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COMPARATIVE STUDY OF POST-OPERATIVE ANALGESIC EFFECTS OF WOUND INFILTRATION OF EQUIVALENT DOSES WITH ROPIVACAINE (0.75%) VERSUS LEVOBUPIVACAINE (0.5%) IN MODIFIED RADICAL MASTECTOMY

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Abstract

Background: Surgery still has a pivotal role in the management of breast cancer & surgery is invariably associated with pain. Present study was aimed to compare post-operative analgesic effects of wound infiltration of equivalent doses with Ropivacaine (0.75%) versus Levobupivacaine (0.5%) in Modified Radical Mastectomy. **Material and Methods:** Present study was single-center, prospective, comparative study, conducted in patients aged between 20-65 years, belonging to ASA physical status grade I and grade II, weight between 50-70 kg, underwent Modified Radical Mastectomy. At the end of the surgery, before closing the surgical incision, as per the randomization, group R was infiltrated with 0.75% Ropivacaine 20 ml, 13.3 ml of Ropivacaine (0.75%) while Group L was infiltrated with 0.5% Levobupivacaine 20 ml (100 mg). **Results:** Our study included 60 patients undergoing elective modified radical mastectomy belonging to ASA grade 1 and 2. In the study, there was no significant difference in mean pulse rate between two groups at different time intervals. At 15 minutes, 30 minutes, at 45 minutes, the average MAP was significantly higher in ropivacaine group when compared with that of levobupivacaine group. Despite of being statistically insignificant, the VAS scores at initial intervals (15min, 30mins, and 45mins) were low in group R when compared to group L. At 60 mins and 90 minutes, there was a marked increase in VAS score in group R and thereafter it was akin in two groups. We found that the maximum analgesic effect after wound infiltration was up to 6hrs in both the groups and thereafter the study was terminated. **Conclusion:** Ropivacaine infiltration provided rapid onset and adequate depth of analgesia in the immediate postoperative hours especially during the initial 90 minutes, whereas levobupivacaine had a slow and constant depth of analgesia. The maximum duration of analgesia noted in our study was 6 hours.

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Keywords: Wound infiltration, ropivacaine, levobupivacaine, modified radical mastectomy, postoperative pain

Introduction

Breast cancer has captured the attention throughout the ages. Surgery still has a pivotal role in the management of breast cancer, even though recent advances in oncology are trending towards more conservative techniques followed by chemotherapy.[1,2] Surgery is invariably associated with pain. According to Indian Association for Study of Pain (IASP), pain is defined as an "unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage".

Recently pain management has evolved into a multidimensional entity involving sensory, cognitive, motivational and affective qualities.[3] Poorly managed pain following surgery can produce pathophysiologic process in both peripheral and central nervous system which have the potential to produce chronicity. Various strategies like NSAIDs, opioids, peripheral nerve blocks, wound infiltration with local anaesthetics were found to have significantly improved postoperative pain relief.[4]

Optimal acute postoperative pain relief after major breast surgery is still a matter of controversy. Surgical wound infiltration with a local anaesthetic solution is currently performed in many surgical procedures.[5,6] paravertebral blocks and brachial plexus blocks have been practiced from long back for pain relief.[7,8] Present study was aimed to compare post-operative analgesic effects of wound infiltration of equivalent doses with Ropivacaine (0.75%) versus Levobupivacaine (0.5%) in Modified Radical Mastectomy.

Material And Methods

Present study was single-center, prospective, comparative study, conducted in department of anaesthesiology, at Kidwai Memorial Institute of Oncology, Bangalore, India. Study duration was of 18 months (December 2017 to May 2019). Study approval was obtained from institutional ethical committee.

Inclusion criteria

- Patient aged between 20-65 years, belonging to ASA physical status grade I and grade II, weight between 50-70 kg, underwent Modified Radical Mastectomy, willing to participate in present study

Exclusion criteria

- History of allergy.
- Severe renal, liver, cardiac and pulmonary dysfunction
- Who are unable to comprehend VAS scale.

Study was explained to patients in local language & written consent was taken for participation & study. They were made well conversant with pain scoring on VAS scale with 0 as no pain and 10 as worst possible pain.

