

Postoperative Analgesic Efficacy of Nalbuphine vs Dexmedetomidine as Adjuvants to Ropivacaine in Ultrasound Guided Transversus Abdominis Plane Block for Abdominal Hysterectomies: A Randomised Clinical Study

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ABSTRACT

Introduction: Transversus Abdominis Plane (TAP) block has been practised as an effective alternative to systemic analgesics to achieve adequate postoperative analgesia, with minimal systemic side effects. Dexmedetomidine, an alpha-2 agonist and nalbuphine, an opioid, have been studied as adjuvants to local anaesthetics to improve the analgesic profile of regional anaesthetic blocks.

Aim: To compare the duration and quality of postoperative analgesia of dexmedetomidine and nalbuphine when used as adjuvants to ropivacaine for TAP block.

Materials and Methods: This was a randomised double blinded study conducted on 60 patients undergoing total abdominal hysterectomies under spinal anaesthesia. Patients were randomly distributed into two groups of 30 patients each, to receive either 39 mL of 0.2% ropivacaine+50 µg dexmedetomidine (1 mL)

(group D) or 39 mL of 0.2% ropivacaine+10 mg nalbuphine (1 mL) (group N), for bilateral TAP block. Postoperative pain scores, time for first rescue analgesic request and incidence of side effects were compared.

Results: Duration of postoperative analgesia was similar in both groups (409.14±48.92 minutes in group D vs 419.03±54.11 minutes in group N) (p-value=0.462). Postoperative pain scores and total amount of rescue analgesic requirement (105.17±42.98 vs 106.45±46.08) was also similar in both the groups (p=0.912). In Nalbuphine group, 16.7% reported pruritis (p-value=0.02) and 13.3% reported nausea (p-value=0.213). However, in group D only one patient reported nausea two hours postoperatively.

Conclusion: Nalbuphine when compared to dexmedetomidine, as an additive to ropivacaine for TAP block, provides similar postoperative analgesic duration and efficacy, but increases the incidence of pruritus and nausea.

Keywords: Gynaecological surgeries, Postoperative pain score, Regional anaesthesia

INTRODUCTION

Total Abdominal Hysterectomy (TAH) is a gynaecological surgery performed for conditions such as fibroid uterus, abnormal uterine bleeding etc. TAH is usually done under regional anaesthesia, the effect of which wears off after 3-4 hours and patient starts experiencing pain postoperatively. Even in patients who receive general anaesthesia, pain in the operative period is significant. Failure to adequately control this pain results in delayed wound healing and recovery, prolonged hospital stay and also psychosocial dissatisfaction to the patient.

TAP block has been practised as an effective alternative to systemic analgesics to achieve adequate postoperative analgesia, with minimal systemic side effects. The components of the anterior abdominal wall (skin, subcutaneous tissue, muscles and parietal peritoneum) are supplied by sensory nerves derived from the anterior rami of spinal nerves T7 to T11. These nerves traverse through the neurofascial plane between the internal oblique and the transversus abdominis muscles. TAP block is aimed at blocking these nerves in the neurofascial plane. Ultrasound guidance not only improves the technical ease but also makes the block safe to perform [1].

Local anaesthetic medications like 0.25% and 0.375% bupivacaine, 0.2% and 0.5% ropivacaine are used in TAP block for achieving adequate postoperative analgesia after abdominal and gynaecological surgeries. The duration of analgesia was reported to be around 0-12 hours [2,3]. Various adjuvants have been used along with local anaesthetics to prolong the duration of analgesia after TAP block.

Dexmedetomidine provides sympatholytic, sedative, analgesic, and anaesthetic-sparing effects. Dexmedetomidine as an adjuvant to local anaesthetic provides better and longer duration of analgesia. It exerts its effect on presynaptic neuronal receptors and reduces norepinephrine release at peripheral afferent nociceptors. One of the meta-analysis has concluded that dexmedetomidine is a favourable local anaesthetic adjuvant with lower postoperative pain intensity and a significant reduction in opioid consumption as well as enhanced duration of the TAP block [4].

