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Comparative Assessment of Analgesic Efficacy of TAP Block with Dexmedetomidine, Ropivacaine and with Ropivaciane Alone in Open Open Lower Abdominal Gynecological Surgeries

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Abstract

Background: Transversus Abdominis Plane (TAP) block is a simple and unique method for regional analgesia, especially for lower abdominal surgeries. The aim of this study was to compare the analgesic efficacy of TAP block on addition of 0.5 *mcg/kg* Dexmedetomidine to 0.2% Ropivacaine and 0.2% Ropivacaine alone in lower abdominal gynecological surgeries. *Patients and Methods:* Total of 60 female patients, scheduled for open lower abdominal surgery under general anesthesia, were recruited into two Groups: Ropivacaine (R) and Ropivacaine and Dexmedetomidine (RD). Group R received USG-guided TAP block with 30 *ml* of 0.2% Ropivacaine and saline. Group RD received USG-guided TAP block with 30 *ml* of 0.2% Ropivacaine and 0.5 *mcg/kg* of Dexmedetomidine. Post-operative pain scores, sedation score, time to first rescue analgesic, and total opioid requirement in first 24 *hours*, were calculated. *Results:* The difference between the duration of time to first rescue analgesic, between two groups, was statistically significant ($p = 0.018$). Further, it was observed that the VAS scoring was lower in group RD as compared to Group R, at al. the time intervals. The RD Group showed a significant difference between Modified Wilsons sedation score at first hour in both the groups, $p < 0.001$. All the patients in both the groups were oriented without sedation and with statistical significance ($p < 0.05$). *Conclusion:* The analgesic efficacy of Dexmedetomidine with 0.2% Ropivacaine in TAP block showed a positive result when compared to 0.2% Ropivacaine alone. The analgesic efficacy of Dexmedetomidine with 0.2% Ropivacaine was more pronounced when compared to the 0.2% Ropivacaine individually in TAP block procedure during Lower Abdominal Gynecological Surgeries.

Keywords: Analgesia; Dexmedetomidine; Ropivacaine; TAP block.

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Introduction

A significant number of patients experience pain following an abdominal surgery.[1] This pain is severe and causes physiological and psychological consequences which include patient dissatisfaction, prolonged hospital stay, and potential progression to the chronic pain. Transversus abdominis plane (TAP) block is a novel regional analgesia technique which is technically simple and provides reliable analgesia for both intra-operative and post-operative period for lower abdominal surgeries.

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This technique was first described as a landmark technique *via* lumbar triangle of petit in 2001 by Rafi *et al*.,[2] and it was further developed by McDonnell *et al*. (2008).[6]

In TAP block, local anesthetics cause blockade of the neural afferents which carries pain signalling from incisional site to the brain and spinal cord, leading to the sensory blocking of pain. The efficacy of TAP block has been proven to provide effective analgesia for lower abdominal surgery such as for open appendectomy,[3] hernia repair,[4] and cesarean section.[5] However, the prolonged duration of analgesic effect, after TAP block, may be related to the fact that TAP is poorly vascularized and therefore, the drug clearance may be slow by reduction of absorption into the blood stream.[6] Therefore, for correct assessment of needle placement and local anesthetic spread, a new approach ultrasound-guided TAP block has been established with increasing success rate and safety of TAP block.[7]

Local anesthetics reversibly inhibit the nerve impulses, thus causing prolonged sensory and motor block appropriate for anesthesia in different types of surgeries. Earlier studies were done using Bupivacaine but in recent studies, Ropivacaine has been used, which is a long acting regional anesthetic, and has less cardiotoxic, neurotoxic, and arrhythmogenic effect, along with having intrinsic vasoconstrictor effect, when compared to bupivacaine and lignocaine. It is, however, structurally related to Bupivacaine.

