VOLUME - 14, ISSUE - 03, MARCH - 2025 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper

Anaesthesiology

A COMPARATIVE CLINICAL STUDY TO EVALUATE POSTOPERATIVE ANALGESIA OF TWO DIFFERENT DRUGS DEXMEDETOMIDINE AND FENTANYL IN COMBINATION WITH 0.25% ROPIVACAINE FOR SURGICAL SITE INFILTRATION IN CASES OF MODIFIED RADICAL MASTECTOMY

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ABSTRACT

Introduction: Pain is an expected side effect following surgery that frequently lasts for several days; if not addressed, it is linked to serious negative outcomes for the patient. **Aims and Objectives:** To compare the efficacy of Surgical site infiltration 0.25% Ropivacaine with Dexmedetomidine (1mcg/Kg) and 0.25% Ropivacaine with Fentanyl (1mcg/Kg) postoperative pain relief in Modified Radical Mastectomy. **Material and Method:** The study was conducted in 70 female patients of age between 30-60 years of ASA grade I and II undergoing elective modified radical mastectomy surgeries. Patients were randomly divided into two groups. GROUP D– 0.25 % ropivacaine (20ml) + dexmedetomidine (1mcg/kg) + 0.9% normal saline and GROUP F– 0.25 % ropivacaine (20ml) + fentanyl (1mcg/kg) + 0.9% normal saline. **Result:** The mean time to rescue analgesia In Group D was 15.09±1.63 hours and in Group F was 8.63±1.26 hours. The difference in mean duration of rescue analgesia between the study groups was statistically highly significant. **Conclusion:** Based on the present study we have concluded that adding dexmedetomidine to ropivacaine local wound infiltration of the surgical site (modified radical mastectomy surgical site) prolongs the duration of analgesia in the postoperative period.

KEYWORDS : Dexmedetomidine, Ropivacaine, Fentanyl, Modified Radical Mastectomy

INTRODUCTION

The International Association for the Study of Pain defines pain as "An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage." [1]

For operable breast cancers, modified radical mastectomy continues to be the standard treatment. Pain is an expected side effect following surgery that frequently lasts for several days.

Wound infiltration with local anaesthetics is a straightforward and affordable procedure that can offer adequate postoperative analgesia and promote an early and more comfortable recovery. In addition to decreasing the local inflammatory response to injury, local anaesthetics are strong, long-lasting drugs that work by preventing the transmission of pain from nociceptive afferents directly from the wound surface. [2]

Pure S-enantiomer ropivacaine, a novel long-acting amide local anaesthetic, has a high pKa and comparatively limited lipid solubility. The onset, quality, and duration of the sensory block produced by ropivacaine are almost equal to those of bupivacaine, but it appears to generate less motor block. [3]

Fentanyl is typically used as an adjuvant to local anaesthetics for peripheral analgesia since it releases less histamine than morphine or meperidine [4]

Alpha 2 adrenergic agonists (clonidine and dexmedetomidine) are another promising adjuvant to enhance the quality and duration of analgesia of local anaesthetics, with dexmedetomidine being found to be superior to clonidine due to its dual mechanism of action for peripheral antinociception. [5,6] Dexmedetomidine when administered in wound infiltration provides effective postoperative analgesia as on intravenous administration but with minimal side effects. [7]

Aims and Objectives

To compare the efficacy of Surgical site infiltration 0.25% Ropivacaine with Dexmedetomidine (1mcg/Kg) and 0.25% Ropivacaine with Fentanyl (1mcg/Kg) postoperative pain relief in Modified Radical Mastectomy in terms of

1. To observe VAS score postoperatively
2. To compare the time for rescue analgesia
3. To observe postoperative hemodynamic parameters
4. To observe any untoward side effects and complications of local anaesthetic and adjuvant drugs used

MATERIAL AND METHOD

The study was conducted in Department of Anaesthesiology, J.A. Group of Hospitals and G.R. Medical College, Gwalior after obtaining approval from the institutional ethics committee. 70 female patients of age between 30-70 years of ASA grade I and II were included in this study. Patients were randomly divided into two groups by putting out computer-generated random number tables and closed envelope technique undergoing elective modified radical mastectomy surgeries.