Nalbuphine is an opioid agonist-antagonist and is widely used as adjuvant to local anaesthetics to enhance the duration of analgesia, for various regional anaesthetic blocks due to its affinity to κ -opioid receptors. Nalbuphine has significantly extended the duration of postoperative analgesia, when given as an adjuvant to 0.5% bupivacaine in supraclavicular brachial plexus block without any adverse effects [5]. In this study, nalbuphine was administered along with local anaesthetic around the nerve plexus. However, the efficacy of nalbuphine in prolonging the duration of action of local anaesthetics, when administered in "neurofascial plane" needs to be established.

The primary aim of the study was to evaluate and compare the efficacy of nalbuphine versus dexmedetomidine as adjuvants to ropivacaine for TAP block. Primary outcome measures included Time to First Analgesic (TFA) request and pain scores in the first 24 hours. Secondary, outcome variables were incidence of Postoperative Nausea and Vomiting (PONV), patient satisfaction

scores and incidence of adverse events such as bradycardia, hypotension, respiratory depression, pruritus.

MATERIALS AND METHODS

This was a randomised, double blinded study conducted between July 2019 to December 2020 at R.L. Jalappa Hospital, Kolar, Karnataka. Institutional Ethical Committee Clearance (No. SDUMC/KLR/ IEC/195/2018-19) was obtained prior to the start of the study and written informed consent was taken from all the patients enrolled in the study. Total number of 60 patients were included in the study.

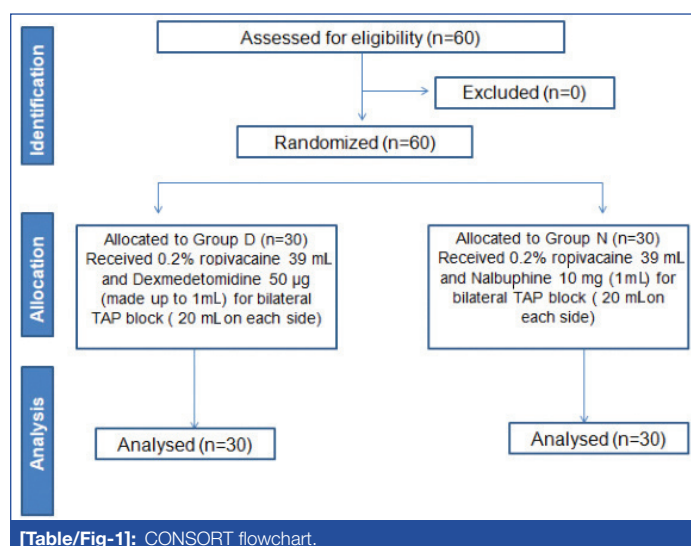
Inclusion criteria: Women aged 30-70 years belonging to American Society of Anesthesiologists (ASA) physical status I and II, scheduled for elective Total Abdominal Hysterectomy (TAH) surgeries.

Exclusion criteria: Patients who refused to participate in the study, allergic to local anaesthetics, had infection at needle insertion site for block, morbidly obese and patients on chronic pain medication.

Sample size calculation: A pilot study was done with 10 patients in each group. Based on its results, with an α of 5% and power of study 80%, a total of 56 patients was estimated as sample size. Therefore, 60 patients were included with 30 in each group.

Study Procedure

Patients who satisfied the inclusion and exclusion criteria, were randomly allocated into one of the following 2 groups using a computer generated random number table [Table/Fig-1].



Group D: Patients in this group received 0.2% ropivacaine 39 mL and Dexmedetomidine 50 µg (made upto 1 mL) for bilateral TAP block (20 mL on each side).

Group N: Patients in this group received 0.2% ropivacaine 39 mL and Nalbuphine 10 mg (1 mL) for bilateral TAP block (20 mL on each side).

