Effects of Caudal and Penile Blocks on the Complication Rates of Hypospadias Repair

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Background: The major influencing factors for complications during hypospadias repair are the original location of the meatus, previous urethral surgery, surgical technique, and surgeon's experience. While the effect of the technique of regional analgesia on complication rates has been considered in some studies, this issue remains controversial.

Aims: To determine the effect of caudal block and penile block on complication rates of hypospadias repair in patients with subcoronal hypospadias.

Study Design: Retrospective cross-sectional study.

Methods: Data of children who underwent hypospadias repair between 2011 and 2019 in our clinic (n = 770) were reviewed retrospectively. Only patients with subcoronal hypospadias and who underwent tubularized incised plate urethroplasty, performed by the same two experienced surgeons (n = 279), were included in the study. The exclusion criteria were incomplete data and follow-up time

shorter than 12 months. Data of 279 patients were analyzed. Patients were divided into two groups according to the analgesia type: caudal block (n = 95) and penile block (n = 184), and complication rates were compared between these groups.

Results: The median age was 36 months in the caudal block group and 30 months in the penile block group ($P = 0.390$). The median follow-up times were 54 and 42.7 months in the caudal and penile block groups, respectively. Total complication rates did not differ significantly between the groups and were determined as 10.5% and 12.5% in the caudal and penile groups, respectively. Urethrocutaneous fistula rates were observed as 2.1% and 4.3% (p=0.50). None of the patients had penile chordee and no penile plication was performed in the whole group.

Conclusion: This study shows that there is no increase in post-repair complications in patients with subcoronal hypospadias who underwent caudal block.

INTRODUCTION

Hypospadias is a congenital urethral abnormality that occurs in 1 of 150-300 births.[1] Hypospadias repair is the most commonly performed surgical procedure in pediatric urology. However, it is a highly technical procedure, which still results in significant complications such as meatal stenosis, urethral fistula, strictures, and dehiscence. The main risk factor for these complications is the original location of the meatus.[2] Other factors that may affect repair

outcomes are age at the time of surgery, urethral chordee, groove and width of the urethral plate, diameter of glans, history of urethral surgery, experience of the surgeon, urethral catheter, dartos flap, spongioplasty, suture type, presence of midline raphe deviation, and use or non-use of tourniquet.[3,4] Urethrocutaneous fistula is the most common complication of hypospadias repair.[1] Kundra et al.[5] reported a prospective study in 2012 with higher rates of urethrocutaneous fistula in patients undergoing hypospadias repair under caudal block

(CB). Then, the debate in the literature began, and the effect of the regional analgesia technique on complication rates of hypospadias repair has been discussed.[5-15]

Penile block (PB) had been reported as a safe procedure with mild complications such as hematoma and bleeding.[16] A penile nerve block provides better postoperative analgesia than a CB.[17,18] However, CB is another safe, effective, and reliable analgesia technique. It is widely recommended for sub-umbilical procedures in children[19] and causes less blood loss during hypospadias repair.[20] Notwithstanding, it may cause penile enlargement because of vasodilation and the pooling of blood in the venous sinuses of the penis.[21] It is disputed whether these factors cause poor wound healing and urethrocutaneous fistula.

The majority of the studies have shown that complications after hypospadias repair depend on the severity of hypospadias, age at the time of surgery, and surgical technique.[18,22,23] Most of the studies have represented different CB and non-CB groups in terms of these major factors. In contradistinction to the literature [23,24], we included only one surgical technique and only one hypospadias type. This retrospective cross-sectional study aimed to determine the effects of PB and CB on complication rates after hypospadias repair with two homogenous groups in terms of age, hypospadias severity, and surgical technique.

