Ain-Shams Journal of Anesthesiology

ORIGINAL ARTICLE Open Access

Safety and efficacy of dexamethasone as an adjuvant to bupivacaine in bilateral transversus abdominis plane block in children undergoing major abdominal surgery

Wael Abd Elmoneim Mohamed Abdelwahab, Hany Mohamed Elzahaby, Hanaa Abd Allah ElGendy, Ahmad Taha Saeed Abd Elwahab* and Rania Maher Hussien

Abstract

Background: This prospective randomized controlled double-blind clinical study was conducted on 52 patients of both genders divided into two groups (26 patients each). Local anaesthetic solution of isobaric bupivacaine 0.25% (0.3 ml/kg) was prepared. Group A received bilateral transversus abdominis plane (TAP) block with bupivacaine and dexamethasone (0.3 mg/kg) while group B received bilateral TAP block with bupivacaine and volume of saline equal to the amount of dexamethasone given in group A. Patients were observed for FLACC pain scale at the time of discharge from the post-anaesthesia care unit and then every 2 h for 36 h after the operation. This study was conducted to assess the safety and efficacy of adding dexamethasone to bupivacaine on the quality of bilateral US-guided transversus abdominis plane (TAP) block in children undergoing major abdominal surgery

Results: Dexamethasone added to local anaesthetic in ultrasound-guided TAP block significantly decreased FLACC score at 8, 10, and 12 up to 24 h postoperatively, The time to the first requested analgesia was prolonged in the dexamethasone group ($P = 0.000$). The total dose of acetaminophen consumption over 36 h after surgery was also reduced ($P = 0.000$), but no difference was found regarding the total dose of rectal diclofenac ($P = 0.068$).

Conclusion: Adding dexamethasone to isobaric bupivacaine TAP block reduces postoperative pain and analgesic requirements compared to isobaric bupivacaine TAP block alone in children undergoing major abdominal surgery.

Keywords: Bupivacaine, Dexamethasone, FLACC, Transversus abdominal plane block

Background

Abdominal surgery is considered one of the most commonly performed surgeries in paediatrics (Ford et al., 2014). General anaesthesia is the most common anaesthetic technique used in children; however, regional anaesthesia is required as an adjuvant to reduce the intraoperative and postoperative need for analgesia (De Beer & Thomas, 2003).

Abdominal wall blocks including ilioinguinal/iliohypogastric nerve block, rectus sheath block, and TAP block are considered efficient regional anaesthetic techniques minimizing pain and demand for analgesics in abdominal surgeries thus reducing undesired adverse effects of opioids as sedation, respiratory depression, nausea, and vomiting (Tan et al., 2012).

* Correspondence: Ahmadtahasaeed@gmail.com
Department of Anesthesiology, Intensive care and Pain Management, Faculty of Medicine, Ain-Shams University, Cairo 11591, Egypt

TAP block is a straightforward regional technique used for postoperative analgesia. It is used to block the neural afferents of the anterior rami of the spinal nerves T7–L1 innervating the anterolateral abdominal wall (Carney et al., 2008; Bonnet et al., 2009).

The analgesic efficacy of TAP block using local anaesthetic alone is satisfactory; however, adding adjuvants such as clonidine, ketamine, and opioids such as fentanyl, magnesium, tramadol, dexmedetomidine, and dexamethasone was found to prolong the duration of the sensory block provided by regional anaesthesia thus increasing the time to first requested analgesia after surgery (Baeriswyl et al., 2015).

Dexamethasone is a synthetic glucocorticoid acting as an anti-inflammatory. It inhibits the release of inflammatory mediators such as interleukins and cytokines (Golwala et al., 2009). Several studies have shown that a preoperative dose of dexamethasone added to local anaesthetic agents has promising results in reducing postoperative pain and improving the quality of analgesia (Tandoc et al., 2011).

The aim of this study was to assess the safety and efficacy of adding dexamethasone to bupivacaine on the quality of bilateral US-guided TAP block in children undergoing major abdominal surgery as data are insufficient regarding dexamethasone as an adjuvant in TAP block in paediatrics.