Dexmedetomidine is an alpha-2 agonist which has analgesia and sedation effect. It acts by inhibiting the substances of nociceptive pathway at the level of dorsal root neuron and further by activating alpha-2 adrenoreceptor in the locus coeruleus.[8] Dexmedetomidine, when added to local anesthetic drug, *i.e.,* 0.2% Ropivacaine, prolongs the duration of TAP block and reduces total opioid requirement post-operatively.[9]

Therefore, this study was undertaken to assess the analgesic efficacy of dexmedetomidine by comparing 0.2% Ropivacaine with Dexmedetomidine *vs* Ropivacaine only in ultrasound-guided TAP block for post-operative analgesia, after general anesthesia-induced open lower abdominal gynecological surgeries.

Materials and Methods

After getting approval from the Institutional Ethical and Scientific Committee and written informed consent from patients, 60 female patients, between *18* and *60 years* of age, with American Society of Anesthesiologists (ASA) Physical Status I and II, and scheduled for open lower abdominal gynecological surgeries under general anaesthesia, were enrolled in this prospective, double blind, randomized, comparative study. The study was carried out at Department of Anesthesiology in, KLE's Prabhakar Kore hospital and MRC, Belagavi.

Patients were randomized by using a computer-generated random number table provided to the interventional anesthesiologist using sealed envelopes on the day of surgery to ensure blinding. All patients were randomly allocated in two Groups—Group RD and R, with 30 patients in each group.

Group RD: Administered with 0.2% Ropivacaine (*15 ml*) + *0.5 mcg/kg* Body Weight (BW) Dexmedetomidine, diluted with normal saline to *1 ml*.

Group R: Administered with 0.2% Ropivacaine (*15 ml*) + *1 ml* normal saline only.

To maintain the double-blind design, an investigator, not involved in the study, mixed the anesthetic solution for the anesthetist who was performing the block and observing the result.

Methodology

A through pre-anaesthetic evaluation was done. Standard monitoring of Heart Rate (HR), Systolic Blood Pressure (BP), Diastolic Blood Pressure, Mean Arterial Pressure (MAP), respiratory rate, and peripheral capillary oxygen saturation (SpO_2) were performed. The patients were informed about the VAS pain scale for assessment of pain where 0 depicts 'no pain' and 10 depicts 'worst possible pain'. Additionally, history of co-existing diseases and allergies were also investigated. Patients enrolled in the study were not given any sedative. All patients were kept on fast—solid food fastfor *6h* and clear fluid fast for *2h* for clear fluids, before administering the anesthesia.

Anesthetic Technique

After the signing of the informed consent form, patients were brought to the operation theatre and an intravenous cannula (18 G) was secured in their peripheral forearm vein. Standard monitors including Non-invasive Blood Pressure (NIBP), ECG Lead, and pulse oximetry probe, were attached to the patient. Baseline MAP and HR were recorded and mean value of three readings of each

of the parameters was taken as the baseline value.

All patients received standardized general anesthesia with intravenous injection: Propofol *2 mg/kg* (BW), fentanyl *2 mcg/kg* (BW), and vecuronium *0.1 mg/kg* (BW), to facilitate tracheal intubation. Capnometer was attached to confirm the tube placement and monitor the $EtCO_2$ intra-operatively. Lungs were ventilated with volume control mode and oxygen/nitrousoxide/sevoflurane were used for the maintenance. The study drugs were prepared by an anesthesiologist who was not involved with the rest of the study. The drug mixtures, in two syringes, were made up to *16 ml* each by the same anesthesiologist.

Before skin incision, bilateral TAP block was performed using portable Sonosite Ultrasound and linear *6–13 Mhz* ultrasound transducer. The puncture area and the ultrasound probe were prepared in a sterile manner. The probe was placed at the level of the umbilicus along the anterior axillary line. A *23-gauge* Quincke's needle was attached to a *10-cm* extension. Using in-plane USG technique, tip of the needle was placed in space between internal oblique and transversus abdominis muscles. After negative aspiration, *15 ml* of 0.2% ropivacaine was administered with *1 ml* normal saline in Group R and *0.5 µg/kg* (BW) dexmedetomidine, diluted with normal saline to *1 ml*, in Group RD. Drugs were administered under the direct ultrasound guidance. Similarly, contralateral block was also performed.

