Journal of Pediatric Urology (xxxx) xxx xxx

Impact of caudal block on revision rates after hypospadias repair: Multi-institution review

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Keywords
Hypospadias; Anesthesia; Caudal; Postoperative complications

Abbreviations
MAGPI, meatal advancement and glanduloplasty; HS, hypospadias repair

Received 29 June 2022
Revised 1 February 2023
Accepted 7 February 2023
Available online xxx

Summary

Introduction
There is controversy surrounding the association between caudal block and complication rates after hypospadias repair. Conflicting results have been reported mostly from single-center, low volume studies and those that did not include relevant variables.

Objectives
We hypothesized that caudal block is not associated with increased rates of reoperation after primary repair and is associated with more complex hypospadias surgery.

Study design
The Clinical Practice Solutions Center database was queried to identify patients who received a primary hypospadias repair between 2009 and 2010. Primary hypospadias repair was further categorized as meatal advancement and glanduloplasty, distal, one-stage proximal, or one-stage perineal repair. Anesthesia coding was evaluated to identify those who received a caudal block. Any revision surgery was captured between 2009 and 2019 and the types of revision surgeries were identified. Variables such as caudal block, age, insurance type, surgeon volume, and surgeon years in practice were analyzed with mixed effects multiple logistic regression models.

Results
The dataset query identified 3343 pediatric males who had primary hypospadias repair. The procedures were performed by 50 surgeons at 27 hospitals. Primary surgeries included meatal advancement and glanduloplasty (23%), distal (69%), proximal (6.9%), and perineal repairs (1%). Caudal block was administered to 42% of patients. Utilization of caudal block was not associated with type of primary surgery ($p = 0.21$). Adjusting for all other variables, increased patient age was associated with decreased usage of caudal block ($p < 0.001$). Analysis did not demonstrate a statistically significant association between utilization of caudal block with rates of revision surgery.

Conclusions
This large, multi-institution study demonstrates that the use of caudal block was not associated with more complex hypospadias surgery nor statistically significantly associated with increased rates of revision surgery after primary hypospadias repair.

Summary Table Mixed Effects Logistic Regression Analysis of Rate of Revision Surgery After Primary Surgery with Caudal Block Variable.

Primary Surgery	Odds Ratio (95% CI)	P-Value
MAGPI	1.45 (0.61—2.14)	0.67
Distal	1.04 (0.77—1.39)	0.81
One Stage Proximal HS Repair	1.47 (0.74—2.92)	0.28
One Stage Perineal HS Repair	0.82 (0.12—5.87)	0.84

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Abbreviations: MAGPI, meatal advancement and glanduloplasty; CI, confidence interval; HS, hypospadias repair.

https://doi.org/10.1016/j.jpurol.2023.02.004

Introduction

Caudal block is one of the most widely administered forms of regional anesthesia for sub-umbilical surgical interventions in the children and has demonstrated minimal anesthesia-related complications [1,2]. Anesthesiologists performing a caudal block typically use landmarks or an ultrasound and a single needle is inserted through the skin past the sacrococcygeal ligament into the sacral canal where local anesthetic such as bupivacaine, levobupivacaine or ropivacaine is applied [3]. This sub-umbilical anesthetic makes it an attractive option for hypospadias repair given its 96% success rate [4].

In 2012, a very small, prospective, randomized, double-blind study noted a concerning association between caudal block and hypospadias surgical complications [5]. This study was focused on pain control and was not designed for analysis of surgical complications. Follow up was unclear but complications were recorded two to four weeks after surgery and numerous patient and surgical variables were not considered. Another retrospective study noted that even after adjusting for confounding variables there was still a 13-fold increase in the odds of a post-surgical complication after receiving a caudal block [6]. With caudal block being a potential contributing cause of complications, a myriad of studies set out to reassess this surprising association [7–13]. The findings from these studies are contradictory with four meta-analyses producing mixed results [14–17].

Our primary hypothesis was that caudal block with a primary hypospadias repair is not associated with increased rates of revision surgery. The secondary hypothesis was that utilization of caudal block is associated with more complex surgery. We were interested in this secondary hypothesis since some papers had suggested this association as the reason for more revision surgeries when a caudal block was utilized.

