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7 **Effect of Erector Spinae Block and PECS Block on Quality of Recovery**
8 **and Analgesia After Modified Radical Mastectomy**

9 *A randomised controlled study*

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17
18 **Abstract**

19 **Objectives:** Postoperative pain after modified radical mastectomy ranges from moderate to
20 severe. Pectoralis block in comparison to Erector Spinae block have been found better in
21 reducing pain scores and reducing consumption of rescue analgesic in postoperative period.
22 This study aimed to compare the effect of Erector Spinae block and Pectoralis block on
23 quality of recovery after Modified Radical Mastectomy using QoR-40 score. **Methods:** After
24 general anaesthesia, patients were given block according to computer generated
25 randomization. Group-I-Pectoralis block including PEC I AND PEC II(PECS), Group-II-
26 Erector spinae block(ESP) and Group III-Control Group (No intervention). Quality of
27 recovery (QoR-40) score was observed on morning of surgery and at 24 hrs. Time to rescue
28 analgesia and total consumption of rescue analgesia in first 24 hrs. were also observed.
29 **Results:** In the postoperative period at 24 hrs. Global QoR-40 scores were 183.64±6.36 in
30 PECS group, 179.68± 6.38 in ESP group and 171.37±6.88 in control group. (p<0.0001) But,
31 there was no statistically significant difference between QoR score of PECS & ESP group
32 patients(p=0.0551). The total requirement of rescue analgesic was significantly lesser in
33 PECS group (137.28±31.46 mg) in comparison to ESP Group(189.46±42.98mg) and control

34 group (229.57±46.80 mg). (p<0.0001). Time to first rescue analgesia was significantly higher
35 in PECS group (6.53±2.78 hrs) in comparison to ESP (4.05±2.91 hrs) and control group
36 (2.15±1.51 hrs). (p<0.0001) **Conclusion:** Both Erector Spinae block and Pectoralis block are
37 effective for improving QoR score and reducing consumption of rescue analgesic after
38 modified radical mastectomy.

39 **Keywords:** breast surgery, cancer, postoperative recovery, postoperative pain

40

41 **Advances in Knowledge**

- 42 • Both Erector Spinae Block and PECS block have been shown very promising
43 results in providing postoperative analgesia after breast surgery. Our study based
44 on these blocks helped us to get more data and knowledge as well as getting
45 accustomed about these blocks.

46

47 **Application to Patient Care**

- 48 • These blocks providing post-operative analgesia resulted in patients being more
49 comfortable post operatively, having a better feel of general over all wellbeing as
50 well as better post operative outcomes.

51

52 **Introduction**

53 In year 2020 female breast cancer was diagnosed as most common cancer worldwide.^{1,2}
54 Radical or Modified Radical Mastectomy (MRM) is main treatment option for locally
55 advanced lesions of breast.³ MRM is usually done under general anaesthesia. Incidence
56 of severe post-operative pain on the first post-operative day after MRM has been
57 reported to be 60%.⁴ Poor management of pain in the postoperative period may produce
58 various acute and chronic detrimental effects.^{5,6} So, adequate control of pain in
59 postoperative period is very important to alleviate these detrimental effects. Also, getting
60 adequate pain management is fundamental right of every patient.⁷ Moreover, adequate
61 control of pain in postoperative period can also have an impact on quality of recovery of
62 patients.⁸ QoR-40 score is a global score for assessing the status of recovery after
63 anaesthesia and surgery. It includes 40 questions covering five domains: patient's
64 psychological support, emotional status, physical comfort, physical independence in
65 doing his work and severity of pain. In a number of surgical settings, the QoR-40 score
66 has been shown to be a valid, and sensitive method, for measuring the dynamic and

