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ORIGINAL PAPER

Monitored Anesthesia Care (MAC) as an Alternative to General Anesthesia (GA): Prospective Double-Blinded Randomized Controlled Study Comparing Efficacy and Safety of Dexmedetomidine and Ketamine Infusions with Ultrasonography (USG) Guided Pectoral Nerve Block (PECs) for Postoperative Analgesia in Breast Surgery

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ABSTRACT

Background and purpose: *PECs blocks are usually combined for breast surgery under general anesthesia (GA) to provide postoperative analgesia rather than primary anesthesia technique.*

Material and methods: *A prospective, interventional, single-center, double-blind, randomized, parallel-group, active-controlled, Helsinki protocol-compliant clinical study was conducted in a tertiary care teaching center after obtaining the Ethics Committee's approval and patients' written informed consent. Forty-eight American Society of Anesthesiologists physical status I/II patients aged 18-60 years, undergoing elective unilateral breast surgery were enrolled. Patients were block-randomized (computer-generated) to two equal groups (24 patients each), with one of them receiving Dexmedetomidine and the other one Ketamine. For concealment, sequentially numbered, sealed, opaque envelopes were used. The study was double-blinded for both the anesthesiologist and outcome assessor anesthesiologist. Obese patients (body mass index > 30), those with infection at block site, coagulopathy and known hypersensitivity to local anesthetics or study medications as well as individuals who refused participation in research were all excluded. The Dexmedetomidine group received a bolus of 0.5 mcg/kg over ten minutes, followed by an infusion of 0.3 mcg/kg/hour, while the Ketamine group received a bolus of 0.5 mg/kg over ten minutes, followed by an infusion of 0.3 mg/kg/hour. Postoperative analgesia was compared using a visual analogue scale (VAS) at regular intervals. When VAS exceeded four, 1 mg/kg intravenous Pethidine was administered as a rescue analgesic.*

Results: *Sub-anesthetic low-dose Ketamine was more effective than low-dose Dexmedetomidine in prolonging PECs block analgesia, which was statistically significant (p value < 0.001). The Ketamine group had lower rescue analgesic Pethidine consumption and longer first-rescue analgesia demand time. There was no significant hemodynamic difference between the study groups.*

Conclusion: *Ketamine was more efficient than Dexmedetomidine for postoperative analgesia.*

Keywords: analgesia, daycare, Dexmedetomidine, general anesthesia (GA), Ketamine, pain relief, surgery, visual analogue scale (VAS).

INTRODUCTION

Breast surgery is mostly performed under general anesthesia (GA). Anesthetic procedures that effectively manage pain, improve safety and minimise problems are becoming more and more necessary due to the increasing demand for breast surgery for both cancer treatment and cosmetic reasons (1). In order to control postoperative pain in patients who undergo breast operations under GA, PECs block is frequently used.

However, when combined with monitored anesthesia care (MAC) using Dexmedetomidine (Dexem®, Themis Medicare Limited) and Ketamine (Ketmin®, Themis Medicare Limited) infusions, PECs block can serve as the primary anesthesia method. Acute postoperative pain that is effectively managed improves patient outcomes and raises satisfaction levels overall.

Aim of the study

The present study aimed to evaluate and compare the analgesic efficacy and safety of Dexmedetomidine and Ketamine infusions under MAC in PECs Block for unilateral breast surgeries.

Objectives of the study

The current study evaluated and compared the time to first rescue analgesia and side effects of Dexmedetomidine and Ketamine infusions. ❑

MATERIAL AND METHODS

Our study was approved by the Institutional Ethical and Research Committee (IERC), Letter No. 230/2018/ACME, date 14-06-2018. The study purpose and procedures were explained to all participants and a written informed consent was obtained from each of the enrolled subjects. The data of all participants was kept confidential.