60 patients posted for Modified Radical Mastectomy who fulfilled the inclusion and exclusion criteria had undergone pre anaesthetic check up on the day prior to surgery and were randomized based on the computer-generated randomization table into one of the two groups: Group R and Group L.

Premedication, induction and maintenance of anaesthesia were standardized. Patients were premedicated with Tab. Pantoprazole 40mg and Tab. Alprazolam 0.5mg at bed time, night before surgery. On the day of surgery, in the operation theatre, NPO status confirmed, standard monitors- pulse oximetry, NIBP, and ECG were connected. Baseline vitals noted. An intravenous access was secured and subsequently premedicated with Inj. Midazolam

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0.05mg/kg, Inj. Glycopyrrolate 0.01mg/kg, Inj. Ondansetron 0.05mg/kg and intubated with appropriate cuffed endotracheal tube. After confirming tube position by auscultation and $EtCO_2$, patients were mechanically ventilated to maintain oxygenation and ventilation.

Anaesthesia was maintained with nitrous oxide 50%, oxygen 50%, isoflurane and vecuronium bromide initial dosing 0.08mg/kg, followed by intermittent doses of 0.02mg/kg. All the vital parameters were monitored throughout the surgery. At the end of the surgery, before closing the surgical incision, as per the randomization, study drug was infiltrated.

- Group R was infiltrated with 0.75% Ropivacaine 20 ml (13.3 ml (100mg) of Ropivacaine (0.75%) made up to 20mlwith normal saline).
- Group L was infiltrated with 0.5% Levobupivacaine 20 ml (100 mg).

Patients were reversed with Inj. Neostigmine 0.05mg/kg and Inj. Glycopyrrolate 0.01mg/kg and extubated after complete neuromuscular recovery in fully awake state. Patients were transferred to the post-anesthesia care unit for further monitoring. Pain score at "0" h was noted after extubation and subsequently at 15mins, 45mins, 60mins, 90mins, 2, 4, 8, 12, 16, 20 and 24 hrs. by the person who does not have knowledge regarding the solution which the patient had received. Post-operative pain was assessed by VAS using a 10 cm VAS (0 - no pain and 10 - worst imaginable pain).

If the VAS exceeded "4" at any point of time, rescue analgesia with Inj. Paracetamol 15mg/kg IV, was administered over 20 minutes. If pain was persisting even after Paracetamol injection and VAS >4, Inj. Fentanyl 0.5 mcg/kg was administered and the study terminated at that time. The duration of analgesia was defined from the time of infiltration of the study drug to the time for the first demand of analgesia. The number of demands and the total cumulative analgesic requirement was noted for 24 h. Surgical site related untoward effects such as hematoma, allergic reactions and wound dehiscence were observed clinically till the patient was discharged from postoperative care unit. Also, adverse effects such as bradycardia, hypotension nausea and vomiting were noted and treated accordingly.

At 0, 15min, 30min, 45 min, 60min, 90mins, 2, 4, 8, 16, 20 and 24 hours after infiltrating the drug, the parameters evaluated were VAS score, Pulse rate, Blood pressure, PONV, Number of rescue analgesics received & Side effects like bradycardia, hypotension, and rashes.

Data was collected and compiled using Microsoft Excel, analyzed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables were tested using chi-square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant.

Results

Our study included 60 patients undergoing elective modified radical mastectomy belonging to ASA grade 1 and 2. There was no significant difference in age distribution between two groups.

In Ropivacaine, 13.3% was ASA grade 1, 86.7% ASA grade II. In Levobupivacaine group, 36.7% belonged to ASA grade 1 and 63.3% ASA grade II. There was significant difference between two groups the two groups with respect to ASA distribution. Group R had more ASA grade II patients when compared to group L. There was no statistically significant difference between the two groups in terms of height and weight.

Table 1: General characteristics

	Ropivacaine	**Levobupivacaine**	**P value**
Age groups (in years)			

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< 40	9 (30 %)	8 (26.7%)	0.548
41- 50	11 (36.7 %)	15 (50 %)	
51-60	10 (33.3 %)	7 (23.3 %)	
ASA			
I	4 (13.3 %)	11 (36.7 %)	0.037*
II	26 (86.7 %)	19 (63.3 %)	
Gender			
Height (cms)	156.53 ± 4.55	156.10 ± 3.99	0.696
Weight (Kgs)	55.47 ± 5.53	53.37 ± 6.13	0.169

Pulse rate was monitored at time intervals 0 min, 15mins, 30mins, 45mins, 60mins, 90mins, 2hrs, 4hrs and 6hrs. In the study, there was no significant difference in mean pulse rate between two groups at different time intervals.

