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"Comparative Study Between USG - Guided Transversus Abdominis Plane Block Vs USG Guided Caudal Epidural Block with ropivacaine For Postoperative Pain Relief In Children Undergoing Lower Abdominal Surgery - A Randomized Prospective Study"

Dr.Gunjan Singh[1], Dr ShashiPrakash[2], DrVaibhav Pandey[3], Dr Rajesh Meena[4]
First author[1] (Senior Resident Dept.of anesthesiology, S.S. Hospital, BHU, Varanasi, India
Second and corresponding author[2] (Associate Professor Dept.of anesthesiology, S.S. Hospital, BHU, Varanasi, India)
Third author[3](Professor Dept.of Pediatric Surgery, S.S. Hospital, BHU, Varanasi, India)
Fourth author[4](Assistant professor Dept.of anesthesiology, S.S. Hospital, BHU, Varanasi, India)

Abstract: ***Background****: Techniques for providing postoperative analgesia have become an integral part of pediatric anaesthesia. TAP block is a regional anaesthetic technique that blocks the neural afferents of anterolateral abdominal wall whereas in caudal epidural block we place a needle through the sacral hiatus for delivering medications into sacral epidural space.*
Materials and Methods*: It is a prospective randomised controlled study, 60 patients of ASA physical status I and II in the age group of 2-7years undergoing lower abdominal surgery were randomly allocated into 2 groups of 30patients each, The ultrasound-guided caudal block group(group A) &the ultrasound-guided TAP block group(group B) (n = 30)*
Results*: The patients in group Bi.e.the ultrasound-guided TAP block group had considerable Postoperative analgesia then patient in group A which is also statistically provable*
Conclusion: *Among paediatric age groups in terms of the effect on postoperative pain in lower abdominal surgeries, the quality of analgesia was good following both the TAP block as well as caudal block in terms of duration of analgesia it was significantly longer in children who received TAP block comparing to caudal block with less number of rescue doses, better pain scores as well as better patients and parent satisfaction.*
Key Word*: TAP; caudal epidural block; Postoperative analgesia;ropivacaine; pediatric*

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I. Introduction

Postoperative pain, particularly when poorly controlled, results in harmful acute effects such as harmful physiological responses and also chronic effects like extended recovery and chronic pain [1].so techniques for providing postoperative analgesia have become an essential part of pediatric anaesthesia practice. TAP block is a regional anaesthetic technique which is used to block neural afferents to the anterolateral abdominal wall, under anatomical landmark guidance or with the help of ultrasound (USG), local anaesthetic [LA] is injected into the transversus abdominis fascial plane, where the nerves from T6 to L1 are present [2].Caudal epidural block involves placing a needle through the sacral hiatus to deliver drugs into the sacral epidural space. Ropivacaine is a new, long-acting, injectable LA which is structurally very similar to other pipecoloxylidide derivatives, it was first synthesized by Ekenstam[3]. It is a pure s-enantiomer and has increasingly taken the place of Bupivacaine, because of its similar analgesic properties, less motor blockade and decreased tendency of cardiotoxicity

II. Material And Methods

This is a prospective, randomized; interventional clinical study. Approved for the Study protocol was taken by the Institutional Ethical Committee and written informed consent was obtained from all patients. All the Interventions were done in the operation theatre.
Study Design: Prospective, Randomized, study
Study Location: SS Hospital and Trauma Centre, Institute of Medical Sciences (IMS), Banaras Hindu University (BHU), Varanasi
Study Duration: The academic year 2016-18.

Sample size: 60 patients with two groups of 30 each.
Subjects & selection method: After Institutional Ethical committee clearance and informed consent 60 patients among the age group of 2 to 7 years of age, scheduled for elective lower abdominal surgeries, were randomly allotted by a computer-generated table into one of the 2 groups; the randomization sequence was kept a secret in a sealed envelopes. The two study groups were as follows:
GROUP A –Caudal epidural block group: n = 30: caudal epidural block with isobaric ropivacaine 0.25% (1 ml/kg) was injected with a 23-gauge needle using USG with the patients in the lateral decubitus position
GROUP B –TAP block group : n = 30 : Transverse Abdominis Plane Block with isobaric ropivacaine 0.25% (1 ml/kg) was injected in the plane between the internal oblique and transversus abdominis muscle under the strict aseptic condition with 50mm Stimuplex D needle under ultrasound guidance with the patients in the supine position