Methods

Informed written consent for participation in the study was obtained from the guardian of patients according to the guidelines of the Faculty of Medicine ethical committee number FMASU M D 56/2018 after describing the procedure. This prospective randomized controlled double-blind clinical study was performed on 52 patients with no medical history, of age 1 to 6 years scheduled for major abdominal surgery.

Exclusion criteria

Patients with a history of developmental delay or mental retardation affecting observational pain intensity assessment, hypersensitivity to any local anaesthetics, bleeding abnormalities, and any infection signs at the injection site of the desired block.

History was taken from the patients' guardians; assessment and examination of the airway and preoperative investigations were done to all patients including complete blood picture, liver function tests, renal function tests, prothrombin time, and partial thromboplastin time; and chest X-ray and ECG were done to all patients The patients were allowed to fast for 6 h preoperatively.

After recording the patients' weight, the volume that would be given in the TAP block was prepared in syringes labelled with the number of the patients. All patients were given midazolam iv form added to apple juice 0.3 mg/kg orally 20 min before the induction of anaesthesia.

Standard monitoring was attached to all patients (heart rate, non-invasive blood pressure, and pulse oximetry). Heart rate and mean arterial blood pressure were recorded before anaesthesia induction and every 5 min till the end of surgery.

All patients received induction by an inhalational agent using 8% sevoflurane in 50% air and 50% O_2. During anaesthesia induction, a 22- or 24-G intravenous cannula was inserted. After securing the intravenous access, an endotracheal tube of a size appropriate for the patients' age was inserted after administrating 0.5 mg/kg of atracurium, and controlled mechanical ventilation pressure control volume guarantee was applied and adjusted to keep end-tidal carbon dioxide at a normal range through capnography and well oxygenation. Maintenance with sevoflurane, atracuruim, and intravenous fluids was performed throughout the surgery.

After induction, patients were divided randomly into two groups: group A (TAP block with dexamethasone) and group B (TAP block only). Patients were placed at the supine position, and bilateral ultrasound-guided TAP block was performed. The linear ultrasound probe (high-frequency probe 10–12 MHz) was placed in the mid-axillary plane transverse to the lateral abdominal wall midway between the lower costal margin and the highest point of the iliac crest. A 50-mm Vygon needle connected to a tubing system with a syringe filled with the local anaesthetic solution was inserted in the plane with the ultrasound probe and advanced until it reached the plane between the internal oblique and transversus abdominis muscles after careful aspiration to exclude vascular puncture then injection of the prepared drug causing separation between the internal oblique and the transversus abdominis muscles, which appeared as a hypoechoic space. The local anaesthetic solution of isobaric bupivacaine 0.25% (0.3 ml/kg) was prepared, dexamethasone (0.3 mg/kg) was added for group A and an equal volume of saline was added for group B, and the total prepared volume was divided into two equal volumes to be injected equally on each side. Skin incision was done 15 min after administrating bilateral TAP block; TAP block was considered as a failed block if haemodynamic parameters increased (> 20%) with skin incision compared to baseline values.

Intraoperative hypotension requiring a fluid bolus (10 ml/kg within 30 min) and bradycardia that needed atropine were recorded.

After the end of the surgery, patients were awakened then kept under observation in the post-anaesthesia care unit for half an hour for monitoring vital data then discharged to the ward. Postoperative paediatric observational FLACC pain scale with its 0–10 score range was

assessed by a blinded observer at the time of discharge from the post-anaesthesia care unit (PACU) and then every 2 h for 36 h after the operation. If FLACC pain scale score at any time was more than 3, intravenous acetaminophen 15 mg/kg/dose was given to achieve a FLACC scale score of 3 or less, with a maximum intravenous daily dose of 75 mg/kg/day. If the FLACC pain scale score remained more than 3 after acetaminophen, rectal diclofenac 1 mg/kg/dose was given. The primary outcome was the time to first requested analgesia in hours (from the onset of TAP block injection to the first observation of FLACC pain scale score > 3). The secondary outcomes were FLACC scale score, total analgesic doses (oral acetaminophen and rectal diclofenac) required during the first 36 h postoperatively, and intraoperative haemodynamic variables (Table 1).