Study design and setting

While there have been sufficient studies on Ketamine infusion following the PECs block, those about Dexmedetomidine infusion were scarce. Hence, we designed a prospective, interventional, single-center, double- blind, randomized, parallel-group, active-controlled, Helsinki protocol-compliant clinical study to compare the analgesia in prolonging the duration of the block, as well as, to compare the safety profiles of Dexmedetomidine and Ketamine infusions with PECs block and MAC. The present study was carried out in an Indian tertiary care teaching center over a year, from February 2018 to January 2019. We used consecutive and convenient sampling to enroll a total number of 48 patients over the one-year study period.

Research question

With PECs block and MAC, is there any difference in efficacy and safety between Dexmedetomidine and Ketamine infusions for unilateral breast surgery?

Study participants

Patients with ASA physical status I and II aged between 18 and 60 years, who were scheduled for unilateral breast surgery, were included in the study. Those with obesity (body mass index > 30), pre-existing infection at the PECs block site, coagulopathy, known hypersensitivity and any contraindication to either local anesthetics or study medications, as well as patients who refused to participate in research were all excluded.

Randomization, allocation concealment and blinding of the study participants

Forty-eight patients were randomly allocated to two equal groups of 24 subjects each. The sequentially numbered, opaque, sealed envelope method was used for both randomization and allocation concealment. All envelopes were sealed against strong light and the physicians who were evaluating and enrolling the patients were not aware of the allocation sequence. Each participant's name and hospital admission number were written on the envelope to guard against manipulation of the allocation sequence. When it was the time for intervention assignment, the

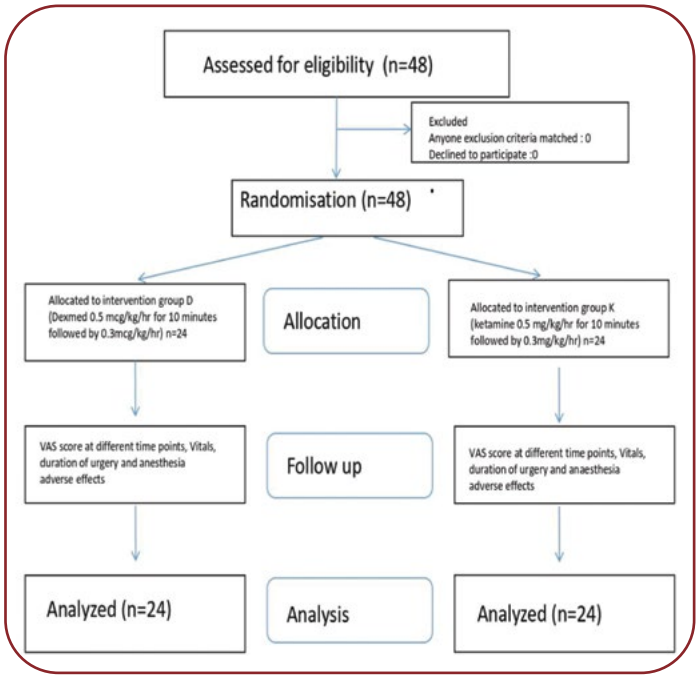

FIGURE 1. Study flow (CONSORT) diagram for patient recruitment

matching envelope was unsealed only after each enrolled individual had finished all baseline evaluations. The allocation was kept secret from the study participants.

Anesthesia protocols

Preoperative management

Comprehensive history elicitation and evaluations including hemogram, bleeding and clotting time, chest X-ray (CXR) and electrocardiogram (ECG) were performed for all study cases. The night before surgery and two hours prior to operation, a tablet of Alprazolam 0.5 mg was given orally with sips of water. Intravenous Ondansetron 4 mg and Midazolam 0.02 mg/kg were administered to all patients immediately before surgery.

Intraoperative management

Before surgery, a 20-gauge intravenous line was placed on the opposite side upper limb to be operated upon. Heart rate (HR), peripheral oxygen saturation (SpO2), non-invasive blood pressure (NIBP) and electrocardiogram (ECG) were monitored throughout the procedure.

