

DEXMEDETOMIDINE AND ROPIVACAINE IN THORACIC EPIDURAL ANAESTHESIA FOR BREAST SURGERY- A CLINICAL COMPARISON WITH GENERAL ANAESTHESIA

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ABSTRACT

BACKGROUND

General anaesthesia is the traditional standard technique for various breast surgery, but Thoracic Epidural Anaesthesia offers advantages like better haemodynamics, early recovery, less postoperative respiratory complications and good analgesia.

The objective of this study is to evaluate the effectiveness of Thoracic Epidural Anaesthesia with Dexmedetomidine and Inj. Ropivacaine (0.5%) for breast surgery (MRM) with conventional general anaesthesia.

MATERIALS AND METHODS

With permission from Institutional Ethics Committee, forty consenting ASA Grades I and II patients posted for MRM were divided into two groups. In Group (TEA) Thoracic Epidural was performed in T4 - T8 intervertebral space and 5 cm of epidural catheter was threaded. Inj. Ropivacaine 0.5% with Dexmedetomidine 1 µg/kg was injected into the epidural space in increments via the catheter to achieve the desired height. In Group (GA), patients were managed in conventional way with Glycopyrrolate (0.2 mg), Fentanyl (2 µg/kg) and Midazolam (0.05 mg/kg) for premedication induced with Inj. Propofol (2 mg/kg). Intubation and maintenance of relaxation thereafter was with Vecuronium. Anaesthesia maintained with N₂O:O₂ in 60:40 ratio with Isoflurane 0.4 - 0.6% in IPPV. Towards the end of surgery, the patients received Ondansetron (4 mg) and Diclofenac (75 mg) infusion and reversed with Neostigmine (0.5 mg/kg) and 20 µg of Glycopyrrolate. Ringer's Lactate was used as maintenance fluid for both the groups. Monitoring of Pulse, NIBP, ECG, SpO₂ and Respiration was done throughout surgery in both the groups.

RESULTS

Adequacy of anaesthesia, surgical condition, bleeding, post-anaesthesia recovery, untoward effects in the perioperative period and overall patient satisfaction were evaluated.

CONCLUSION

Thoracic epidural with 0.5% Ropivacaine in conjunction with Dexmedetomidine did offer an excellent perioperative outcome without any significant untoward effects.

KEYWORDS

Thoracic Epidural, Ropivacaine, Dexmedetomidine, General Anaesthesia, Breast Surgery.

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BACKGROUND

Awareness among the population and early detection of breast malignancies has resulted in increased surgical interventions like lumpectomy, breast conservation therapy, modified radical mastectomy, etc. Psychological and surgical stress can lead to cardiovascular changes and hypercoagulable state in the body.^[1-8] This can be

mitigated by General Anaesthesia (GA) as well as regional anaesthesia techniques like Thoracic Epidural Anaesthesia (TEA), Paravertebral blocks, Intercostal blocks, Field blocks, Pec 1 and Pec 2 blocks. Regional anaesthesia techniques provide better haemodynamic stability, early recovery, less postoperative respiratory complications and good intraoperative as well as postoperative analgesia.^[4-14] However, most of the regional anaesthesia techniques mentioned above have certain limitations in comparison to TEA, which is being used extensively for various breast procedures with or without GA. Besides, in surgical procedures under regional anaesthesia, intra-operative consciousness and awareness among patients remains a major drawback. Dexmedetomidine hydrochloride, an [α-2] agonist has properties of sedation, analgesia and anxiolysis.^[15-19] At present it is being used a lot for sedation in ICU and to provide monitored anaesthesia care during different medical and surgical procedures and as an adjuvant

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to local anaesthetics in different blocks. This study was carried out to evaluate the efficacy of Dexmedetomidine as an adjuvant to Ropivacaine in TEA.^[15-20] for breast surgery.

MATERIALS AND METHODS

Approval of the Ethical Committee was obtained. Considering a confidence level of 90% and a power of 80%, hypothesised difference of 15, our sample size was calculated to be 17; and basing on reports of similar studies, forty female patients of ASA Grades I - II, aged 25 - 60 years were selected and divided randomly into two groups TEA and GA comprising of twenty each. Randomisation was done by draw of cards, after obtaining their informed written consent. All contraindications pertaining to central neuraxial blocks were considered as exclusion criteria including allergy to drugs used for this study.