67 multidimensional process of post-operative recovery.⁹⁻¹¹ Nair et al., in their study found
68 that patients who received regional blocks during breast surgery had higher
69 postoperative QoR scores.¹¹ Yao Y et al. also observed that preoperative ESP block
70 improves postoperative QoR score and postoperative analgesia in patients undergoing
71 MRM.¹² Sinha C et al compared PECS block and ESP after MRM and observed that
72 PECS block patients had lower pain scores and consumptions of analgesics in the
73 postoperative period in comparison to ESP block.¹³ So we hypothesized that PECS
74 block patient would also have better quality of recovery in comparison to ESP, and this
75 study was done to compare the effect of ESP block and PECS block on post-operative
76 quality of recovery after MRM using QoR-40 score. The primary objective of the study
77 was to compare the Quality of Recovery Score (QoR-40) at 24 hrs. after surgery. The
78 secondary objectives were total consumption of analgesics in the first 24hrs, time to
79 rescue analgesia, postoperative VAS score and to compare intraoperative hemodynamic.

80

81 **Methods**

82 This randomized control study was conducted adhering to the Helsinki declaration,
83 CONSORT recommendations for RCT from 20/12/2020 to 20/12/2021 after approval from
84 the institutional ethical committee (***) and after clinical trial registry (***) in department of
85 anaesthesia.

86

87 This study included patients between 18-60 years female with ASA grade I &II, who
88 were planned for unilateral modified radical mastectomy for breast cancer. Written
89 informed consent was obtained from all patients. Exclusion criteria were patient refusal,
90 endocrine disorders (including I and II type of Diabetes Mellitus), any coagulation
91 disorders, cognitive inability to understand QoR-40 questionnaire and allergies to local
92 anaesthetics. 105 patients were assessed for eligibility. (Figure 1) Patients were
93 randomly allocated to one of the following three groups using computer-generated
94 random numbers. Group-I-Pectoralis block (PECS block), Group-II-Erector spinae block
95 (ESP block) & Group III-Control Group. QoR-40 score was noted on the morning of
96 surgery in each patient. After taking the patients in operation theatre, monitors were
97 attached. The patients were monitored for heart rate, BP (SBP, DBP & MAP), SpO₂, and
98 ECG. After that intravenous line was taken in arm contralateral to surgery planned and
99 an intravenous fluid was started. Preoxygenation was done for 3 mins and after that
100 patient were induced with injection fentanyl 1ug/kg, injection propofol 2-2.5 mg/kg and

101 after confirming adequate bag and mask ventilation injection vecuronium 0.1mg/kg was
102 given. After three minutes, either second generation supraglottic airway device or
103 endotracheal tube was inserted. After confirmation of adequate ventilation by
104 auscultation and capnography patients were put on volume-controlled ventilation mode.
105 Anaesthesia was maintained with O₂: N₂O(50:50) and sevoflurane. After that patient
106 received respective block according to randomization.

107

108 The blocks were performed with Stimuplex® needle A100 (0.80 x 100mm (21G x 4"))
109 and Toshiba USG machine with a high frequency linear probe 38mm, 6-13 MHz. Hydro
110 dissection (saline) was used to identify the correct position and plane before injecting the
111 local anesthetic.

112 ***Pectoralis Block***

113 The patient was positioned supine, with the arm ipsilateral to surgery site abducted to 90
114 degrees. The skin was prepared with 10% betadine solution. The sterile USG probe was
115 put longitudinally at the mid clavicular level just below clavicle and was adjusted to
116 identify axillary artery and vein. After that caudal edge of probe was turned laterally and
117 USG probe was moved downwards to identify third rib, fourth rib, pectoralis major
118 muscle, pectoralis minor muscle and serratus anterior muscle. The needle was introduced
119 through an in-plane technique from cranial edge of probe and advances to lie in
120 interfascial plane between pectoralis minor and serratus anterior muscle and 20 ml of
121 .25% bupivacaine was administered (PECS II). After giving PECS II block, the needle
122 was withdrawn slowly and adjusted to lie between pectoralis major and minor muscle
123 and after confirmation by hydro dissection, 10 ml of 0.25% bupivacaine was deposited
124 there (PECS I).

