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The effect of adjunct caudal block on postoperative analgesia in robot-assisted laparoscopic radical prostatectomy: A prospective randomized controlled, single blinded pilot study in a tertiary centre

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KEYWORDS

Caudal block; Robotic radical prostatectomy; Post-operative pain; Analgesia; Opioid Abstract Objective: Caudal block provides satisfactory postoperative pain relief in lower abdominal operations. This pilot study explores its safety and effect on postoperative pain control in patients who underwent robot-assisted laparoscopic radical prostatectomy (RARP). Methods: From 2013 to 2014, 40 consecutive patients were randomized into two groups — one received caudal block using ropivacaine immediately after operation, the other received standard analgesia. Primary outcome measure was pain score based on 11-point Likert scale (0-10)recorded at recovery room, and at 6, 12, 24, 48, and 72 h after operation. All analgesic requirements, opioid-related adverse events and time to passage of flatus were examined. *Results*: Mean age of the two groups was similar (60.4 vs. 62.3 years, p = 0.33), as was American Society of Anaesthesiologists (ASA) class, body mass index (BMI) and operation times. No significant difference in median pain scores was reported in recovery room (2 vs. 3, p = 0.34), and at 6 h (2 vs. 2, p = 0.94), 12 h (0 vs. 0, p = 0.62), 24 h (1 vs. 0, p = 0.58), 48 h (1 vs. 0, p = 0.36) and 72 h (0 vs. 0, p = 0.78) postoperatively between control and caudal block groups, respectively. There was a higher mean opioid usage in the caudal block group which was not statistically significant. Although this was statistically insignificant while no significant difference in mean paracetamol usage was observed postoperatively. Median time to passage of flatus was similar (2.0 vs. 2.0 days, p = 0.97). There was one case of superficial wound infection and no opioid-related adverse events observed. Hospital stay was similar in both groups (2.5 vs. 2.5 days, p = 0.96).

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Conclusion: Although a safe modality, caudal block in post RARP patients does not seem to improve pain control nor reduce analgesia requirements.

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1. Introduction

Robot-assisted laparoscopic radical prostatectomy (RARP) has gained significant popularity in the past decade and has been accepted as a standard treatment for localised prostate cancer. With improved visualisation and flexibility of instruments provided by DaVinci Surgical system, RARP can achieve less blood loss and postoperative pain, more rapid recovery, while maintaining comparable oncological and functional outcome compared to open retropubic radical prostatectomy [1]. Optimal pain control ensures shorter hospital stay by means of early ambulation and bowel movement, lower risk of deep vein thrombosis and nosocomial infection. Opioids remain the mainstay of analgesia for RARP and other major abdominal and pelvic surgeries [2]. However, the notorious adverse effects including nausea, vomiting, prolonged ileus and respiratory depression limits its widespread use and result in poor compliance. A multimodal pain regimen, which includes pre-emptive non-opioids analgesia, intravesical instillation or transversus abdominis plane (TAP) infiltration of local anaesthetics were reported to reduce postoperative use of opioids, some of which demonstrated encouraging results.

Caudal block is widely used in paediatric surgery. It provides satisfactory postoperative pain relief in lower abdominal operations with minimal complications. Evidence showed that caudal block had advantage of higher safety profile over other regional or local anaesthesia modalities [3]. A Chicago retrospective study revealed that caudal block could effectively reduce intraoperative opioids use compared with TAP in paediatric robotic assisted urological surgeries [4]. On contrary, use of caudal block was less desirable in adult patients mainly because of anaesthesiologist's unfamiliarity, inferior location of puncture, lower efficacy and risk of infection [5]. However, although evidence was limited, promising outcome from recent studies favoured the value of adjunctive caudal block as a postoperative analgesia strategy in adult urological surgeries [6-8]. Therefore, we conducted this pilot study to further explore its role in postoperative pain control and its safety in patients who underwent RARP at our institution.

2. Materials and methods

2.1. Inclusion and exclusion criteria

This single centre, randomized controlled, single-blinded study evaluated the effect on postoperative pain control and safety of caudal block in patients who underwent RARP in Singapore General Hospital from May 2013 to February 2014. Patients ranging from 39 to 72 years old with American Society of Anesthesiologists (ASA) Physical Status classification of 1, 2, or 3 who were planned for RARP were included into this study. Patients were excluded if they had a history of allergy to any of the anaesthetic or analgesic agents, were on long-term analgesia, had a history of chronic pain or opioid addiction or took any medicine deemed to affect their perception of pain prior to the surgery.