Table 2: Pulse Rate distribution comparison between two groups

Pulse Rate	**Group**						**P value**
	Ropivacaine		**Levobupivacaine**		**Total**		
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	
Baseline	79.10	10.69	84.50	11.25	81.80	11.22	0.062
0 MIN	97.80	12.31	94.87	13.87	96.33	13.08	0.390
15 MIN	89.47	12.62	83.70	11.60	86.58	12.37	0.071
30 MINS	87.27	11.74	83.13	10.97	85.20	11.46	0.164
45 MINS	84.50	11.43	82.47	10.49	83.48	10.92	0.476
60 MINS	84.33	11.29	82.70	10.15	83.52	10.68	0.558
90 MINS	87.57	10.22	85.33	10.31	86.45	10.24	0.403
2 HRS	93.08	8.30	90.70	10.05	91.78	9.29	0.349
4 HRS	92.00	5.42	93.00	5.75	92.63	5.50	0.714
6 HRS	88.00	.	86.00	.	87.00	1.41	-

In our study, the average mean arterial pressure were compared at different intervals after the wound infiltration with the study drugs, it was found that there was a significant difference between the two groups with respect to MAP at 15 minutes, 30 minutes and 45 minutes. At 15 minutes, 30 minutes, at 45 minutes, the average MAP was significantly higher in ropivacaine group when compared with that of levobupivacaine group.at other intervals there was no statistically significant difference between these two groups with respect to mean MAP.

Table 3: MAP distribution comparison between two groups

MAP	**Group**						**P value**
	Ropivacaine		**Levobupivacaine**		**Total**		
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	
Baseline	97.30	10.68	99.93	13.24	98.62	12.00	0.400
0 MINS	115.20	12.45	112.63	9.59	113.92	11.09	0.375
15 MINS	108.07	12.77	100.70	9.33	104.38	11.69	0.013*
30 MINS	105.70	11.19	99.50	8.33	102.60	10.27	0.018*
45 MINS	103.57	9.47	98.57	7.66	101.07	8.91	0.028*
60 MINS	102.23	9.79	99.63	7.18	100.93	8.61	0.246
90 MINS	105.77	10.13	101.57	6.38	103.67	8.66	0.06
2 HRS	107.68	10.01	105.57	5.67	106.53	7.93	0.330
4 HRS	110.43	15.60	106.00	3.62	107.63	9.69	0.351

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6 HRS	92.00	.	109.00	.	100.50	12.02	-

VAS score after infiltration with study drugs were studied and compared between the two groups at 0 min,15 mins, 30mins, 45mins, 60mins, 90mins, 2hrs, 4hrs, 8hrs, 16hrs, 20hrs and 24hrs. In our study, at 90 mins, 16% of patients in ropivacaine group had VAS score of more than 4 and thereby requiring rescue analgesia whereas in levobupivacaine group none of patients had VAS score of >4. This was statistically significant. At 2 hours, 60% of patients of both groups had VAS score >4. At 4 hours 20% of group R patients complained of pain where as in group it was 28.3% whose VAS score >4. At 6hrs remaining one patient from both the group R and group L had VAS score >4 and required rescue analgesia.

Despite of being statistically insignificant, the VAS scores at initial intervals (15min, 30mins, and 45mins) were low in group R when compared to group L. At 60 mins and 90 minutes, there was a marked increase in VAS score in group R and thereafter it was akin in two groups.

