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Original Article

Anaesthesia Section

Efficacy of Dexmedetomidine as an Adjuvant in Subarachnoid Block versus Transversus Abdominis Plane Block in Patients Undergoing Total Abdominal Hysterectomy under Spinal Anaesthesia: A Double-blinded Randomised Clinical Study

RACHANA S KORI[1], J VASANTHA KUMAR[2], SHILPA NIJALINGAPPA BINGI[3], SHARMILA SOMAYAJI[4]

ABSTRACT

Introduction: Postoperative pain continues to be a major concern in patients undergoing abdominal surgeries despite advances in regional anaesthesia. Dexmedetomidine is found to have analgesic properties, hence used as an adjuvant for enhancing postoperative analgesia in both central neuraxial and peripheral nerve block.

Aim: To compare the efficacy of dexmedetomidine as an adjuvant in subarachnoid block versus Transversus Abdominis Plane (TAP) block in patients posted for total abdominal hysterectomy under spinal anaesthesia.

Materials and Methods: This double-blinded randomised clinical study was conducted at Bangalore Medical College and Research Institute, Bengaluru, Karnataka, India. A total of 70 patients undergoing elective total abdominal hysterectomy under subarachnoid and TAP block. Patients were randomly allocated into two groups (n=35 each). Patients were administered intrathecal 2.8 mL of 0.5% hyperbaric bupivacaine. At the end of surgery, an ultrasound-guided bilateral TAP block was administered using 20 mL of 0.25% bupivacaine on each side (total volume made up to 22 mL). Group SD (Spinal Dexmedetomidine group) received 5 µg (0.05 mL) of dexmedetomidine intrathecally and Group TD (TAP Dexmedetomidine group) received 25 µg dexmedetomidine in TAP block. Haemodynamic parameters, postoperative Visual Analogue Scale (VAS) pain score, time to first rescue analgesia, total rescue analgesic consumption in 24 hours, and sedation scores were noted. Data were analysed using an independent samples t-test and a Chi-square test. A p-value of <0.05 was considered statistically significant.

Results: Demographic parameters were comparable between the groups (age, weight, American Society of Anaesthesiologists (ASA) status). Postoperative VAS scores at 0 hour were significantly lower in Group SD (0.8±1.5) compared to Group TD (1.9±2.1) (p-value <0.05). The time to first rescue analgesia was significantly prolonged in Group SD (396.0±200.7 minutes) compared to Group TD (195.4±92.4 minutes) (p-value <0.001). The total postoperative rescue analgesic requirement within 24 hours was significantly lower in Group SD (144.3±45 mg) compared to Group TD (182.9±45.3 mg) (p-value=0.001) haemodynamic parameters remained stable in both groups.

Conclusion: Intrathecal dexmedetomidine as an adjuvant to spinal anaesthesia provides superior early postoperative analgesia, prolonged duration of analgesia, and reduced postoperative analgesic requirement compared to dexmedetomidine administered in TAP block. Both techniques maintained satisfactory haemodynamic stability with minimal adverse effects.

Keywords: Pain, Postoperative, Regional anaesthesia, Visual analogue scale

INTRODUCTION

Total abdominal hysterectomy remains one of the most widely performed major gynaecological procedures. Despite the advances in anaesthetic techniques and perioperative care, postoperative pain following abdominal hysterectomy continues to remain a significant challenge [1] and is associated with various physiological stress responses that may contribute to increased postoperative morbidity and delayed recovery. Spinal anaesthesia is widely preferred for lower abdominal surgery because it offers greater advantages such as faster onset, reliable sensory and motor blockade decreased blood loss and thromboembolic complications compared to general anaesthesia. However, a major limitation of spinal anaesthesia is the relatively shorter duration of action of postoperative analgesia [2]. Hence, several pharmacological adjuvants have been added to local anaesthetics to prolong the duration of sensory blockade and improve postoperative analgesia [3].

