Pediatric Anesthesia and Critical Care Journal 2018;6(2):68-76
doi:10.14587/paccj.2018.11

PACCJ

Regional techniques for paediatric inguinal scrotal surgery. A randomized non-inferiority trial comparing low concentration caudal block versus ilioinguinal and iliohypogastric nerve block.

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Keypoints

Using the traditionally recommended 0.25% bupivacaine/levobupivacaine dose of local anaesthetic for caudal block leads to a significant incidence of motor block and urinary retention. The use of a lower concentration, 0.125% levobupivacaine provides non-inferior pain relief compared to ilioinguinal/iliohypogastric blocks. Motor block immediately post recovery is still present, but recovers rapidly. No participants suffered from urinary retention as a side effect of low concentration caudal blocks.

Abstract

Introduction

We have designed a prospective, randomised, single blinded non-inferiority trial to determine whether using a lower concentration local anaesthetic in caudal blocks (0.125% levobupivacaine) provides non-inferior analgesia compared to IG/IH blocks with fewer side effects.

Material and methods

We recruited 82 patients for our study at Medway Maritime Hospital. The intervention was caudal block with 0.125% levobupivacaine with clonidine as an additive compared with USS guided IG/IH nerve blocks. Our primary outcome measure was post-operative pain and our predefined non-inferiority margin was a 15% difference in pain. Secondary outcomes included rescue analgesia, motor block, time to discharge and micturition.

Results

80 patients were included in analysis (caudal n=40, IG/IH n=40). We found a 5% absolute decrease in post-operative pain after low concentration caudal blocks compared to IG/IH blocks (95% CI -19.5 to 9.5, p <0.01) demonstrating non-inferiority. There was no evidence of non-inferiority for motor block, with 12.5% more patients experiencing motor block in the caudal group immediately following recovery from general anaesthetic (95% CI -2.4 to 28.4 p=0.379 for non-inferiority). Of these, 2 patients receiving caudal blocks (5%) had remaining motor block on the ward which recovered by discharge.

Conclusions

Our study shows non-inferiority between low concentration local anaesthetic in caudal blocks compared with USS guided IG/IH nerve blocks for analgesic benefit and requirement for post-operative analgesia. We suggest 0.125% levobupivacaine for anaesthetists who use caudal blocks in their practice. This technique demonstrates non-inferiority compared to USS guided IG/IH blocks.

Keywords

Anesthesia, caudal; nerve block; pain, postoperative; analgesia; children; general surgery.

Introduction

Regional anaesthesia, in combination with a general anaesthesia, is a commonly employed technique in paediatric inguinal scrotal surgery, with the two most common forms being caudal epidural blocks and ilioinguinal/iliohypogastric (IG/IH) nerve blocks [1,2]. The ideal regional technique provides good analgesia intra and post-operatively, thus also reducing opioid use [3]. It should also carry minimal side effects and have a very low risk of complications. In addition, it has recently been recommended that 75% of elective surgery be performed as day cases, therefore any anaesthetic technique selected should also support same day discharge [4].

Caudal epidural blocks are commonly used by 92% of paediatric anaesthetist and have been shown to be easy to learn and perform by trainees [2,5]. Complications are rare and the failure rate is documented as very low at around 3% [6,7]. However, in the literature, caudal blocks are associated with significant motor block and urinary retention [8,9]. Ultrasound (USS) guided IG/IH blocks are also a commonly used technique, but requires more skill and proficiency by the operator. The use of USS has allowed more accurate anatomical placement of local anaesthetic and has superseded the landmark technique [10,11]. In order to ensure complete anaesthesia to the inguinal region, a genitofemoral nerve block should also be administered by the surgeon under direct visualisation.

In current literature, superiority of neither IG/IH nor caudal blocks has been convincingly demonstrated. One meta-analysis found that caudal blocks reduced the requirement of early rescue analgesia, but that the incidence of motor block and urinary retention was significantly higher [8]. Another meta-analysis concluded no significant difference between post-operative pain score between the two [9].