125

126 ***Erector Spinae Block***

127 The patient was placed in lateral decubitus position and, following aseptic precautions,
128 sterile USG probe was put longitudinally paramedian to thoracic spine and T4 transverse
129 process was identified. Superficial to transverse process erector spinae, rhomboid major
130 and trapezius muscles were identified. The needle was introduced through an in-plane
131 cephalocaudal approach till the needle tip contacts the transverse process and after
132 confirmation of correct plane by hydro dissection 20ml of 0.25% bupivacaine was given
133 superficial to the transverse process and beneath the erector spinae muscle.

134

135 This study was double blinded as the patients were not aware of the intervention, they had
136 received and the observer who observed the patient and collected data was also not aware of
137 intervention each patient has received. 30 minutes before completion of surgery each patient
138 was given PCM 1gm i.v. and thereafter 1gm i.v. at every 6 hours. If any patient had VAS
139 score > 3 in postoperative period, rescue analgesic injection of Tramadol (100mg) i.v. was
140 given. Time duration between two injection of tramadol was kept >4 hrs. Hemodynamic
141 variables (Heart Rate, MAP, SBP, DBP, & SPO2) were recorded before surgery and after that
142 every 15 minutes till completion of surgery. Time to rescue analgesia and total consumption
143 of rescue analgesia in 1st 24 hrs. were also observed. Quality of recovery (QoR-40) score was
144 observed again at 24 hrs. QoR-40 questionnaires were filled by observer who verbally
145 translated the questionnaire to patients into the regional language.

146

147 *Statistical analysis*

148 Sample size is calculated on the basis of pilot study done on 10 patients in which SD was
149 7.12 for QoR-40 in control group. Assuming a difference of 10 would be clinically
150 significant, minimum sample size was calculated to be 28 in each group. We took 30 patients
151 in each group with the possibility of loss to follow up. Statistical analysis was performed
152 using SPSS software (15.0 version). The continuous variables were evaluated by mean and
153 standard deviation.. The dichotomous variables were presented in number and were analysed
154 using Chi-square or Fisher Extract test. To compare the means between the two groups,
155 Student t-test and for comparing three groups ANOVA tests were used. A p-value of < 0.05
156 was regarded as significant.

157

158 **Results**

159 In our study all groups had comparable demographic profile. (Table No.1) On
160 comparing mean average global QoR-40(0-200) score preoperatively, there was no
161 statistically significant difference between three groups (p =0.8360). At 24 hrs there
162 was a significant difference between three groups. In our study at 24 hours, Global
163 QoR-40(0-200) score was highest in PECS group followed by Erector Spinae group
164 and control group patients. The difference between three groups were statistically
165 significant(p<0.0001). But difference between PECS & Erector Spinae group patients
166 was not significant statistically(P=0.0551). (Table No.2)

167

168 The requirement of rescue analgesic was significantly lower in PECS group in comparison to
169 Erector Spinae Group and Control group patients($p<0.0001$). Time to first rescue analgesic
170 was significantly higher in PECS group in comparison to other two groups. (Table 3)
171 The gradual increase in VAS score was observed in all the three groups after surgery. VAS
172 score was lowest in PECS group. The difference between groups was statistically significant
173 at 6 hours, 12 hours and 24 hours. (Table-4)