Various pharmacological adjuvants such as opioids, clonidine, ketamine, magnesium sulphate and dexmedetomidine have been used with local anaesthetics to enhance the quality and duration of neuraxial blockade [4]. These drugs including opioids, usually result in several side effects include itching, respiratory depression, urinary retention, postoperative gastrointestinal disturbance which can be overcome by preferring them as adjuvant with other analgesic [5].

Dexmedetomidine is a highly selective α_2-adrenergic receptor agonist that produces analgesia by inhibiting norepinephrine release and suppressing nociceptive neuronal transmission in the spinal cord. Intrathecal dexmedetomidine has been shown to prolong sensory and motor blockade, delay the requirement of rescue analgesia, and improve postoperative pain scores [6,7]. Similarly, dexmedetomidine has also been evaluated as an adjuvant in peripheral nerve blocks and fascial plane blocks including TAP block which targets peripheral nociceptive receptors may be an ideal protocol for pain control after

abdominal surgery [8]. The ultrasound-guided TAP block provides anterior abdominal wall analgesia by blocking thoracolumbar nerves (T6-L1) within the fascial plane between the internal oblique and transversus abdominis muscles [9,10].

Several studies [6,8], have independently evaluated the efficacy of intrathecal dexmedetomidine and dexmedetomidine as an adjuvant in TAP block. However, there are no studies directly comparing these two routes of administration in patients undergoing total abdominal hysterectomy under spinal anaesthesia. Furthermore, there are studies comparing intrathecal dexmedetomidine with intravenous dexmedetomidine [11] but none with peripheral block comparing duration of postoperative analgesia, rescue analgesic requirement, haemodynamic effects between these techniques.

Therefore, the present study was conducted to compare the efficacy of dexmedetomidine as an adjuvant in subarachnoid block versus TAP block in patients undergoing total abdominal hysterectomy under spinal anaesthesia. The primary objective of the study was to compare postoperative analgesia using VAS scores and time to first rescue analgesia between the groups, while secondary objective was to compare total postoperative rescue analgesic requirement during the first 24 hours, haemodynamic parameters, postoperative sedation scores and adverse effects between the groups.

MATERIALS AND METHODS

This randomised, double-blinded clinical trial was conducted in Bangalore Medical College and Research Institute, Bengaluru, Karnataka, India over a period of two years (November 2018 to May 2020) following approval from the Institutional Research Committee and the Institutional Ethics Committee No BMC/PG/124/2018-19. This study was conducted and reported in accordance with the CONSORT 2010 guidelines.

Sample size: Based on previous study by Marappa P et al., pain scores at four hour in TAP group was 3.0±0.728 and in ITB group were 1.80±0.422 and expecting minimum difference in pain scores between two groups [12].

The sample size calculation:

$$n=\frac{2(Z_{\alpha}\pm Z_{1-\beta})^2S^2}{d^2}$$

where, Z_{α}=standard table value for 95% confidence interval

$Z_{1-\beta}$=standard table value for 80% power

S=standard deviation=0.575

d=effect size=0.4

$$n=\frac{2(1.96+0.84)^2(0.575)^2}{(0.4)^2}$$

The calculated sample size was 32 patients in each group. This was rounded off to 35 patients per group, giving a total sample size of 70 patients.