Table 4: VAS score distribution comparison between two groups

VAS Score	Group									P value
	Ropivacaine			Levo Bupivacaine			Total			
	Mean	SD	Median	Mean	SD	Median	Mean	SD	Median	
0 MINS	0.30	.53	0	0.30	.53	0	0.30	.53	0	1.000
15 MINS	0.37	.56	0	0.50	.68	0	0.43	.62	0	0.496
30 MINS	0.70	.79	1	0.80	.92	1	0.75	.86	1	0.772
45 MINS	1.23	.86	1	1.27	.83	1	1.25	.84	1	0.795
60 MINS	1.90	.92	2	1.63	1.07	1	1.77	1.00	2	0.301
90 MINS	2.97	.72	3	2.43	1.01	3	2.70	.91	3	0.016*
2 HRS	3.52	.92	4	3.57	.94	4	3.55	.92	4	0.647
4 HRS	3.86	.38	4	4.00	.85	4	3.95	.71	4	0.711
6 HRS	4.00	.	4	4.00	.	4	4.00	.00	4	1.00

Rescue analgesia requirement were studied and compared between the two groups at 0 min, 15 mins, 30mins, 45mins, 60mins, 90mins, 2hrs, 4hrs and 6hrs.

In our study, 16% of patients in ropivacaine group had VAS score of more than 4 at 90 min, and thereby requiring rescue analgesia whereas in levobupivacaine group none of patients had VAS score of >4. At 2 hours, 60% of patients of both groups had VAS score >4 and so rescue analgesia in the form of Inj. Paracetamol 15mg/kg were given to them. At 4 hours 20% of group R patients required rescue analgesia where as in group L it was 28.3%. At 6hrs remaining one patient from both group R and group L had VAS score >4 and required rescue analgesia. We found that the maximum analgesic effect after wound infiltration was up to 6hrs in both the groups and thereafter the study was terminated.

Table 5: Rescue analgesia distribution comparison

Rescue Analgesia		Group						P value
		Ropivacaine		Levobupivacaine		Total		
		Count	%	Count	%	Count	%	
0 MIN	No	30	100.0%	30	100.0%	60	100.0%	-
15 MIN	No	30	100.0%	30	100.0%	60	100.0%	-
30 MIN	No	30	100.0%	30	100.0%	60	100.0%	-
45 MIN	No	30	100.0%	30	100.0%	60	100.0%	-
60 MINS	No	30	100.0%	30	100.0%	60	100.0%	-
90 MINS	No	25	83.3%	30	100.0%	55	91.7%	0.020*

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	Yes	5	16.7%	0	0.0%	5	8.3%	
2 HRS	No	12	40.0%	12	40.0%	24	40.0%	1.000
	Yes	18	60.0%	18	60.0%	36	60.0%	
4 HRS	No	24	80.0%	19	63.3%	43	71.7%	0.152
	Yes	6	20.0%	11	36.7%	17	28.3%	
6 HRS	No	29	96.7%	29	96.7%	58	96.7%	1.000
	Yes	1	3.3%	1	3.3%	2	3.3%	

In Ropivacaine and Levobupivacaine group, none of the patients had nausea or vomiting during the study period. In both Ropivacaine and Levobupivacaine group, none of the patients required antiemetics.

We observed for any side effects in both the groups. In both Ropivacaine and Levobupivacaine group, none of our patients had any adverse effects such as bradycardia, hypotension and surgical site rashes.

Discussion

Uncontrolled postoperative pain produces a range of detrimental acute and chronic effects which increase morbidity and mortality. Poorly controlled acute postoperative pain is an important predictive factor in the development of chronic post-surgical pain (CPSP). CPSP is relatively common after procedures such as limb amputation (30%to 83%), thoracotomy (22% to 67%), sternotomy (27%), breast surgery (11% to 57%), and gallbladder surgery (up to 56%).The optimization of perioperative analgesia may decrease complications and facilitate recovery during the immediate postoperative period and after discharge from the hospital.[4]

Various regional and systemic techniques such as local wound infiltration, wound instillation, thoracic epidural, thoracic paravertebral block, NSAID's, opioids, and more recently ultrasound guided fascial plane blocks have been used to provide analgesia in breast surgeries. Despite the availability of wide variety of options for Pain management, satisfactory pain relief remains elusive.

Wound infiltration in fact is an effective, simple and economical method of post-operative analgesia. Till date, many local anesthetic drugs are in use for local wound infiltration, for example, Lidocaine, Bupivacaine, Levobupivacaine, and Ropivacaine. Local anesthetic drugs are becoming increasingly popular because of their analgesic properties and lack of opioid-induced adverse effects for treating postoperative surgical pain. With its lower toxicity, especially of cardiovascular system and central nervous system, Ropivacaine and Levobupivacaine are replacing their parent molecule – Bupivacaine.