Inclusion criteria:
1. Patients belonging to American society of Anaesthesiologist [ASA] physical status 1 and 2
2. Patients candidates for lower abdominal surgery
3. Age between 2 to 7 years
4. Hemodynamically stable

Exclusion criteria:
1. Patients who had a history of allergy to amide group of local anaesthetic [LA]& nonsteroidal anti-inflammatory drugs[NSAIDS]
2. Patient not giving consent
3. Spinal deformity
4. Patients with deranged coagulation profile(INR >1.5)
5. Infection at the local site of the proposed block (such as soft tissue infection of abdominal wall and skin)
6. Patients undergoing emergency surgery
7. Patients having a history of mental retardation or developmental delay
8. Presence of communicative or cognitive limitation hindering with pain measurements
9. History of epilepsy

Procedure methodology
The ultrasound-guided caudal block group (group A) (n = 30)

After general anaesthesia is induced, the left lateral position is obtained by flexing the upper hip by 90 degrees and the lower hip by only 45 degrees. Skin over the caudal area is cleaned with an iodine or alcohol (70%) based solution, which is given time to dry. Then using strict sterile technique, the caudal epidural block is given under a linear ultrasound probe (high-frequency probe (7–12 MHz) which is connected to a portable ultrasound unit. the probe was placed in the transverse plane keeping the level at coccyx just cephalic to the point of drug injection, sacral hiatus is visible between the two hyperechoic lines: of which the superior line represents sacrococcygeal ligament whereas the inferior represents the dorsum of the pelvic surface of the sacrum. The sacral hiatus is the hypoechoic region which is between the 2 band- like hyperechoic structures. The ultrasound transducer was rotated 90 degrees at this level for the longitudinal view of the sacral hiatus. When the probe is placed in a longitudinal plane between the sacral cornua, the dorsal surface of the sacrum, dorsal aspect of the pelvic surface of the sacrum as well as the sacrococcygeal ligament are viewed: then the block needle is inserted using the "in-plane" technique. The block needle is visible in real-time, piercing the SCL and entering the sacral hiatus, but it is not visible beyond the apex of sacral hiatus. Following this advancement of the needle tip <5mm beyond the apex of the sacral hiatus was done and the drug was injected as a bolus of 1.0ml/kg ropivacaine 0.25% using the 23-G needle.

The ultrasound guided TAP block group (group B) (n = 30)

In group B, with the child in the supine position, TAP block was performed under the ultrasound guidance, The linear ultrasound probe (high-frequency probe (7–12 MHz) was connected to a portable ultrasound unit which was placed in the mid-axillary line in the transverse plane to the lateral abdominal wall the level being midway between the lower costal margin and the highest point of the iliac crest. A 50mm needle which is attached with tubing system to a syringe filled with the local anaesthetic solution was inserted under strict condition under ultrasound probe guidance and is advanced until it reaches the plane between the internal oblique and transversus abdominis muscle following which after careful aspiration to rule out vascular puncture; the local anaesthetic solution of isobaric ropivacaine 0.25% (1.0 ml/kg) was injected, leading to the separation between the internal oblique and the transversus abdominis muscles, which appears as a hypoechoic space in ultrasound monitor. The skin incision is to be made 15 min after administration of the drug.

An increase in blood pressure(BP) or heart rate(HR)by> 20%, with the skin incision, compared with baseline values 15 mins after administration of caudal epidural or TAP Block analgesia was defined as insufficient analgesia or failed blockade and was treated by using fentanyl 0.5 µg/kg. Saline dextrose 5% solution was given at a dose of 12ml / kg / hr. After the surgery is completed, patients were awakened and extubated after reversal of muscle relaxant and transferred to the postanesthesia care unit (PACU). The duration of the surgical procedure (time from skin incision till extubation) was recorded.

The primary outcome measures i.e. Quality of analgesia and pain was assessed immediately postoperatively and then at 2, 4, 6, 8, 12 and 24 h postoperatively with the help of Children's Hospital Eastern Ontario Pain Scale (CHEOPS) and the Objective behavioural pain score (OPS) scores.

The CHEOPS is a behavioural scale for children between the age of 1–7. Initially, it was developed for children in the PACU. It comprises of six indicators. Children should be observed for a minimum duration of 1 min to fully assess each indicator. The score ranges from 4 to 13. A score of P10 is usually used as an indication to treat pain. However, this is subjective and should be decided on an individual basis for each patient. In the current study, rescue analgesia was administered if the score is above 6 to prevent irritability and agitation.