Intra-operative Data Collection

Intra-operatively, MAP and HR were recorded at *5*, *10*, and *15 min*, after TAP block, and then every *15 min*, till the end of the surgery (up to *120 min*). Intravenous fluids (RL/RS) were administered by replenishing maintenance, deficit, and replacement requirements. The patients were observed for intra-operative complications such as hypotension, bradycardia, nausea, and vomiting. Hypotension (defined as fall in MAP below *65 mm Hg*) was treated with IV fluids and if required, then with *6 mg* of injection, mephentermine IV. Bradycardia (defined as HR < *50 beats per min*) was treated with IV injection, atropine *0.6 mg*. Nausea and vomiting was treated with injection, ondansetron with *0.1 mg/kg* IV. All physiological variables and drugs used were recorded in a data collection chart. After standardized extubation and awakening at completion of surgery, patients were shifted to Post-anesthesia Care Unit (PACU).

Post-operative Management and Data Collection

Patients were observed in recovery room for hemodynamic stability and side effects and were monitored for additional medications. After normalization of vital parameters, the patients were shifted to the ward and were monitored for *3h* by Anesthesiology team members and thereafter, by the on-duty nursing staffs for *24h*, following end of the surgery. Both were blinded to group allocation of the patients.

In the recovery room and ward, the following parameters such as visual analog scale, time of first rescue analgesia, total opioid (Tramadol) requirement, degree of sedation by Modified Wilson's Sedation Scale, occurrence of side-effects and hemodynamic parameters were recorded.

1. *Visual Analog Scale* (*VAS*): VAS score was observed at *1*, *3*, *6*, *12*, *18* and *24h* post-operatively (0: No pain, 1–2: Least pain, 3–4: Mild pain, 5–6: Moderate pain, 7–8: Severe pain, 9–10: Excruciating pain as shown in Fig. 1.

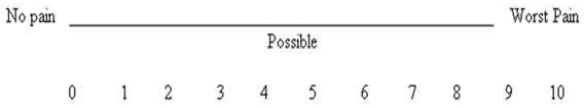

Fig. 1: Visual Analog Scale

2. Time *of First Rescue Analgesia*: Rescue analgesia was provided by injecting Tramadol *2 mg/kg* (BW). This indicated the duration of analgesia from the time of administration of TAP block to VAS score > 4 or on patients requested for analgesia.
3. *Total Opioid* (*Tramadol*) *Requirement*: It is the total amount of supplemental Tramadol, calculated for *24h*, starting from the administration of TAP block.
4. *Degree of Sedation*: Degree of sedation was assessed by Modified Wilson's Sedation Scale (ranging from 1–4) at *1*, *3*, *6*, *12*, *18* and *24h* (1 = oriented, 2 = drowsy but easily roused, 3 = arousable only to mild physical stimulation, 4 = unarousable to mild physical stimulation).
5. *Hemodynamic Parameters*: HR and MAP were recorded at *1*, *3*, *6*, *12*, and *18h*, post-operatively (*i.e.*, after skin closure).
6. *Occurrence of Side-effects*: Nausea, vomiting, drowsiness, bradycardia, or hypotension, were recorded and treated accordingly.

Statistical Analysis

Statistical analysis was done by using Pearson's Chi-square test for independence of attributes for categorical variables which were presented as number of patients and percentage of patients and compared across the two groups. Continuous variables were presented as mean (standard deviation) and compared across the two groups using unpaired *t* - test, if the data followed normal distribution, and Mann—Whitney *U* test, if the data did not follow normal distribution. An alpha level of 5% was taken *i.e.*, if any *p* - value was less than 0.05, it was considered statistically significant. Statistical analysis was performed with the SPSS 20 statistical package.

Results

A total of 60 number of patients were enrolled in the study and randomly divided into two groups of 30 patients each, depending on the drugs used. All enrolled patients completed the study, as specified in Table 1.