There is some evidence that using a concentration lower than the recommended 0.25% levobupivacaine/bupivacaine may reduce the incidence of motor block and urinary retention following caudal blocks [12,13]. However, the lower concentration can lead to a shorter duration of analgesia. No additives were used in the cited studies, however, this research team regularly uses clonidine as an additive in all paediatric caudal blocks. We hope that this will provide long lasting analgesic benefit with few adverse effects such as urinary retention and motor block. We hypothesise that using the above cocktail in caudal blocks will be non-inferior to USS guided IG/IH blocks to a predetermined non-inferiority margin, which have also proven to be an excellent regional technique. We have designed a prospective, randomised, single blinded non-inferiority trial consisting of 80 paediatric patients who were scheduled for elective inguinal scrotal surgery at Medway Maritime Hospital. Recognising that choice of anaesthetic technique is often individual to the paediatric anaesthetist involved, we do not aim to demonstrate superiority of either technique. We have therefore used the format of a non-inferiority clinical trial to demonstrate that using a lower concentration in caudal blocks is no worse than USS guided IG/IH blocks.

Material and Methods

Study design

This trial is a single-centre, prospective, single-blinded randomised non-inferiority trial. It was approved by the NHS Health Research Authority, IRAS number 205800 in October, 2016. Local R&D approval was received to perform the trial in the day surgery unit of Medway Maritime Hospital.

Patients

Children eligible to participate in the paediatric regional block trial were identified and introduced to the study via written documentation in the pre-operative assessment clinic. Patients were included if they were between the age of 1 month and 16 years, undergoing elective day case inguinal scrotal surgery. Patients were excluded if they had contraindications to either nerve or epidural block such as coagulopathies, allergy to local anaesthetic or parent or patient refusal.

On the day of surgery, written informed consent was obtained from parents, either by the consultant anaesthetist assigned to the list or one of the investigators. If consent was obtained by the latter, the patients' anaesthetic consultant was present during consent.

Randomisation and blinding

Patients were randomised in a 1:1 ratio to receive either a caudal epidural block, or an IG/IH block. The research investigators provided opaque, sealed, unmarked envelopes in a folder on the day surgery unit to the consultant anaesthetists assigned to the paediatric surgery list. These envelopes contained a slip of paper which specified either caudal block or IG/IH block in a 1:1 ratio. Following written consent, the anaesthetist chose an envelope at random and the block specified on the slip of paper was performed.

The trial was single blinded and the parents and children were not informed of which block they had received. During the consent process, both caudal and IG/IH blocks were explained to the parent and they were informed that their child would be randomised to receive either of the two. The consultant anaesthetist, recovery and paediatric nurses were not blinded to the block received.

Intervention

Patients all received a general anaesthetic prior to the intervention. Both blocks were performed with an aseptic technique.

Patients randomised to receive a caudal block were placed in left or right lateral position. 0.125% levobupivacaine at a volume of 1.5ml/kg and clonidine at 1mcg/kg was prepared and injected via the caudal epidural route using a 20 or 22 gauge Abbocath catheter, using a landmark technique.

Patients randomised to receive an IG/IH block remained supine following induction of general anaesthesia. A linear USS probe was placed 1 to 1.5cm above the superior anterior iliac spine. The ilioinguinal and iliohypogastric nerves are located between the internal oblique and transverse abdominis muscles. A solution of 0.25% levobupivacaine at a volume made up to 2mg/kg was injected under direct vision with USS via a 21 gauge SonoPlex Pajunk® cannula. In patients receiving IG/IH block, a genitofemoral nerve block was also administered. This occurred under direct visualisation by the surgeon intra-operatively. 1-1.5ml of 0.25% levobupivacaine was administered.