On the night before surgery, patients in both the groups were advised to take Tab. Lorazepam (2 mg) and Tab. Ranitidine (150 mg) and were advised to be nil per os after midnight. On the day of surgery, an intravenous line with 18G cannula was set and a Ringer’s Lactate drip was started. Monitors were attached and baseline values were recorded.

Patients in Group GA were premedicated with Inj. Glycopyrrolate 0.2 mg, Inj. Midazolam 0.05 mg/kg and Inj. Fentanyl 2 µg/kg. Patients were induced with Inj. Propofol 2 mg/kg. Orotracheal intubation was facilitated with Inj. Vecuronium 0.1 mg/kg. After ascertaining the proper placement of tube, cuff was inflated and tube was fixed. Anaesthesia was maintained with N₂O : O₂ in a ratio of 60: 40 with Isoflurane at 0.4 - 0.8% in volume controlled mode with a tidal volume of 500 mL and rate of 14 breaths/min. Intraoperative relaxation was maintained with incremental dose of Vecuronium 1 mg. Ringer’s Lactate was the only fluid used for maintenance. Towards the end of surgery, patients were given Inj. Diclofenac 75 mg in infusion and Inj. ondansetron 4 mg slow IV, residual paralysis was reversed with 0.05 mg/kg of Inj. Neostigmine and 0.02 µg of Inj. Glycopyrrolate. The patients were extubated after ascertaining complete reversal of neuromuscular block.

In the TEA Group, Epidural space was identified with an 18G Tuohy needle in T4 - T8 intervertebral space by LOR technique with saline in the sitting position and 5 cms of epidural catheter was threaded. Proper placement of epidural catheter was confirmed by negative aspiration and with administration of 3 mL of Inj. Lignocaine 2% with Adrenaline. After fixation of the catheter, patients were made supine. Inj. Ropivacaine 0.5% with Inj. Dexmedetomidine 1 µg/kg was injected at a volume of 1 mL/segment into the epidural space in increments. Surgery was allowed to start after confirmation of block from subcostal margin below to infraclavicular fossa above. The patients were administered Oxygen at a flow rate of 6 L/min by Hudson’s face mask. Patients received Ringer’s Lactate solution at a rate of 8 mL/kg/hr for coloadng and as maintenance fluid.

In both the groups continuous monitoring of pulse, non-invasive blood pressure, ECG, oxygen saturation and respiration were done in the intraoperative period and the values were recorded. Any rise or fall in blood pressure ± 20% from the baseline was considered as hypertension/hypotension. Hypotension was treated with Inj. Ephedrine 5 mg IV in increments. Fall in heart rate below 60 bpm was considered as bradycardia and was treated with Inj.

Atropine 0.3 mg IV. Hypertension and tachycardia was controlled by vasodilators and/or by increasing the concentration of isoflurane.

Subjective assessment of blood loss and quality of surgical condition was made from the operating surgeon’s feedback. The postoperative discharge criteria were assessed basing on Aldrete score at first and second hour and a score of 9/10 was considered adequate for discharge from the post-anaesthesia recovery room, the patient satisfaction score was assessed by The IOWA Satisfaction with Anaesthesia Scale (ISAS), a self-administered questionnaire for evaluating a Patient’s satisfaction with monitored anaesthesia care received.

Inj. Diclofenac sodium 75 mg IM was used as rescue analgesic in either of the groups in the postoperative period.

Statistical analysis was done by using SPSS 17 Software with suitable tables. Chi square test and student’s ‘t’ test were performed for qualitative and quantitative estimation of the test for significance and p ≤ 0.05 was considered significant.