Table 1: Specification of groups

Groups	Drugs Received	Number of Patients
Group R	*15 ml* of 0.2% Ropivacaine with *1 ml* with normal saline. (Total volume *16 ml*)	30
Group RD	*15 ml* of 0.2% Ropivacaine with *0.5 mcg/kg* of Dexmedetomidine diluted to *1 ml* with normal saline. (Total volume *16 ml*)	30

We observed that majority of the subjects in Group RD were within the age of "41–50", followed by "21–30", whereas in Group R, most of the subjects were of the age group "31–40", followed by "41–50". Average height and weight of the subjects in the Group RD sample was *159.03* (*cm*) and *63.8* (*kg*), respectively, whereas in Group R, it was *158.37* (*cm*) and *63.07* (*kg*), respectively. The MAP as well as mean HR, at baseline, was not significantly different between the groups ($p = 0.4407$, $p = 0.7612$, respectively). ASA status of subjects in both groups were equally distributed ($p = 0.2949$). The duration of surgery was also similar in both the groups. Majority of the subjects underwent myomectomy surgery followed by salpingo-opherectomy surgery. All these parameters are summarized in Table 2.

Table 2: Summary of statistics of various factors

Factor	Sub-category	Group	
		Group RD *n* (%)	Group R
Age group (*years*)	21–30	8 (26.67%)	2 (6.67%)
	31–40	6 (20%)	12 (40%)
	41–50	10 (33.33%)	9 (30%)
	51–60	6 (20%)	5 (16.67%)
	61–70	0	1 (3.33%)
	71–80	0	1 (3.33%)
Age (*years*)		38.73 ± 11.74	42.87 ± 12.15
Weight (*kg*)		63.8 ± 9.14	63.07 ± 10.19
Height (*cm*)		159.03 ± 7.09	158.37 ± 6.99
B MP		93.8 ± 11.59	96.27 ± 12.98
B Pulse		80.03 ± 9.36	80.8 ± 10.07
ASA	Grade I	20 (66.67%)	15 (50%)
	Grade II	10 (33.33%)	15 (50%)
Duration of surgery (*hours*)		2.10 ± 0.66	2.07 ± 0.69
Type of surgery	myomectomy	8 (26.67%)	7 (23.33%)
	tah with bso	6 (20%)	6 (20%)
	exp laprortomy for ectopic	6 (20%)	5 (16.67%)
	ovarian mass laprotomy	4 (13.33%)	5 (16.67%)
	B/lsalpingoopherectomy	6 (20%)	7 (23.33%)

Abbreviation: B MP: Baseline mean atrial pressure; B Pulse: Baseline Pulse rate; ASA: American Society of Anesthesiologists

Table 3: Mean time (*in hours*) for 1st rescue analgesia

	Group			
	Group RD Mean ± SD	Group R Mean ± SD	*p* - Value	Significance
Time to 1st rescue analgesia post-operatively (in hrs)	17.63 ± 8.76	12.6 ± 6.61	0.018	Significant

The study showed that the duration of time to first-rescue analgesic was much longer and significant (p = 0.018) in Group RD than in Group R (Table 3).

The study also assessed the comparison of the total amount of opioid requirement, *i.e.*, tramadol (*mg/kg* BW) in first *24h*, post-operation, between both the groups which was statistically significant (p = 0.011). *i.e.*, there was more opioid requirement in Group R than in Group RD (Table 3).

VAS score was significantly lower (p < 0.05) in Group RD as compared to Group R at all the time intervals during the post-operative period at fixed time intervals (*i.e.*, *1*, *3*, *6*, *12*, *18* and *24h*), after skin closure (Table 4).

There was a difference observed in terms of mean sedation scores of the groups at fixed time intervals. About 15 patients in Group RD had Modified Wilsons score of 2, *i.e.*, they were sedated but arousable, whereas in Group R, all the patients had Modified Wilsons score of 1, *i.e.*, they were oriented, without sedation, during first hour of post-operation (p < 0.05). All patients in both the groups were in conscious state without giving any sedation at *3*, *6*, *12*, *18* and *24h*, post-operatively (Table 5).