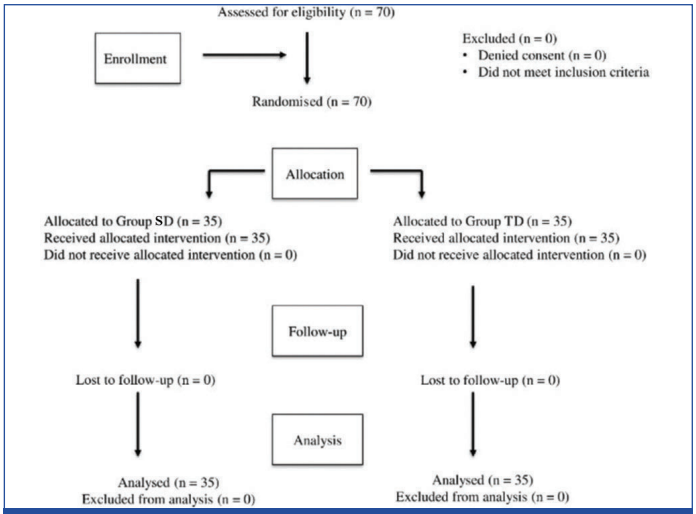
Inclusion criteria: A total of 70 patients aged 18-50 years with weight 50-80 kg, belonging to ASA grade-I and II, scheduled for elective total abdominal hysterectomy under spinal anaesthesia were included in the study.

Exclusion criteria: Patients' refusal to participate, with history of allergy to local anaesthetics, hepatic or renal dysfunction, cardiac dysrhythmias, contraindication to spinal anaesthesia, ASA-PS grade III were excluded from the study.

Randomisation

Randomisation was performed using a simple random sampling technique. Patients were randomly allocated into two groups using computer-generated random numbers. Allocation concealment was maintained using sealed opaque envelopes [Table/Fig-1].

The random allocation sequence was generated by an anaesthesiologist who was not involved in patient enrolment, intraoperative management, postoperative assessment, or data analysis. Patient enrolment and assignment to intervention groups were carried out by another investigator to maintain blinding and minimise selection bias.



[Table/Fig-1]: CONSORT flow diagram.

A total of 70 patients were divided into two groups of 35 each:

- Group SD- Dexmedetomidine as adjuvant to subarachnoid block;
- Group TD- Dexmedetomidine as adjuvant in TAP block.

Study Procedure

After preoperative assessment, patients who met the inclusion criteria were selected; informed written consent was obtained from those patients who were willing to participate. All patients were advised to follow standard fasting guidelines. The procedure was explained to all the patients the day before surgery. On the day of surgery, once the patient was transferred to the operating theatre, standard monitors, including Non-Invasive Blood Pressure (NIBP), Electrocardiogram (ECG) and peripheral Oxygen Saturation (SpO_2) were attached, and baseline readings were recorded. An 18 G intravenous (IV) cannula was secured and was co-loaded with 500 mL of Ringer's lactate. A standardised fluid strategy was adopted for all patients rather than an individualised formula-based calculation to maintain uniformity. The study drug was set up in a sterile tray by following all aseptic precautions. Patients were positioned in the sitting position. Following strict aseptic protocols, lumbar puncture with a 25 G Quicke needle at the L3-L4 space was performed by a qualified anaesthesiologist. After confirmation of free flow of cerebrospinal fluid, the corresponding study drug was administered. After administration of spinal anaesthesia, patients were positioned supine. Surgery was commenced after confirming a sensory blockade up to T6 dermatome level.

Vital signs were monitored throughout the entire duration of the surgery at 1, 5, 10, 15, 20, 25, 30 minutes, thereafter every 10 minutes till 60 minutes, and then every 30 minutes till the end of surgery, which included Heart Rate (HR) and MAP. Hypotension in the intraoperative period i.e., Systolic Blood Pressure (SBP) <90 mm of Hg or <20% of the baseline was treated with ephedrine (3 mg aliquots). Bradycardia defined as HR decreased to <60/min or < 20% of the baseline was treated with atropine 0.02 mg/kg. At the end of the surgical procedure, under strict aseptic precautions with the patient in the supine position, the TAP block was administered with a high-frequency linear ultrasound probe (6-13 MHz, Sonosite TM, Bothell, Washington) placed transversely over the anterolateral abdominal wall between the costal margin and iliac crest. TAP was identified between the internal oblique and transversus abdominis and the study drug was injected into the TAP under real-time ultrasound guidance.