MATERIALS AND METHODS

Institutional review board approval was obtained before chart review and data analysis. Informed consent was provided by the parents of all patients. The records of children who underwent hypospadias repair between 2011 and 2019 in our clinic were reviewed. Patients with subcoronal hypospadias who underwent tubularized incised plate urethroplasty (TIPU), performed by two senior pediatric urologists (first and last authors), were included in the study. Patients treated with another technique or by other surgeons were excluded. Other exclusion criteria were coronal, midshaft, penoscrotal, and scrotal hypospadias, incomplete data, and follow-up time shorter than 12 months. The type of the hypospadias depending on the meatal position was considered regardless of the division of the spongiosum. There were 742 patients with complete data and adequate follow-up. Twenty-eight patients with incomplete data due to failed follow-up were not documented. Of the 742 patients with hypospadias, 279 who underwent surgery during the study period were included (Figure 1). Data collected included age, type of hypospadias, year of the operation, surgeon, follow-up time, complications, and perioperative analgesia.

Patients were divided into two groups according to the analgesia type: CB (n = 95) and PB (n = 184) groups. The overall complication rate and urethrocutaneous fistula rate were compared between the groups.

All patients underwent surgery within 9 years. Statistical analysis by using the Chi-square test for each year is not suitable. Then, we divided the operation years into two groups: 112 patients who underwent surgery in the first 4 years; therefore, the first 4 years were considered the "first years," and the other 5 years were considered the "last years."

Operative Technique

The same technique was used by two surgeons. All procedures were performed under general anesthesia. Antibiotic prophylaxis was applied intravenously 1 h preoperatively. The procedures started with a U incision around the hypospadiac meatus ending on both sides of the plate. Degloving and dissection of the glanular wings were performed. A deep midline incision limited inside the urethral plate was performed. Then, the urethral plate was tubularized over 6- or 8-Fr urethral catheter in two layers: the first layer with continuous subcuticular 7/0 Vicryl sutures and the second layer with interrupted subcuticular 7/0 Vicryl sutures. A pedicle flap from the dartos fascia was prepared and placed on the neourethra to cover it. Glanuloplasty was performed with 6/0 PDS sutures. Tourniquet was used, and the glanular wings were dissected for <15 min. Subcutaneous administration of epinephrine was not used in any of the patients during surgery.

PB was performed at the end of the procedure by the surgeon using 0.25% bupivacaine, with 1 mg/kg per dose. We prefer to perform PB at the end of the procedure to prevent extravasation in the tissue of the dissection area. CB was performed preoperatively by an anesthesiologist with 0.25% bupivacaine at 1 ml/kg.

Hospitalization and Follow-up

All patients were hospitalized for at least 3 days, and the urethral catheter was removed on postoperative day 7. After discharge, patients were followed up regularly in the outpatient clinic at 1 week, 1 month, 3 months, and later once in 3 months for the first year. After the first year, follow-up was continued once every year.

Statistical Analysis

Data were analyzed retrospectively using IBM SPSS Statistics for Windows, version 28 (IBM Corp., Armonk, NY, USA). Quantitative variables are presented in numbers as mean or median (standard deviation [SD]). All p values of <0.05 were considered significant. The Mann-Whitney U test was used to compare quantitative data. The Chi-square test and Fisher's exact test were used to compare categorical variables between the CB and PB groups and between patients with and without complications.

RESULTS

Data of 279 patients with subcoronal hypospadias (CB group, n = 95; PB group, n = 184) were analyzed (Figure 1). No significant difference was found between the two surgeons in terms of complication rates ($P = 0.847$). The median age was 36 months in the CB group and 30 months in the PB group (Table 1). No significant difference was found in age between the groups ($P = 0.390$).

The median follow-up time of the study population (n = 279) was 47 months (Table 1). This period was 54 and 42.7 months in the

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CB and PB groups, respectively, and the difference was significant ($P < 0.01$) (Table 1).

None of the patients had penile chordee, and no penile plication was performed in this study group.

The only associated anomalies in this study group were undescended testis and hydronephrosis. In these groups, no patients had disorders such as spinal dysraphism or connective tissue disorders that could affect the use of CB.