When the comparison was done for mean HR and MAP during intra-operative condition at fixed time intervals, it was concluded that there were no significant differences found between the groups (Fig. 2). Similar results were also foundin post-operative condition as well for both the mean heart rate as well as MAP (Fig. 3).

When the occurrence of hypotension and bradycardia were monitored and compared, it was found that none of the patients, in either groups, were reported with these conditions.

Table 4: Total opiod requirement in first *24 hours* post-operatively (*in milligrams*)

	Group			
	Group RD	**Group R**		
	Mean ± SD	**Mean ± SD**	***p* - value**	**Significance**
Total Opioid requirement (Tramadol in mg)	86.67 ± 81.93	143.33 ± 81.72	0.011	Significant

Table 5: Post-operative mean VAS scores at fixed time intervals

Post-operative VAS score at different intervals	Group			
	Group RD	**Group R**		
	Mean ± SD	**Mean ± SD**	***p* - value**	**Significance**
VAS at *1 hour*	0.03 ± 0.18	0.33 ± 0.48	0.003	Significant
VAS at *3 hour*	0.57 ± 0.68	1.2 ± 0.66	0.001	Significant
VAS at *6 hour*	1.67 ± 1.58	2.6 ± 1.25	0.012	Significant
VAS at *12 hour*	3.17 ± 0.46	4.23 ± 0.43	< 0.001	Significant
VAS at *18 hour*	4.27 ± 0.45	3.5 ± 1.38	0.030	Significant
VAS at *24 hour*	3.33 ± 1.15	4.3 ± 0.79	< 0.001	Significant