GROUP D (n=35) – 0.25 % ropivacaine (20ml) + dexmedetomidine (1mcg/kg) + 0.9% normal saline

GROUP F (n=35) – 0.25 % ropivacaine (20ml) + fentanyl (1mcg/kg) + 0.9% normal

Inclusion Criteria

1. Consent to the patient in the study
2. ASA Physical Grade I and II
3. Age group 30 to 70 years
4. Weight 30-70 kg

Exclusion Criteria:

1. Patient's refusal
2. ASA grade III and IV
3. Patients who are unable to understand VAS assessment.
4. Patients with a history of drug allergy to local anaesthetic, dexmedetomidine, and opioids
5. Drug addict / Patient on long-term steroid therapy
6. Pregnancy and lactating women.

The pre-anaesthetic evaluation was done on the day before

surgery. The patient has well explained the procedure. After a thorough routine preanesthetic assessment, the patient was taken to the operation theatre, standard ASA monitors were attached and baseline parameters were recorded (Pulse rate, SBP, DBP, and SPO2). After induction with general anaesthesia maintenance of anaesthesia was done with 33% oxygen and 67% nitrous mixture + sevoflurane + Inj. Atracurium. ECG, EtCO2, NIBP, SpO2, respiratory rate (RR), and pulse rate (PR) were monitored. Group D was infiltrated with ropivacaine (20ml) with dexmedetomidine (1 mcg/kg) and group F was infiltrated with 0.25% ropivacaine (20ml) + fentanyl (1 mcg/kg) + 0.9% normal saline to make the total drug volume to 25 ml for wound infiltration. After induction standard parameters were recorded. At the end of the procedure, the operating surgeon was requested to infiltrate the study drug at the wound site intradermally.

PR, NIBP (SBP, DBP), and SP02 were recorded at baseline, intraoperatively, just before wound infiltration and postoperatively at PACU arrival and then at 0 min, 1, 2, 4, 6,8,10, 12,14,16,20, and 24 hr.

The postoperative analgesic effect of the study drug on each patient was assessed at the time of arrival to post anaesthesia care unit (0 min) and then at 1, 2, 4, 6,8,10, 12,14,16,18,20, and 24 h after surgery using VAS score (0–10) with 0 = no pain and 10 = maximum pain Duration of analgesia is taken from the time of drug infiltration at the end of surgery till the time of 1st rescue analgesic requirement.

Primary Outcome :-

1. To observe VAS score postoperatively
2. To compare the time for rescue analgesia.
3. To observe postoperative hemodynamic parameters.

Secondary Outcome :-

1. To observe any untoward side effects and complications of local anaesthetic and adjuvant drugs used

The statistical analysis of this study was carried out by paired t-test and Pearson chi-square test. P value > 0.05 was statistically insignificant while p value < 0.05 was considered statistically significant and p value <0.01 was statistically highly significant. The statistical analysis was done using SPSS software

OBSERVATION AND RESULT

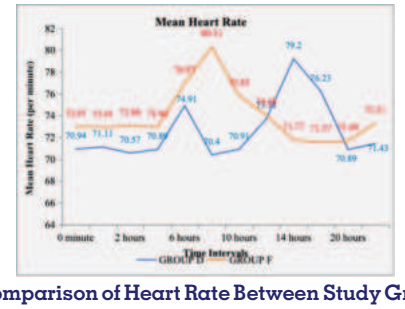

Fig. 1: Comparison of Heart Rate Between Study Groups

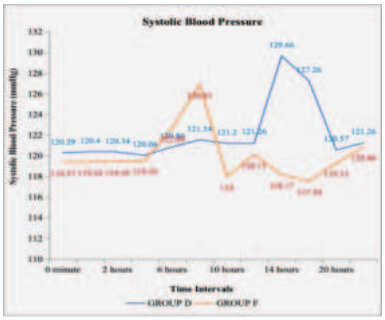

Fig 2: Comparison of Systolic Blood Pressure Between Study Groups at Different Time Intervals

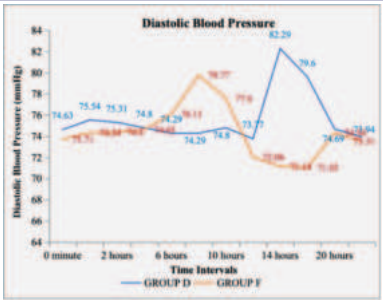

Fig. 3: Comparison of Diastolic Blood Pressure Between Study Groups at Different Time Intervals

