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Efficacy of Dexmedetomidine as an Adjuvant to Bupivacaine in Ultrasound-Guided Transverse Abdominis plane Block for Laparoscopic appendicectomy: A Randomised Controlled Study

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Abstract

Objective: Dexmedetomidine is an alpha 2-adrenergic agonist that prolongs analgesia as an adjuvant when added in neuraxial and peripheral nerve blocks. The aim of the present study was to evaluate the efficacy of dexmedetomidine as an adjuvant to bupivacaine in ultrasound (USG)-guided transverse abdominis plane (TAP) block for postoperative analgesia in laparoscopic appendicectomy.

Methods: A total of 60 American Society of Anesthesiologists I and II adult patients aged between 16 and 60 years planned for laparoscopic appendicectomy were randomised into two groups (A and B). Group A patients received 20 mL of 0.125% bupivacaine+1 μg kg^{-1} dexmedetomidine, whereas group B patients received 20 mL of 0.125% bupivacaine alone on both sides at the time of USG-guided TAP block. Haemodynamic variables, pain scores, sedation scores, time to first dose of rescue analgesic and side effects, if any, were assessed and compared between the groups.

Results: Demographic and operative characteristics were comparable in both groups. The mean duration of analgesia was more in group A (7.33 h) than in group B (4.8 h). The requirement of rescue analgesics was more in group B (80%) than in group A (56.7%). The sedation and pain scores at 2, 4 and 6 h were better in group A than in group B ($p<0.05$). The heart rate, systolic blood pressure and diastolic blood pressure were lower in group A during the postoperative period than in group B.

Conclusion: The addition of dexmedetomidine as an adjuvant to bupivacaine in TAP block provides prolonged postoperative analgesia and better pain control with reduced need for rescue analgesics than bupivacaine alone in patients undergoing laparoscopic appendicectomy.

Keywords: Bupivacaine, dexmedetomidine, laparoscopic appendicectomy, postoperative pain, rescue analgesia, transverse abdominis plane block

Introduction

Postoperative pain management is an important component for enhanced postoperative recovery in sophisticated laparoscopic procedures (1-3). Inadequate postoperative analgesia can lead to several undesirable effects, such as patient's discomfort, thromboembolism due to prolonged immobility and reduced pulmonary clearance leading to complications (3). Among several modalities available (4), transverse abdominis plane (TAP) block is a simple and efficient modality for pain relief in patients undergoing laparoscopic appendicectomy (5-8). Several studies have shown that TAP block is perfectly suited for use after lower abdominal and gynaecological surgeries (8, 9). Being a highly selective α2 agonist (10), the use of dexmedetomidine with local anaesthetic (LA) agents prolongs the LA effect, thus prolonging postoperative analgesia (11-13). There are inconsistent reports in the literature about the use of TAP block for laparoscopic appendectomies. The aim of the present study was to evaluate the efficacy of dexmedetomidine as an adjuvant to bupivacaine in ultrasound (USG)-guided TAP block for postoperative analgesia