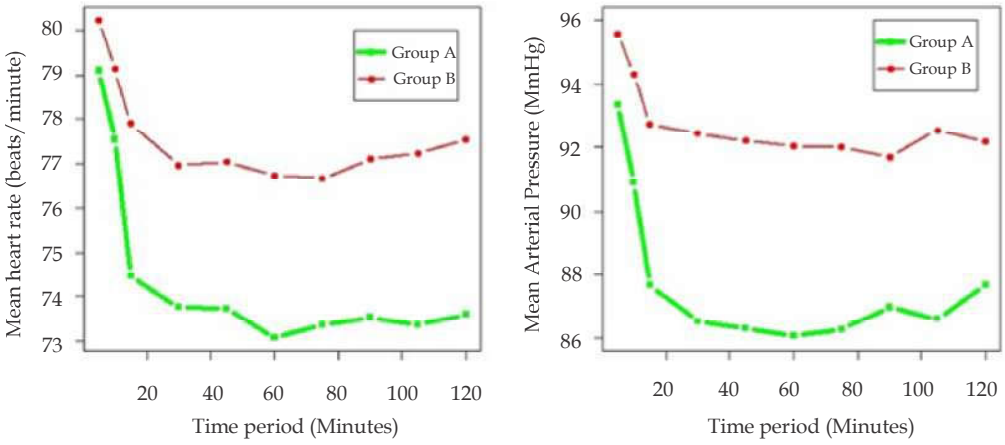

Fig. 2: Intra-operative mean HR and mean MAP between 2 Groups

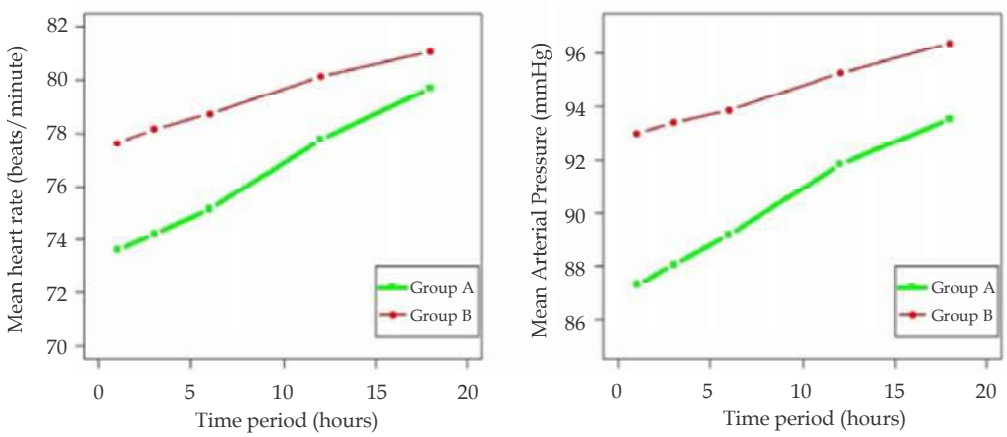

Fig. 3: Comparison of post-operative mean heart rate and mean MAP

Discussion

The present study was a prospective, double blinded, randomized, comparative study which aimed to assess the efficacy of dexmedetomidine with ropivacaine and ropivacaine alone, by using the USG TAP block technique.

In the present study, we compared 0.2% ropivacaine and 0.2% ropivacaine with dexmedetomidine in TAP block, in terms of prolongation of duration of post-operative analgesia. We observed that the duration of post-operative analgesia (*in hours*) was more prolonged in Group RD in comparison to the Group Rand the difference was statistically significant (17.63 ± 8.76 *vs* 12.6 ± 6.61) which was comparable to a study conducted by Ramesh Kumar *et al*. (2017).[10] They observed that, in Group RD, the duration of analgesia was *482 ± 52.94 min* and for Group R, it was *352 ± 22.88 min*. Thus, the mean duration of analgesia was significantly increased ($p < 0.001$) in the Group RD.

Bala Bhaskar *et al*., (2016)[11] stated that addition of adjuvants like dexmedetomidine with local anesthetics have been associated with prolongation of the duration of the TAP block and this study support our findings as well.

In our study, opioid (tramadol *2 mg/kg*) was used as a rescue analgesic. We calculated the total opioid requirement in first *24h*, post-operatively. The total opioid requirement in was much lesser in Group RD (86.67 ± 81.93) than in Group R (143.33 ± 81.72). This difference in total opioid requirement in first *24h* was statistically significant when compared between the groups and was also supported by Kumar *et al*., (2017)[12] who also used tramadol, *2 mg/kg* intravenous as rescue analgesic in patients who had VAS score > 4 post-operatively. They reported that lesser total dose of opioid in first *24h* was seen in the Group RD which received Dexmedetomidine as an analgesic adjuvant as compared to Group R ($p < 0.001$). Our findings were also supported by the findings of Rai *et al*., (2016)[13] who observed that the total dose of tramadol used was less among patients in Group RD when compared to Group R (*98 ± 34.9 mg vs 71 ± 24.9 mg*, $p < 0.001$), during the first *24 h* of post-operative condition.

In our study, VAS scores were recorded in post-operative period at fixed time intervals of *1*, *3*, *6*, *12*, *18*, and *24h*. VAS scores were observed to be lower in Group RD as compared to Group R, at intervals. The differences in between the VAS score of the groups were found to be statistically significant at all the respective time intervals ($p < 0.05$).

The mean VAS score was < *1 during 1st* and *3rd hour* in Group RD. Whereas in Group R, mean VAS score was < 1 only during *1st hour*. In RD Group, the VAS score was appeared to be > 4 first time during *18th hour* and in R Group, it appeared during *12th hour* itself following which rescue analgesia was given. The *1st* rescue analgesia post-operatively was given at a mean duration of *17.6h* in Group RD and at *12.6h* in Group R.

Our findings were in concordance with Mishra *et al*., (2017)[14] who found that pain scores in Group RD were significantly lower than pain scores in Group R at 1 ($p = 0.014$), 3 ($p = 0.027$), 12 ($p = 0.011$) and *18h* ($p = 0.041$). The pain scores in Group RD were higher than Group R, at *6h* as well, but the difference was not statistically significant ($p = 0.203$). Rai *et al*., (2016)[13] found that the mean VAS score was significantly less at post-operative time intervals of *1*, *4*, and *6h* in Group RD when

compared with the Group R ($p < 0.05$). Thus, we can infer that dexmedetomidine significantly lowered post-operative VAS scores as proved in studies by Mishra *et al*.,[14] and Rai *et al*., which was similar to findings in our study.