174

175 There was no clinically significant difference between haemodynamic in three groups
176 intraoperatively. (Fig 2,3)

177

178 **Discussion**

179 After MRM, patients report moderate to severe postoperative pain and various drugs and
180 regional analgesic techniques are being used for providing postoperative pain relief. Opioids
181 are the drugs which are most commonly used for providing postoperative analgesia but using
182 opioid in cancer patients is related to suppression of cellular immunity and increase in cancer
183 recurrence.¹⁴ NSAIDs are the other class of drugs which are also commonly used for
184 postoperative analgesia but their efficacy is limited to mild to moderate pain. Also, patients
185 with MRM has high incidence of postoperative nausea and vomiting and using opioids and
186 NSAIDs may increase the incidence of PONV.¹⁵ Transdermal patch is a non-invasive
187 method of providing postoperative analgesia and they have been found very effective in
188 reducing pain scores in postoperative period in various other surgeries. But transdermal
189 patches generally contain opioids and NSAIDs which can again increase the incidence of
190 nausea and vomiting after MRM surgery. So, regional analgesia is best modality for
191 providing postoperative analgesia in MRM patients. Further, it has also been found that using
192 regional analgesia also decreases the incidence of chronic pain.¹⁶

193

194 Among, regional analgesia thoracic epidural and paravertebral blocks are still gold
195 standard analgesic techniques.¹⁷⁻¹⁹ But, sometimes it may be difficult to give thoracic
196 epidural and paravertebral block and they are also associated with complications such
197 as pneumothorax, vascular puncture, or nerve injury. So, there is always a need to find
198 alternatives to these blocks, which are easy to give, having a higher safety profile and
199 can provide equivalent pain relief. Both PECS block and ESP block are blocks which
200 are easy to perform and with very less complications in expert hands. They also reduce
201 the requirement of analgesia in postoperative period with decrease in pain scores.^{20,21}

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Quality of recovery of any patient after surgery may be related to quality of perioperative analgesia. Myles PS et al in their study observed that patient's quality of recovery after anaesthesia and surgery can be assessed effectively by using QoR-40 score.¹⁰

In our study at 24 hours, the Global QoR-40 score was 183.64 ± 6.36 in PECS group, 179.68 ± 6.38 in ESP group, and 171.37 ± 6.88 in control group and the inter mean difference between groups was statistically significant at 24 hours global QoR-40(0-200) ($p < 0.0001$). However, the difference between PECS group and ESP group was statistically insignificant. Kamiya Y et al studied the effect of PECS block on postoperative pain and QoR score in breast cancer surgery patients and observed that pain score in PECS group was lower than control group till 24 hrs.²² But there was no statistically significant difference between requirement of rescue analgesic and QoR-40 score in their study. In our study, we reported a significant difference between PECS and control group in requirement of rescue analgesic and QoR score. It may be because of that for PECS II block Kamiya Y., et al injected the drug deep to serratus anterior muscle and in our study drug was administered superficial to serratus anterior muscle.

In a study conducted by Yao Y et al., it was also found that ESP block improves pain score QoR score in the postoperative period.¹²

Similar to our study Sinha et al., also observed that PECS block administered prior to MRM leads to decreased requirement of postoperative analgesics in first 24 hours. The mean duration of analgesia was 7.26 ± 0.69 hrs in patients with PECS block and 5.87 ± 1.47 hrs in individuals with ESP block.¹³

Similar to our study Altiparmak B et al, also observed that PECS group patients had lower consumption of tramadol in postoperative period. In their study consumption of tramadol was 132.78 ± 22.44 mg in PECS group and 196 ± 27.03 mg in ESP group ($p = 0.001$).²³

Gad M et al also observed that patients in PECS group had lower consumption of morphine in postoperative period in comparison to ESP block patients.²⁴

236 Regarding complications, we have not encountered any procedure related complications in
237 any of group which is similar to other studies.

238

239 The limitation of our study is that we used original version of QoR-40 score which is in
240 English and score was filled by clinician verbally translating it into regional language. So it
241 might have affected the interpretation of score. Other limitations of our study were its small
242 sample size and single-centric approach. Another limitation was that the block was given
243 after inducing the patients so we could not access the level of sensory block.