Statistical analysis

Data were collected, revised, coded, and entered to the Statistical Package for Social Science (IBM SPSS) version 23. The quantitative data were presented as mean, standard deviations, and ranges when their distribution found parametric, and median with inter-quartile range (IQR) when non-parametric. Also, qualitative variables were presented as number and percentages.

The comparison between the groups regarding qualitative data was done by using the *chi-square test*. The comparison between the two independent groups with quantitative data and parametric distribution was done by using the *independent t test* while with non-parametric distribution done by using the *Mann-Whitney test*. The comparison between more than two paired groups with quantitative data and parametric distribution was done by using the *repeated measures ANOVA*.

The confidence interval was set to 95%, and the margin of error accepted was set to 5%. So, the *P* value was considered significant as the follows: $p > 0.05$, non-significant; $P < 0.05$, significant; and $P < 0.01$, highly significant.

Sample size

Based on El Fawy and El Gendy primary outcome results which is the duration needed for rescue analgesia to be given and total dose of the required analgesic (El Fawy & El Gendy, 2014) a relatively expected large effect size (0.8) using two independent *t* test for means and a significance level of 0.05 and power of 0.8 at least 26 cases per group is needed. Numerical data will be analysed using the Student *t* test, and non-parametric data will be assessed using the chi-squared test.

Results

Our study was performed on 52 patients divided into two groups (26 patients in each group): group A (TAP with dexamethasone) and group B (TAP only). The primary outcome which is the time to first requested analgesia was prolonged in the dexamethasone group ($P = 0.000$).

There was no significant difference found between the two groups regarding demographic data (Table 2).

Regarding the paediatric FLACC score as shown in Table 4, no significant difference was found between the two groups at arrival to 6 h follow-up with *P* value > 0.05. There was a significant increase in FLACC score in group B at 8 h and 10 h with a *P* value = 0.000 and 0.030, respectively, while there was a significant increase in group A than in group B at 12 h with a *P* value = 0.000. Also, there was a significant increase in group B from 14 to 24 h than in group A. Finally, no significant difference was found between the two groups at 28 h, 32 h, and 36 h with a *P* value = 0.258, 0.705, and 0.073, respectively.

Time to first analgesia was significantly prolonged in group A than in group B with a *P* value < 0.001 with a significant decrease in a total dose of acetaminophen in group A than in group B with a *P* value <0.001. However, there was no significant difference found between the two groups regarding the total dose of rectal diclofenac with a *P* value = 0.068 as shown in Table 5.

Table 1 FLACC behavioural pain assessment scale score (Merkel et al., 1997)

Categories	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No cry (awake or asleep)	Moans or whimpers, occasional complaint	Crying steadily, screams or sobs; frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to; distractible	Difficult to console or comfort

Table 2 Comparison between group A and group B regarding demographic data of the studied patients

		Group A, no. = 26	Group B, no. = 26	Test value	*P* value	Sig.
Age (years)	Mean ± SD	2.75 ± 1.31	2.78 ± 1.21	− 0.088[b]	0.930	NS
Sex	Females	12 (46.2%)	10 (38.5%)	0.315[a]	0.575	NS
	Males	14 (53.8%)	16 (61.5%)			
Weight (kg)	Mean ± SD	12.77 ± 2.44	12.85 ± 1.99	− 0.125[b]	0.901	NS
Duration of surgery (min)	Mean ± SD	69.62 ± 7.34	70.00 ± 7.48	− 0.187[b]	0.852	NS

There was no significant difference found between the two groups regarding heart rate and MBP preoperative, intraoperative, and postoperative as shown in Table 3

P value > 0.05, non-significant (NS); *P* value < 0.05, significant (S); *P* value < 0.01, highly significant (HS)

[a]Chi-square test

[b]Independent *t* test

Discussion

This study was conducted to assess the safety and efficacy of adding dexamethasone to bupivacaine on the quality of bilateral US-guided TAP block in children undergoing major abdominal surgery. The main finding of this study was that when dexamethasone was added to local anaesthetic in ultrasound-guided TAP block, it significantly decreased FLACC score at 8, 10, and 12 up to 24 h postoperatively. The time to first requested analgesia was prolonged in the dexamethasone group. The total dose of acetaminophen consumption over 36 h after surgery was also reduced.