Statistical analysis

Predesigned patients record form (PRF), Case record form (CRF) and other required formats were utilised for collecting and recording the data obtained at the time of intervention inside the operation theatre. PRF will serve the purpose of source data verification document.

Summary statistics and frequency tables were used to summarize the baseline patient's characteristics. Mean, median, range and other descriptive statistics were calculated for the study outcomes. Statistical comparison was made by comparison between groups by using the chi-square test to a contingency table and two-sample t-test was applied. Nonparametric Mann-Whitney test was used for comparison between the groups at each time point and within groups by Wilcoxon signed rank-sum test.

The level of significance was fixed at the 5% level for all statistical tests; a p-value > 0.05 indicates no significant difference whereas a p-value < 0.05 indicates significant difference. The smaller the p-value obtained, the more significant was the difference. Post Hoc power test was used for Power analysis post-study.

III. Result

Baseline characteristics – age, sex, weight, height, ASA grades, clinical parameters and duration of surgery were comparable in both groups

Table: Comparison of pain on CHEOPS scores in both groups.

	Group	N	Mean	Std. Deviation	Std. Error Mean
CHEOPSArrival	A	30	4.80	.761	.139
	B	30	4.70	.702	.128
CHEOPS 2Hrs	A	30	5.03	.718	.131
	B	30	4.87	1.408	.257
CHEOPS 4Hrs	A	30	6.50	2.224	.406
	B	30	5.03	.928	.169
CHEOPS 6Hrs	A	30	6.00	2.000	.365
	B	30	4.80	1.064	.194
CHEOPS 8Hrs	A	30	5.37	.765	.140
	B	30	4.73	.691	.126
CHEOPS 12Hrs	A	30	5.87	1.137	.208
	B	30	4.60	1.003	.183
CHEOPS 24Hrs	A	30	6.13	1.279	.234
	B	30	4.40	.932	.170