There were 10 complications in the CB group and 23 complications in the PB group (Table 1). No significant difference was found in the complication rate between the groups ($P = 0.773$). A urethrocutaneous fistula was observed in two patients of the CB group and eight patients of the PB group; however, this difference was not significant ($P = 0.503$).

Another analysis was performed because of the complication status (present or absent). Independent risk factors such as age, years, surgeon, and CB vs. PB were analyzed because of complication status (Table 2). No significant difference was found between patients with and without complications (Table 2). Therefore, the logistic regression test was not performed.
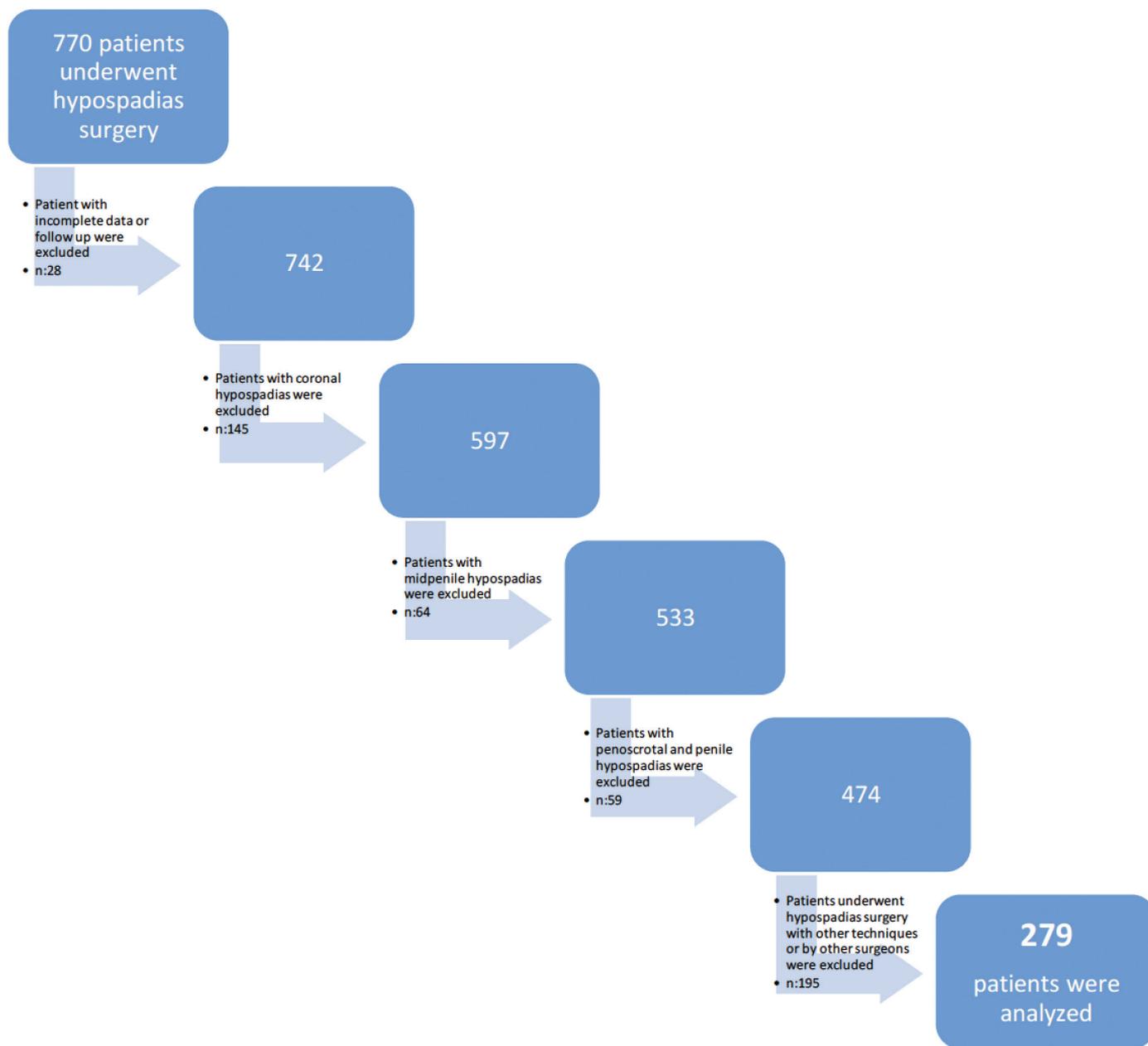