Group SD (Subarachnoid Dexmedetomidine Group)- Patients received intrathecal 2.8 mL of 0.5% hyperbaric bupivacaine with dexmedetomidine 5 µg (0.05 mL). The total intrathecal volume was made up to 3 mL using normal saline. At the end of surgery, a bilateral ultrasound-guided TAP block was administered with 20 mL of 0.25% bupivacaine±2 mL normal saline on each side (total volume 22 mL per side). Group TD (TAP Dexmedetomidine Group)- Patients received intrathecal 2.8 mL of 0.5% hyperbaric bupivacaine, with the total volume made up to 3 mL using normal saline. At the end of surgery, a bilateral ultrasound-guided TAP block was administered with 20 mL of 0.25% bupivacaine with dexmedetomidine 25 µg (0.25 mL), and the total volume was made up to 22 mL with normal saline on each side.

The doses and concentrations used were based on previously published studies and standard clinical practice [12,13]. After completion of the TAP block, patient's vital parameters were recorded and patients were shifted to the Post-Anaesthesia Care Unit (PACU) for postoperative monitoring and further assessment of analgesia. The Primary outcome measures were postoperative pain intensity using the (VAS; 0-10) at 0 hour (on arrival to PACU), two hours, four hours, eight hours, 12 hours, 24 hours. Rescue analgesia was given to patients with a VAS score >4 in the form of injection tramadol 50 mg i.v and time to first rescue analgesia from completion of spinal anaesthesia to administration of first rescue analgesic and the secondary outcome measures were total Analgesic Requirement in 24 hours postoperatively and haemodynamic parameters like HR, Mean Arterial Pressure (MAP) recorded postoperatively at predefined intervals and Sedation was assessed using a Wilson sedation score at 0 hour, 2, 4, 8, 12 and 24 hours [14].

STATISTICAL ANALYSIS

Data were analysed using the Statistical Package for Social Sciences (SPSS) windows version 18.0. Data presented as numbers (%) or mean±SD as appropriate. Quantitative variables were analysed by employing the independent samples t-test. Qualitative variables were compared using the Chi-square test. A p-value <0.05 was considered statistically significant. Graphical representation of data was performed using Microsoft Excel and Microsoft Word, and included bar diagrams and line graphs where appropriate.

RESULTS

The demographic parameters (age, weight, height, Body Mass Index (BMI), ASA) were comparable between the study groups [Table/Fig-2].

Parameters	Group SD Mean±SD	Group TD Mean±SD	p-value
Age (y)	45.7±4.3	47.3±6.4	0.087
Weight (kg)	54.7±6.6	58.7±10.2	0.052
Height (cm)	148.8±4.8	148.6±5.5	0.853
ASA (n%)			
I	21 (60.0)	17 (48.6)	0.34
II	14 (40.0)	18 (51.4)	
BMI (kg/m^2)	25.7±2.7	26.6±4.2	0.077

[Table/Fig-2]: Comparison of mean age, mean anthropometric parameters and ASA-PS between study groups.

The mean postoperative VAS scores were significantly lower in Group SD compared to Group TD during the early postoperative period (0-8 hours) with p-value <0.05, the mean VAS scores were lower in Group TD compared to Group SD at 12 hours and 24 hours postoperatively [Table/Fig-3].

The mean time to first rescue analgesia in Group SD was significantly longer compared to Group TD with p-value <0.001. The mean total dose of rescue analgesic required during the first 24 hours was significantly lower in Group SD compared to Group TD with p-value= 0.001 [Table/Fig-4].