244

245 **Conclusion**

246 To conclude, both Erector Spinae and Pectoralis blocks in comparison to control group are
247 effective for improving postoperative quality of recovery after modified radical mastectomy.
248 But, in Pectoralis blocks group time to first rescue analgesic was higher and requirement of
249 rescue analgesic was lesser in comparison to Erector Spinae Block. As our study is single
250 centred, a multicentric study with large sample size is required for generalizability of results.

251

252 **Conflicts of Interest**

253 The authors declare no conflict of interests.

254

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256 No funding was received for this study.

257

258 **Author Contributions**

259 Collection of data and drafting the manuscript was done by MHM. Analysis and
260 interpretation of data were handled by MHM and RV. RV, H, DS, SS and KS contributed to
261 the concept and design as well as the critical revision of the manuscript. All authors approved
262 the final version of the manuscript.

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335 **Figure 1:** Consort flow chart

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Assessed for eligibility (n= 105)

Excluded(n=15)
Not meeting exclusion criteria(n=10)
Declined to participate(n=5)

Randomized(n=90)

Allocated to PECS Block(n= 30)
Received PECS Block (n= 30)
Did not receive PECS Block (n= 0)

Allocated to Erector Spinae Block(n= 30)
Received Erector Spinae block (n= 30)
Did not receive Erector Spinae Block (n= 0)

Allocated to control group (n= 30)
No intervention (Control Group) (n= 30)

Lost to follow-up (n= 0)
Discontinued intervention (n= 0)

Lost to follow-up (n= 0)
Discontinued intervention (n= 0)

Lost to follow-up (n= 0)

Analysed (n= 30)
Excluded from analysis (n= 0)

Analysed (n= 30)
Excluded from analysis (n= 0)

Analysed (n= 30)
Excluded from analysis (n= 0)

Table 1: Demographic Profiles

	Group-I(PECS group) [n=30]	Group-II(ESP group) [n=30]	Group-III(Control Group) [n=30]	p-value
Age(in years)	43.52±9.6	42.26±7.64	44.13±8.9	F=0.3563 p=0.7013 [#]
Weight (in kg)	59.4±9.1	57.2±5.28	56.71±8.1	F=1.048 p=0.3551 [#]
Height (in cms)	162.6±7.6	159.0±46.5	156.21±3.9	F=0.4132 p=0.66283 [#]
BMI(kg/m ²)	22.5±3.8	23.9±3.6	22.0±3.1	F=1.118 p=0.21963 [#]
ASA I:II	24:6	26:4	25:5	X=0.48 p=0.7866 [#]
Duration of Anaesthesia(in minutes)	86.8±18.1	89.4±19.4	87.7±17.5	F=0.1553 p=0.8564 [#]

370 *p value < 0.05 = significant, #p value > 0.05 = non-significant

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372 **Table 2:** Tabular presentation of mean global QoR-40(0-200) of Group-I, Group-II and
373 Group-III patients

Global QoR-40 (0-200)	Group-I(PECS group) [n=30]	Group-II(ESP group) [n=30]	Group-III(Control Group) [n=30]	p-value
Pre-OP	186.63±7.78	185.53±6.73	186.34±7.56	F=0.1795 p=0.8360
	¥p=0.8322, €p=0.9873, £p=0.9051			
At 24 hrs	183.64±6.36	179.68± 6.38	171.37±6.88	F=27.47 p<0.0001*
	¥p=0.0551, €p<0.0001*, £p<0.0001*			

374 *p value < 0.05 = significant, #p value > 0.05 = non-significant

375 ¥Group-I Vs Group-II, € Group-I Vs Group-III, £ Group-II Vs Group-III

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384 **Table 3:** Time to first rescue analgesic requirement and total rescue analgesic in first 24 hrs