All patients were induced using either an inhalational or intravenous induction according to anaesthetist and patient choice. Children were maintained with sevoflurane, oxygen and air and received intravenous paracetamol according to body weight intra-operatively. Intravenous morphine was not routinely given to any children during the operation, if required, it was given on incremental doses of 0.1mg/Kg based on physiological parameters. It was also prescribed post-operatively to be administered by recovery staff according to their discretion.

Outcomes

The primary outcome measure for this study was presence of post-operative pain. We defined this as a binary outcome and a FLACC scale or VAS scale of more than 1 indicated the presence of pain. In preverbal children, the FLACC scale was used [14,15]. In verbal children, the VAS score was used [16,17].

Secondary outcome measures included requirements for post-operative opioid analgesia prior to discharge home. This was given at the discretion of the paediatric or recovery nurses following assessment of pain. Other secondary outcome measures include presence of motor block, post-operative nausea and vomiting, time in minutes from entering recovery to passing urine and discharge home.

Motor function was measured as a binary outcome with a Bromage score of less than 4 indicating motor block. Bromage score was measured immediately after emergence of anaesthesia. If full motor function was not witnessed, repeatedly hourly assessment was performed by the anaesthetist until full function was regained.

Children on the day surgery unit routinely follow nurse led discharge at Medway Maritime Hospital.

Exceptions to this include any anaesthetic or surgical complications or pre-existing conditions requiring overnight stay.

Statistical Analysis

An intention-to-treat analysis was performed for this study and patients who were randomised to either block were included in the final analysis, regardless of block failure.

A non-inferiority margin of 15% was selected. This was based on a meta-analysis where approximately 30% of patients receiving both caudal and non-caudal blocks had post-operative pain with no significant difference between either method [8]. This was halved to 15% as the non-inferiority margin, as it was judged that 15% absolute difference in positive pain scores between caudal and IG/IH blocks was not clinically relevant. The non-inferiority margin was also applied to the domain of rescue analgesia and bromage score.

The primary outcome is presented as the absolute difference in percentage of patients with pain following either caudal or IG/IH blocks with 95% CIs. Non-inferiority is shown, if the lower limit of the CI does not cross the non-inferiority margin of 15%. Risk ratios and 95% CIs are also shown. The non-inferiority principle was applied to the primary outcome and secondary outcomes of rescue analgesia and motor block. Student's t-test was applied to the outcomes of time to discharge and time to micturition to determine superiority. A one-sided significance level of 0.025 was used for non-inferiority analyses, and a two-sided significance level of 0.05 was used for superiority analyses.

Subgroup analyses were carried out for the primary outcome of post-operative pain for ages <4 and ≥4 years, type of procedure (orchidopexy, PPV ligation or herniotomy) and weight <15kg and ≥15kg. The age 4 years and weight of 15kg was chosen as these were the median values for children recruited to the study. Statistical analysis was not applied due to the low number in each subgroup.

*Sample size calculation*A calculation of sample size showed that 78 patients were required, to detect post-operative in pain in 20% of patients with a power of 50% and a significance value (alpha) of 5%. This was rounded up to 80 patients in total allowing for two patient drop-outs, with 40 patients randomised to each block group. For the power calculation, we assumed that the incidence of post-operative pain in both groups would be around 20%, based on a 2013 meta-analysis by Baird et al. which showed that around 23% of patients required supplemental analgesia post-operatively following caudal injections [9].

A power level of 50% was selected as increasing the power to 80% gave us a sample size of 176 and was not practically achievable for our research site.

Results

Results were collected over a period of 17 months from November 2016 to March 2018. A total of 82 patients were recruited with 42 patients randomly allocated to the caudal group and 40 patients randomly allocated to the IG/IH group. 2 patients were excluded from the caudal group due to failure to adhere to protocol (clonidine not given as additive). No patients were lost to follow up. A total of 80 patients were included in analysis with 40 patients in either group (table 1 and figure 1)