FIG. 1. Distribution of the patients (flow chart)

DISCUSSION

Our study results revealed that CB and PB have no significant effect on the complication rates after TIPU in patients with subcoronal hypospadias. Owing to the major influence of factors such as surgical technique, surgeon's experience, and severity of hypospadias, we designed two homogeneous groups for comparison of the effect of CB on complications after hypospadias repair. Since "age at the time surgery" is another important risk factor, it was important to have similar groups in this regard. No significant difference was found between groups in terms of age at surgery in our study.

The complication rate after hypospadias repair ranged from 5% to 63%.[22] However, the major risk factors for these complications were the severity of hypospadias, history of urethral operation, correction technique, and surgeon's experience.[3,10,22] Studies have discussed the effect of CB and PB on the complication rates of hypospadias repair as a risk factor in recent years.[5,15]

TABLE 1. Demographic Features of the Patients and Complications in the Caudal and Penile Block Groups

		Caudal block (n = 95)	Penile block (n = 184)	Total (n = 279)	P value
Age (months)	**Mean**	48.2	42.2	44.3	0.390[a]
	Median	36	30.5	33	
	Min-max	6-184	6-194	6-194	
	Standard deviation	39	34.2	36	
Follow-up time (months)	**Mean**	56.4	43.7	48.1	<0.001[a]
	Median	54	42.7	47	
	Min-max	20.7-99	13.2-98.1	13.2-99	
	Standard deviation	13.6	18.8	18.2	
Clavien Dindo Classification	**Complications**	**n/%**	**n/%**	**n/%**	
III[a]	**Meatal stenosis**	2/2.1%	3/1.6%	5/1.7%	1.0[b]
III[b]	**Urethral stenosis**	1/1.05%	4/2.1%	5/1.7%	0.664[b]
III[b]	**Urethrocutaneous fistula**	2/2.1%	8/4.3%	10/3.5%	0.503[b]
III[b]	**Urethral diverticula**	0	3/1.6%	3/1%	0.553[b]
III[b]	**Urethral dehiscence (Partial/complete)**	5/5.2%	4/2.1%	9/3.2%	0.281[b]
III[b]	**Chordee**	0	1/0.5%	1/0.3%	1[b]
	Complication rates	10/10.5%	23/12.5%	33/11.8%	0.773[c]

[a]Mann-Whitney U test was used for statistics.
[b]Fisher's Exact Test.
[c]Yates Chi-square test was used for statistical analysis.

TABLE 2. Comparison of the Independent Risk Factors Due to Complication Status (Present or Absent)

		Complication (-)			Complication (+)			Total	P values
		Mean ± SD / n-%		Median	Mean ± SD / n-%		Median		
Age (month)		44.7 ± 36.3		34.5	41.1 ± 34.1		27.0		0.430[a]
First years		99	88.4%		13	11.6%		100%	0.925[b]
Last years		147	88.1%		20	11.9%		100%	
Surgeon	**A**	25	10.2%		3	9.1%			0.847[b]
			89.3%			10.7%		100%	
	B	221	89.8%		30	90.9%			
			88%			12%		100%	
Method	**Caudal block**	85	34.6%		10	30.3%			0.773[b]
			89.5%			10.5%		100%	
	Penil block	161	65.4%		23	69.7%			
			87.5%			12.5%		100%	

[a]Mann-Whitney U test was used for statistics.
[c]Yates Chi-square test was used for statistical analysis.

