have been demonstrated as safe and effective include trans-anastomotic externalized stents, internal stents/nephrostomy tubes and

stentless open or laparoscopic/robotic approaches,^{2–11} with a lack of clear evidence of efficacy of intraoperative urinary diversion.

Regardless of surgical approach or urinary diversion, the Anderson-Hynes pyeloplasty is a well established procedure with low overall complication rates ranging from 3% to 15% and approximately a 95% success

rate in relieving obstruction.^{2,4,12,13} It is estimated that intraoperative stenting rates have decreased in recent years, potentially due partly to higher costs and longer hospitalization, requirement of a second anesthetic for internal stent removal and increased risk of urinary tract infection.^{2,6} There are numerous single institution analyses of stent efficacy with conflicting results biased by surgeon or institutional practice patterns. A formal multi-institution population based analysis of stent use and risk of secondary procedures is lacking in the literature.

Given the potential lack of cost-effectiveness and indeterminate use of intraoperative ureteral stent/NT during pediatric pyeloplasty,¹² we sought to determine the use of intraoperative ureteral stent/NT, and to analyze patient and surgeon characteristics associated with outcomes. We hypothesized that there would be a higher rate of postoperative urinary diversion and second pyeloplasty procedures in those individuals who did not undergo stent placement during pyeloplasty, although the absolute difference would be less than 5%.

MATERIALS AND METHODS

The Faculty Practice Solutions Center is a national database developed by the University Health System Consortium and the Association of American Medical Colleges to collect benchmarking data regarding clinical, operational and financial performance of academic clinical practices throughout the United States. Coding data collected include hospital, deidentified provider and patient demographic information, and CPT and ICD-9 codes with service site, date and payer category. FPSC is unique for its large scale of data capture, including more than 90 participating institutions and 60,000 physicians, and for its role in tracking billing information.

The FPSC database was queried to identify all individuals younger than 18 years who underwent pyeloplasty (CPT 50400, 50405 or 50544) between January 1, 2009 and June 30, 2012, with secondary procedures analyzed through December 31, 2012. All individuals undergoing urinary diversion during the initial pyeloplasty procedure (stented cohort) were defined based on intraoperative coding for stent or nephrostomy tube placement (52332, 50605, 50392 or 50393) and/or a stent removal code (52310 or 52315) on a date after primary pyeloplasty and before any stent/NT placement or second pyeloplasty.

All individuals were further identified by surgical approach, either open (50400, 50405) or laparoscopic/robotic (50544 or robotic identifier S2900). Since use of a robotic identifier was rare (84 of 643 laparoscopic cases) and did not allow for reliable differentiation between a laparoscopic vs robotic approach, these cases were placed in a single cohort for analysis. All demographic characteristics available were queried. Outcome variables assessed included postoperative stent/NT placement and/or second pyeloplasty.

The association between baseline characteristics and outcomes of postoperative stent/NT placement and second pyeloplasty was analyzed using a mixed effects logistic regression model including random effects for surgeon and hospital. The model also included an interaction effect between patient age and surgery type, allowing for a differential effect of age depending on whether the patient underwent open or laparoscopic surgery. Analyses were conducted using lme4, version 0.999999-2 in the statistical software environment R, version 3.0.0 (R Project for Statistical Computing, Vienna, Austria).¹⁴

Time to postoperative stent/NT placement was compared between patients with and without an intraoperative stent using a mixed effects Cox proportional hazards model including random effects for surgeon and hospital. This analysis evaluated patient gender, use of intraoperative stent/NT, surgeon and hospital volume, geographic region, insurance status, patient age and surgical approach. Patients who had not undergone postoperative stenting as of December 31, 2012 were censored at this date.