Undesired postoperative sequel as respiratory distress, prolonged hospital stays, and increased incidence of chronic pain occur due to inadequate control of pain after surgery. Proper postoperative analgesia is important for reducing the postoperative morbidity and stress response and improving the operative outcome (Merkel et al., 1997).

The transversus abdominis plane (TAP) block is commonly used as a new safe regional anaesthetic technique alternative to neuroaxial blockade for abdominal surgeries to spare use of opioids (El Fawy & El Gendy, 2014). Local anaesthetics (LAs) used throughout regional blocks provide better operative conditions but have a short duration of postoperative analgesia (McDonnell et al., 2007). Therefore, many clinical trials used additives to enhance the action of local anaesthetics and prolong the duration of postoperative analgesia (Milan et al., 2011).

In the current study, FLACC score showed a significant increase in group B at 8 h and 10 h indicating that adding dexamethasone to TAP block prolongs the

Table 3 Comparison between the two groups regarding heart rate and MBP preoperative, intraoperative, and postoperative

		Group A, no. = 26	Group B, no. = 26	Test value[a]	*P* value	Sig.
HR preop	Mean ± SD	106.92 ± 13.04	106.54 ± 12.55	0.108	0.914	NS
	Range	80–125	85–125			
HR intraop	Mean ± SD	96.54 ± 10.84	93.46 ± 9.25	1.101	0.276	NS
	Range	75–115	80–105			
HR post	Mean ± SD	101.92 ± 10.50	100.38 ± 10.29	0.534	0.596	NS
	Range	80–120	80–115			
MBP pre	Mean ± SD	75.00 ± 5.29	77.69 ± 5.52	− 1.795	0.079	NS
	Range	65–85	70–90			
MBP intra 5 min after induction	Mean ± SD	68.62 ± 5.72	70.19 ± 3.60	− 1.19	0.24	NS
	Range	60–80	65–80			
MBP intra 5 min after TAP block	Mean ± SD	71.58 ± 5.35	73.88 ± 3.40	− 1.856	0.069	NS
	Range	63–83	68–82			
MBP intra 5 min after skin incision	Mean ± SD	75.81 ± 5.25	77.96 ± 3.48	− 1.744	0.087	NS
	Range	66–86	70–85			
MBP post	Mean ± SD	72.62 ± 5.58	74.46 ± 4.47	− 1.316	0.194	NS
	Range	65–85	70–85			

P value > 0.05, non-significant (NS); *P* value < 0.05, significant (S); *P* value < 0.01, highly significant (HS)

[a]Independent *t* test

Table 4 Comparison between group A and group B regarding FLACC score at different times of measurement

		Group A, no. = 26	Group B, no. = 26	Test value[a]	*P* value	Sig.
At arrival to PACU	Median (IQR)	0 (0–0)	0 (0–0)	0.000	1.000	NS
	Range	0–0	0–0			
Discharge from PACU	Median (IQR)	0 (0–0)	0 (0–1)	− 1.190	0.234	NS
	Range	0–1	0–1			
2 h	Median (IQR)	1 (1–1)	1 (1–1)	1.207	0.227	NS
	Range	0–1	0–1			
4 h	Median (IQR)	1 (1–1)	1 (1–2)	− 1.564	0.118	NS
	Range	1–2	1–3			
6 h	Median (IQR)	2 (2–3)	3 (2–3)	1.834	0.067	NS
	Range	1–4	2–4			
8 h	Median (IQR)	2 (2–2)	3 (3–4)	− 4.381	0.000	HS
	Range	1–3	1–4			
10 h	Median (IQR)	2 (2–2)	3 (2–4)	− 2.168	0.030	S
	Range	2–3	1–5			
12 h	Median (IQR)	3 (2–3)	0 (0–2)	− 3.629	0.000	HS
	Range	2–4	0–5			
14 h	Median (IQR)	2 (1–3)	3 (3–3)	− 2.954	0.003	HS
	Range	0–5	2–5			
16 h	Median (IQR)	3 (2–3)	4 (3–4)	2.818	0.005	HS
	Range	2–4	1–5			
18 h	Median (IQR)	2 (2–3)	3 (2–5)	2.361	0.018	S
	Range	1–4	1–5			
20 h	Median (IQR)	2 (2–3)	3 (2–4)	− 2.329	0.020	S
	Range	0–4	0–4			
22 h	Median (IQR)	2 (2–3)	3 (2–4)	− 2.367	0.018	S
	Range	1–4	0–4			
24 h	Median (IQR)	2 (2–3)	3 (2–4)	− 2.177	0.029	S
	Range	1–4	0–4			
28 h	Median (IQR)	2 (2–4)	3 (2–4)	− 1.132	0.258	NS
	Range	2–4	1–5			
32 h	Median (IQR)	3 (2–4)	3 (2–4)	− 0.378	0.705	NS
	Range	1–5	1–4			
36 h	Median (IQR)	3 (2–3)	4 (3–4)	− 1.792	0.073	NS
	Range	2–4	2–4			