Block performance

An experienced anesthesiologist performed PECs blocks I and II with an 8 cm x 22 gauge Echogenic, Stimulating Single Shot Nerve Block Needle (Pajunk® GmbH Medizintechnologie, Karl-Hall-Straße 1, 78187 Geisingen, Germany – Sonoplex® Stim Cannula) using the ultrasound machine (Micromaxx® Ultrasound System, Bothell, USA – SonoSite®) and a linear array probe (38 mm, 7-12 MHz frequency).

After local anesthesia using two milliliters of Lignocaine 2% injection, the needle was advanced into the gap between the pectoralis minor and serratus anterior muscles, and 20 mL of Ropivacaine 0.5% were deposited. Pin-prick testing revealed T2-T6 dermatomes anesthesia and patients were observed for 30 minutes after the block. Once the block was successful, patients enrolled in the two study groups received either Dexmedetomidine or Ketamine by syringe pump. After injection, subjects were given gentle pinpricks every five minutes for ten minutes and were asked if it was hurting.

Patients in group D received an infusion of Dexmedetomidine at a loading dose of 0.5 mcg/kg for ten minutes, followed by a maintenance infusion dose of 0.3 mcg/kg/h, while those in group K received Ketamine at a loading dose of 0.5 mg/kg for ten minutes, followed by a maintenance infusion dose of 0.3 mg/kg/h with titration. The target sedation level of Ramsay sedation score (RSS) 2 or 3 was maintained during the procedure (Table 1). The infusion was stopped immediately before the conclusion of surgery. To eliminate observer bias, an independent anesthesiologist loaded Dexmedetomidine or Ketamine into an identical 20 mL syringe, which was labelled as "study drug".

Score	Response
1	Anxious or restless or both
2	Cooperative, oriented and tranquil
3	Responding to commands
4	Brisk response to stimulus
5	Sluggish response to stimulus
6	No response to stimulus

TABLE 1. Ramsay sedation score (RSS)

Score	Severity of pain
0 to 1	No pain
2 to 3	Mild pain
4 to 7	Moderate pain
8 to 9	Severe pain
10	Worst pain ever

TABLE 2. Visual analogue scale (VAS) score

General anesthesia was provided to block failure patients and they were excluded from the study. Monitored anesthesia care was continued for all patients throughout the surgical intervention.

Preoperative, intraoperative and postoperative measurements of HR, RR, NIBP and SpO_2 were done. The VAS score was used for pain assessment (Table 2).

Postoperative management

Postoperatively, another blinded observer with pin-prick sensibility assessed the block's sensory level – every five minutes for 30 minutes, every hour for four hours, and then every two hours for 24 hours – in each dermatomal distribution from T1 to T8. Total dermatomes with pinprick pain lesser than the opposite side were recorded. The VAS score was used to assess the degree of pain. PECs block was considered a failure if any segment's pin-prick sensation persisted for 30 minutes. 1 mg/kg of Pethidine IV injection was ad-

ministered as a rescue analgesic to individuals with VAS pain scores >3 after an effective block.

Outcome

Outcome measures included pain assessment using a standard VAS pain scale at different time intervals, sedation score assessment using RSS, time for first-rescue analgesia and subsequent demands, total Pethidine consumption, duration of surgery and adverse effects like nausea, vomiting, pruritus, respiratory depression, hypotension, rest pain and pain on shoulder abduction (dynamic pain score).

Statistical analysis

Data were entered using MS Excel and statistical analysis was done using Statistical Package for The Social Sciences (SPSS) version 24 (IBM®, SPSS® Inc., Chicago, USA). We have represented the data in terms of measures of central tendency (mean and median) and dispersion measures – standard deviation (SD) and inter quartile range (IQR). Descriptive statistical tools like mean, standard deviation, frequency and percentages were used for data analysis. Student's t test was used to compare quantitative variables in the case of parametric data. When dealing with non-parametric data, the Mann-Whitney test was employed to compare two quantitative variables.