2.2. Randomisation

Randomisation was carried out by means of sealed envelope method (20 cases, 20 controls) and was administered by an independent party not involved in the study. Patients randomized to caudal block group (cases) received postoperative caudal block and standard analgesia in the ward, which included oral paracetamol, and opioid-based analgesia, which included intravenous morphine in the form of patient-controlled analgesia (PCA), intramuscular pethidine *pro re nata* (PRN) as well as oral tramadol PRN. The control group did not have caudal block postoperation but had the same standard analgesia described above as the cases.

2.3. Caudal block technique

A single dedicated senior consultant anaesthesiologist administered the caudal blocks on the subjects after operation had been completed and before reversal of general anaesthesia. Patients were placed in left lateral position with knees and hip flexed, while still under general anaesthesia. Using anatomical landmarks to identify the sacral hiatus, which forms a equilateral triangle with both posterior superior iliac spines, superior to the coccyx. Ultrasound was not used in any case. Correct positioning of needle in sacral canal was judged by the feel of popping through sacrococcygeal ligament and the ability to advance needle into sacral canal. Incorrect positioning of the needle is determined by aspiration of blood or cerebral spinal fluid (CSF). The ease of injection of saline without subcutaneous swelling would help exclude superficial placement of needle. Lignocaine (2%, 1.8 mL) with adrenaline (1/80 000) was injected prior to administering the full dose of 20 mL 0.5% ropivacaine to exclude inadvertent intravenous injection. Single shot caudal technique was done using B Braun Sterican 21G 3.81 cm hypodermic needle. Clinical success of caudal block was assessed by patient reported numbness of sacral and lumbar dermatomes as well as lack of urinary catheter discomfort. As patient was still under general anaesthesia during administration of caudal block, clinical

success of block could only be retrospectively assessed in the recovery room after patient awakens.

2.4. RARP

Three consultant urologists performed all operations and intra-peritoneal approach with six laparoscopic ports was used for all patients. Port sites were all closed with subcuticular Vicryl sutures and local anaesthesia (20 mL of 0.25% marcaine) was given for all port sites. All patients also had a single small bore Redivac drain placed in the pelvis. There were no cases of conversion to open surgery.

2.5. Measurement of pain score and use of oral analgesia

Pain score was assessed and recorded by operating theatre and ward nurses who were blinded to subject allocation. These data along with the total amount of opioids and other analgesics used in the postoperative period were collected and analysed by a dedicated research assistant who was also blinded to the allocation of the study subjects avoiding any interviewer and investigator bias in the study. Opioidbased analgesia used included intravenous morphine. intramuscular pethidine as well as oral tramadol. In order to facilitate analysis, all doses of opioids were converted to oral morphine equivalents doses (Gloucestershire Joint Formulary, National Health System). As part of postoperative care and monitoring, assessment of pain was done using verbalised pain scores based on an 11-point numeric Likert scale (0-10) in recovery room, and at 6, 12, 24, 48 and 72 h after the operation by nurses. Of note, pain or discomfort from indwelling urinary catheter (IDC) was taken into account as well when recording pain score. Opioid related adverse effects such as nausea, vomiting, and pruritus related to histamine release was recorded, as well as time taken for patient to pass flatus.

2.6. Statistical analysis

IBM SPSS 21.0 (IBM Corp, Armonk, NY, USA) was used to perform all statistical analyses. Continuous variables was analysed using Independent Student's *t*-test and categorical variables were analysed with Mann–Whitney *U* test. Statistical significance in this study was set at p < 0.05.

2.7. Ethics

The study protocol and ethical considerations had undergone approval by our institutional review board (CIRB no. 2012/985/D) and all recruited participants had been well explained regarding this study with the help of a patient information sheet and written informed consent was obtained from each subject.

3. Results

A total of 40 patients were enrolled into this study with equal numbers in each arm (Fig. 1). The demographic features between caudal block and control group were

comparable in terms of age (60.4 \pm 6.7 vs. 62.3 \pm 5.5 years, p = 0.33), ASA classification, and body mass index (BMI) (24.7 vs. 24.3 kg/m², p = 0.72). Both groups had similar operation time (245.0 \pm 55.8 vs. 243.0 \pm 50.8 min, p = 0.90) (Table 1).