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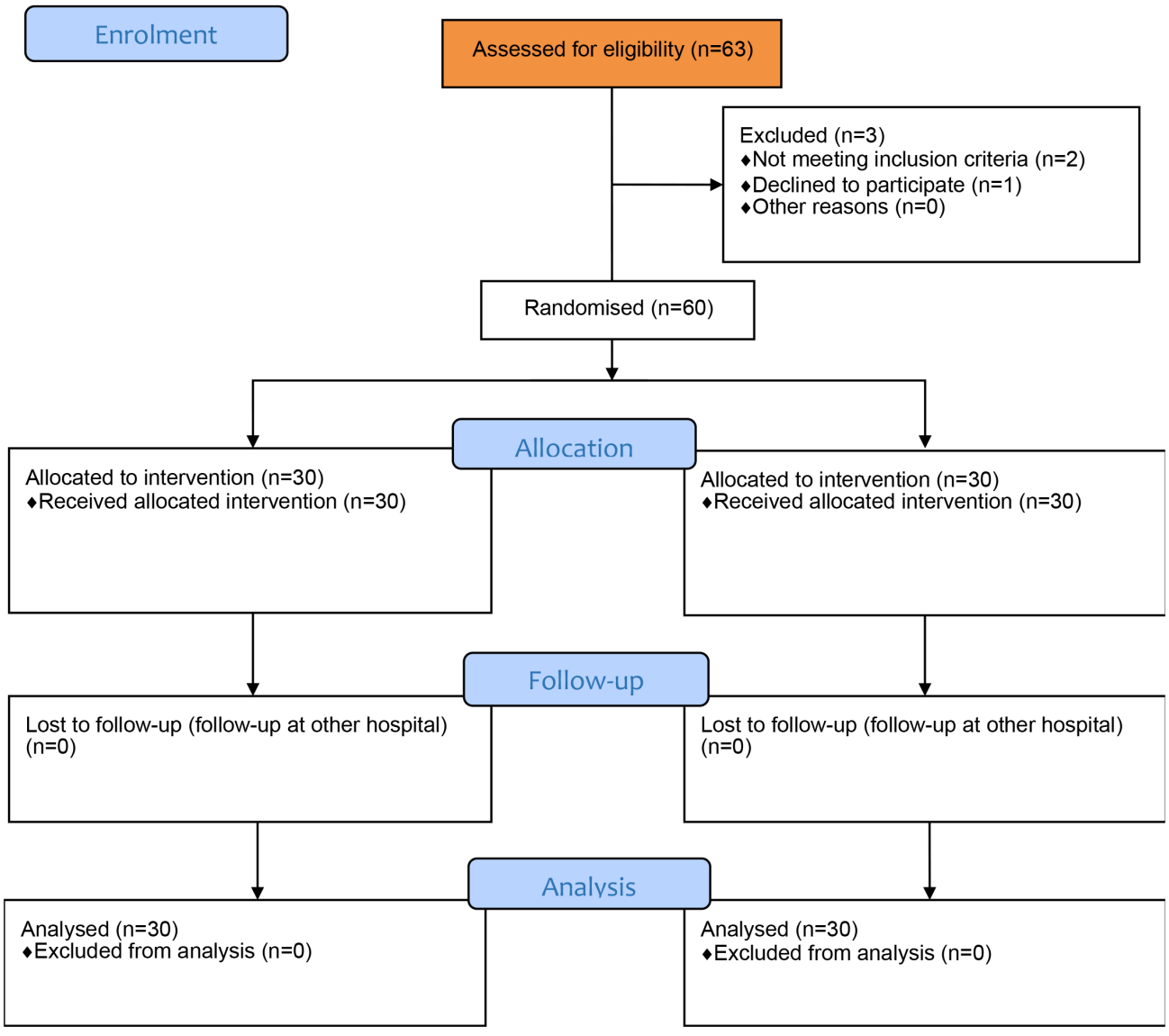

Figure 1. CONSORT 2010 flow diagram

in laparoscopic appendicectomy in a prospective randomised, double-blinded study.

Methods

After institutional ethics committee approval and written informed consent, a prospective, randomised, double-blinded study was conducted at our tertiary care university hospitals on 60 American Society of Anaesthesiologists I and II adult patients undergoing laparoscopic appendicectomy. A total of 63 patients were enrolled for the study, of which two patients did not meet the inclusion criteria and one patient did not want to participate in the study (Figure 1). Assuming the duration of analgesia as the primary outcome variable, the subjects were aged between 16 and 60 years. Patients with a duration of surgery <3 h were only included in the study. Patients were allocated randomly to two groups, group A (dexmedetomidine) and group B (control), using a computer-generated random number sequence. Allocation concealment was done by the serially numbered opaque sealed envelope method. After randomisation, group A received 20 mL of 0.125% bupivacaine+1 μg kg^{-1} dexmedetomidine (10 mL of 0.5% bupivacaine+30 mL of sterile water+1 μg kg^{-1} dexmedetomidine in 2 mL), and group B received 20 ml of 0.125% bupivacaine (10 ml of 0.5% bupivacaine+30 mL of sterile water) bilaterally in TAP block. The medication was prepared by an independent investigator, other than the person administering the intervention and doing the outcome assessment.