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Kundra et al.[5] reported the first study in this issue in 2012, i.e., a prospective, randomized, double-blinded study with 27 patients in the CB group and 27 patients in the PB group. In this study, a 27% increase in penile volume from the baseline at 10 min post-CB compared with the 2.5% increase in patients who received PB was observed. In addition, all children with urethral fistula belonged to the CB group. Kundra et al.[5] concluded that CB, due to penile enlargement, is one of the causes of fistula formation. This study initiated a debate on whether CB is a risk factor for complications of hypospadias repair. Similarly, Kim et al.[7] reported 342 patients who underwent TIPU and found that the complication rates of patients receiving CB were 2.1 times higher than the rates of those not receiving CB. They emphasized that the independent risk factors associated with the complications were surgical duration, CB, and hypospadias type (midshaft and proximal).[7] Taicher et al.[11] also reported that caudal analgesia was highly associated with complications after hypospadias repair. The mechanism of complications after hypospadias repair due to CB is unclear; however, CB causes penile enlargement, which may result in inadequate wound healing. Central neural blockade, such as caudal anesthesia, may lead to the reduction of sympathetic activity; therefore, the decrease in vascular tone may result in pooling in the venous system of the lower body, perineum, and penis.[11] According to Kundra et al.[5], increased venous pooling may explain the penile enlargement after CB. However, no evidence-based data prove that CB results in penile edema.[6] Goel et al.[15] conducted a meta-analysis and showed the association between CB and complications after hypospadias repair; nevertheless, the report observed bias in published studies in the literature.

By contrast, Zaidi et al.[8] reported 135 patients who underwent distal hypospadias repair using the TIPU technique by six surgeons, which included 45 patients with fistula and 90 controls without fistula. They determined that CB or PB is not a risk factor for fistula formation. Braga et al.[10] also reported that the risk of surgical complications of hypospadias repair is mainly associated with the severity of hypospadias rather than the analgesia technique. In another retrospective analysis of 70 patients (CB, n = 33; non-CB, n = 37), fistula formation was seen in five patients, and no association between the CB and fistula formation was determined.[12] However, Ngoo et al.[13] reported a prospective study of the experience of eight surgeons and determined that penile nerve block was a risk factor for re-operation following distal hypospadias repair. In a systematic review and meta-analysis, Zhu et al.[18] reported that CB is safe for hypospadias repair with equal success rate and analgesia comfort after distal hypospadias repair, whereas CB appears to have better outcomes after proximal hypospadias repair but emphasized that the reviewed studies have selection bias.

The complication rate in our series was 9.4% and 11.9% in the CB and PB groups, respectively. The difference was not significant ($P < 0.05$). Urethrocutaneous fistula was observed in two patients in the CB group and eight patients in the PB group, but this difference was not significant ($P > 0.05$). Our results demonstrated that the selection of CB or PB did not affect the complication rates of hypospadias repair in patients with subcoronal hypospadias. Additionally, the numbers were slightly higher in the PB group

than in the CB group in case of complications, but the difference was not significant.

Urethral diverticulum was seen in 1.6% of the cases in the PB group. It is an interesting complication after TIPU repair, which was also experienced by some other surgeons according to personal communications; however, it was not mentioned in previous literature. This complication is possibly caused by insufficient corpus spongiosum or inadequate dartos flap lay on the neourethra.

Urethral chordee may be seen with distal hypospadias.[25] No patients had urethral chordee in this study group. We only included 279 of 770 patients, which may be due to our strict exclusion criteria. Some cases of mild chordee may have been overlooked preoperatively.

The timing of the CB, before or after the procedure, maybe also an important factor. Kundra et al.[5], who determined an association between CB and fistulas, administered CB perioperatively; however, Kreysing and Höhne[12], who did not find an association between CB and fistula formation, performed CB at the end of the hypospadias repair. In our center, CB is administered before the hypospadias repair. However, we did not evaluate whether this factor affects the outcome.