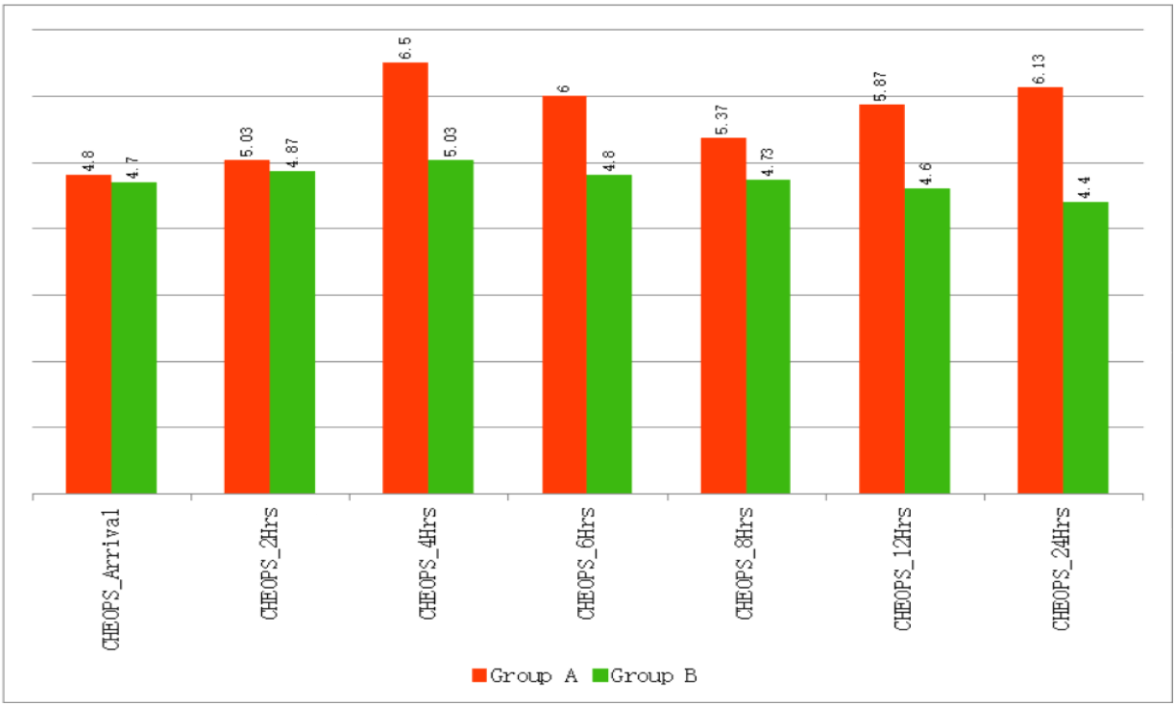
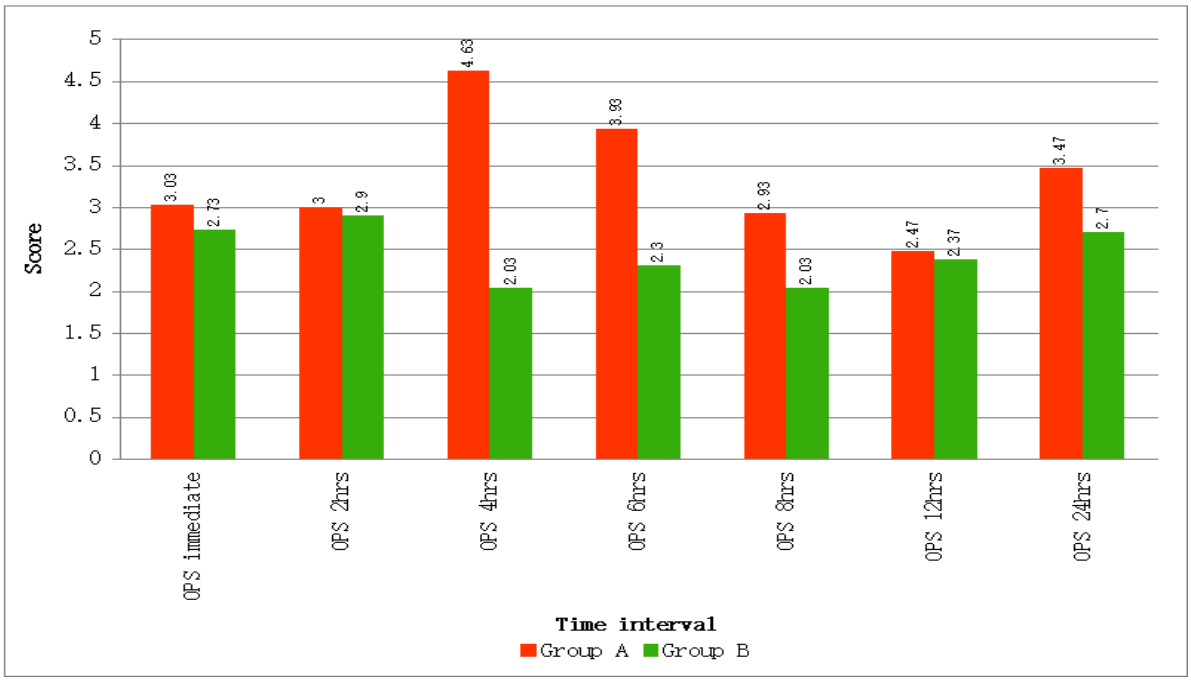


Table: Analysis of pain on CHEOPS score on t-test

	F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference
CHEOPS_Arrival	.124	.726	.529	58	.599	.100	.189
			.529	57.628	.599	.100	.189
CHEOPS_2Hrs	3.747	.058	.578	58	.566	.167	.289
			.578	43.146	.567	.167	.289
CHEOPS_4Hrs	37.958	.000	3.333	58	.002	1.467	.440
			3.333	38.795	.002	1.467	.440
CHEOPS_6Hrs	11.461	.001	2.902	58	.005	1.200	.414
			2.902	44.186	.006	1.200	.414
CHEOPS_8Hrs	1.008	.319	3.364	58	.001	.633	.188
			3.364	57.420	.001	.633	.188
CHEOPS_12Hrs	1.057	.308	4.576	58	.000	1.267	.277
			4.576	57.122	.000	1.267	.277
CHEOPS_24Hrs	.163	.688	5.998	58	.000	1.733	.289
			5.998	53.022	.000	1.733	.289

Based on results we came to conclusion that difference observed in mean pain on CHEOPS scoring between groups A vs. group B was not significant in the first 2 hrs post-surgery ($p > 0.05$), but after 4 hrs post-surgery it was significant throughout till next 24 hrs. P values were < 0.05. ($p^4 = .002$, $p^6 = 0.005$, $p^8 = 0.001$, $p^{12} < 0.001$, $p^{24} < .001$).Thus suggesting the value to be significant 4 hrs after the operation and strongly significant especially at 12 and 24 hrs. Post-surgical procedure.