RESULTS

Population Characteristics

There were 2,435 children identified who underwent open (1,792) or laparoscopic (643) pyeloplasty between January 1, 2009 and June 30, 2012, with secondary procedures analyzed through December 31, 2012. Median followup was 27.3 months (range 6.1 to 47.8) from date of pyeloplasty until conclusion of secondary procedure analysis. Overall rate of intraoperative stenting was 55%, and stenting was more commonly used in those who underwent a laparoscopic/robotic approach (83%) compared to an open approach (45%). Table 1 outlines patient demographics, surgeon and hospital volume, surgical approach and outcomes for intraoperatively stented, unstented and all pyeloplasties combined. Race distribution, insurance status and gender were comparable between the stented and unstented cohorts but there were significant differences in age, surgeon and hospital volume, and followup time ($p < 0.001$).

Median age was 0.9 years (range 0 to 18.2) in patients undergoing open pyeloplasty vs 8.7 years (0.1 to 18.2) in those undergoing a laparoscopic/robotic approach. As a consequence, the median age of the stented cohort was greater, at 4.1 years (range 0 to 18.2), vs 1.0 year (0 to 18.2) in the unstented cohort ($p < 0.001$). Unstented status was associated with higher volume hospitals (18.6 vs 12.3 pyeloplasties yearly, $p < 0.001$) and higher volume surgeons (8.3 vs 5.7 pyeloplasties yearly, $p < 0.001$). Part A of the figure shows time to removal of intraoperatively placed ureteral stents, with the majority removed at 20 to 60 days postoperatively. Removal time of intraoperative NTs

Table 1. Patient characteristics and outcomes

	Unstented Pyeloplasties		Stented Pyeloplasties		All Pyeloplasties	
No. pts (%)	1,103	(45.3)	1,332	(54.7)	2,435	(100)
Median yrs age (range)*	1	(0–18.2)	4.1	(0–18.2)	2.1	(0–18.2)
Median yearly surgeon vol (range)*	8.3	(0.3–21.4)	5.7	(0.3–21.4)	6.3	(0.3–21.4)
Median yearly hospital vol (range)*	18.6	(0.3–64.9)	12.3	(0.3–64.9)	14.6	(0.3–64.9)
No. gender (%):						
Female	328	(29.7)	395	(29.7)	723	(29.7)
Male	775	(70.3)	937	(70.3)	1,712	(70.3)
No. geographic region (%):						
A (Northeast)	316	(28.6)	430	(32.3)	746	(30.6)
B (Midwest)	165	(15)	211	(15.8)	376	(15.4)
C (South)	279	(25.3)	436	(32.7)	715	(29.4)
D (West)	343	(31.1)	255	(19.1)	598	(24.6)
No. race (%):						
Asian	9	(0.8)	6	(0.5)	15	(0.6)
Black	51	(4.6)	75	(5.6)	126	(5.2)
Hispanic	80	(7.3)	57	(4.3)	137	(5.6)
Native American	2	(0.2)	3	(0.2)	5	(0.2)
White	348	(31.6)	433	(32.5)	781	(32.1)
Other/unknown	613	(55.6)	758	(56.9)	1,371	(56.3)
No. insurance (%):						
Commercial	558	(50.6)	739	(55.5)	1,297	(53.3)
Medicaid/Medicare	433	(39.3)	489	(36.7)	922	(37.9)
Self-pay	25	(2.3)	9	(0.7)	34	(1.4)
All others	87	(7.9)	95	(7.1)	182	(7.5)
No. surgery type (%):						
Open	991	(89.8)	801	(60.1)	1,792	(73.6)
Laparoscopic	112	(10.2)	531	(39.9)	643	(26.4)
No. postop stent/NT (%):						
Stent	79	(7.2)	69	(5.2)	148	(6.1)
NT	14	(1.3)	9	(0.7)	23	(0.9)
Stent + NT	82	(7.4)	75	(5.6)	157	(6.4)
Mean days to postop stent/NT (range)	35	(1–1,064)	71	(1–926)	57	(1–1,064)
No. second pyeloplasties (%)	49	(4.4)	43	(3.2)	92	(3.8)
Median mos followup (range)*	28.9	(6.1–47.8)	26	(6.1–47.8)	27.3	(6.1–47.8)

* Median patient age, surgeon volume, hospital volume and followup differed significantly between stented and unstented pyeloplasties (Wilcoxon rank-sum test $p < 0.001$).

cannot be determined, but the assumption is that most were removed within 30 days of surgery.