PACU post-anaesthesia care unit
P value > 0.05, non-significant (NS); *P* value < 0.05, significant (S); *P* value < 0.01, highly significant (HS)
[a]Mann-Whitney test

analgesia of LA postoperatively, while there was a statistically significant increase in the FLACC score in group A at 12 h as analgesics (paracetamol and rectal diclofenac) were given to group B causing the FLACC score to become low while patients in group A did not receive any analgesics.

We also found that time to first analgesia and total dose of analgesia were significantly increased in group A which indicates that patients who received dexamethasone with TAP requested postoperative analgesia later than the patients who did not receive dexamethasone while there was a significant increase in the total dose of acetaminophen in group B showing that patients who did not receive dexamethasone needed more doses of postoperative analgesics than those who received dexamethasone with TAP.

So, the results agree with Zhang et al. who performed nine randomized controlled trials (RCTs) on 575 adult

Table 5 Comparison between group A and group B regarding time to first analgesia given and total dose of analgesia

		Group A, no. = 26	Group B, no. = 26	Test value[a]	*P* value	Sig.
Time to first analgesia (h)	Mean ± SD	15.54 ± 2.14	9.08 ± 1.90	11.525	0.000	HS
	Range	12–18	6–12			
Total dose of acetaminophen (mg)	Mean ± SD	338.46 ± 80.38	542.31 ± 89.10	− 8.662	0.000	HS
	Range	150–450	400–650			
Total dosed of rectal diclofenac (mg)	Mean ± SD	13.75 ± 3.85	16.67 ± 6.02	− 1.870	0.068	NS
	Range	12.5–25	12.5–25			

There was no major complications occurred in the patients who underwent the procedure
P value > 0.05, non significant (NS); *P* value < 0.05, significant (S); *P* value < 0.01, highly significant (HS)
[a]Independent *t* test

patients undergoing abdominal surgery to compare dexamethasone added to local anaesthetics in ultrasound-guided TAP block with the control group who received TAP block alone for postoperative analgesia. Dexamethasone added to local anaesthetics significantly decreased visual analogue scale (VAS) scores at rest, 4 h, 6 h, and 12 h after surgery ($P < 0.00001$). Also, the time to the first request for additional analgesics was prolonged in the dexamethasone group ($P < 0.00001$). In addition, opioid consumption over 24 h after surgery was also reduced ($P = 0.0001$) (Mukherjee et al., 2014).

Also, Chen et al. who compared the effects of perineural dexamethasone mixed with local anaesthetic versus local anaesthetic alone in the TAP block found that perineural dexamethasone prolonged the analgesia duration of LA effect in the TAP block by 2.98 h ($P < 0.00001$) from a baseline of 5.34 h without dexamethasone and reduced analogue pain scores at 2 h ($P = 0.02$), 6 h ($P = 0.0003$), and 12 h ($P < 0.00001$) postoperatively which comes in agreement with our results. Furthermore, they observed that the use of perineural dexamethasone was associated with less analgesic consumption ($P < 0.00001$) postoperatively which also mimic our findings (Carr & Cousins, 2014).