Methodology

A day before surgery, a thorough pre-anaesthetic evaluation was performed, written informed consent was obtained and patients were sensitised regarding the study protocol and Wong Baker Faces pain scoring. A senior anaesthesiologist, who administered spinal anaesthesia to the patient and was not involved in the study, was given the sealed opaque envelope that contained the details of drugs for TAP block. The principal investigator who recorded all the study parameters was blinded to the injectate administered.

Technique of TAP Block

A single injection ultrasound-guided TAP block was performed in all patients using Mindray Z6 (Mindray DS USA Inc.) linear transducer probe (6-12 MHz). With patient in supine position, the ultrasound probe was placed in the midaxillary line, in a transverse plane on the lateral abdominal wall, midway between sub-costal margin and the

iliac crest. A 23G Quinke Babcock spinal needle was positioned in plane and directly under the ultrasound probe, and then advanced till it reached the plane between internal oblique and transversus abdominis muscles. Upon reaching this plane, 2-3 mL of saline was injected, to confirm the needle tip position in the neurofascial plane as the solution appears hypoechoic spreading between the planes. Careful aspiration was performed before injection to exclude vascular puncture and 20 mL of solution containing local anaesthetic and adjuvant mixture was injected. Similarly, the TAP block was performed on the opposite side, using the same technique and the same injectate. After surgery, the patients were transferred to the Postanaesthesia Care Unit (PACU).

Parameters Measured

Time at which the TAP block was given was considered as T0. The duration of 1 hour, 2 hours, 4 hours, 6 hours, 12 hours and 24 hours after performing the block were considered as T1, T2, T4, T6, T12 and T24, respectively. Mean Arterial Pressure (MAP), Heart Rate (HR) and intensity of pain assessed using Wong-Baker Faces pain rating scale were recorded at all these time intervals.

The TFA request, defined as the time from completion of the block till the time patient requests for analgesic was documented. Inj. tramadol 50 mg i.v. was given as rescue analgesic. Patients also received rescue analgesic when the pain severity on Wong-Baker Faces pain rating score exceeded six at any point of time. Total dose of rescue analgesic used at the end of 24 hours after surgery was also recorded.

The PONV was assessed as: 0=No nausea and vomiting, 1=nausea but no vomiting, 2=vomiting present. Inj. ondansetron 4 mg i.v. was used to treat any episodes of nausea or vomiting. Patient satisfaction was assessed at 24 hours after the block using a Likert scale from 1 to 5, where 5=extremely satisfied and 1=extremely dissatisfied. Incidence of hypotension, bradycardia, respiratory depression, pruritus, if observed in the first 24 hours, were recorded.

STATISTICAL ANALYSIS

Data was entered into Microsoft Excel data sheet and analysed using Statistical Package for the Social Sciences (SPSS) version 22 (International Business Machines (IBM) SPSS Statistics, Somers NY, USA). Categorical data was represented in the form of frequencies and proportions. Chi-square test was used as test of significance for qualitative data. Continuous data was represented as mean and Standard Deviation (SD). Independent t-test or Mann-Whitney U test was used as test of significance to identify the mean difference between two quantitative variables and qualitative variables respectively.

RESULTS

Demographic data such as age, height, weight, Body Mass Index (BMI) and duration of surgery were comparable in both the groups [Table/Fig-2]. There was no significant difference in mean TFA between the two groups (409.14±48.92 in group D vs 419.03±54.11 in group N). Also, the total amount of rescue analgesic requirement was similar in both groups (105.17±42.98 vs 106.45±46.08) [Table/Fig-3] HR, MAP and pain scores were also similar in both groups [Table/Fig-4,5].

Variables	Group D	Group N	p value*
	Mean±SD	Mean±SD	
Age (years)	46.31±8.36	47.29±8.06	0.646
Weight (kg)	63.21±7.72	63.39±8.68	0.933
Height (m)	1.58±0.10	1.60±0.10	0.593
BMI (kg/m ²)	25.43±3.69	24.82±3.95	0.539
Duration of surgery (min)	125.52±18.00	126.94±14.36	0.736

[Table/Fig-2]: Comparison of demographic data between two groups.