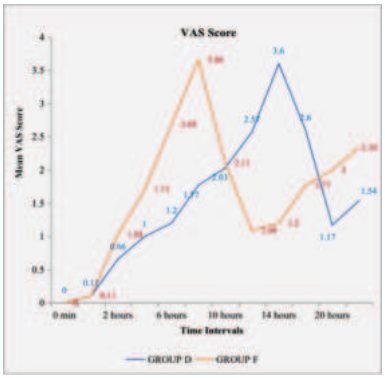

Fig. 4: Comparison of VAS Score Between Study Groups at Different Time Intervals

Table 1: Comparison of the Mean Time to Rescue Analgesia Between Groups

Group	Number of Cases	Mean time to rescue analgesia (minutes) [Mean ± SD]	T value	P value
Group D	35	15.09 ± 1.63	18.504, df=68	<0.001
Group F	35	8.63 ± 1.26		
Total	70	11.86 ± 3.56		

Table 2: Comparison of Complications Between the Groups

Complications	Group D		Group F		Total	
	No.	%	No.	%	No.	%
Vomiting	0	0.0%	1	2.86%	1	1.43%
Nausea	0	0.0%	2	5.71%	2	2.86%
No complications	35	100.0%	32	91.43%	67	95.71%
Total	35	100.0%	35	100.0%	70	100.0%

DISCUSSION

In our study, the demographic characteristics such as age, ASA grade, and weight were comparable between both groups.

HR- At 0min, 1hr, 2hr, 4hr, 6hr, 12hr, 20hr, and 24hr postoperatively, there were no significant differences in heart rate between the two groups, as evidenced by p-values greater than 0.05.

At 8hr and 10hr postoperatively Group F had significantly higher heart rates as compared to Group D while at 14 and 16 hr postoperatively Group D had significantly higher heart rates than Group F as seen in figure 1.

Our results were similar to the study done by Bharadwaj S et al[8] in which they found that postoperatively the baseline HR was comparable between the 2 groups and postoperative HR was lower in group ropivacaine with dexmedetomidine than in group ropivacaine.

SBP- As seen in figure 2 systolic blood pressure (SBP) was compared between Group D and Group F at various time intervals in the postoperative period.

At 8 hr and 10 hr postoperatively, Group F had significantly higher SBP compared to Group D. There was a more gradual fall in SBP in Group D than Group F.

At 14 hr and 16 hr postoperatively, Group D had significantly higher SBP than Group F.

Our results were similar to the study done by Prieto BIY et al[9] who found that SBP was statistically insignificant between group infiltration of ropivacaine 7.5% and group instillation of ropivacaine 7.5 %. (p-value > 0.05)

DBP- As seen in figure 3 Diastolic blood pressure (DBP) was compared between Group D and Group F at various time intervals in the postoperative period. At 8 and 10 postoperatively, there were significant differences in DBP between Group D and Group F, as indicated by p-values less than 0.05. At 8 hr and 10 hr postoperatively, Group F had significantly higher DBP.

DBP compared to Group D At 14 hr and 16 hr postoperatively Group D had significantly higher DBP than Group F.

At 0min, 1hr, 2hr, 4hr, 6hr, 12hr, 20hr, and 24 hr postoperatively, there were no significant differences in DBP between the two groups, as evidenced by p-values greater than 0.05.

Our results were similar to the study done by Prieto BIY et al[9]

SPO2- At 0min, 1hr, 2hr, 4hr, 6hr, 8hr, 10hr, 12hr, 14hr, 16hr, 20hr, and 24hr postoperatively there were no significant differences between Group D and Group F, as indicated by p-values greater than 0.05.

Our results were in concordance with the study done by Modir H et al[10] who found that ropivacaine group, ropivacaine plus dexmedetomidine group, ropivacaine plus fentanyl group were comparable for spo2

VAS Score- Visual Analog Scale (VAS) scores were compared between Group D and Group F at various time intervals in the postoperative period, ranging from 0 minutes to 24 hours.

From 2 to 8, 16, 20, and 24 hours postoperatively, Group D had significantly lower mean VAS scores compared to Group F, as evidenced by p-values less than 0.05.

Our results were similar to the study done by Praveena BL et al[11] in which they found that VAS over 24 hours postoperatively was significantly lower in Group Ropivacaine with dexmedetomidine than Group Ropivacaine with fentanyl.

Rescue Analgesia- As can be seen in table no 1, in Group D, the mean time to rescue analgesia was 15.09±1.63 minutes. In contrast, Group F had a significantly shorter mean time to rescue analgesia of 8.63±1.26 hours. The mean time to rescue analgesia for the study population was 11.86±3.56 hours.