VAS	Group SD Mean±SD	Group TD Mean±SD	p-value
0 h	0.8±1.5	1.9±2.1	0.015*
2 hrs	3.1±2.8	5.0±2.1	0.002*
4 hrs	5.1±2.5	7.1±1.4	<0.001*
8 hrs	6.6±1.5	7.3±1.0	0.027*
12 hrs	6.6±0.9	6.0±0.8	0.005*
24 hrs	4.5±1.0	4.1±1.0	0.145

[Table/Fig-3]: Comparison of mean VAS score between study groups.
*significant at 5% level of significance (p<0.05)

Parameters	Group SD Mean±SD	Group TD Mean±SD	p-value
Time of first rescue analgesia	396.0±200.7	195.4±92.4	<0.001*
Total dose of rescue analgesia	144.3±45.0	182.9±45.3	0.001*

[Table/Fig-4]: Time for first rescue analgesia between study groups (in minutes) and total dose of rescue analgesia between study groups (in mg).
*significant at 5% level of significance (p<0.05)

The baseline mean HR between the two groups was comparable. Following administration of spinal anaesthesia, a reduction in HR was observed in both groups, which was more pronounced in Group SD. From one minute to 90 minutes, the mean HR remained significantly lower in Group SD compared to Group TD with p-value <0.05. During the postoperative period (0, 2, 4, 8, 12, and 24 hours), no statistically significant difference was found in mean HR (p-value >0.05) [Table/Fig-5].

HR		Group SD Mean±SD	Group TD Mean±SD	p-value
Preoperative		82.5±9.4	84.0±11.9	0.543
Intraoperative	0 min	79.7±9.7	88.7±10.7	<0.001*
	1 min	78.5±9.9	88.7±11.0	<0.001*
	2 mins	76.6±10.3	86.5±10.8	<0.001*
	3 mins	73.5±10.3	84.4±10.6	<0.001*
	5 mins	70.2±9.9	82.4±10.3	<0.001*
	10 mins	68.2±9.0	77.7±11.2	<0.001*
	15 mins	66.4±8.1	75.4±10.5	<0.001*
	20 mins	65.6±6.6	73.6±10.0	<0.001*
	25 mins	65.4±7.7	73.6±9.4	<0.001*
	30 mins	65.1±7.0	73.1±8.7	<0.001*
	45 mins	64.7±6.5	72.8±9.4	<0.001*
	60 mins	66.1±6.9	75.2±8.6	<0.001*
	90 mins	67.8±5.7	74.9±9.1	0.003*
	120 mins	71.3±7.7	73.3±8.0	0.531
Postoperative	0 h	69.2±8.0	72.1±8.3	0.141
	2 hrs	76.3±11.3	80.3±12.7	0.171
	4 hrs	82.5±12.6	79.1±12.2	0.254
	8 hrs	87.5±9.9	82.7±13.3	0.088
	12 hrs	87.7±7.6	84.3±11.7	0.153
	24 hrs	83.3±7.2	82±10.2	0.544

[Table/Fig-5]: Comparison of mean HR between study groups.
*significant at 5% level of significance (p<0.05)

The baseline MAP was comparable between the two groups. Following spinal anaesthesia, a reduction in MAP was observed in both groups. The mean MAP was significantly lower in Group SD compared to Group TD (p-value <0.05) from five minutes to 90 minutes but comparable in early three minutes and in the later time period. During the postoperative period (0, 2, 4, 8, 12, and 24

hours), the mean MAP values showed no statistically significance (p-value >0.05) [Table/Fig-6].