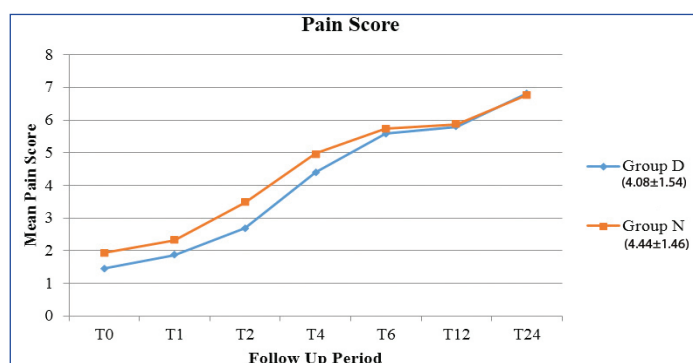
*Independent t-test; Group D: Dexmedetomidine; Group N: Nalbuphine

Variables	Group D		Group N		p-value*
	Mean±SD	Median	Mean±SD	Median	
TFA (min)	409.14±48.92	405	419.03±54.11	420	0.462
Total dose of tramadol in first 24 hrs	105.17±42.98	100	106.45±46.08	100	0.912

[Table/Fig-3]: Comparison of postoperative analgesic profile between two groups.
*Independent t-test; Group D: Dexmedetomidine; Group N: Nalbuphine; TFA: Time for first analgesic request

Variables	Group D		p-value*
	Mean±SD	Mean±SD	
HR T0	81.21±9.93	82.42±9.73	0.635
HR T1	75.97±8.55	77.58±9.44	0.491
HR T2	74.56±9.22	77.57±7.8	0.56
HR T4	79±7.40	78.74±7.79	0.896
HR T6	82.31±8.10	79.28±8.2	0.73
HR T12	78.6±6.83	77.64±6.84	0.94
HR T24	75.4±7.22	73.2±8.1	0.82
MAP T0	84.69±8.05	84.90±9.96	0.928
MAP T1	84.14±6.09	84.35±6.81	0.897
MAP T2	79.61±5.84	82.34±6.34	0.732
MAP T4	82.76±6.21	83.42±6.76	0.696
MAP T6	73.42±7.45	77.62±6.92	0.761
MAP T12	86.55±8.02	79.56±7.04	0.582
MAP T24	81.72±7.86	75.84±6.82	0.623

[Table/Fig-4]: Comparison of Heart Rate (HR) and Mean Arterial Pressure (MAP).
*Independent t-test, Group D: Dexmedetomidine; Group N: Nalbuphine



[Table/Fig-5]: Comparison of pain scores.
Mann-Whitney U test; Group D: Dexmedetomidine; Group N: Nalbuphine; p-value 0.447

Though statistically not significant, 4 (13.3%) patients in nalbuphine group reported nausea when compared to only 1 (3.3%) in dexmedetomidine group. One patient in nalbuphine group had vomiting also [Table/Fig-6].

Variables		Group				p-value
		Dexmedetomidine		Nalbuphine		
		Count	%	Count	%	
0 Hrs	None	30	100	30	100.0	-
	Only Nausea	0	0	0	0	
	Nausea+Vomiting	0	0	0	0	
1 Hrs	None	30	100	30	100	-
	Only Nausea	0	0	0	0	
	Nausea+Vomiting	0	0	0	0	
2 Hrs	None	29	96.7	25	83.3	0.213
	Only Nausea	1	3.3	4	13.3	
	Nausea+Vomiting	0	0	1	3.3	
4 Hrs	None	30	100	30	100	-
	Only Nausea	0	0	0	0	
	Nausea+Vomiting	0	0	0	0	

6 Hrs	None	30	100	30	100	-
	Only Nausea	0	0	0	0	
	Nausea+Vomiting	0	0	0	0	
12 Hrs	None	30	100	30	100	-
	Only Nausea	0	0	0	0	
	Nausea+Vomiting	0	0	0	0	
24 Hrs	None	30	100	30	100	-
	Only Nausea	0	0	0	0	
	Nausea+Vomiting	0	0	0	0	

[Table/Fig-6]: Comparison of PONV between the groups.
Chi-square test; p=0.213; Group D: Dexmedetomidine; Group N: Nalbuphine

Five patients (16.7%) who received nalbuphine complained of pruritus postoperatively [Table/Fig-7]. There were no incidences of bradycardia, hypotension and respiratory depression in either group. Patient satisfaction scores were comparable in both the groups [Table/Fig-8].