Materials and methods

After IRB approval (#720220–3), the sample population was obtained from the Association of American Medical Colleges (AAMC) -Vizient Clinical Practice Solutions Center © (CPSC) database. CPSC is a partnership between Vizient, Inc. And the AAMC. Currently, 92 participating organizations send billing data to CPSC which generates reports and benchmarks for these organizations. The CPSC database includes robust hospital coverage and unique datapoints such as de-identified provider, patient, medical group information, productivity, billing codes for all procedural types, and insurance payer categories. During the primary surgery period of January 1st, 2009–December 31st, 2010, 84 surgeons performed at least 1 hypospadias repair in the first 3 months of 2009 at 46 participating academic institutions during that time (Fig. 1). The dates were chosen to capture primary surgeries during a two-year period to ensure a large population and ensure a long enough period to analyze individual surgeon volume. From prior data, rates of revision surgery plateau around 6 years after primary surgery [18].

Inclusion criteria included surgeons who performed at least 1 hypospadias repair in the first 3 months of 2009. All patients under the age of 18 years who had primary hypospadias surgery performed by these surgeons between January 1, 2009, and December 31, 2010, were included. Hypospadias repairs were identified by the following Current Procedural Terminology (CPT)® codes in order of complexity: meatal advancement and glanduloplasty (MAGPI) (54,322), distal repair (54,324, 54,326, 54,328), one stage proximal hypospadias repair (54,332), and one stage perineal hypospadias repair (54,336). For each occurrence of hypospadias surgery, the presence of anesthesia CPT® codes for caudal block were recorded (64,450, 62,310, 62,311, 62,318, 62,319). Exclusion criteria included institutions that do not report anesthesia billing and staged hypospadias repairs. Surgeons with specialty descriptions other than "Urology", "Pediatrics: Urology", and "Surgery: Pediatric" were also excluded. Using tools provided by CPSC, the database was filtered to identify our inclusion and exclusion criteria.

Data from January 1st, 2009, to May 29th, 2019, was examined to determine whether patients underwent revision surgery, providing a follow up period of 9–11 years after primary surgery. Revision surgeries of the penis were identified by the relevant CPT® codes (Appendix 1). Of note, "second-stage" surgery, after planned first-stage repair were not included **as it was noted that many surgeons did not code with second-stage CPT.** We did not query for additional surgical revision encounters after the first revision surgery. We examined American Society of Anesthesiology (ASA) Physical Status Classification System scores through the database using CPT® codes (00920 with modifier P1-5) corresponding to each class. Patient age, race, insurance type, geographic region, surgeon volume, surgeon years in practice, and caudal block were recorded to evaluate variables that might be associated with the need for further surgery. **Surgeon volume was defined as number of primary hypospadias cases during the 2-year surgical period.** Insurance payer categories included Medicaid, commercial insurance, self-pay and other. Geographic region was limited to the United States and included Northeast, Midwest, South, and West. In addition, this manuscript adheres to the applicable Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [19].

Statistical analyses

We analyzed the post hoc joint effects of caudal block, age, insurance type, region, race, surgeon volume and years-in-practice on the rate of revision surgery using a mixed effects multiple logistic regression model incorporating random effects for surgeon and hospital. This was a retrospective study utilizing all patients in the database who met eligibility criteria and with this large dataset no prospective power calculations were performed. Analyses were conducted separately for each primary surgery group. When sub-groups were analyzed, there were no repeated measures as only the first revision surgery of a given type was considered for each subject. For multiple sub-group analysis, no p-value adjustments were done for multiple testing. As data on race was missing for more than half of the subjects, race was not included in multivariable analyses.

Please cite this article as: Hu JC et al., Impact of caudal block on revision rates after hypospadias repair: Multi-institution review, Journal of Pediatric Urology, https://doi.org/10.1016/j.jpurol.2023.02.004