We prefer to perform PB at the end of the procedure to prevent extravasation in the tissue of the dissection area, based on a study that observed no difference in the analgesia effect between groups of patients who underwent PB before and after hypospadias repair.[26]

In the literature, the follow-up time after hypospadias repair is commonly less than 12 months[8,10,11] and is rarely reported longer than 1 year.[12,14] Pfistermuller et al.[4] published a meta-analysis of complication rates of TIPU and determined that urethral fistula presents 42% after 6 months postoperatively, 31% after a year, and 23% after 2 years. Despite the reduction in the complication rate after 6 months postoperatively[27], the risk remains.[4,22,28] Therefore, we reviewed patients who had a follow-up of more than 1 year. The median follow-up time of the patients in our report was 47 months.

Impairment in micturition is another side effect of CB after hypospadias repair.[29] In our series, all patients were catheterized with 8-Fr catheters for 7 days. Thus, we did not observe such a micturition problem after CB.

Splinter et al.[23] assessed the effect of anesthesia technique on complications after hypospadias repair and determined that only surgical technique and hypospadias type affect the complications of hypospadias repair. Most studies have included more than one surgical technique for hypospadias repair.[5,8,13,14,29] As the surgical technique is a major factor that affects the outcomes of surgery,[3,9] we reviewed only patients who underwent TIPU. The incidence of complications after hypospadias repair ranges from 5% for distal hypospadias to 63% for proximal hypospadias.[22,30] This huge range of complication rates is significantly due to the inclusion of different groups in terms of hypospadias type in most studies.[7,11] Therefore, the difference in the type of hypospadias in the CB and non-CB groups may affect the outcome. In this study, we reported

only data from patients with subcoronal hypospadias to eliminate this limitation and selection bias. To eliminate the influence of surgeon's experience, surgeries performed by only two expert surgeons have been analyzed in our study. No significant difference was found between these expert surgeons in terms of complication rates ($P = 0.847$).

In some clinics, CB is not preferred for older children; therefore, the CB and non-CB groups become non-homogeneous in terms of age at the time of surgery.[23] The age at the time of surgery, which is considered an important risk factor for outcomes, affects the analysis of the effect of the block type on complications after hypospadias repair.[24] Therefore, it is important to have similar groups in terms of age at surgery while comparing the effect of CB and PB on complications of hypospadias repair. Our study groups were similar in terms of age, chordee, and use of tourniquet or epinephrine. Braga et al.[9] described these limitations in the literature to determine the effect of CB and PB on complications after hypospadias repair; therefore, we designed the most homogenous groups from our documents.

This study has some limitations. First, the study followed a retrospective design. Second, because of nearly similar fistula rates in the groups, 1005 patients had to be included in this study to achieve an 80% power. This number of patients is very difficult to reach; this is also more than the numbers reported in most of previous studies. Therefore, we prefer to analyze only patients with subcoronal hypospadias who underwent only TIPU by the same two surgeons to provide a more homogenous study group. We included 279 patients of 742 patients to provide homogeneous groups in many aspects. Third, analyzing only the data from patients with subcoronal hypospadias limits the power of this study. Notwithstanding, the number of patients in both groups is sufficient for commenting on the results. Fourth, we could not reach the information about penile lengths, such as the diameter of the glans and width of the urethral plate in all patients, and duration of the surgery; therefore, we did not include these factors in the analysis. Fifth, there was no documented information about pain control after CB and PB. Although the main issue in this study is not pain relief, this may be another limitation. Further studies with prospective design, including all types of hypospadias with a sufficient number of patients, analyzed in subgroups and comparing each complication between groups separately are required.

In conclusion, our study suggests that both the total complication rates and urethrocutaneous fistula rates are not influenced by analgesia technique (CB vs. PB) after hypospadias repair. Therefore, it appears that CB is not a risk factor for complications after TIPU in patients with subcoronal hypospadias.

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