There was no significant difference in the median pain scores reported in recovery room (2 vs. 3, p = 0.34), and at 6 h (2 vs. 2, p = 0.94), 12 h (0 vs. 0, p = 0.62), 24 h (1 vs. 0, p = 0.58), 48 h (1 vs. 0, p = 0.36), and 72 h (0 vs. 0, p = 0.78) postoperatively between control and caudal block group (Table 2).

There was no statistically significant difference in opioids usage between the two groups although it appears that caudal block patients were given more opioid analgesia at every time point (Table 3). Most patients did not require any opioids (intramuscular pethidine or oral tramadol) in general ward (three patients from caudal block group received opioids at 24 h; two patients from caudal block group and one from control group received opioids at 48 h) and were under optimal pain control with paracetamol only.

Similarly, there was no significant difference observed in terms of paracetamol usage between the two groups (Table 4). The median time to passage of flatus was similar at 2.0 days for both caudal block group and control group (p = 0.97). One case of superficial wound infection and another case of urethral stricture on self-dilatation were observed, neither of which were related to anaesthetic or analgesic drug use. In particular, no complications arose from the administration of the caudal block and clinical success was reported in all 20 cases in the caudal block group. There were no cases of opioid related adverse effects observed for the whole cohort. Hospital stay was similar in both groups (median 2.5 vs. 2.5 days, p = 0.96).

4. Discussion

The acceptance of RARP for non-metastatic prostate cancer has greatly reduced the incidence of postoperative complications that had been widely observed in previous open retropubic surgery and allowed speedy recovery [1,9,10]. As a major regional anaesthesia technique in paediatric surgery, caudal block provides satisfactory pain control for lower abdominal surgery and has a better safety profile over other regional anaesthesia modalities [11]. Limited implementation of caudal block in adult patients was also reported in some urological case series [6,7]. Although various efforts have been taken to further ameliorate the incisional pain associated with abdominal laparoscopic surgery as well as operations requiring the use of indwelling catheter postoperation, there is still no convincing evidence favouring adjunctive use of local or regional anaesthesia for postoperative pain optimization. Our study, which looks at a group of patients undergoing a laparoscopic surgery, aims to investigate the efficacy of caudal block in postoperative pain control and in reducing the requirement of opioids in the early postoperative period.

In line with a Chicago retrospective study in paediatric patients [11], our study did not show any statistically significant difference in postoperative pain scores between the two groups. Given the fact that the median pain score

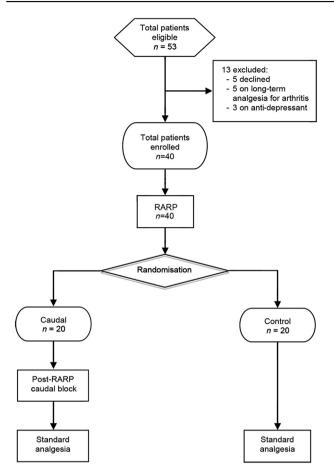


Figure 1 Flow diagram of patient recruitment and allocation. RARP, robot-assisted laparoscopic radical prostatectomy.

within the first 24 h were \leq 3, we expect this mild pain to be sufficiently managed with only paracetamol. Therefore, the study did not reach the statistical power to detect the impact of caudal block on relieving postoperative pain.

Table 1 Baseline demographics of the two study groups.				
	Control $(n = 20)$	Caudal (n = 20)	p-value	
Age (year) ^a	62.3 ± 5.5	60.4 ± 6.7	0.33	
Race				
Chinese	16	17		
Malay	0	1		
Indian	2	1		
Others	2	1		
Height (cm) ^a	$\textbf{168.7} \pm \textbf{5.4}$	$\textbf{170.0} \pm \textbf{7.1}$	0.52	
Weight (kg) ^a	$\textbf{70.3} \pm \textbf{10.5}$	$\textbf{70.5} \pm \textbf{9.7}$	0.95	
BMI (kg/m²) ^a	$\textbf{24.3} \pm \textbf{5.2}$	$\textbf{24.7} \pm \textbf{3.7}$	0.72	
ASA class, n (%)				
1	1 (5)	4 (20)		
2	16 (80)	16 (80)		
3	3 (15)	0 (0)		
Operation time (min) ^a	$\textbf{243.0} \pm \textbf{50.8}$	$\textbf{245.0} \pm \textbf{55.8}$	0.90	
ASA, American Society of Anesthesiologists; BMI, body mass index.				

^a Values are presented as mean \pm SD.

Table 2Comparison of median pain scores of the twogroups at different time points.

