



TO EVALUATE THE EFFECT OF CLONIDINE AS AN ADJUVANT TO 0.5% ROPIVACAINE IN ERECTOR SPINAE PLANE BLOCK FOR POSTOPERATIVE ANALGESIA IN MODIFIED RADICAL MASTECTOMY: A RANDOMISED CONTROLLED TRIAL

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Introduction

Breast surgeries often result in significant postoperative pain. Erector spinae plane (ESP) block is employed for both intraoperative and postoperative analgesia.[1] This study compares effect of adding clonidine as an adjuvant to 0.5% ropivacaine in ESP block for postoperative analgesia in modified radical mastectomy(MRM)

Methods

- 72 patients of ASA status I,II posted for MRM
- Exclusion: Patients refusal, pregnant patients, patients with baseline cognitive deficits, coagulopathy, liver/renal dysfunction, allergy to amide local anaesthetics
- Randomized (random number table), Groups R and RC of 36 each
- Group R** (20ml inj 0.5% Ropivacaine in ESP block), **Group RC** (inj Clonidine 1µgm/kg with 20ml 0.5% Ropivacaine in ESP block)
- Group allocation concealed(sealed opaque envelopes), opened only in preoperative area by person not involved in study. He also prepared drug for block. ASA standard monitoring applied
- ESP block on ipsilateral side (**T4 level**), sitting position 22 gauge echogenic needle, Sonosite ultrasound machine, Linear array probe 30 minutes prior to general anaesthesia(GA)

Sensory level of block assess: **pin-prick sensation** (T1 to T8) compared from other side. **Sensory block graded** on 3-point scale: 0 (no loss of sensation to pinprick), 1 (analgesia ie. patient feels touch but not pin prick), 2 (anaesthesia ie. patient does not feel touch)[2]

- If sensation did not decrease in 30minutes of block - **block failure**; excluded
- Onset of sensory block** : time from drug administration to sensory grade 1
- GA: Induction was done using 2µg/kg fentanyl IV, 2.5mg/kg propofol and 0.6mg/kg rocuronium and isoflurane 1-1.2% for maintenance. Inj paracetamol 1gm IV was given on surgical closure and 6 hourly in postoperative period.
- VAS score: at rest and during movement** recorded in post anaesthesia care unit(Baseline), every 30mins till 2 hours,4, 6, 9, 12, 18, 24hour
- Duration of sensory block**: time of ESP block to onset of pain
- Duration of analgesia**: defined as time to first rescue analgesic
- Rescue analgesia**: IV diclofenac 1.5mg/kg, patient demand or VAS ≥ 4
- Patient satisfaction** was recorded on 5-point Likert scale

Statistics

- Sample size calculated based on primary objective of study i.e. **duration of analgesia**. Singh S et al [3] reported mean (SD) duration of analgesia as 5.8±0.75 hours with ESP block in patients undergoing spine surgery
- We assumed that addition of clonidine to ESP block would increase duration of analgesia and an **increase of >20%** in mean duration of analgesia would be clinically significant
- Sample of 35 subjects in each group was required to detect this difference at standard deviation(SD) of 1.75, significance of 5% and power of 95%
- Statistical analysis: SPSS software version 21.0
- Data normality checked using Shapiro -Wilk test
- Quantitative data presented as mean ± SD or median (IQR) analyzed using Independent t test or Mann-Whitney U test
- Ordinal data analyzed using Fischer's exact test (for two groups)
- P values < 0.05 considered statistically significant

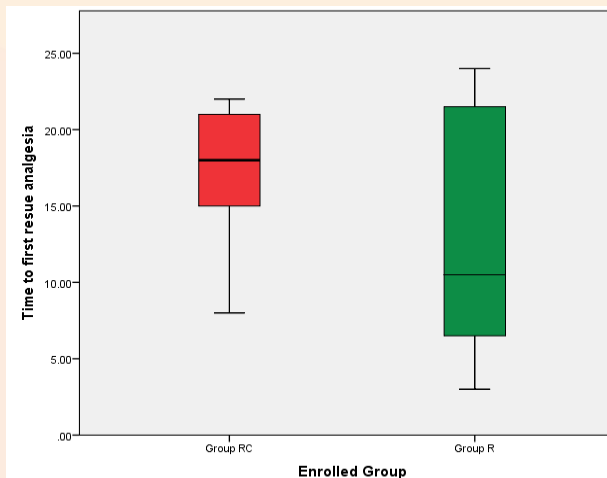
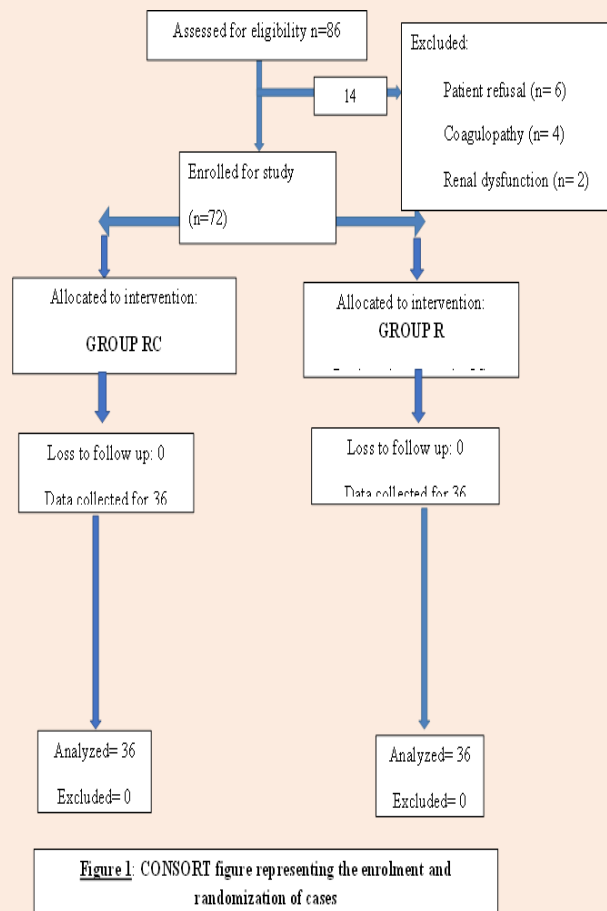