The degree of sedation was assessed at *1*, *3*, *6*, *12*, *18*, and *24h*. It was observed that none of the patients had sedation score of more than 1 in Group R at all the time intervals and Group RD, similar to a study conducted by Waleed *et al*., (2014) who also observed that the incidence of sedation was statistically significant only for the first post-operative hour in patients who received dexmedetomidine ($p < 0.005$).[15] In our study, in the post-operative period, the groups were compared based on the changes in HR and MAP, at fixed time intervals. The differences were statistically significant in median HR for at least a pair of time periods. In a study, conducted by Madhuri *et al*., (2017) HR and blood pressure were monitored at *0*, *2*, *4*, *6*, *12*, *24*, *36*, and *48h*.[16] They found that statistically significant difference was noted between groups in terms of HR and blood pressure up to *6h*, with no statistically significant difference noted afters *6h*. Hence, in our study, we found significant difference in HR or MAP between the groups at time interval from *5 min* and *10 mins* (p Adj < 0.05), in both groups.

The distribution of ASA status of patients in both the groups was comparable and difference was not statistically significant. Hence, influence of ASA status, if any, was also similar in both groups. The mean duration of surgery and distribution of patients according to surgery were almost similar in both groups without any statistical significance. Therefore, the influence of these parameters on this study was also same in the groups.

In our study, we have found that the two groups were comparable in HR and MAP intra-operatively and post-operatively at fixed time intervals and there was no difference observed. Similarly, Kumar *et al*., (2017)[12] reported in their study that there is no statistically significant difference in HR, after giving TAP block, between the Group R and RD Group which received Ropivacaine and Dexmedetomidine. In concordance to our study, it was also reported that the results between the groups were not statistically significant, in MAP, at all time intervals.

In our study, peri-operative as well as post-operative hypotension or bradycardia was not observed in any patient. These findings were in accordance to the findings noted by Kumar *et al*., (2017)[17] where none of patients reported any significant hypotension or bradycardia. Thus, we can infer from the above studies that dexmedetomidine leads to some degree of sedation when added as an adjuvant in nerve blocks and this is in concordance with our study, (Table 6 and 7).

Table 6: Distribution of subjects by Hypertension and Bradycardia

	Status	Group RD	Group R	*p* - value
Hypotension	Absent	30 (100%)	30 (100%)	–
Bradycardia	Absent	30 (100%)	30 (100%)	–

Limitations of the study

We had limited access with respective to eligible subjects; A larger sample size would help us in giving more detailed information about the efficacy. The effectiveness of TAP block could not be accurately assessed as it was performed following the induction of general anesthesia, but placement of the needle with USG and skill of the operator was taken into consideration. Secondly, the plasma concentration was not measured of dexmedetomidine, so, determination of its action related to systemic absorption or pure local effect couldn't be found out.

Table 7: Mean Sedation Scores of the groups at Fixed Time Intervals

Post operative modified Wilsons Sedation Score at Various Intervals		Group		Total	p - value	Significance
		Group RD	Group R			
Sedation score at *1 hour*	1	15 (50%)	30 (100%)	45 (75%)	< 0.001	Significant
	2	15 (50%)	0 (0%)	15 (25%)		
Sedation score at *3 hour*	1	30 (100%)	30 (100%)	60 (100%)	NA	NA
Sedation Score at *6 hour*	1	30 (100%)	30 (100%)	60 (100%)	NA	NA
Sedation Score at *12 hour*	1	30 (100%)	30 (100%)	60 (100%)	NA	NA
Sedation Score at *18 hour*	1	130 (100%)	30 (100%)	60 (100%)	NA	NA
Sedation Score at *24 hour*	1	30 (100%)	30 (100%)	60 (100%)	NA	NA

Conclusion

We can conclude that the TAP block technique with dexmedetomidine and ropivacaine increases the duration of time to first rescue analgesia, reduces total opioid requirement, VAS scores in the post-operative period with no side-effects when compared to 0.2% ropivacaine-mediated TAP block technique.

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