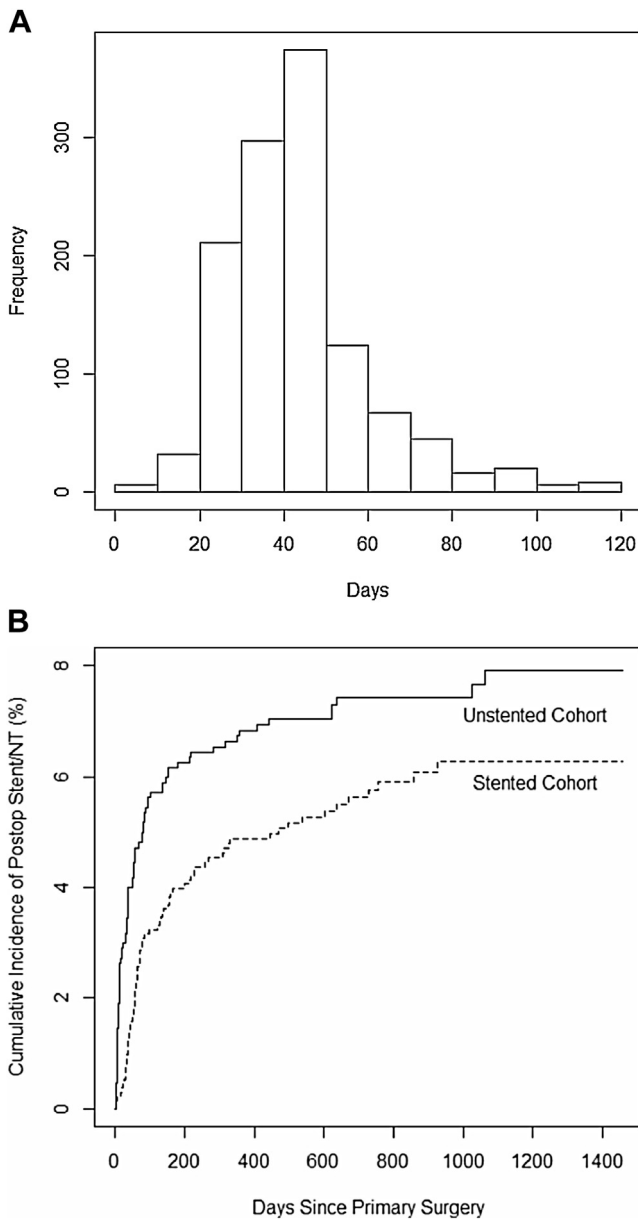
Postoperative Urinary Diversion with Stent/NT

Of the 2,435 patients who underwent pyeloplasty 157 (6.4%) required ureteral stent/NT placement postoperatively. No significant difference was noted between postoperative diversion rates in the open (5.7%) and laparoscopic (8.6%) cohorts (2.9% difference, $p = 0.16$). Median time to postoperative stent/NT placement was 35 days for the unstented cohort and 71 days for those with intraoperative stent/NT placement. At 6 months postoperatively 6.2% of patients without intraoperative urinary diversion and 4.0% of those with intraoperative stent/NT had undergone postoperative stent/NT placement ($p = 0.01$). At maximum followup the rates increased to 7.4% (82 of 1,103 patients) and 5.6% (75 of 1,332), respectively (1.8% difference, $p < 0.001$, part B of figure).

Use of an intraoperative stent/NT ($p < 0.001$, HR 0.42, CI 0.28–0.62), geographic location in region D (the West, $p = 0.01$, HR 0.48, CI 0.27–0.85) and increased surgeon volume ($p = 0.001$, HR 0.92, CI 0.87–0.97) were independently associated with decreased odds of postoperative stent/NT placement.