Demographic Profile	Group TEA	Group GA
Age (Yrs.)	50.8 ± 12.11	51.28 ± 9.5
Height (cms)	150.04 ± 4.9	152.38 ± 4.6
Duration of Surgery (min)	118.02 ± 3.2	115.41 ± 3.9
Baseline Systolic BP	124.10 ± 9.94	122.07 ± 9.35
Baseline Diastolic BP	76.53 ± 5.50	75.33 ± 4.4
Baseline Heart Rate	84 ± 4.48	83 ± 5.42

Table 1. Demographic Profile (Mean ± SD)

*p ≥ 0.05

	Group TEA	Group GA
Hypotension	3 (15%)	1 (5%)
Hypertension	0 (0%)	5 (25%)*
Bradycardia	5 (25%)*	2 (10%)
Tachycardia	0 (0%)	4 (20%)

Table 2. Incidences of Intraoperative Haemodynamic Variations

*p ≤ 0.05

Parameter	Group TEA	Group GA
Nausea and Vomiting	3 (15%)*	12 (60%)*
Respiratory Distress/Discomfort	0	2 (10%)
Dural Puncture	0	0
Hypotension	2 (10%)	4 (20%)
Bradycardia	5 (25%)	2 (10%)
Shivering	1 (5%)	2 (10%)
Aldrete Score @ 1 hr (> 9/10)	17 (85%)*	12 (60%)*
Aldrete Score @2 hrs. (> 9/10)	20 (100%)	17 (85%)

Table 3. Postoperative Observations

*p ≤ 0.05

Postop Time Interval	Group TEA	Group GA
At 0 hrs.	2.4*	5.8*
8 hrs.	3.2*	5.2*
16 hrs.	3.8	4.1
24 hrs.	4.1	3.8

Table 4. Postoperative VAS Score (Mean)

*p ≤ 0.05

Group	Satisfied	Not Satisfied
TEA	17 (85%)	3 (15%)
GA	16 ((80%)	4 (20%)

Table 5. Surgeon's Observation

Group	Satisfied	Not Satisfied
TEA	18 (90%)	2 (10%)
GA	16 (80%)	4 (20%)

Table 6. Patient's Opinion

Group TEA	29/33 (87.87%)
Group GA	22/33 (66.66%)

Table 7. IOWA Satisfaction with Anaesthesia Scale (ISAS) Score

RESULTS

The demographic picture and the baseline variables in both the groups were found to be similar (Table 1) and without any significance

The incidence of Bradycardia in the intraoperative period was found to be significantly high (25%) in Group TEA, while the incidence of Hypertension (25%) was remarkable in the GA Group. The surgical site bleeding was more in GA group as assessed by the operating surgeons, but they considered it to be acceptable. Apart from these there was not a significant variation in the haemodynamics in either of the groups. (Table 2) Remarkably significant incidence of nausea and vomiting was observed in GA (60%) group, occurrence of shivering (10%) and respiratory discomfort (10%) were also observed more in GA Group in comparison to the TEA group. Bradycardia (25%) was observed in the TEA Group. The incidence of shivering and respiratory discomfort, hypertension were high, but were statistically not significant in GA group. Aldrete score which was significant in Group TEA (85%) in the first hour as compared to the GA group (60%) after the discontinuation of anaesthetics. At the end of two hours the scores in TEA group was (100%) compared to (85%) in GA group, which was not significant (Table 3). Pain control was better in Group TEA with a significantly low mean VAS score of (2.4 at 0 hrs. and 3.2 at 8 hrs.) as compared to the Group GA (5.8 and 5.2 in the respective period) postoperatively. The decrease in VAS score in Group GA towards 16 hrs. and 24 hrs. could be attributed to the effect of rescue analgesic used for pain control in the immediate postoperative period. The overall requirement of rescue analgesics was far less in the TEA group compared to GA group. The mean VAS score was quite less in the TEA group overall in the first twenty four hours (Table 4). There was not much difference considering the feedbacks given by the surgeons (85% in TEA group and 80% in GA group were satisfied) regarding bleeding and quality of surgical field in either of the groups (Table 5). Patients in both the groups seemed to be quite comfortable and satisfied (90% in TEA and 80% in the GA group were satisfied) in the techniques. The IOWA satisfaction score was of not much significance in either of the groups, as the patients of both the groups (87.87% in TEA and 66.66% in GA group) were comfortable (Table 7).