Figure 2:- Comparison of median time to first rescue analgesic (hours) in RC and R groups

Results (Table1)

- Duration of Analgesia/Time to first rescue analgesic**: not significant between both groups [median (IQR), 18.0(8) in RC vs 10.5(15) hours in R]
- Time to sensory block onset** similar in both groups
- Number of dermatomes blocked**: Insignificant difference
- Duration of sensory block**: 26 hours in both groups, insignificant difference
- Rescue analgesic**: 16% patients of RC and 33.3% of R group demanded
- Quality of analgesia (VAS)** : comparable (P >0.05)(Table 2)
- No adverse effects noted

Parameter	Group RC(n=36)	Group R(n=36)	p-value
Time to sensory block onset (minutes) ^A	10.7 +/- 3.0	10.3 +/- 0.9	0.513
Number of dermatomes blocked ^A	4.4 +/- 1.0	4.5 +/- 0.5	0.606
Duration of sensory block (hours) ^B	26(0)(10-26)	26(6)(5-26)	0.114
Time to first rescue analgesic (hours) ^C	18.0(8)	10.5(15)	0.400
No of patients requiring rescue analgesic	6(16%)	12(33.3%)	0.086

Table 1: Observed parameters
^Acalculated as Mean+/-SD; P<0.05 is significant
^Bcalculated as Median(IQR)(Range)
^Ccalculated as Median(IQR)

Parameter	Group RC	Group R	p-value
VAS _R :30mins	0.000(1)(0-1)	0.000(1)(0-1)	0.244
VAS _R :60mins	2.000(1)(0-2)	2.000(1)(0-2)	0.414
VAS _R :90mins	2.000(0)(1-5)	2.000(0)(1-5)	0.414
VAS _R :2hrs			0.894
	2.000(0)(2-4)	2.000(0)(2-4)	
VAS _R :4hrs	2.000(0)(2-5)	2.000(0)(2-5)	0.355
VAS _R :6hrs	2.000(0)(2-5)	2.000(0)(2-5)	0.463
VAS _R :9hrs	2.000(0)(2-5)	2.000(0)(2-5)	0.168
VAS _R :12hrs	2.000(0)(3-6)	2.000(0)(3-6)	0.675
VAS _R :18hrs	2.000(0)(1-6)	2.000(0)(1-6)	0.817
VAS _R :24hrs	2.000(0)(1-5)	2.000(0)(1-5)	0.790
VAS _M :30mins	1.000(1)(1-2)	1.000(1)(1-2)	0.323
VAS _M :60mins	3.000(1)(1-3)	3.000(1)(1-3)	0.053
VAS _M :90mins	3.000(0)(2-6)	3.000(0)(2-6)	0.435
VAS _M :2hrs	3.000(0)(3-5)	3.000(0)(3-5)	0.630
VAS _M :4hrs	3.000(0)(3-6)	3.000(0)(3-6)	0.595
VAS _M :6hrs	3.000(0)(3-6)	3.000(0)(3-6)	0.595
VAS _M :9hrs	3.000(0)(3-7)	3.000(0)(3-7)	0.391
VAS _M :12hrs	3.000(0)(3-6)	3.000(0)(3-6)	0.749
VAS _M :18hrs	3.000(0)(2-7)	3.000(0)(2-7)	0.233
VAS _M :24hrs	3.000(0)(2-6)	3.000(0)(2-6)	0.420

Table 2: VAS calculated as Median(IQR)(range); P<0.05 is significant, VAS_R(Rest), VAS_M (at movement)

Conclusions

Addition of Clonidine has no effect on time to first rescue analgesic, time to sensory block onset, quality of analgesia, number of dermatomes blocked and duration of sensory block but has lower total analgesic requirement. No adverse effects are noted

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