An unpaired t test was used to calculate the p value. A confidence interval (CI) of 95% and more and a p value of < 0.05 was considered statistically significant.

Since the effect is measured in terms of analgesic effect (VAS score), it is not worth to represent the effect size here. ❑

RESULTS

Results were presented in the form of graphs and tables. Patients' demographics is shown in Table 3. Out of 48 participants, 46 (95.8%) were females and two (4.2%) males. Thirty-six subjects (75%) belonged to ASA physical status I and 12 (25%) to ASA physical status II.

Preoperative vital parameters were similar for both groups, who had near-identical anesthesia and surgical duration (Table 4). Except for one (2.08%) patient with 104 beats per minute (bpm) tachycardia, both groups had similar intraoperative HR and NIBP (Table 4). Systolic BP exceeded 120 mm Hg in only three (6.2%) individuals. The p value was not statistically significant.

The mean VAS scores at 30 minutes, one hour, two hours, four hours, eight hours and 24 hours indicated that Ketamine was a better analgesic

TABLE 3. Demographic variables including sex, type of surgery, American Society of Anesthesiologists (ASA) physical status and mean duration of surgery and anesthesia

Parameter	Numbers (%)	
Sex	Female	46 (95.8%)
	Male	2 (4.2%)
	Total	48 (100%)
Type of Surgery	Fibroadenoma	46 (95.83%)
	Gynaecomastia	2 (4.16%)
	Total	48 (100%)
ASA physical status	Physical status-I	36 (75%)
	Physical status-II	12 (25%)
	Total	48 (100%)
MDOS (Mean±SD)	Group D	24.08±4.353
	Group K	23.04±3.141
MDOA (Mean±SD)	Group D	54.08±4.353
	Group K	53.04±3.141

ASA: American Society of Anesthesiologists;
MDOS: mean duration of surgery;
MDOA: mean duration of anesthesia

TABLE 4. Preoperative, intraoperative and postoperative vital parameters for successful completion of surgery

Vitals		Group D (Mean±SD)	Group K (Mean±SD)	Cumulative in both groups	
				Normal	High
HR (bpm)	Mean preoperative	86.92±8.382	91.54±6.713	43 (89.6%)	5 (10.4%)
	Mean intraoperative	80.96±6.757	82.13±7.798	47 (97.9%)	1 (2.08%)
	Mean postoperative	80.00±6.757	82.58±7.740	47 (97.9%)	1 (2.08%)
Systolic BP (mm Hg)	Mean preoperative	113.92±12.21	115.54±7.301	35 (72.9%)	13 (27.8%)
	Mean intraoperative	1.09.33±11.279	108.92±7.945	45 (93.8%)	3 (6.2%)
	Mean postoperative	105.50±11.279	105.67±7.998	45 (93.8%)	3 (6.2%)
Diastolic BP (mm Hg)	Mean preoperative	71.7±8.641	67.71±5.409	45 (93.8)	3 (6.2%)
	Mean intraoperative	67.21±7.706	61.67±4.993	47 (97.9%)	1 (2.08%)
	Mean postoperative	64.83±7.927	59.17±5.260	48 (100%)	0 (0%)

BP: blood pressure; HR: heart rate

TABLE 5. Postoperative VAS scores at different time intervals

VAS Score	Dexmedetomidine group		Ketamine group		p value (unpaired t test)
	Median	Mean ± SD	Median	Mean ± SD	
At 30 minutes	3.00	2.67 ± 0.482	2.00	1.54± 0.509	0.0001
At one hour	2.00	1.58±0.504	0.00	0.42±0.504	0.0001
At two hours	1.00	0.67±0.637	0.00	0.13±0.358	0.0007
At four hours	3.00	2.88±0.537	2.00	1.54±0.509	0.0001
At eight hours	4.00	4.13± 0.850	3.00	2.63±0.498	0.0001
At 24 hours	4.00	4.42±0.584	4.00	3.63±0.647	0.0001

VAS: visual analogue scale

than Dexmedetomidine in PECs block with MAC (Table 5). Ketamine reduced postoperative 24-hour VAS ratings, which was statistically significant ($p < 0.001$).