DISCUSSION

In spite of advancement in various regional techniques for breast surgery general anaesthesia is still the preferred technique by many of the practitioners as well as the patients,

a combination of general anaesthesia with a thoracic epidural for postoperative pain relief is also a standard by most of the surgical teams, hence an attempt was made to evaluate the feasibility of using thoracic epidural with dexmedetomidine and ropivacaine^[13,19,21,22] as the sole technique for the complete procedure. It is seen that epidural technique imparts a better haemodynamic stability and perioperative outcome.^[4-14] Psychological or physical stress manifests its effects like hypercoagulability by enhancing the procoagulable state.^[1,2] This can also lead to plaque instability and acute coronary syndrome.^[2,3,6,7] Thoracic epidural causes a selective chemical sympathectomy provides segmental block which can attenuate the stress response and this segmental block is compensated by the sympathetic overactivity by the unblocked segments.^[4-7] Also the stress of laryngoscopy and intubation is avoided, as this can add to the stress response and its hazards during general anaesthesia and intubation. TEA also increases the repolarisation refractoriness of the myocardium thus preventing arrhythmia, maintains the myocardial demand/supply ratio and coronary perfusion pressure in the ischaemic myocardium, thus optimising the myocardial oxygen delivery and decreasing the cardiac work and benefitting the cardiovascular status^[6,7,9,8] by its positive effects on respiratory system^[9,8,10] and minimal change in ventilatory mechanics even in chronic obstructive respiratory disease and prevents perioperative adverse events.^[10-14,20,23] TEA with ropivacaine and dexmedetomidine improves the quality of block, increases the duration of block while decreasing the latency period, imparts better anxiolysis, sedation and analgesia minimises the requirement of analgesic and sedative supplement during axillary node clearance.^[15-18,21] In this study, it was observed that the haemodynamic and respiratory pattern was better, our findings were similar to the findings of A Clemente et al,^[8] Salgado PF et al in their study had reported synergistic effect of Ropivacaine with Dexmedetomidine in epidural anaesthesia, which might be a reason for non-supplementation of sedative or analgesics in TEA group in our study, some cases of hypotension and bradycardia were observed which were well managed by ephedrine and atropine. The patients in TEA group had less incidence of postoperative nausea and vomiting, Borgeat A et al^[24] in their study too had mentioned about lesser incidence of nausea and vomiting in epidural anaesthesia with ropivacaine and alpha-2 agonist clonidine.^[24] There was less incidence of shivering observed in our study in the TEA group, which can be attributed to the effect of dexmedetomidine. These findings corroborates to the study of Grewal A,^[15] Parnjape JS^[16] and Maroof A.^[19] In the postoperative period our patients had less incidence of pain, which might be due to the effect of dexmedetomidine and ropivacaine, Grewal A,^[15] Salgado PF et al^[19] Paranjape JS.^[16] This could have extended into the second postoperative day too with the catheter in situ, but it was not in our study design so was not assessed.^[15-18,21,22,25] Bajwa SJ et al,^[17] Martha V et al,^[18] Salgado PF et al and Arunkumar S et al^[21] in their studies on alpha-2 agonists had demonstrated the beneficial effects of dexmedetomidine when used in conjunction with ropivacaine for epidural anaesthesia. Our findings also demonstrated similar facts.

TEA may have some beneficial effect on postoperative scar and phantom breast pain, but it was beyond the scope of

this study so could not be assessed, Kroner K et al.^[26] The quicker recovery pattern than GA group is also established and reported owing to the typical effect of dexmedetomidine, which causes conscious sedation and lack of respiratory depression.^[11,15,16,21,23] Early recovery and discharge can decrease the load on caregivers at PACU and minimise the financial burden on the health system. The patient satisfaction though was not statistically significant, but more number of patients (87.87%) were satisfied with the technique.^[27] This may be due to the effect of dexmedetomidine imparting its sedative, hypnotic and analgesic effect during the procedure.^[15,16] Addition of dexmedetomidine can extend the scope of TEA to elderly patients with comorbidities (though it could not be studied as the study was on ASA I-II patients) due to its inherent properties of sedation, analgesia and least effect on cardiorespiratory system in therapeutic dose and its synergistic effect with ropivacaine as has been studied by various authors.^[13,14,15,16,19]

CONCLUSION

Thoracic epidural anaesthesia with ropivacaine and dexmedetomidine is a safe and reliable alternative as the sole anaesthetic to general anaesthesia, for breast surgery owing to better cardiorespiratory stability, perioperative analgesia and lesser incidence of shivering and nausea and vomiting.

Limitations

A bigger sample size will validate our findings, so further multicentric trials are awaited. Patients with comorbidity and elderly patients and patients having comorbidity were not evaluated in the study.

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