Older patient age in the open cohort was associated with increased odds of postoperative stent/NT placement ($p < 0.01$, HR 1.07, CI 1.02–1.13, table 2). After adjusting for other factors each additional 5 cases per year in surgeon volume was associated with a 53% decrease in odds of postoperative stent/NT. There was no change in risk of postoperative stent/NT placement associated with patient gender ($p = 0.08$), age in the laparoscopic cohort ($p = 0.17$), insurance status ($p > 0.4$), hospital volume ($p = 0.39$) or surgical approach (open vs laparoscopic, $p = 0.16$).

Of the 199 surgeons evaluated 13% never recorded use of an intraoperative stent/NT and 33% placed a stent/NT in all pyeloplasties performed. In the subgroup analysis of the remaining surgeons (54%) who used urinary diversion during initial pyeloplasty selective use of an intraoperative stent/NT ($p < 0.001$, HR 0.34, CI 0.22–0.52), geographic location in region D (the West, $p = 0.01$, HR 0.45, CI 0.24–0.84) and increased surgeon volume ($p < 0.001$, HR 0.9, CI 0.85–0.95) were independently associated with decreased odds of postoperative stent/NT placement. As in the entire study population, older patient age in the open cohort was associated with increased odds of postoperative stent/NT placement ($p = 0.01$, HR 1.07, CI 1.02–1.13).



A, histogram of time to removal of intraoperative ureteral stent placed during initial pyeloplasty. B, Kaplan-Meier plot represents cumulative incidence of postoperative stent/NT placement. Solid line signifies cumulative incidence of ureteral stent/NT placement in cohort without intraoperative stent/NT during primary pyeloplasty. Broken line depicts cumulative incidence of stent/NT placement in patients who did not undergo intraoperative stent/NT placement.

Second Pyeloplasty

The overall rate of second pyeloplasty was 3.8%, inclusive of all redo ipsilateral and contralateral metachronous pyeloplasties. The database does not allow distinction between ipsilateral redo pyeloplasty for recurrent obstruction from contralateral primary pyeloplasty. There was no difference in risk of second pyeloplasty associated with either surgical approach ($p = 0.39$, HR 0.68, CI 0.28–1.66) or use of

Table 2. Mixed effects logistic regression analysis of postoperative stent/NT

	Odds Ratio (95% CI)	p Value
Gender (male vs female)	1.41 (0.96–2.09)	0.08
Intraop stent (yes vs no)	0.42 (0.28–0.62)	<0.001
Surgeon vol (surgeries/yr)	0.92 (0.87–0.97)	0.001
Surgeon vol (5 surgeries/yr)	0.65 (0.51–0.85)	0.001
Hospital vol (surgeries/yr)	1.01 (0.99–1.02)	0.39
Geographic region:		
B (Midwest) vs A (Northeast)	0.76 (0.42–1.40)	0.38
C (South) vs A (Northeast)	0.69 (0.41–1.15)	0.15
D (West) vs A (Northeast)	0.48 (0.27–0.85)	0.01
Insurance:		
Medicaid/Medicare vs commercial	1.12 (0.78–1.61)	0.54
Self-pay/other vs commercial	0.74 (0.37–1.50)	0.41
Age:		
Open pyeloplasty	1.07 (1.02–1.13)	0.004
Laparoscopic pyeloplasty	1.04 (0.98–1.10)	0.17
Surgery type (laparoscopic vs open)*	1.50 (0.86–2.62)	0.16
Surgery type + age interaction†	0.97 (0.90–1.05)	0.42

* Effect of surgery type for 4-year-old patient.

† Incremental change in odds ratio for laparoscopic/robotic vs open surgical approach for each additional year of age.

an intraoperative stent/NT ($p = 0.59$, HR 0.87, CI 0.53–1.43).

Using a mixed effects logistic regression model, the only factor that was noted to be significant was age, with an increased risk of second pyeloplasty associated with decreased age in the open cohort ($p = 0.001$, HR 0.83, CI 0.74–0.93), which may reflect the incidence of bilateral disease in younger patients. Among all children evaluated there was no change in risk of second pyeloplasty associated with patient gender ($p = 0.06$), age in the laparoscopic/robotic cohort ($p = 0.44$), insurance status ($p > 0.1$), region ($p > 0.3$), surgeon volume ($p = 0.19$) or hospital volume ($p = 0.19$).