Pearson's test examined the connection between postoperative vital parameters and VAS scores at various intervals for 24 hours. A statistically significant moderately positive connection existed (p value < 0.001).

The average time for first-rescue analgesia time was 2.945 hours (SD 0.490) in group D, and 5.756 hours (SD 0.727) in group K.

Ketamine has been proved to be a better pain reliever than Dexmedetomidine because it is a water-soluble agent of the phencyclidine family affecting N-methyl-D-aspartate (NMDA) receptors and causing amnesia and central analgesia.

None of the study participants experienced any complications after the administration of the PECs block technique. Additionally, none of the subjects exhibited any adverse effects attributed to the pharmaceutical agents employed in the study, as sub-anesthetic doses of Dexmedetomidine and Ketamine were utilized. ❑

DISCUSSIONS

PECs block types I and II are unique methods for blocking the pectoral, intercostobrachial, third to sixth intercostal and long thoracic nerves. Better anaesthesia is provided via thoracic para vertebral block (TPVB), thoracic epidural anaesthesia (TEA), intercostal nerve block, and erector spinal block (ESB), with fewer risks. However, these invasive regional procedures cause perioperative complications that are inappropriate for daycare surgery (1). Regional anaesthesia strategies work better to lessen acute postoperative pain, decreasing not only the frequency of chronic pain but also the difficulties associated with general anaesthesia after breast surgery (1). PECs block is less invasive and has fewer complications, providing good analgesia both during and after ambulatory breast surgery (1).

Unlike TPVB and spinal anaesthesia, PECs block poses no risk of sympathectomy and has less restrictions on anticoagulants. Furthermore, the long thoracic, thoracodorsal, or medial pectoral nerves cannot be blocked by TPVB. Consequently, axillary dissection during breast surgeries may lack appropriate analgesia. The PECs block is also safer than TPVB for any unintended intravascular injection.

The α2-adrenergic receptor agonist Dexmedetomidine is extremely selective. It impacts the locus coeruleus, which regulates arousal and sleep, and spinal cord α2-adrenergic receptors, causing sedative, analgesic and anxiolytic effects. It also decreases intestinal motility, glandular production, postoperative nausea and vomiting, plasma epinephrine and nor epinephrine. It inhibits sympathetic activity and stabilizes hemodynamics. The dose-dependent sedation action of intravenous Dexmedetomidine is distinct and non-addictive (2). Conversely, α-2 adrenoceptor agonists like Dexmedetomidine are also known to decrease the central sympathetic outflow. When administered with total intravenous anesthesia (TIVA), it reduces surgical stress responses without affecting hemodynamic stability and without intraoperative side effects (3). Additionally, it controls intraoperative Interleukin-6 (IL-6) and tumour necrosis factor-alpha (TNF-α) levels and reduces surgical stress by lowering plasma cortisol, epinephrine and nor epinephrine levels (3). It inhibits cytokines release and reduces inflammation and mortality (4).

Ketamine is a phencyclidine derivative that has unique anesthetic qualities and low cardiorespiratory systemic effects. It is an NMDA receptor antagonist that causes dissociative anesthesia in the central nervous system (CNS) at dosages over 1.0 mg/kg IV (5, 6). Only during the anesthetic procedures without benzodiazepines or another hypnotic or amnesic drug does ketamine produce psycho-mimetic effects such as dysphoria, vivid dreams, hallucinations and an out-of-body experience. Clinical evidence suggests that major psycho-motor disturbances are only infrequently caused by bolus dosages less than 0.5 mg/kg. No psycho-mimic effects were found in 24-72 hours of inpatient ketamine infusions of 0.12-0.2 mg/kg/h (6-11).