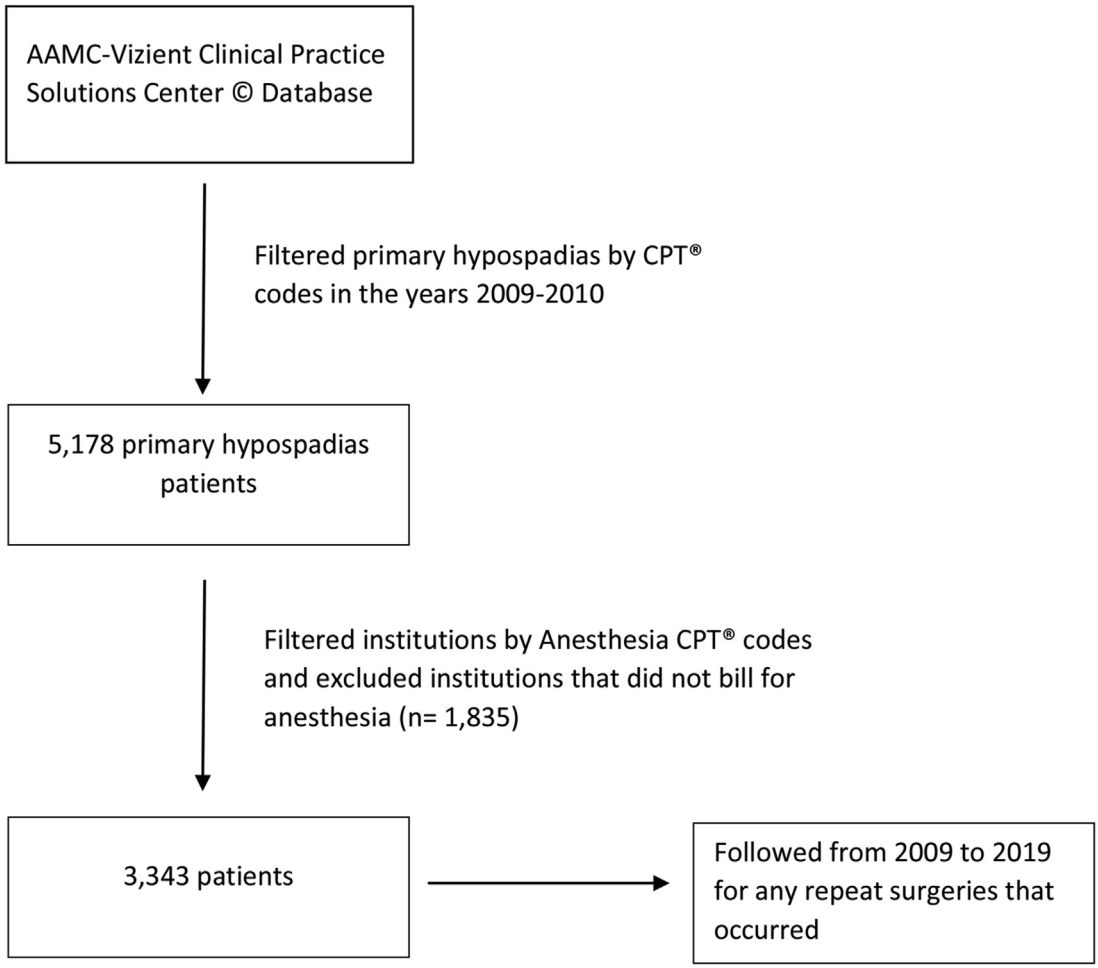

Fig. 1 Flow Diagram of Methodology. This illustration better depicts how we filtered our patient population. Using the AAMC-Vizient Clinical Practice Solutions Center © Database we filtered the database for any primary hypospadias procedure using CPT® codes. Subsequently, we delineated any institutions that did not bill for anesthesia billing excluded these patients from our cohort. This led to the final study population of 3343 patients and this group was queried for any repeat surgery from 2009 to 2019. Abbreviations: AAMC, Association of American Medical Colleges; CPT, Current Procedural Terminology.

However, in our previous analysis of an earlier version of the same data, sensitivity analyses were done including race for the subset of complete cases and conclusions were unchanged. Data extraction was conducted using (Statistical Analysis System) SAS®, version 9.2 for Windows®. Statistical analyses were conducted using R, version 2.13.0, with mixed effects logistic regression modeling conducted using the R package lme4 (0.999375−39).