Time point	Pain score, median (range)		p-value
	Control $(n = 20)$	Caudal $(n = 20)$	
Recovery	2 (0-8)	3 (0-8)	0.34
6 h postoperation	2 (0-5)	2 (0-4)	0.94
12 h postoperation	0 (0-4)	0 (0-5)	0.62
24 h postoperation	1 (0-8)	0 (0-5)	0.58
48 h postoperation	1 (0-4)	0 (0-6)	0.36
72 h postoperation	0 (0-3)	0 (0-3)	0.78

Although our hypothesis suggests that eliminating painful stimuli via a caudal block could possibly increase focal pain threshold which in turn prolongs the efficacy of short-term analgesics [12], one should not ignore the short half-life of ropivacaine which only lasts 5.7–7.1 h.

Unlike other studies [2,8,12], our patients' requirement for opioids in general ward was minimal. It was consistent with rarity of opioids-related adverse effects. This could be attributed to generally low pain scores and the high threshold to prescribe opioid-based analgesia in our culture [13]. Subjectively, patient verbalized less IDC-related discomfort in the recovery room. But the study failed to show benefits of caudal block over control group in terms of both pain scores and opioids or paracetamol usage.

Despite being a prospective, randomized, single-blinded controlled study, it is worth noting its limitations. It is believed that IDC-related discomfort is a common complaint reported by the patients [8,12]. To many patients, the interpretation of postoperative pain may be confused with catheter-related discomfort hence introducing variability in the reporting of pain scores. There was no standardization in the method of assessing pain. In particular there was no specific effort to assess the pain only when patient is resting in bed as such patients who had just completed ambulatory or chest physiotherapy as part of post-operative recovery may report a higher pain score while an immobile patient would report a much lower pain score. Similarly, the study did not take into account the timing of pain score assessment with serving of pain medications and hence a patient who had just been served oral analgesia would have understandably a lower pain score compared to another patient who was due to his analgesia

Table 3Comparison of mean opioid usage of the twogroups at different time points.

Time point	Opioid usage (mg), mean \pm SE		p-value
	Control $(n = 20)$	Caudal $(n = 20)$	
Recovery	$\textbf{2.8} \pm \textbf{1.2}$	$\textbf{4.3} \pm \textbf{1.3}$	0.41
24 h postoperation	0	$\textbf{2.3} \pm \textbf{1.4}$	0.11
48 h postoperation	$\textbf{0.3} \pm \textbf{0.3}$	$\textbf{1.3} \pm \textbf{1.0}$	0.35
72 h postoperation	0	$\textbf{0.3}\pm\textbf{0.3}$	0.32

Table 4Comparison of mean paracetamol usage of thetwo groups at different time points.

Time point	Paracetamol us mean \pm SE	p-value	
	Control	Caudal	
Recovery	250.0 ± 99.3	300.0 ± 105.1	0.76
24 h postoperation	$\textbf{1950.0} \pm \textbf{256.2}$	$\textbf{2150.0} \pm \textbf{232.6}$	0.57
48 h postoperation	$\textbf{1927.5} \pm \textbf{271.4}$	$\textbf{1850.0} \pm \textbf{334.6}$	0.86
72 h postoperation	$\textbf{527.5} \pm \textbf{233.6}$	$\textbf{650.0} \pm \textbf{181.7}$	0.68

but has yet to receive it. An important source of bias would come from the patients themselves who are not blinded and may subjectively report a lower pain score if they received a caudal block. Therefore, it was inevitable that biases would occur during charting and reporting of the pain scores. We were also unable to explore the use of different anaesthetic agents for caudal block and their effects in this small study for which a difference in postoperative analgesic effect has been reported [14].

This study revealed low pain scores throughout the postoperative recovery. It was likely that the efficacy of caudal block was overestimated, which, on the contrary, underpowered the study given its small cohort of 40 patients. Re-estimation of the size of the study will be needed to reach statistical significance and can be based on the current study findings. Above all, there was no complication related to caudal block.

5. Conclusion

Safety concern should not be a barrier to use caudal block in patients who undergo RARP. However, this study has not shown tangible benefits to favour the routine use of caudal block in RARP patients. A larger cohort and more structured and objective assessment of pain and IDC-related discomfort are imperative for future study.

Conflicts of interest

None of the contributing authors have any conflict of interest, including specific financial interests or relationships and affiliations relevant to the subject matter or materials discussed in the manuscript.

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