DISCUSSION

To our knowledge this is the largest investigation to date to evaluate intraoperative stent/NT use during pediatric pyeloplasty. This analysis captures the breadth of surgical practices, including variations in surgical approach within academic institutions across the United States. The variety of practice patterns observed highlights the inconclusive nature of the literature addressing the use and efficacy of intraoperative urinary diversion during pediatric pyeloplasty.

The primary outcome measure for this study was the risk of postoperative urinary diversion, which we hypothesized would be decreased following pediatric pyeloplasty with intraoperative stent/NT placement. This multi-institutional study does, indeed, reveal an increase in risk of postoperative stent/NT placement associated with unstented pyeloplasty, although the absolute difference was 1.8% (7.4% vs 5.6%). Despite this finding being statistically significant, the small difference in

postoperative diversion, the need for a second anesthetic procedure for stent removal and the risks associated with a stent itself complicate the decision regarding whether to place a stent.

In a meta-analysis that included 339 stented and 494 unstented pyeloplasties the number of complications was equivalent (12% vs 14%), although the type of complications differed.² In particular unstented pyeloplasties were associated with an increased rate of secondary procedures compared to the stented cohort (9.1% vs 3.5%, $p < 0.01$). This finding of differential complications is also consistent with a 10-year retrospective review of 105 consecutive pediatric pyeloplasties in which surgical complication rates including urine leak (8.5%) and obstruction (2.1%) were higher in unstented patients, whereas stented patients manifested infection (5.2%) and stent related complications including migration and calculus (10.3%).⁶ Given these findings, it is noteworthy that our study is limited by its inability to evaluate the full range of postoperative complications, nor does it provide the indication for stent placement.

Our findings must be applied in light of the formerly cited complication risks as well as cost analyses. A recently published study for the United States market found that either external trans-anastomotic stents or no stenting was superior to internal stenting in terms of cost-effectiveness.¹² Although that study did not specifically evaluate all surgical approaches or the use of antegrade vs retrograde stenting for each approach, even theoretically decreasing the complication and failure rates of internal stents to zero did not render stents cost effective.

From the analysis of all pyeloplasties performed we found that approximately half (55%) involved ureteral stent/NT placement intraoperatively, with urinary diversion more common during a laparoscopic/robotic (83%) vs an open approach (45%), similar to formerly published reports.¹⁵ Previous studies have demonstrated equivalent outcomes between stented and unstented laparoscopic/robotic pyeloplasties in adults and single institution series of unstented laparoscopic pyeloplasties in children.^{9–11}

In the FPSC database 26% of pyeloplasties performed between 2009 and 2012 were done via a laparoscopic or robotic approach. Reflective of current surgical practice, younger patients were more likely to undergo open pyeloplasty (mean age 2.9 years) than laparoscopic/robotic pyeloplasty (8.9 years). In subgroup analysis it was also noted that younger patients in the open pyeloplasty cohort were less likely to undergo placement of a ureteral stent/NT intraoperatively. The lower stenting rates within the younger cohort overall may be attributable to greater

difficulty and risk, in particular of ureterovesical junction injury during antegrade ureteral stent placement in infants. Beyond these comparisons, although there was an absolute difference of 2.9% in rate of postoperative diversion between the laparoscopic and open cohorts, the small number in the laparoscopic cohort may not have provided the statistical power necessary to detect a differential risk.

We further completed a subset analysis of patients treated by surgeons who selectively placed stents. We hypothesized that a surgeon who places stents selectively, rather than never or always, makes this decision based on anatomy or concern for a greater risk of obstruction in a specific patient. Patients who had an intraoperative stent/NT placed by selective surgeons still had significantly lower postoperative stent/NT rates. However, surgeon experience continued to have a significant role, with decreased risk of postoperative stent/NT placement associated with surgeon experience independent of baseline stenting practices.