Results

Over the initial two-year period, 5178 primary hypospadias repairs were identified. After excluding institutions that did not report anesthesia billing, 3343 cases of primary hypospadias were included. The types of surgery in order of complexity included: MAGPI - 759 (23%) by 44 surgeons, distal hypospadias repair - 2319 (69%) by 49 surgeons, one-stage proximal hypospadias repair - 230 (6.9%) by 38 surgeons, and one-stage perineal hypospadias repair - 35 (1%) by 13 surgeons. Further detailed demographics and variables are listed in Tables 1 and 2. Of the 3343 patients, 1399 (42%) received a caudal block.

Revision surgery

Four hundred and thirty-nine revision surgeries (13%) were performed. Rates of revision surgery after MAGPI, distal repair, one-stage proximal repair, and one-stage perineal repair were 6.5%, 12.7%, 36.1% and 34.3%, respectively. A further detailed breakdown of each type of revision surgery is depicted in Table 3. After adjusting for age, insurance type, region, surgeon volume and years in practice, a statistically significant association between utilization of caudal block with rates of revision surgery was not found (OR 1.14 CI [0.89−1.5] $p = 0.31$). All the primary repair types (distal, one-stage proximal, and one-stage perineal repair) had significantly higher odds of revision surgery than MAGPI. Distal repair versus MAGPI (OR 2.8 CI (2.0−3.9) $p < 0.001$), proximal repair versus MAGPI (OR 15.5 CI (9.8−24.4) $p < 0.001$) and perineal repair versus MAGPI (OR

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Table 1 Patient and surgery characteristics by primary surgery type.

	MAGPI	Distal Hypospadias Repair	One Stage Proximal HS Repair	One Stage Perineal HS Repair
Primary Surgery (N)	759	2319	230	35
Age (Months)				
Mean (SD)	19.5 (26.7)	16.6 (22.3)	18.3 (20.8)	22.3 (33.1)
Region				
Midwest	204 (26.9%)	919 (39.6%)	58 (25.2%)	13 (37.1%)
Northeast	186 (24.5%)	389 (16.8%)	37 (16.1%)	a
South	331 (43.6%)	787 (33.9%)	69 (30%)	8 (22.9%)
West	38 (5%)	224 (9.7%)	66 (28.7%)	11 (31.4%)
Insurance Type				
Commercial	411 (54.2%)	1277 (55.1%)	116 (50.4%)	11 (31.4%)
Medicaid/Medicare	321 (42.3%)	962 (41.5%)	96 (41.7%)	19 (54.3%)
Self Pay	a	26 (1.1%)	a	a
All Other	24 (3.2%)	54 (2.3%)	15 (6.5%)	a

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Abbreviations: MAGPI, meatal advancement and glanuloplasty; HS, hypospadias; N, number; SD, standard deviation.
[a] Values less than 5 are suppressed to deidentify data.

Table 2 Surgeon volume and years in practice 2009–2010.

	MAGPI	Distal Hypospadias Repair	One Stage Proximal HS Repair	One Stage Perineal HS Repair
Number of Surgeons	44	49	38	13
Surgeon Volume				
Mean (SD)	7.9 (8.5)	24.1 (16.1)	2.4 (3.1)	0.4 (1)
Median (Range)	3.8 (0–27)	20.8 (0–65)	1.2 (0–16.5)	0 (0–5)
Years in Practice				
Mean (SD)	17.3 (10.6)	15.9 (10.1)	16.4 (10.2)	13.2 (6.4)
Median (Range)	16 (0–41)	14 (0–41)	15 (0–41)	13 (4–24)

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Abbreviations: MAGPI, meatal advancement and glanuloplasty; HS, hypospadias; SD, standard deviation.

Table 3 Revision surgery by primary surgery type.

	MAGPI	Distal Hypospadias Repair	One Stage Proximal HS Repair	One Stage Perineal HS Repair
Primary Surgery (N)	759	2319	230	35
Cystoscopy	6 (0.8%)	36 (1.6%)	12 (5.2%)	5 (14.3%)
Dilation or DVIU	a	23 (1%)	10 (4.3%)	a
Meatal Revision	10 (1.3%)	56 (2.4%)	7 (3%)	a
Adhesion	9 (1.2%)	22 (0.9%)	13 (5.7%)	a
Penoplasty or Correction of Skin Chordee	5 (0.7%)	17 (0.7%)	8 (3.5%)	a
Major Revision	21 (2.8%)	181 (7.8%)	52 (22.6%)	8 (22.9%)
Repair of Fistula, Stricture, Diverticula ± skin flaps	21 (2.8%)	150 (6.5%)	44 (19.1%)	6 (17.1%)

-Data from the AAMC-Vizient Clinical Practice Solutions Center®. All rights reserved.
Abbreviations: MAGPI, meatal advancement and glanuloplasty; HS, hypospadias; N, number; DVIU, direct visual internal urethrotomy.
[a] Values less than 5 are suppressed.