Also, Sachdeva and Sinha who studied the effect of dexamethasone as an additive to ropivacaine on the duration of ultrasound-guided transversus abdominis plane block in adult female patients who underwent CS under subarachnoid block found that the time to first analgesia (TFA) was significantly longer in dexamethasone group ($P = 0.00$) and also postoperative tramadol requirement was decreased ($P = 0.046$) while the total amount of diclofenac consumed by the patients in the two groups did not differ significantly ($P = 0.07787$) which also come in agreement with our results (Zhang et al., 2019).

Also, the results of our study agreed with those reached by Ammar and Mahmoud who concluded that the addition of dexamethasone to bupivacaine during TAP block provided lower postoperative VAS for pain score at 2 h ($P = 0.01$), 4 h ($P = 0.01$), and 12 h ($P = 0.02$). Furthermore, TFA was significantly longer in the dexamethasone group ($P = 0.002$), with lesser morphine requirements 48 h postoperatively ($P = 0.003$) (Ammar & Mahmoud 2012, Chen et al., 2018).

The results of the above studies prove that dexamethasone added to local anaesthetics in ultrasound-guided TAP block was a safe and effective strategy for postoperative analgesia explained by binding of dexamethasone to glucocorticoid receptors and inhibiting potassium conductance, thus reducing stimulus transmission in unmyelinated c-fibres which carry nociceptive information by inhibiting the activity of the potassium channels on these fibres. In addition, dexamethasone causes a degree of vasoconstriction to the tissues, and local anaesthetic will have a slower uptake and absorption, thus prolonging its duration and comfort felt by the patient. Also, dexamethasone exhibits a potent anti-inflammatory effect by suppressing the synthesis and secretion of various inflammatory mediators interleukins and cytokines which prolongs the period of analgesia up to 48 h (Mukherjee et al., 2014; Carr & Cousins, 2014; Zhang et al., 2019).

A contradictory result to our data has been reported by Wegner et al. who performed a randomized controlled trial on 82 patients who underwent inguinal hernia repair or spermatocelectomy. There was no statistically significant prolongation of analgesia for TAP blocks with ropivacaine when dexamethasone was added (Wegner et al, 2017). There was an improvement in the pain scores from the baseline, at 12 h after the administration of the block in both the groups. Although the dexamethasone group showed less pain score than the saline group, the difference between the 2 groups was not statistically significant (Sachdeva & Sinha, 2016). The difference between our results and Wegner et al. can be justified by the different age groups, also the higher dose of dexamethasone that we used. Moreover, they did not calculate opioid or other analgesic consumption postoperatively that may have affected the pain scores, and they did not unify for the expertise of the provider that performed the block, as some

of the providers may have been junior residents with limited experience and expertise in this field.

Conclusion

Adding dexamethasone to isobaric bupivacaine TAP block reduces postoperative pain and analgesic requirements compared to isobaric bupivacaine TAP block alone in children undergoing major abdominal surgery.

Abbreviations

ASA: American Society of Anaesthesiology; GA: General anaesthesia; HR: Heart rate; HS: Highly significant; IO: Internal oblique muscle; IQR: Interquartile range; LA: Local anaesthetics; MBP: Mean blood pressure; NS: Non-significant; NSAID: Non-steroidal anti-inflammatory drugs; RCTs: Randomized controlled trials; S: Significant; TA: Transversus abdominal muscle; TAP: Transversus abdominal plane; TFA: Time to first analgesia; US: Ultrasound; VAS: Visual analogue scale

Acknowledgements

Not applicable.

Authors' contributions

WA designed the study, revised the literature, performed the block, followed the patients, and wrote the manuscript. HM designed the study, performed the block, and wrote and critically revised the manuscript. HA revised the literature, performed the block, and critically reviewed the manuscript. AT and RM revised the literature, followed the patients, measured and collected the data, performed the block, and critically reviewed the manuscript. All authors approved the final version of the manuscript.

Funding

None.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Approval of the research ethics committee of the Faculty of Medicine was obtained (code number: FMASU M D 56/2018), and informed written consent was obtained from the patients' legal guardians after the description of the procedure and its potential complications.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Received: 28 July 2020 Accepted: 11 October 2020
Published online: 20 October 2020

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