The participant and the data analyst were also blinded for the intervention.

An experienced anaesthesiologist who is not involved in the postoperative monitoring will administer the TAP block. Baseline heart rate (HR), mean blood pressures and oxygen saturation were noted. All surgeries were performed under general anaesthesia with endotracheal intubation and controlled ventilation. Anaesthesia was induced with fentanyl injection 2 μg kg^{-1}, midazolam injection 1 mg intravenous (iv) and propofol injection 2 mg kg^{-1} iv. Endotracheal intubation was facilitated with vecuronium injection 0.1 mg kg^{-1} iv, after ventilating with 100% oxygen for 3 min and sevoflurane to a minimum alveolar concentration (MAC) of 1. All patients were intubated with an appropriate size cuffed oral endotracheal tube. Anaesthetic maintenance was a mixture of oxygen and nitrous oxide (33%:67%) with 1% sevoflurane adjusted to achieve a MAC of 1.3. Paracetamol injection 1 mg iv and ondansetron injection 4 mg iv were given to the patient 30 min prior to performing the block. At the end of the surgical procedure and before extubation, the TAP block was performed under USG guidance by lateral approach. USG probe transducer (Sonosite, Bothell, WA, USA) with a frequency of 10 MHz was used. Once the TAP was identified between the internal oblique and transversus muscles, a 50 mm short bevel needle was inserted in the plane with the USG probe, the needle tip was guided into the TAP and 20 ml of the study drug was injected after negative aspiration of blood while looking for the local spread of the drug in the plane between internal oblique and transversus abdominis muscle using USG. The sequence was repeated on the opposite side. All the patients who complained of pain in the post anaesthesia recovery room after the block were excluded from the study, assuming that the TAP block was ineffective.

In the Post Anaesthesia Care Unit, HR, mean arterial pressure, oxygen saturation, pain score using visual analogue scale (VAS) and sedation score using Ramsay Sedation Score were monitored for the first hour at every 15-minute interval by a personnel trained in pain management. For the first 24-hour period in the ward, the pain scores and sedation scores were noted at 2, 4, 6, 8, 12 and 24 h. If pain score at any time was ≥4, ketorolac injection 30 mg was administered as a rescue analgesic to a maximum of three doses in 24 h. The time of requirement of first dose of rescue analgesic and number of rescue analgesics needed over 24 h in all patients in both groups were noted. The number of patients in both groups who did not require any rescue analgesics for the first 24 h was also analysed. Pain score was assessed using VAS (14), and a score of 2-4 was considered mild pain, 5-7 was considered as moderate and 8-10 was considered as severe pain. The Ramsay Sedation Score (15) was used to monitor sedation. Bradycardia was defined as HR <50 bpm and was treated with atropine injection 0.6 mg iv. Hypotension was defined as a mean arterial pressure <30% of the baseline value and was treated with fluid bolus of 200 mL (up to 2 doses) and ephedrine injection 6 mg iv. Excessive sedation was defined as a score >4/6.

Statistical analysis

Sample size was calculated assuming the duration of analgesia as the primary outcome. Almarakbi et al. (16) reported that the expected duration of analgesia is 281.25 min, with a standard deviation of 10.11. We have defined minimal clinically significant difference in primary outcome as 10 min. To be able to detect this difference, with a power of 95% and 5% two-sided alpha error, the required sample size in each group was 28. To account for lost to follow-up of approximately 5%, we have included another 2 subjects and have taken 30 participants in each group. Sample size was calculated using G*Power statistical software version 3.1.0 (Institute of Experimental Psychology, Heinrich Heine University, Dusseldorf, Germany).