MAP		Group SD Mean±SD	Group TD Mean±SD	p-value
Preoperative		93.2±7.4	92.1±9.4	0.588
Intraoperative	0 min	92.5±7.1	92.8±7.8	0.89
	1 min	90.4±8.2	88.4±8.7	0.331
	2 mins	86.8±7.1	84.9±8.8	0.325
	3 mins	82.9±7.1	85.4±6.2	0.114
	5 mins	79.1±6.8	84.0±6.1	0.003*
	10 mins	76.2±5.4	80.3±5.8	0.003*
	15 mins	73.4±5.4	78.5±7.7	0.002*
	20 mins	74.1±4.1	79.8±6.1	<0.001*
	25 mins	73.9±3.7	81.4±4.5	<0.001*
	30 mins	74.2±3.9	80.5±4.5	<0.001*
	45 mins	73.6±13.5	81.7±5.2	0.001*
	60 mins	68.0±28.5	84.2±6.2	0.002*
	90 mins	78.4±4.5	84.5±6.2	<0.001*
	120 mins	84.2±4.9	85.2±4.2	0.588
Postoperative	0 h	80.9±5.1	83.1±12.0	0.327
	2 hrs	86.1±8.2	87.9±6.5	0.294
	4 hrs	90.4±8.9	94.7±13.7	0.124
	8 hrs	93.9±6.4	95.5±13.5	0.536
	12 hrs	94.5±4.7	96.5±5.8	0.107
	24 hrs	91.1±4.4	92.5±5.5	0.252

[Table/Fig-6]: Comparison of mean MAP between study groups.
*significant at 5% level of significance (p<0.05)

The mean Wilson sedation score at 0 hour (on arrival to PACU) was significantly higher in Group SD compared to Group TD with p-value <0.05. At subsequent postoperative time intervals (2, 4, 8, 12, and 24 hours), the mean Wilson sedation scores had no significant differences between the two groups (p-value >0.05) [Table/Fig-7].

WSC	Group SD Mean±SD	Group TD Mean±SD	p-value
0 h	1.37±0.5	1.0±0	<0.001*
2 hrs	1.03±0.2	1.0±0.0	0.321
4 hrs	1.0±0.0	1.0±0.0	-
8 hrs	1.0±0.0	1.0±0.0	-
12 hrs	1.0±0.0	1.0±0.0	-
24 hrs	1.0±0.0	1.0±0.0	-

[Table/Fig-7]: Comparison of mean Wilson sedation score between study groups.
*significant at 5% level of significance (p<0.05)
SD = 0 indicates all subjects scored identically

DISCUSSION

The present study compared the efficacy of dexmedetomidine as an adjuvant in subarachnoid block versus TAP block. Baseline demographic characteristics including age, weight, ASA physical status were comparable between the two groups, indicating homogeneity of the study population. Intraoperatively, Group SD demonstrated a lower intraoperative HR compared to Group TD, although the reduction was clinically insignificant and did not require intervention. Similar findings were reported by Gupta R et al., Malawat A et al., who reported no clinically significant bradycardia with 5 µg of intrathecal dexmedetomidine [13,15]. Likewise studies by Parameshwari AR and Udayakumar P and Rai P et al., also demonstrated satisfactory haemodynamic stability with dexmedetomidine used as an adjuvant in TAP block [16,17].

In the present study, postoperative VAS scores during the early postoperative period (0-8 hours) were significantly lower in Group SD compared to Group TD (at 0 hour 0.8±1.5 vs 1.9±2.1), indicating superior early postoperative analgesia with intrathecal dexmedetomidine. If compared, it is obvious that Group SD will have good immediate postoperative (at 0 hour) analgesia compared to Group TD because Group SD has received dexmedetomidine with bupivacaine preoperatively and this is reflected by lower VAS Score at 0 hour (i.e., before TAP block acted). These findings correlate with studies by Gupta R et al., Malawat A et al., who reported lower early postoperative pain scores with intrathecal dexmedetomidine [13,15]. The Group SD showed longer time to first rescue analgesia compared to Group TD. This was consistent with previous studies like Gupta R et al., [13]. Akhter M et al., these findings reinforce that intrathecal dexmedetomidine significantly prolongs postoperative analgesia [18].

The present study demonstrated that blood Pressure (MAP) in Group SD showed statistically lower intraoperatively compared to Group TD; however, these changes were clinically insignificant, and all patients remained haemodynamically stable similar to studies by Gupta R et al., Malawat A et al., which demonstrated that intrathecal dexmedetomidine provides stable haemodynamics without clinically significant hypotension [13,15]. In the postoperative period, no significant differences were noted in MAP between the groups, consistent with studies by Rai P et al., and Almarakbi WA and Kaki AM confirming haemodynamic stability with dexmedetomidine in TAP block [17,19].