Complications		Group D		Group N		p-value
		Count	%	Count	%	
Bradycardia	Yes	0	0	0	0	-
	No	30	100	30	100	
Hypotension	Yes	0	0	0	0	-
	No	30	100	30	100	
Pruritis	Yes	0	0	5	16.7	0.02*
	No	30	100	25	83.3	
Respiratory depression	Yes	0	0	0	0	-
	No	30	100	30	100	

[Table/Fig-7]: Comparison of incidence of complications between two groups.
Chi-square test; p-value=0.002; Group D: Dexmedetomidine; Group N: Nalbuphine

Patient satisfaction	Group D		Group N	
	Count	%	Count	%
Very much dissatisfied	0	0	0	0
Dissatisfied	0	0	0	0
Neither satisfied nor dissatisfied	0	0	0	0
Satisfied	6	20	7	23.3
Very much satisfied	24	80	23	76.7

[Table/Fig-8]: Comparison of patient satisfaction scores.
 $\chi^2=0.098$; df=1; p=0.754; Chi-square test

DISCUSSION

The TAP block is a regional anaesthetic technique that provides analgesia to the parietal peritoneum as well as the skin and muscles of the anterior abdominal wall. Ultrasound guided TAP block has been known to overcome the difficulties associated with traditional landmark guided technique. TAP block has been studied for various surgical procedures by Bharti N et al., Conaghan P et al., Mukhtar K and Singh S and concluded that it is effective in creating a sensory disruption within the abdomen and providing effective postoperative analgesia [6-8].

Usually longer acting amide local anaesthetics such as bupivacaine and ropivacaine are selected for TAP procedure. As they are weak bases, they are readily absorbed into the vasculature, probably due to migration of injectate from the neurofascial plane into the surrounding musculature [9]. In one of the studies, ropivacaine plasma levels were measured following supplemental ultrasound guided bilateral TAP block, with total dose of 3 mg/kg ropivacaine in saline (20 mL on each side), to 28 women undergoing elective gynaecological surgery. The peak serum concentration (Cmax) levels occurred within 30 minutes after TAP block. The median total concentrations of ropivacaine were above 2.20 µg/mL for upto 45 minutes post TAP block. This study by Griffiths JD et al., concluded that TAP block using 3 mg/kg of ropivacaine produces

venous plasma concentrations that are potentially neurotoxic [10]. Hence, authors have chosen 39 mL of 0.2% ropivacaine in our study to remain within the acceptable dose range.

Though clinical safety profile of ropivacaine for TAP block is acceptable, its main disadvantage lies in its short acting ability, having only 4-6 hours of nerve block window. Adjuvants can be added to prolong the duration of TAP block. Various additives have been studied, out of which dexmedetomidine has shown promising results without any systemic side effects.

Dexmedetomidine acts on pre and postsynaptic nerve terminals, thereby decreasing the sympathetic outflow and norepinephrine release, to cause sedation, analgesia and haemodynamic effects. It acts peripherally by blocking conduction through A α and C fibres to enhance the effects of local anaesthetics. This prolongation of effect could be due to synergism between local anaesthetic and α_2 adrenoreceptor agonists [4].