29.3 CI (11.8–72.9) $p < 0.001$). Odds ratios for revision surgery following a primary surgery with caudal block are listed (Table 4).

Patients with non-commercial insurance had significantly higher odds of revision surgery **post distal hypospadias repair** (OR 1.37 CI [1.05–1.8] $p = 0.02$). **Post-**proximal and perineal hypospadias repair increased surgeon volume was associated with significantly reduced odds of revision surgery [OR 0.81 CI (0.7–0.94) $p = 0.01$] and [OR 0.48 CI (0.24–0.96) $p = 0.04$], respectively.

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Table 4 Mixed effects logistic regression analysis of rate of revision surgery after primary surgery with caudal epidural block variable.

Primary Surgery	Odds Ratio (95% CI)	P-Value
MAGPI	1.45 (0.61–2.14)	0.67
Distal	1.04 (0.77–1.39)	0.81
One Stage Proximal HS Repair	1.47 (0.74–2.92)	0.28
One Stage Perineal HS Repair	0.82 (0.12–5.87)	0.84

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Abbreviations: MAGPI, meatal advancement and glanuloplasty; CI, confidence interval; HS, hypospadias repair.

Utilization of caudal block for hypospadias repair

Utilization of a caudal block was categorized by primary repair type, MAGPI, distal, one-stage proximal, and one-stage perineal repair, were 36%, 44%, 43% and 29%, respectively.

Utilization of a caudal block was not associated with type of primary surgery ($p = 0.21$). There was also no association of receiving caudal block with insurance type ($p = 0.75$), geographical region in the United States ($p = 0.8$), surgeon volume (OR 0.99 CI [0.97-, 1.0] $p = 0.12$) or increased surgeon years in practice (OR 0.98 CI [0.96–1.0] $p = 0.11$). The reporting of ASA class was insufficient for analysis. Adjusting for all other variables, increased patient age was associated with decreased usage of a caudal block (OR 0.97 CI [0.98, 0.99] $p < 0.001$).

Discussion

The results support the primary hypothesis showing no statistically significant association between caudal block and rates of revision surgery. This analysis disproved the secondary hypothesis that utilization of a caudal block was associated with more complex surgeries such as one-stage proximal or perineal hypospadias repair.

The manuscript that initiated the interest in hypospadias complications after a caudal block included 54 patients [5]. The study was designed to evaluate quality of analgesia rather than postoperative surgical complications. There were relevant variables associated with hypospadias outcomes not included in the analysis such as patient age, surgeon volume, surgeon experience and complexity of repair [18,20,21]. Follow up was only two to four weeks thus missing the majority of complications that manifest much later [18].

Despite skepticism regarding pathophysiologic mechanisms, further published studies suggested an increase in postoperative complication rates after hypospadias repair performed with a caudal block. However, these were single institution observational studies limited to one pediatric urologic surgeon [6,9,10]. The retrospective study by Taicher et al. of 395 patients found usage of caudal block and location of proximal hypospadias were independently associated with postoperative complications after controlling for duration of surgery and surgeon experience [6].

Compared to other studies, the CPSC database is similar regarding mean age and proportion of complex cases. The studied population had a revision surgery rate of 13% whereas complication rates in the literature varied between 5.8% and 28% [6,7,9,11,13]. This multicenter population had a lower rate of caudal block utilization of 42% compared to 58%–87% in the literature. Given that the national use of caudal block has increased yearly, it is possible that the lower caudal block utilization of this study is a reflection of the period, 2009–2010 [2].