A double-blind, randomized, placebo-controlled study was conducted on laparotomy patients to study the effect of adding ketamine to IV morphine patient-controlled analgesia (PCA). Pain ratings, morphine intake and adverse events were recorded for 48 hours from the initiation of PCA. In both groups, VAS scores were similar ($p = 0.3083$) and significantly declined with time ($p = 0.0001$). At 48 hours, the ketamine group consumed a considerably smaller amount of cu-

mulative morphine (28 mg) than the control group (54 mg) ($p < 0.0003$). In the ketamine group, nausea was less common ($p = 0.03$), suggesting that ketamine was working as a standalone analgesic (7).

In a previous study, pre-incisional PVB has been shown to offer substantial immediate postoperative analgesia following breast cancer surgery (5). To see if PVB could also lower the prevalence of postoperative chronic pain, a one-year follow-up was conducted. The authors concluded that preoperative PVB appeared to lower the prevalence of chronic pain one year after breast cancer surgery in addition to relieving immediate postoperative pain; also, pre-incisional PVB provided significant immediate postoperative analgesia after breast cancer surgery, as well as 14 days, one month, six months and one year postoperatively (5). Whether axillary dissection had been done or not, it had no bearing on these results. There were only two and three patients with a low incidence of neuropathic pain in the PVB and control groups, respectively.

On the same lines, PECs blocks in our study are used for immediate postoperative period for up to 24 hours, with similar postoperative pain relief.

Given that many breast operations are performed as outpatient procedures, PECs block might be a better option for anaesthesia in order to reduce hospital length of stay (LOS) and enhance bed rotations.

There are two types of PECs blocks: I and II. Targeting the lateral and median pectoral nerves at the pectoralis major-pectoralis minor inter fascial plane, PECs I is a straightforward and efficient superficial block. The long thoracic nerve, the T2-T6 intercostal nerves and the thoracodorsal nerve are the targets of PECs II block, which acts on the lateral branches of the intercostal nerves that exit at the mid-axillary line and innervate the skin and mammary gland from T2 to T6 (12–14).

Our study evaluated the efficacy and safety profile of PECs block combined with MAC and Dexmedetomidine and Ketamine infusions, using VAS score at different postoperative intervals.

Patients who received Ketamine infusion showed better analgesia and needed rescue analgesia later than those who were given Dexmedetomidine infusion.

In the present study, 46 (95.8%) patients were females and two (4.2%) males, as shown in Table 3. Thus, females outnumbered males, as noticed in most similar studies, with fibroadenoma being a benign common condition in young females and gynecomastia an uncommon condition in males (1).

Garg N *et al* evaluated postoperative pain-free time, pain ratings and rescue medication usage with Dexmedetomidine and Ketamine infusions after spine surgery to find a safe analgesic adjuvant that would afford opioid-sparing properties (15). During the postoperative phase, study medications were administered for 24 hours. For 48 hours following surgery, the pain-free interval, pain scores, need for rescue analgesics and side effects were recorded. All hemodynamic parameters were kept within the usual range. While all patients in the Ketamine and Dexmedetomidine groups were asleep, none of them needed help to keep their airways open. While nausea, vertigo and diplopia were less common in the Ketamine group than the other ones, the difference was not statistically significant ($p > 0.05$). The authors came to the conclusion that postoperative analgesia could be effectively achieved with minimum side effects by infusions of low-dose ketamine and dexmedetomidine. For the purpose of reducing pain following surgery, both analgesic regimens were safe to employ. The need for rescue analgesics was significantly reduced. Ketamine reduced rescue analgesic needs at 24 and 48 hours postoperatively (15). Over the course of the 48-hour observation period, the mean pain-free durations for the Ketamine (860 min) and Dexmedetomidine (580 min) groups were longer than that for the saline group (265 min), which was statistically significant ($p < 0.002$).