Table 1. Baseline characteristics

	Caudal (n=40)	**IG/IH (n=40)**
Mean age in years	3.9	4.0
Median age in years (range)	3.5(0.4-11)	3(0.3-15)
Male gender (%)	36(90)	39(98)
Mean weight (kg) (range)	17.5(6.5-36.5)	17.6(3.8-73)
Operation		
PPV ligation	13	12
Orchidopexy	17	14
Inguinal hernia repair	9	10
Other	1	4
ASA		
1	35	33
2	4	2
3	1	5
Induction		
Gaseous induction	30	35
IV induction	4	2

Pediatric Anesthesia and Critical Care Journal 2018;6(2):68-76
doi:10.14587/paccj.2018.11

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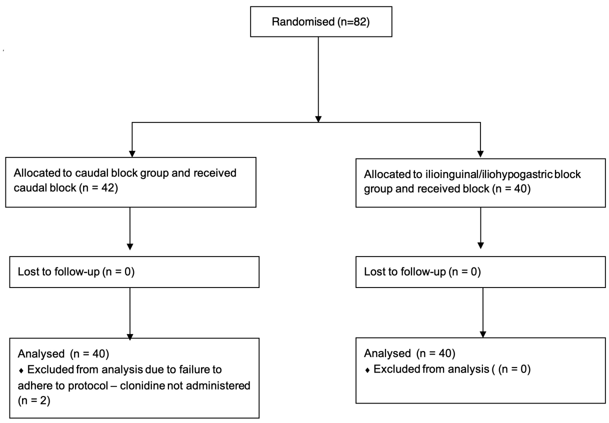
Intraoperative		
Mean fluids received (ml/kg)	12.1	13.5
Intraoperative analgesia		
Fentanyl/alfentanil (%)	28 (70)	32(80)
Paracetamol (%)	38(95)	39(97.5)
Intraoperative anti-emetics		
Ondansetron	39 (97.5)	38(95)
Dexamethasone	39(97.5)	38(95)

Figure 1. Consort diagram representing flow of patients through study



As seen in Table 1, baseline characteristics are largely comparable in terms of mean and median age and weight. By chance, there were slightly more males in the caudal group. The IG/IH group appears to have slightly more ASA 2/3 patients. The most common co-morbidity was ex-prematurity.

Primary outcome measure

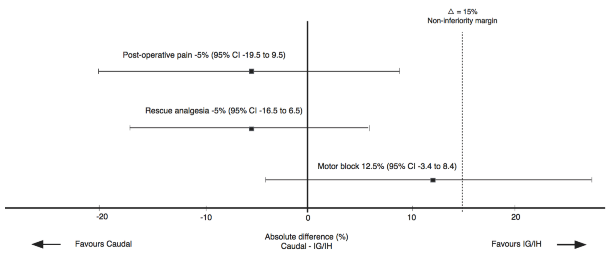
Statistically significant non-inferiority was shown for post-operative pain between the IG/IH and caudal groups. 5% fewer patients had pain in the caudal group compared to the IG/IH group, with the upper border of the 95% CI falling at 9.5%, which was within the predetermined non-inferiority margin of 15% (*p* <0.01 for non-inferiority).

Secondary outcome measures

Results for the requirement of rescue analgesia supports findings from the primary outcome. 5% fewer patients required further analgesia consisting of oral or IV opioids in the caudal block group. The upper border of the 95% CI is 6.5%, also lying within the non-inferiority margin (*p* <0.001 for non-inferiority).

Regarding post-operative motor block, 12.5% more patients in the caudal group experienced motor block immediately following recovery from anaesthesia (9 children in the caudal group versus 4 children in the IG/IH group), with no evidence of non-inferiority (p=0.379). The research anaesthetists revisited all patients with recorded motor block in recovery 1 hour later. Out of the 13 patients with motor block, all but 2 (both caudal block group) regained full motor function appropriate to their age (figure 2).