Our results were concordant with the study done by Baghel KS et al[12], they found that the mean duration of analgesia in patients receiving ropivacaine was significantly less than the patients receiving ropivacaine with fentanyl.

Complications- as seen in table no. 2, in Group F, one patient (2.86%) experienced vomiting, and two patients (5.71%) experienced nausea. The remaining 32 patients (91.43%) in this group did not experience any complications. The incidence of complications was lower in Group F, while it was approximately nil in Group D.

Our results were similar to the study done by Praveena BL et al[11] who found that both group Ropivacaine with dexmedetomidine and Ropivacaine with fentanyl were comparable in terms of complications

CONCLUSION

Based on the present study we have concluded that adding dexmedetomidine to ropivacaine local wound infiltration of the surgical site (modified radical mastectomy surgical site) prolongs the duration of analgesia in the postoperative period. It provides hemodynamic stability, and analgesia during the postoperative period and is associated with minimal side effects.

Conflict Of Interest- NIL

REFERENCES

1. Fields HL, Martin JB. Harrison's Principles of Internal Medicine. 16th ed. New York: McGraw-Hill; 2005. p. 71-6.
2. Hansen TG. Ropivacaine: a pharmacological review. Expert Rev Neurother [Internet]. 2004;4(5):781–91. Available from: http://dx.doi.org/10.1586/14737175.4.5.
3. Jyothi, B., Govindaraj, K. and Shaikh, S.I., 2017. Comparison of analgesic efficacy of levobupivacaine, levobupivacaine and clonidine, and levobupivacaine and dexmedetomidine in wound infiltration technique for abdominal surgeries: A prospective randomized controlled study. Indian Journal of Pain, 31(2), p.127.
4. Dodson, B.A. and Miller, K.W., 1985. Evidence for a dual mechanism in the anesthetic action of an opioid peptide. Anesthesiology: The Journal of the American Society of Anesthesiologists, 62(5), pp.615-620.
5. Gertler, R., Brown, H.C., Mitchell, D.H. and Silvius, E.N., 2001, January. Dexmedetomidine: a novel sedative-analgesic agent. In Baylor University Medical Center Proceedings (Vol. 14, No. 1, pp. 13-21). Taylor & Francis.
6. Abd El-Hamid, A.M., Alrabiey, M.I. and Abd El-Fattah, M.H., 2016. A comparison of the postoperative analgesic effects of intravenous dexmedetomidine with a combination of dexmedetomidine and bupivacaine wound infiltration for lower segment cesarean section: A prospective, randomized study. Ain-Shams Journal of Anaesthesiology, 9(2), p.235.
7. Luan H, Zhu P, Zhang X, Tian L, Feng J, Wu Y, Yan Y, Zhao Z, Gu X. Effect of dexmedetomidine as an adjuvant to ropivacaine for wound infiltration in patients undergoing open gastrectomy: A prospective randomized controlled trial. Medicine. 2017 Sep 1;96(38):e7950
8. Bhardwaj S, Devgan S, Sood D, Katyal S. Comparison of local wound infiltration with ropivacaine alone or ropivacaine plus dexmedetomidine for postoperative pain relief after lower segment cesarean section. Anesthesia Essays and Researches. 2017 Oct 1;11(4):940-5.
9. Yolanda-Prieto BI, Millán-Corrales AL, Palacios-Ríos D, GarduñoChávez BI, López-Cabrera NG, Millán-Cornejo GA, González-Rocha BT. Infiltration vs. instillation of ropivacaine 7.5% in radical mastectomies for postoperative analgesia. Medicina Universitaria. 2014;16:15–18.
10. Yazdi B, Modir H, Piri M, Almasi-Hashiani A. An investigation of the effects of dexmedetomidine and fentanyl as an adjuvant to ropivacaine on pain scores and hemodynamic changes following laparoscopic cholecystectomy. Med Gas Res [Internet]. 2021;11(3):88. Available from: http://dx.doi.org/10.4103/2045-9912.314327
11. Bharathi B, Praveena B, Sahana VR. Intraperitoneal ropivacaine with dexmedetomidine or fentanyl for postoperative analgesia following laparoscopic cholecystectomy: A comparative randomized trial. Anesth Essays Res [Internet]. 2019;13(1):169.
12. Baghel KS, Bhargava J, Tiwari RL, Trivedi S. Efficacy of port-site infiltration with ropivacaine alone versus ropivacaine with fentanyl for postoperative analgesia in patients undergoing laparoscopic procedures. Medica Innovative. 2022 Jan 1;11(1).