Statistical analysis was performed using IBM software (released 2012, IBM SPSS Statistics for Windows, version 21.0; IBM Corp., Armonk, NY, USA). Data were analysed by intention-to-treat analysis. Data were expressed as either mean and standard deviation or numbers and percentages. The demographic data of patients were studied for both groups using Student's t-test and chi-square test. Haemodynamic variables (HR and systolic (SBP) and diastolic blood pressures (DBP)), pain scores and sedation scores were analysed and compared between the two groups using independent samples t-test. The time to first dose of rescue analgesic, i.e. the duration of analgesia, was analysed using the Mann-Whitney U test. A p-value of <0.05 was considered to be statistically significant.

Results

The mean ages of the patients were 32.2±10.36 years in group A and 34.62±10.27 years in group B. The difference in the proportion of age between the two groups was not statistically significant (p=0.93). In group A, 6 (20%) patients were female, and 24 (80%) patients were male. In group B, 8 (26.7%) patients were female, and 22 (73.3%) patients were male. The difference in the proportion of gender between the two groups was not statistically significant (p=0.095). The mean body mass indices (BMIs) of the patients were 28.10±4.2 kg m^{-2} in group A and 27.6±3.9 kg m^{-2} in group B. The difference in the proportion of BMI between the two groups was not statistically significant (p=0.23) (Table 1).

The mean durations of analgesia of the patients were 7.33 h in group A and 4.80 h in group B. The difference in the proportion of duration of analgesia between the two groups was

Table 1. Comparison of demographic parameters between the study groups (n=60)

Parameter	Group A (n=30)	Group B (n=30)	p
Age (years) (mean±SD)	32.2±10.36	34.62±10.27	0.930
Gender			
Female	6 (20%)	8 (26.7%)	0.095
Male	24 (80%)	22 (73.3%)	
BMI (mean±SD)	28.10±4.2	27.6±3.9	0.230

BMI: body mass index; SD: standard deviation

Table 2. Comparison of the duration of analgesia, total number of analgesics and rescue analgesics between the study groups (n=60)

Parameter	Group A (n=30)	Group B (n=30)	p
Duration of analgesia (mean)	7.33±1.51	4.80±1.24	0.023
Total no. of analgesics (mean±SD)	0.73±0.640	1.03±0.850	0.128
Rescue analgesic			
Required	17 (56.7%)	24 (80%)	0.0278
No analgesic	13 (43.4%)	6 (20%)	

statistically significant (p=0.023). The mean total numbers of analgesics were 0.73±0.640 in group A and 1.03±0.850 in group B. The difference in the proportion of the total number of analgesics between the two groups was not statistically significant (p=0.128). Among group A, 17 (56.7%) patients had required rescue analgesics. In group B, 24 (80%) patients had required rescue analgesics. The difference in the proportion of rescue analgesics between the two groups was statistically significant (p=0.027) (Table 2).

There was a statistically significant difference in HR at 0 min, 15 min, 30 min, 45 min and 60 min between the two groups (p<0.001). There was no statistically significant difference in HR at baseline between the two groups (p=0.311). There was a statistically significant difference in SBP at 15 min, 30 min, 45 min and 60 min between the two groups (p<0.001). There was no statistically significant difference in SBP at baseline and 0 min between the two groups (p>0.05). There was a statistically significant difference in DBP at 15 min, 30 min, 45 min and 60 min between the two groups (p<0.001). There was no statistically significant difference in DBP at baseline and 0 min between the two groups (p>0.05). There was a statistically significant difference in sedation score at baseline, 2, 4, 6 and 8 h between the two groups (p<0.05). There was no statistically significant difference in sedation score at 12 h between the two groups (p>0.05) (Table 3).