Figure 2. Non-inferiority diagram for primary and secondary outcome measures



These 2 patients were both observed on the paediatric day care ward and later discharged home. No patients required overnight stay due to motor block. Children receiving caudal blocks passed urine an average of 26 minutes later than the IG/IH group, a finding which was non-significant (p=0.11). Time to discharge was longer by 29 minutes in the caudal group and was found to be statistically significant (p=0.03). Four children stayed overnight, of which two overnight stays were planned. The two planned overnight stays were due to pre-existing conditions or parental request. One child had an unplanned admission overnight (caudal block group) as they required IV morphine due to pain and therefore stayed overnight for observation. One child stayed overnight due to a delay in passing urine (IG/IH block group). All four children were discharged home the following day with no further problems.

Table 2. Primary and secondary outcome measures Absolute difference in percentage for post-operative pain and requirement for rescue analgesia, error bars represent two-sided 95% confidence intervals

	Number (%)		Absolute difference (%)	Risk ratio	*p* value for non-inferiority
	Caudaln =40	IG/IH n=40	Caudal – IG/IH (95% CI)	Caudal/IG/IH (95% CI)	
Pain	4(10)	6(15)	-5 (-19.5 – 9.5)	0.67 (0.20 – 2.18)	0.003
Rescue analgesia	2(5)	4(10)	-5 (-16.5 – 6.5)	0.50 (0.10 – 2.57)	<0.001
Motor block	9(22.5)	4(10)	12.5 (-3.4 – 28.4)	2.25 (0.75 – 6.71)	0.379
PONV	1(2.5)	1(2.5)	0		
	Time (min)		Absolute difference		*p* value
	Caudal	IG/IH	IG/IH – Caudal (min)		
Mean time to micturition (range)	160	134	-26		0.11
Mean time to discharge (range)	193	164	-29		0.03

Subgroup analysis

An attempt was made at subgroup analysis with regards to age, weight and type of procedure. Caudal blocks appear to be more effective for younger children. This is supported by the fact that children who weigh less are likely to have less pain following a caudal block. IG/IH blocks did not follow the same pattern. As the numbers collected within each subgroup were very small, statistical analysis was not attempted.

Table 3 subgroup analysis of pain and motor block

	Number with pain (%)		Number with motor block (%)	
	Caudal	IG/IH	Caudal	IG/IH
Age <4 years (n=43)	0 (0)	4 (17.4)	5 (25)	2 (8.7)
Age ≥4 years (n=37)	4 (20)	2 (11.8)	4 (20)	2 (11.8)
Weight <15kg (n=39)	1(5.6)	4(19.0)	3 (16.7)	2 (9.5)
Weight ≥15kg* (n=3	3 (15)	2(10.5)	6 (30)	2(10.5)
Type of procedure				
Orchidopexy (n=31)	2(11.8)	4(28.5)		
PPV (n=25)	2(15.4)	1 (8.3)		
Herniotomy (n=19)	0(0)	1(10)		

Adverse events

2 patients who received IG/IH blocks were judged to have block failure as they both had a FLACC score of 8 post-operatively and required additional pain relief. No patients with caudal blocks were judged to have block failure. Other than mentioned in the primary and secondary outcomes, no other adverse events were reported

following any regional techniques, including adverse reactions to local anaesthetic, prolonged drowsiness or postoperative neuropathy.