We used the same strategy in a different set of patients scheduled for breast surgery. In line with these findings, in our study, Ketamine reduced postoperative 24-hour VAS ratings, which was statistically significant (Table 5, $p < 0.001$). Hence, we can conclude that Ketamine and Dexmedetomidine infusions are effective in both spine and breast surgery patients.

The next parameter analyzed by us was patients' preoperative HR. Before surgery, tachycardia was encountered in six (12.48%) subjects, which could be attributed to patients' preoperative anxiety. Preoperatively, 35 (72.9%) patients

had normal systolic blood pressure (BP) and 45 (93.8%) normal diastolic BP. Only one (2.08%) patient developed 104 bpm tachycardia. Intraoperatively, 45 (93.8%) patients had normal systolic BP and 47 (97.9%) normal diastolic BP, which matched the pain control provided by PECs block combined with Dexmedetomidine and Ketamine infusions. Postoperatively, 47 (97.9%) patients had a normal HR. Just one (2.08%) patient developed tachycardia. This matches greater postoperative analgesia with PECs block combined with Dexmedetomidine and Ketamine infusions.

In our study, 45 (93.8%) surgical patients had normal systolic BP and 48 (100%) normal diastolic BP. This supports the concept that PECs block with Dexmedetomidine or Ketamine relieves post-surgery pain. There were statistically significant differences in VAS scores across treatment groups at various time intervals (Table 5, p value < 0.001).

There were no postoperative complications in our study. To avoid abrupt hemodynamic abnormalities from quick bolus doses of Dexmedetomidine and Ketamine, we administered boluses of these drugs over ten-minute infusions (10). Sapate *et al* compared Dexmedetomidine with Lignocaine IV boluses for pain relief (16). Their study utilized 0.2 μg/kg Dexmedetomidine and venous ligation to slow systemic release. Rapid IV bolus administration of Dexmedetomidine causes a biphasic BP response, featuring initial hypertension (α-2B adrenoceptor-mediated), prolonged hypotension (α-2A adrenergic receptor-mediated), bradycardia and potentially sinus stop (11, 17). In our study, gradual IV administration and sub-anesthetic dosages of Dexmedetomidine and Ketamine reduced the initial transient hypertensive response, bradycardia and hypotension. Ketamine did not elicit intraoperative hypertension or tachycardia, which might be due to the low dose of Ketamine used by us.

Study limitations

The fact that our study was carried out in a single-center was a limitation. More multi-center prospective studies with larger sample sizes are required in the future to support our data and provide a better understanding of patient outcomes. This will also help in the generalization of our study data for other types of surgical interventions.

Even though the present study has significant applicability in clinical practice by improving postoperative pain management for breast surgery patients, the need for trained personnel for ultrasound–guided blocks may limit the immediate widespread adoption. It is expected that with the increasing availability of ultrasound machines and trained personnel, this technique will pick up in due course. ❑

CONCLUSION

The VAS score for pain at different time intervals showed the sub-anesthetic dose of Ketamine to be more efficient than the sub-anesthetic dose of Dexmedetomidine in prolonging the duration of analgesia after PECs block for breast surgery under MAC.

Postoperative Pethidine consumption was also lower in patients who received Ketamine. Subjects in the Ketamine group required rescue analgesia much later than those included in the Dexmedetomidine group. There was no statistically significant hemodynamic difference between the two groups, as we used sub-anesthetic doses of Dexmedetomidine and Ketamine. There were no significant complications in the groups.

Therefore, we can draw the conclusion that patients undergoing simple breast surgery benefit from a combination of PECs blocks with low-dose Dexmedetomidine and Ketamine infusions. PECs block has just been reported lately, but because of its simplicity and relative lack of complications and contraindications, it has a great potential.

Practical applications include better pain relief, increased duration of the requirement of rescue analgesic and early recovery. All these factors will lead to patients' reduced length of stay and ultimately may result in better financial implications for the patient population. ❑

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Ethics statement: Institutional Ethical and Research Committee (IERC), Letter No. 230/2018/ACME, Date 14-06-2018.

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