Table 3. Comparison of mean haemodynamic parameters between the study groups (n=60)

Parameter	Study group: Group A (n=30)	Study group: Group B (n=30)	p
Sedation score			
Baseline	3.60±0.5	1.30±0.46	<0.001
2 h	2.73±0.45	1.13±0.47	<0.001
4 h	2.23±0.43	1.33±0.47	<0.001
6 h	2±0	1.43±0.50	<0.001
8 h	2±0	1.77±0.43	0.004
12 h	2.03±00.18	2±0	0.321
24 h	2±0	2±0	1.0
Pain score (VAS)			
Baseline	0±0	0.03±0.18	0.321
2 h	0±0	0.83±0.46	<0.001
4 h	0.47±0.86	1.43±1.00	<0.001
6 h	1.20±1.32	3.03±1.67	<0.001
8 h	2.07±1.68	2.57±1.30	0.203
12 h	2.50±2.08	2.03±0.85	0.260
24 h	0.50±0.68	1.17±0.46	<0.001
Heart rate			
Baseline	79.10±6.5	80.73±6.5	0.311
0 min	68.87±7.45	80.77±5.8	<0.001
15 min	59.57±5.86	77.60±3.78	<0.001
30 min	56.03±3.98	77.07±3.60	<0.001
45 min	55.33±3.14	76.30±3.64	<0.001
60 min	54.17±3.35	76.90±3.52	<0.001
Systolic blood pressure			
Baseline	123.33±9.97	123.03±5.43	0.886
0 min	120.93±7.72	123.03±5.63	0.234
15 min	107.97±6.00	122±5.37	<0.001
30 min	103.20±7.01	121.87±6.02	<0.001
45 min	102.23±6.60	121.77±5.9	<0.001
60 min	101.67±4.47	121.93±5.32	<0.001
Diastolic blood pressure			
Baseline	70.50±5.63	70.67±4.30	0.898
0 min	68.77±5.24	70.80±4.31	0.168
15 min	59.30±3.76	71.47±4.62	<0.001
30 min	57.93±4.41	71.70±4.76	<0.001
45 min	56.77±3.54	71±4.77	<0.001
60 min	56±3.32	71.53±4.98	<0.001

Discussion

TAP block is now being regarded as a successful method for excellent postoperative pain relief, even in patients with complicated appendicitis (17). Dexmedetomidine, a highly selec-

tive α2 agonist, has been evaluated for its efficacy and safety in prolonging the duration of TAP block when added as an adjuvant in various surgical procedures (18). Many studies have found that the addition of dexmedetomidine to LAs in central neuraxial blocks and in peripheral nerve blocks is a safe and effective way to potentiate the LA effect and thus reduces the need for further analgesics, enhancing postoperative recovery (16, 19, 20).

The key findings of the present study were that the addition of dexmedetomidine to bupivacaine in TAP block provides prolonged postoperative analgesia and better pain control than bupivacaine alone. The duration of analgesia was significantly prolonged with the addition of dexmedetomidine and reduced the need for rescue analgesics postoperatively in our study. Dexmedetomidine also resulted in significantly lesser pain scores at 2, 4, 6 and 24 h after surgery. However, pain scores were comparable at 8 and 12 h. It should be noted that although the mean number of analgesics is not statistically significant, the number of patients in the dexmedetomidine group (56.7%) who needed rescue analgesics is less than those in the bupivacaine alone group (80%). This could be attributed to some pain from visceral component in patients where TAP block may need supplementation by other analgesics. It is well known that dexmedetomidine reduces the requirement of analgesics in the perioperative period that could explain this issue.