Discussion

Main findings

Our primary outcome results supports our hypothesis that using a lower concentration of local anaesthetic in caudal blocks results in non-inferior analgesia compared to IG/IH nerve blocks. This is supported by the secondary outcome measures requirement for rescue analgesia. Our outcome rates for pain were lower than expected from the literature, with fewer children experiencing pain and even fewer children requiring additional pain relief. A 2014 meta analysis suggests that around 23.8% of children receiving caudal blocks (all higher concentration) and 25.4% receiving non-caudal blocks required additional analgesia[8]. This compares to 5% for both domains in our study. One possible cause of this is the meta-analysis includes several heterogenous studies including publishing dates ranging from 1982 to 2012. With earlier studies, USS guidance was not used for IG/IH blocks and therefore the rate of block failure may have been significantly higher [10]. Secondly, the anaesthetists participating in the study were very proficient at both techniques with a very low block failure rate.There was no evidence of non-inferiority for motor block, with more children in this study experiencing motor block in the caudal group immediately after recovery from anaesthesia. However, this appeared to largely resolve within 1 hour following recovery of anaesthesia and no children required an overnight stay due to motor block. There was a difference of approximately half an hour between both time to passing urine and time to discharge between the two groups, with the caudal block group performing worse in both domains. Statistical analysis showed statistical superiority for the IG/IH group for time to discharge. One child in the IG/IH group was admitted because of urinary retention, they later passed urine on the ward and did not require catheterization. Another child in the caudal group was admitted because of post-operative pain. It is unclear whether there is much clinical significance to the additional half an hour for both domains in the two groups. Some difficulty was noted in recording the actual time of passing urine, especially in children wearing nappies. The time that the nurse checked for a wet nappy was often recorded rather than the actual time of urination. Reasons for delay in discharge was rarely recorded and when it was, was often due to social rather than medical reasons. A subgroup analysis was done in children under 4 years versus children aged 4 years and over for outcomes of post-operative pain and motor block. Our findings suggest, though not to statistical significance, that caudal blocks were more effective in preventing post-operative pain for children under 4. The same pattern is not followed in the IG/IH block group. This theory is supported by the anatomical variations in the spinal cords of younger children. As the dural sac terminates at a lower level in younger children, there is some evidence that dermatomes under the umbilicus are more reliably blocked in children under 20kg [7], whilst only sacral dermatomes are blocked in older, heavier children. Our results may suggest that caudals may be more effective in younger, lighter children, and that IG/IH blocks may be better for older, heavier children. We are unable to prove this conclusively to statistical significance and further research is required to prove this.

Implications of research and application to clinical practice

We believe we have adequately demonstrated that using 0.125% levobupivacaine with clonidine as an adjuvant in caudal blocks provides good pain relief as compared with IG/IH nerve blocks for children undergoing inguinal scrotal surgery. Although in our study, caudal block had a higher incidence of motor block immediately post recovery, this recovered rapidly. We suggest that paediatric anaesthetists who regularly use caudal blocks in their practice consider using a lower concentration of local anaesthetic to minimise motor block and urinary retention.

Study weaknesses

This study is single blinded and therefore children and parents were blinded to the type of block they had received. Unfortunately, we were not able to blind the medical or research team. We felt that two blocks on each child, with one being a placebo solution, would be exposing the child to an unnecessary procedure and therefore risk. The lack of double blinding may have enabled a degree of observer bias in data collection. We attempted to mitigate this by using well validated pain and motor scores. In addition, all outcome measures were recorded by a paediatric recovery or ward nurse, instead of a member of the research team. Another limitation is that our non-inferiority margin was based on an assumption of an event rate of 30%. The incidence of pain in our study was lower at 15% and 10% in the IG/IH and caudal groups respectively. An absolute difference of 15% is thus a larger relative difference to that expected, with the confidence interval of the risk ratio consistent with a doubling in the risk of both postoperative pain and use of rescue analgesia in the caudal groups. Ideally, including a larger number of participants would allow smaller effect sizes and smaller relative differences to be explored, although this was not feasible in the current study.

Conclusion

Our study suggests non-inferiority of caudal blocks compared to IG/IH blocks in providing pain relief for children undergoing inguinal scrotal surgery. Whilst there was no evidence of non-inferiority for motor block immediately post-operatively, any residual block appears to be short lived. As caudal blocks are often more favoured by anaesthetists due to their ease of administration, our study provides evidence for the effectiveness of an alternative local anaesthetic mixture which produces good post-operative outcomes.

Disclosures

1. *Ethical approval from NHS Health Research A thority, IRAS number 205800 in October, 2016*
2. *Trial registration: ClinicalTrials.gov, trial registration number: NCT03167047*
3. *This research was carried out without funding.*
4. *Declarations of interest: none*

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