	Group	Mean	Std. Deviation	Std. Error Mean
OPS immediate	A	3.03	.964	.176
	B	2.73	1.015	.185
OPS2hrs	A	3.00	1.597	.292
	B	2.90	1.213	.222
OPS4hrs	A	4.63	2.456	.448
	B	2.03	1.217	.222
OPS6hrs	A	3.93	2.050	.374
	B	2.30	1.317	.240
OPS8hrs	A	2.93	1.048	.191
	B	2.03	1.217	.222
OPS12hrs	A	2.47	1.106	.202
	B	2.37	1.629	.297
OPS24hrs	A	3.47	.629	.115
	B	2.70	2.037	.372



While applying independent t-Test and Mann-Whitney U test the difference observed on mean pain on scoring between groups A vs. group B was not significant in the first 2 hrs immediately after surgery ($p > 0.05$).

But after 4 hrs. Post-surgery it was significant throughout till next 24 hrs let remaining at 12-hour post-surgery where the patient in both groups were nearly equally relieved from pain

(12 hr OPS grp A =2.47, 12 hr OPS grp B=2.37; Mean difference =0.1; p=0.782 in t-test and 0.448 in Mann Whitney which are not significant $p > 0.05$)

But at 4hr, 6hr, 8hr and 24 hr post-surgery all values were in favour of group B and proved to be strongly significant, statistically in both t-test and Mann Whitney U test respectively($p^4 < 0.001$ in both tests, $p^6 = 0.001$ and 0.002, $p^8 = 0.003$ and 0.004, $p^{24} < 0.054$ and 0.002).

Thus the results demonstrate, at these particular time frames the patients in group B had a substantial pain relief than patients in group A which is also statistically provable, while at rest of the times mean differences still show pain relief more in group B which is clinically appreciable

Table: Significance of rescue doses required by both groups.

	F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference
No. of rescue doses	.229	.634	2.948	58	.005	.533	.181

In Group A, patients requiring post-op analgesia in form of Paracetamol 15mg/kg body weight as only one dose was in '15' patients and requiring two doses were '5' making the total count to "**25**".

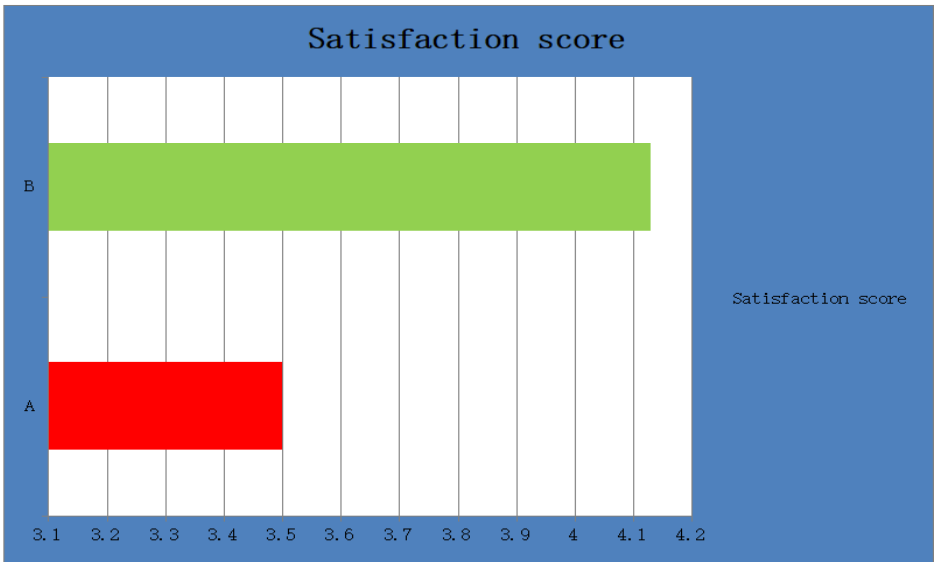
While in group B one patient required single dose and four patients required two shots, making a total count of doses to be "**9**".

Since the difference of required doses of Rescue analgesia in Grp A vs. Grp B patients is 16 more in Group A, the **p-value is 0.005**; $p < 0.05$, which is statistically significant.

It shows better post-op coverage of pain relief in group B patients as compared to group A.