We could not find any study documenting the safety and efficacy of dexmedetomidine as an adjuvant to bupivacaine in TAP block in laparoscopic appendicectomy. However, its efficacy in TAP block was evaluated in a wide range of surgical procedures, including laparoscopic hernia repair, hysterectomy and caesarean section. An Indian study conducted on individuals undergoing laparoscopic repair of abdominal wall hernia under TAP block has reported significantly lower VAS scores with dexmedetomidine than with normal saline as adjuvant (21). Another Indian study on women undergoing caesarean section has reported longer time to request rescue analgesic and lesser dose of rescue analgesia with dexmedetomidine as adjuvant to bupivacaine in TAP block (22). However, Ozalp et al. (23) in their study reported comparable pain scores between the dexmedetomidine adjuvant and control groups. In our study, similar pain scores were also noted at 8 and 12 h. Niraj et al. (24) also reported that in open appendicectomy, USG-guided TAP block significantly reduces postoperative morphine consumption in the first 24 h (mean (SD) 28 (18) vs 50 (19) mg, $p<0.002$) in the bupivacaine and dexmedetomidine group compared to the bupivacaine only group. Almarakbi et al. (16) also observed that the addition of dexmedetomidine to bupivacaine in TAP block achieves better local anaesthesia and provides better pain control postoperatively without any major side effects in open abdominal hysterectomy. Xue et al. (20) in their study had also observed that the USG-guided TAP block combined with dexmedetomidine as adjuvant improves recovery from anaesthesia and reduces postoperative pain during gynaecological laparoscopy. A recently published systematic review and meta-analysis by Sun et al. (25) has concluded that dexmedetomidine as an adjuvant provides better postoperative analgesia in addition to reducing postoperative analgesic and prolonging the LA effect when administered in TAP blocks for abdominal surgery.

In our study, there was a statistical significance with sedation scores higher in group A till the 8-hour postoperative period than in group B, but they remained comparable at 12 and 24 h. Though there is a significant difference statistically in both groups, the sedation score remained approximately 2. A study with a large number of study population might probably help to understand the difference. HR was significantly lower in the dexmedetomidine group than in the control group in the entire postoperative period. Both SBP and DBP were significantly lower from the 15-minute to 24-hour postoperative period in the dexmedetomidine group. Agarwal et al. (26) in their study also observed that patients in the bupivacaine+dexmedetomidine group were adequately sedated (modified Ramsay Sedation Score=2/6 or 3/6) with no adverse effects except bradycardia in one patient with dexmedetomidine. As per this study, except for the initial recordings (at 0, 5, 10 and 15 min), HR levels were significantly lower in the bupivacaine control group ($p<0.001$), whereas SBP and DBP levels were significantly lower in the bupivacaine+dexmedetomidine group at 15, 30, 45, 60, 90 and 120 min than in the bupivacaine control group ($p<0.001$). No difference in the incidence of bradycardia, hypotension and other adverse effects, such as pruritus, nausea and vomiting, with dexmedetomidine was noted.

The present results indicate that the addition of dexmedetomidine to bupivacaine in TAP block provides prolonged postoperative analgesia and better pain control than bupivacaine alone in laparoscopic appendicectomy.

The total amount of analgesic requirement and the need for rescue analgesic doses were less when dexmedetomidine was added to bupivacaine. The safety profile of dexmedetomidine is comparable with the control group, with no additional risk of haemodynamic fluctuations.

The key limitation of our study was the inability to determine serum dexmedetomidine levels to associate whether the analgesia is due to its systemic effect or potentiation of LA effect locally in TAP block. However, all the efforts were made to minimise bias in the study. The role of confounding is also very limited, as the randomisation process had resulted in good balance with respect to all the potential confounding baseline parameters between the study groups.

Conclusion

Based on the current study findings and the recent meta-analysis, dexmedetomidine appears to be safe and effective as an adjuvant for TAP block. However, there is a need for further randomised controlled trial on different population groups undergoing laparoscopic appendicectomy to enhance the available quality of evidence.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Sri Ramachandra Medical College (IEC/17/APR/132/15).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - A.P., S.G.R.; Design - A.P., S.K.; Supervision - S.G.R., A.P.; Resources - S.K., A.P.; Materials - S.K., A.P.; Data Collection and/or Processing - S.K., S.G.R.; Analysis and/or Interpretation - S.K., S.G.R., A.P.; Literature Search - S.K., S.G.R.; Writing Manuscript - S.G.R.; Critical Review - S.G.R., A.P.

Conflict of Interest: The authors have no conflicts of interest to declare.

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