Persistent pain is a major clinical worry following breast cancer surgery. Surgical wound infiltration with a local anesthetic solution is speculated to reduce the pain and it has become part and parcel of multimodal analgesia. The technique of wound infiltration has been effectively and successfully used in breast cosmetic surgeries for immediate pain relief.

Tam KW *et al.*,[9] conducted a systematic review and meta-analysis, they noted that infusion of Ropivacaine or Bupivacaine following breast cancer surgery decreased immediate postoperative pain but did not reduce pain at 12 and 24 h postoperatively. In our study, we noticed that despite of being statistically insignificant, the VAS scores at initial intervals (15min, 30mins, and 45mins) were low in group R when compared to group L. At 60 mins and 90 minutes, there was a marked increase in VAS score in group R and thereafter it was similar in two groups.

In study by Anna Zaira *et al.*,[10] patients received local infiltration of either 20ml of 0.75% Ropivacaine or 0.5% of Levobupivacaine and assessed VAS score at 2,4,6 and 24

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hours. They found that Ropivacaine and Levobupivacaine had similar analgesic effects at 2 and 6 hours, which is much similar to our findings.

In present study, total duration of analgesia for both the groups lasted for only 6 hours post wound infiltration in contrast to the study of Anna Zaira *et al.*,[10] where the analgesia with Levobupivacaine was noted till 24 hours.

Aline Albi-Feldezer *et al.*,[11] in their study, found that Ropivacaine wound infiltration significantly decreased immediate postoperative pain for the first 90 min. This is in concordance with our findings wherein the VAS score was relatively low in the initial time intervals (15min, 30min, and 45min) in group R.

Kakagia D *et al.*,[12] conducted a double blinded study to compare the analgesic properties of levobupivacaine and ropivacaine in a bilaterally symmetrical mastopexy model. Both anesthetics provided satisfactory analgesia for at least 10 hours, whereas in our study, the total duration was 6 hours. In their study, at 2 hours postoperatively, no difference was found between the 2 local anesthetic agents in terms of analgesic efficacy which was similar to ours. They concluded that both anesthetics provided satisfactory analgesia for at least 10 hours, but constantly low pain scores were recorded for levobupivacaine postoperatively. But in our study, ropivacaine group provided better analgesia during the initial period, later on there was similar VAS score between the two groups.

Moshe Fayman *et al.*,[13] compared the analgesic effect of bupivacaine and ropivacaine for infiltration analgesia for bilateral breast surgery, where they concluded that local anaesthetic infiltration was shown to be more effective in patients who had breast reduction surgeries when compared to breast augmentation surgeries and also they found that use of Ropivacaine rather than Bupivacaine in high dose is more efficacious. Our study confirms the above results, suggesting that ropivacaine have effective pain relief in the initial postoperative hours whereas levobupivacaine provided a slow and constant pain relief.

In our study, we observed for side effects like bradycardia, hypotension, rashes, postoperative nausea and vomiting. However, none of the patients in both the groups was found to have any side effects. Kakagia DD *et al.*,[14] had compared the efficacy of levobupivacaine and ropivacaine in mini abdominoplasty. They did not observe any systemic toxicity or infection at surgical site. Our result is in concordance with this study in terms of adverse effects, which is similar to the findings of our study.

Wound infiltration with local anaesthetics like levobupivacaine and ropivacaine in modified radical mastectomy is a simple, safe, inexpensive and effective method of providing adequate postoperative analgesia. With the reduction in the opioid requirement, it brings down the complication associated with opioids and also is cost effective. Local anaesthetic drugs can be safely used provided they are in optimal doses in wound infiltration. Limitations of the study were, only ASA I & II grade patients were studied, & sample size was small.

Conclusion

Wound infiltration of ropivacaine and levobupivacaine in modified radical mastectomy reduces postoperative pain scores, provide better quality of postoperative analgesia, reduces opioid consumption and hence its side effects like nausea, vomiting & does not increase the incidence of side effects if used in optimal doses.

In our study, we found that, ropivacaine infiltration provided rapid onset and adequate depth of analgesia in the immediate postoperative hours especially during the initial 90 minutes, whereas levobupivacaine had a slow and constant depth of analgesia. The maximum duration of analgesia noted in our study was 6 hours.

Conflict of Interest: None to declare

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