This study demonstrated lower dose of rescue analgesic requirement in first 24 hour in Group SD compared to Group TD. If Group SD was not to receive dexmedetomidine preoperatively, then probably Group TD would have had better postoperative VAS and lesser requirement of rescue analgesia because dexmedetomidine was given postoperatively in TAP. This correlates with findings by Rai P et al., Bharti N et al., (65% reduction in opioid consumption with TAP block) [17,20].

Group SD had received dexmedetomidine prior to start of surgery, the said group had lower VAS Score and lesser requirement of rescue analgesia initially. However, lower VAS in Group TD compared to Group SD at 12 hours and 24 hours postoperatively prove that postoperative dexmedetomidine in TAP block or the higher doses of rescue analgesia given in Group TD probably worked beyond 12 hours and may be upto 24 hours which reduced the VAS. In current study, Wilson sedation score was higher in Group SD during the immediate postoperative period (0 hour), although the sedation was mild and clinically insignificant and did not persist beyond the immediate postoperative period comparable to those reported by Malawat A et al., Rai P et al., higher sedation only in early postoperative period [15,17].

No clinically significant adverse effects such as severe bradycardia, hypotension or visceral injury were observed in the present study. The lower incidence may be attributed to the use of low doses of dexmedetomidine and ultrasound guidance during TAP block administration. Overall, the findings of the present study demonstrated that dexmedetomidine used as an adjuvant to spinal anaesthesia provides superior early postoperative analgesia, prolonged duration of analgesia and reduced postoperative rescue analgesic requirement compared to dexmedetomidine used as an adjuvant in TAP block. However, TAP block with dexmedetomidine still provided satisfactory postoperative analgesia and may remain as useful as a component of multimodal analgesia, particularly in patients where neuraxial adjuvants or systemic analgesics are contraindicated. Thus, both techniques are effective and safe.

Limitation(s)

The present study had certain limitations. First, the temporal difference in dexmedetomidine administration between the groups may have influenced early postoperative analgesic outcomes. Second, the study was conducted at a single tertiary care centre with a relatively small sample size, which may limit generalisability of findings. Third, long-term postoperative outcomes and patient satisfaction scores were not evaluated.

CONCLUSION(S)

The present study demonstrated that dexmedetomidine, when used as an adjuvant to spinal anaesthesia, provides superior postoperative analgesia compared to its use as an adjuvant in TAP block. It was associated with lower early postoperative pain scores, prolonged duration of analgesia, delayed requirement of rescue analgesia, and reduced total analgesic consumption, while maintaining stable haemodynamic and minimal side-effects. However, dexmedetomidine may be considered as an adjuvant to TAP block in situations where no adjuvants are used with spinal anaesthesia, as it can still provide effective postoperative analgesia as part of a multimodal analgesic regimen.

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PARTICULARS OF CONTRIBUTORS:

1. Assistant Professor, Department of Anaesthesiology, SDM College of Medical Science and Hospital, Dharwad, Karnataka, India.
2. Professor and Head, Department of Emergency Medicine, Akash Institute of Medical Sciences and Research Centre, Bengaluru, Karnataka, India.
3. Assistant Professor, Department of Anaesthesiology, Gadag Institute of Medical Sciences, Gadag, Karnataka, India.
4. Additional Consultant, Department of Anaesthesiology, Fortis Hospital, Bannerghatta Road, Bengaluru, Karnataka, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Rachana S Kori,
Flat No. 203, Shreyas Block, SDM Medical Staff Quarters, Ratnashree Vihar,
Sattur, Dharwad, Karnataka, India.
E-mail: rachana.kori@gmail.com

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