Duration of postoperative analgesia: In this study, the mean duration of postoperative analgesia, measured as time for first rescue analgesic, in patients who received dexmedetomidine as adjuvant to ropivacaine for TAP block was 410 minutes. This was similar to another study done by Bansal P and Sood D where addition of dexmedetomidine to ropivacaine for TAP block in patients undergoing caesarean section prolonged the time to initial onset of pain (6.6 vs 5.03 h) and time to first rescue analgesia (7.8 vs 6.47 h) [11]. Varshney A et al., conducted a study using dexmedetomidine as adjuvant to levobupivacaine in parturients undergoing Lower Segment Caesarean Section (LSCS) and concluded that TAP block using levobupivacaine provided good postoperative analgesia whereas addition of dexmedetomidine further improved postoperative pain control with better patient satisfaction. Median time for first rescue analgesic increased from 352.5 minutes to 600 minutes on addition of dexmedetomidine to levobupivacaine [12]. This prolonged duration of postoperative analgesia could be attributed to levobupivacaine used as local anaesthetic instead of Ropivacaine.

Nalbuphine derived from 14 hydroxymorphine, is a potent analgesic, possessing a mixture of κ agonist and μ antagonist profiles. Though its pain relieving potency is considered identical to morphine, it has a ceiling effect on respiratory depression. It provides intense sensory blockade and reduced opioid consumption without any serious side effects [5].

In a study done by Gupta K et al., nalbuphine has significantly extended the duration of postoperative analgesia, when given as an adjuvant to 0.5% bupivacaine in supraclavicular brachial plexus block without any adverse effects. The mean duration of postoperative analgesia was 481 minutes [5]. Also, in a study done by Omar Mostafa M et al., nalbuphine provides effective postoperative analgesia in patients who received paravertebral block for mastectomies [13]. These studies showed that nalbuphine can be safely and effectively used as adjuvant to local anaesthetics in interfascial plane blocks. In this study, women who received nalbuphine as an adjuvant to ropivacaine for TAP block had similar duration of postoperative analgesia when compared to those who received dexmedetomidine.

Rescue analgesic requirement: In this study, total dose of tramadol consumption in the first 24 hours was used as surrogate marker for assessing the efficacy of TAP block. Median dose of tramadol requirement was similar in both groups, suggesting that nalbuphine is equally effective as dexmedetomidine in reducing the opioid requirements in the postoperative period. In a study done by Abdelaal W et al., the total dose of meperidine consumption was less when they received dexmedetomidine as adjuvant along with levobupivacaine for TAP block in abdominoplasties [14]. Similarly, in another study lesser number of patients (n=16) requested for rescue opioids in patients who received dexmedetomidine when compared to levobupivacaine alone (n=25) [12].

Haemodynamic variables such as HR and MAP were comparable between both the groups. None of the patients in dexmedetomidine group had any episodes of bradycardia or hypotension. In the study done by Bansal P and Sood D, two patients who received dexmedetomidine had episodes of hypotension and three patients complained of excessive sedation [11]. Though the dose of dexmedetomidine used was same in both studies, hypotension was reported in a few cases.

Patients who received nalbuphine experienced systemic side effects in the form of nausea (13.3%), vomiting (3.3%) and Pruritus (16.7%). This was in contrast to findings from a study which showed no evidence of nalbuphine related side effects such as nausea, vomiting pruritus [5]. Overall satisfaction scores were similar in both the groups.

Limitation(s)

One of the main limitations of the study is that it employed lateral TAP block rather than posterior approach for lower abdominal surgeries done under transverse incision. Posterior approach can have longer duration of action compared to lateral approach for two reasons. Firstly, a posterior injection point might allow the TAP block to block lateral cutaneous branches of thoracolumbar nerves even before they enter into the TAP where they undergo anastomoses and extensive branching. Secondly, the posterior technique results in a retrograde spread of local anaesthetic in to the paravertebral space potentially producing some degree of block along the thoracolumbar sympathetic chain.

CONCLUSION(S)

Nalbuphine, when compared to dexmedetomidine as an additive to ropivacaine for TAP block, provides similar postoperative analgesic duration and efficacy. Adding nalbuphine to ropivacaine in TAP block is associated with increased incidence of side effects such as pruritis and nausea.

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