Although a billing database is likely to be more accurate than administrative data sets, there are limitations. We were limited to a 4-year period of data collection. However, we ensured a minimum followup of 6 months, by which time 6.2% of patients without and 4.0% with intraoperative stents had returned for postoperative stent placement. In addition, although internal stents could be captured either due to placement or removal, we have been unable to differentiate and/or capture all types of stent placement intraoperatively, particularly externalized stents if not coded. This circumstance would place a certain fraction of uncaptured stented pyeloplasties in the unstented cohort for analysis. Given that the unstented cohort overall required a higher rate of stent placement, we would predict that the uncaptured stents in the unstented cohort would tend to favor the null hypothesis and cause an underestimate of the true difference in risk of postoperative urinary diversion for the unstented patients.

As a secondary outcome measure, we found no difference in the rates of second pyeloplasty associated with stented (3.2%) vs unstented procedures (4.4%). This observation may be limited by the inability to exclude contralateral metachronous pyeloplasty. For example the bilateral disease cohort, which likely has a higher rate of intraoperative stent/NT placement, could artificially inflate the second pyeloplasty rate for the stented cohort as a whole. If this population could be removed, it is possible that the data would show a lower secondary surgery rate for recurrent obstruction in the stented unilateral cohort compared to the unstented cohort. However, a retrospective study of 76 pediatric pyeloplasties found a recurrent ureteropelvic junction obstruction rate of 5.7% and

did not reveal a significant difference between the stented and unstented cohorts ($p = 0.58$).

We anticipate that this analysis of stenting patterns and risk of second urinary diversion may improve future cost-effectiveness and utility models, which are increasingly relevant in a health system challenged by the need for optimization of outcomes while containing unnecessary costs. As highlighted by the outcome of the deterministic decision tree model for cost-effectiveness by Yiee and Baskin,¹² the findings of the present study must be balanced with the risks and costs of intraoperative stenting

for the majority of individuals who would have an uncomplicated procedure regardless of the use of an intraoperative stent/NT.

CONCLUSIONS

Intraoperative stent/NT use and increased surgeon volume were each independently associated with a significant but small decrease in the risk of postoperative stent/NT. Use of an intraoperative stent/NT was not associated with the rate of second (redo ipsilateral or contralateral metachronous) pyeloplasty.

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EDITORIAL COMMENT

The authors used the FPSC database to evaluate the use and efficacy of intraoperative urinary diversion with ureteral stent or nephrostomy tube during pediatric pyeloplasty. The attractiveness of administrative databases as a research apparatus can be attributed to their easy accessibility, the large patient populations they cover, their low cost and their applicability in daily clinical practice. Nevertheless, limitations to their use as an outcome assessment tool should not be overlooked.

In the present study intraoperative stent/nephrostomy tube insertion, the main outcome of interest, is not the most important surgical procedure code. Primary pyeloplasty is. As a secondary billing code, stent/nephrostomy tube use is often not recorded and, therefore, not captured by such databases. As a result, not all intraoperative external

diversions (internal diversion was captured during stent removal as a secondary procedure) performed could be documented, affecting the comparison of postoperative stent/nephrostomy tube rates between patients with and without a history of intraoperative diversion. The same issue is valid for the distinction between redo pyeloplasty and contralateral pyeloplasty, which are both grouped under the same code of second pyeloplasty. Coding problems such as these may threaten the validity of any billing databases, weakening the strength of evidence resulting from this type of research.

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REPLY BY AUTHORS

Regarding the limitations of database studies, a typical “administrative” database includes data recorded for administrative and/or academic purposes. By comparison, the FPSC database is derived from billing data, from which CPT procedural codes are far superior for inclusion and accuracy. It is correct that not all stents and nephrostomy tubes were captured, since not all surgeons record this

code during the initial procedure. The stent removal provided an additional and unique encounter for finding stents. We believe the sensitivity of the data was high, since intraoperative diversion was identified in 45% of open pyeloplasties and 83% of robotic/laparoscopic pyeloplasties, which is consistent with the utilization reported in the literature.