Table: Comparison of satisfaction score of the patients in both group

	Group	N	Mean	Std. Deviation	Std. Error Mean
Satisfaction score	A	30	3.50	.820	.150
	B	30	4.13	.860	.157



	F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference
Satisfaction score	.255	.615	-2.919	58	.005	-.633	.217

Finally, when we compare the satisfaction level of all the patients and their parents in both groups it was observed that mean score on satisfaction scale was '3.50' in group A while mean score in group B was '4.13' The mean difference comes to be 0.63 base points among 30 patients of each group which was found to be statistically significant (p= 0.005). Hence emphasizing that patient on a general who were given TAP block in group B are much more satisfied than patients given CAUDAL block in group A overall.

IV. Discussion

Our study revealed that TAP block and caudal block provide auxiliary benefits to multimodal analgesia in pediatric patients undergoing lower abdominal surgery with the TAP block being better as evidenced by lower pain scores, decreased rescue postoperative analgesia, and better parent satisfaction. These results are consistent with the double-blind, placebo-controlled trial of Carney et al. [4] who enrolled 40 children undergoing open appendectomy in an emergency to receive TAP block on the surgical site using a landmark technique and received either saline as placebo or ropivacaine. The result of the study concluded that the use of unilateral TAP block as a part of multimodal analgesia regimen is superior to placebo in the first 48 h postoperatively.

In one of the other study done by Aveline et al. [5] who made a comparison between blind ilioinguinal/ iliohypogastric nerve block and ultrasound-guided TAP block in 273 adult patients undergoing day-care open inguinal mesh hernioplasty, it was found that postoperative need of morphine during the first 24 h in the TAP block group was less,

Cheon et al. [6] made a comparison between the effects of the caudal epidural block with local infiltration (splash block) in children who underwent inguinal herniorrhaphy. The results of the study showed that the patients in the caudal group did not need an additional dose of analgesia, but it is worth mentioning that the last evaluation point for pain assessment in this study was only 120 min unlike in our study which was 24 h.

Also, results of our study were consistent with the RCT of Sahin et al. [7] which proposed lower CHEOPS pain scores in children who received ultrasound-guided TAP block in comparison to wound infiltration at all the time points of their assessment.

However, in the RCT by Petersen et al [8], it was concluded that the ultrasound-guided block did not decrease pain after inguinal hernioplasty in adults when it was compared to wound infiltration and placebo. Further, they found that VAS scores were better in wound infiltration group when compared to TAP block group. This result may be elucidated by the use of two techniques (ilioinguinal nerve block with local infiltration) in the wound infiltration group.

Ray et al. [9] concluded the mean duration of analgesia after caudal bupivacaine of around 8 hours which is nearly comparable to our results.

Our results showed that there was no incidence of complications especially under the direct visualization of site of infiltration which is neurofascial plane in case of TAP block (group B) and sacral canal in case of Caudal block (group A) and real-time injection of the local anaesthetic under USG guidance.

In one of the case report that describes a complication that is related to the blind landmark technique for TAP block. A posterior TAP block was done on a woman undergoing abdominal hysterectomy (50 kg in weight and 160 cm tall). At laparotomy, about 50 ml of fresh blood was found in the abdominal cavity, due to needle perforation of the liver parenchyma [10].

Beyaz et al. [11] in their retrospective study of 2088 pediatric age group patients[5.6 years (±2.8SD)] who received a single shot of caudal block by the same two anaesthetists without any aid showed the lower incidence of complications due to caudal block.

In one of the other multi-institutional study of Polaner et al [12], they found the most common adverse event was the inability to place the block or block failure. Single-shot caudal blocks were mainly performed without using any technical aids or imaging and under ultrasound guidance n 3% of cases.

In the study done by Wafaa Mohamed Alsadek et al, it was concluded that the mean arterial pressure and the heart rate were higher in group C[who received conventional anaesthesia] than that in groups A & B at all times but without any significant difference. This may be because of the use of Fentanyl 2 μg/kg with the induction of anaesthesia before skin incision to decrease the stress response of intubation

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V. Conclusion

Our t study demonstrates that ultrasound-guided Caudal block and ultrasound-guided TAP block with 0.25% ropivacaine provides an additional benefit to multimodal analgesia in children undergoing lower abdominal surgeries. Moreover, the patients who received TAP block required less postoperative rescue analgesia with superior performance on pain scores and better patients and parent satisfaction than the caudal block. It was also found, that the USG technique was easier to perform and without any adverse effect especially with direct visualization of the site of injection and drug delivery. Moreover, TAP as well as the caudal block was hemodynamically safe with minimal changes in intraoperative and postoperative hemodynamic parameters Duration of analgesia was significantly longer in children who received TAP block as compared to caudal block with less number of rescue doses, better pain scores and with better patients and parent satisfaction.

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