The results of this study are consistent with four other investigations which found that caudal block was not associated with postoperative complications [7,8,11,13]. Of note, the current study evaluated rates of revision surgery, not complication rates. Many reported complications (urinary tract infection, hematoma, or vomiting) may not lead to revision surgery [8]. Zaidi et al. performed a nested case–control analysis with more than 6 months of follow up. Forty-five patients experienced postoperative fistula and for every fistula, two controls were randomly selected from a total population of 1647 patients with six surgeons. A subgroup analysis was performed given the disproportionate number of distal cases compared to the control group. The subgroup analysis noted no statistically significant increase in postoperative complications associated with a caudal block. The duration of surgery, which is a correlate of complexity, was associated with fistula formation [8].

Braga et al. reviewed outcomes of 518 patients using the same technique for distal (78%), mid (12%), and proximal (10%) hypospadias repairs by two surgeons. A higher proportion of patients with mid shaft and proximal hypospadias received a caudal block compared to those with distal procedures. Hence, a subgroup analysis of distal repairs was performed, which showed no association of receiving a caudal block with postoperative complication rates [7]. A recently controlled retrospective cohort study examined 983 patients who underwent primary hypospadias repair by 14 pediatric urologic surgeons with a minimum of one year follow up. The multivariable analysis noted only age, surgery duration, and meatal position, but not choice of anesthetic technique, were associated with increased rates of postoperative complication [11].

It was curious that after a primary distal hypospadias repair, patients with non-commercial insurance after adjustment of all other variables in the model had significantly higher odds of a revision surgery. This was seen in a previous study and suggests disadvantaged groups or low income families may have an effect on healing through poor nutrition and stress [18]. In other pediatric cases such as appendicitis or scoliosis fusions non-commercial insurance also showed increased risk of complications [22,23]. Surgical outcomes and the social determinants of health are complex and may have many other confounding factors that are not accounted for in this study. The level of participation by residents and fellows cannot be assessed.

There were only two studies that evaluated utilization of caudal block and complexity of surgery. Braga et al. noted that upon the discretion of the anesthesiologist midshaft/proximal hypospadias received more caudal block than distal hypospadias repairs, 84% vs 67% ($p < 0.05$). However, Adler et al. found no difference in utilization between

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proximal and distal hypospadias repairs, 73% vs 79% ($p = 0.09$). **Prior meta-analyses from Tanseco and Goel revealed association between caudal block and post operative complications rates. However, meta-analyses from Zhu and, most recently in 2022, Adler did not show association with postoperative complication rates.** [14—17] In our study, utilization of a caudal block for primary repair was not associated with complex hypospadias surgeries which contradicts opinions that complexity of surgery drives the anesthesiologist and/or surgeon to recommend a caudal block [6,24]. As expected, we did find that utilization of a caudal block decreased with increased patient age. This was consistent with the pediatric regional anesthesia network study [25].

The strength of this study is the multicenter source with a large cohort. Benefits of evaluating multiple institutions include different geographic regions with the inclusion of a wide range of population groups (genetic, environmental, and ethnic or cultural background). There are several limitations of the study inherent in retrospective analyses. First, even though this database is comprised of many different institutions with 50 surgeons, one cannot account for practice patterns that may bias the data. A surgeon may delay treatment of a complication. Yet, the 9—11 years follow up period should obviate this factor. Second, some editorials have suggested that with the variability in phenotype and surgical technique, a single surgeon study might limit bias compared to multiple surgeons [24,26]. We attempted to address this with a multivariable regression model that included complexity of repair, surgeon volume and surgeon years in practice. Some revision surgeries that were included in this analysis, such as penoplasty and adhesiolysis, do not fit under the proposed pathophysiologic mechanism of caudal anesthesia. Yet, these represented less than 2% of revisions and most patients, who had these codes, had more than one revision CPT code. Institutions that did not post anesthesia billing were excluded and this may or may not add bias. Although most surgeons would perform a penile block, when a caudal is not placed, the dataset does not provide information on whether the surgeon placed a penile block.

Conclusion

This large, multi-institution study demonstrates that the use of a caudal block was not associated with more complex hypospadias surgery. There was also no association with insurance type, geographic region, increased surgeon years in practice or surgeon volume. Increased patient age was associated with decreased usage of a caudal block. Most importantly, when other variables are controlled, utilization of caudal block for pediatric males undergoing hypospadias surgery is not statistically significantly associated with rates of revision surgery.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Acknowledgments

None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jpurol.2023.02.004.