	Group-I(PECS group) [n=30]	Group-II(ESP group) [n=30]	Group-III(Control Group) [n=30]	p-value
Time to first rescue analgesics requirement(hrs)	6.53±2.78	4.05±2.91	2.15±1.51	F=23.5 p<0.0001*
	¥p=0.0006*, €p<0.0001*, £p=0.0108*			
Total rescue analgesics requirement (in mg) in first 24 hrs	137.28±31.46	189.46±42.98	229.57±46.80	F=38.34 p<0.0001*
	¥p<0.0001*, €p<0.0001*, £p=0.0008*			

385 *p value < 0.05 = significant, #p value > 0.05 = non-significant,

386 ¥Group-I Vs Group-II, € Group-I Vs Group-III, £ Group-II Vs Group-III

387

388 **Table 4:** Tabular presentation of mean VAS score of Group-I, Group-II and Group-III

389 patients

VAS Score	Group-I(PECS group) [n=30]	Group-II(ESP group) [n=30]	Group-III(Control Group) [n=30]	p-value
At 1 Hour	0±0	0±0	0±0	---
At 2 Hour	0±0	0±0	0±0	---
At 4 Hour	0.52±0.37	0.54±0.82	0.59±0.21	F=0.1371 P=0.8721
At 6 Hour	1.04±0.19	2.01±0.54	4.13±1.45	F=92.48 P<0.0001*
At 12 Hour	1.44±0.54	2.28±0.90	4.80±1.09	F=120.2 P<0.0001*
At 24 Hour	2.10±1.14	3.41±1.19	4.94±1.95	F=27.9 P<0.0001*

390 *p value < 0.05 = significant, #p value > 0.05 = non-significant,

391 ¥Group-I Vs Group-II, € Group-I Vs Group-III, £ Group-II Vs Group-III

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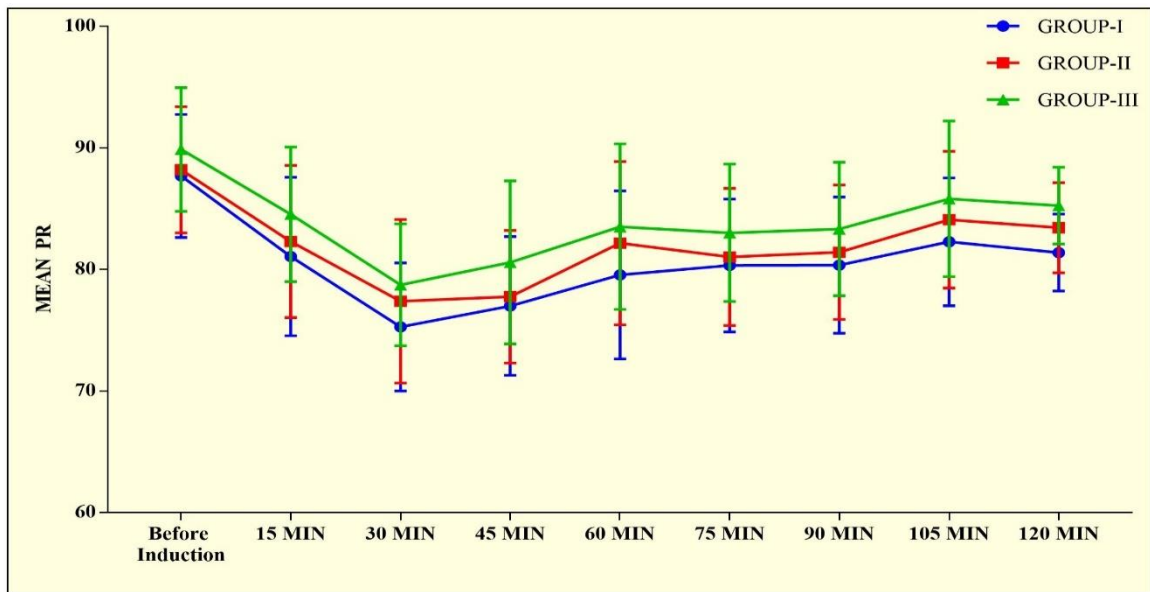
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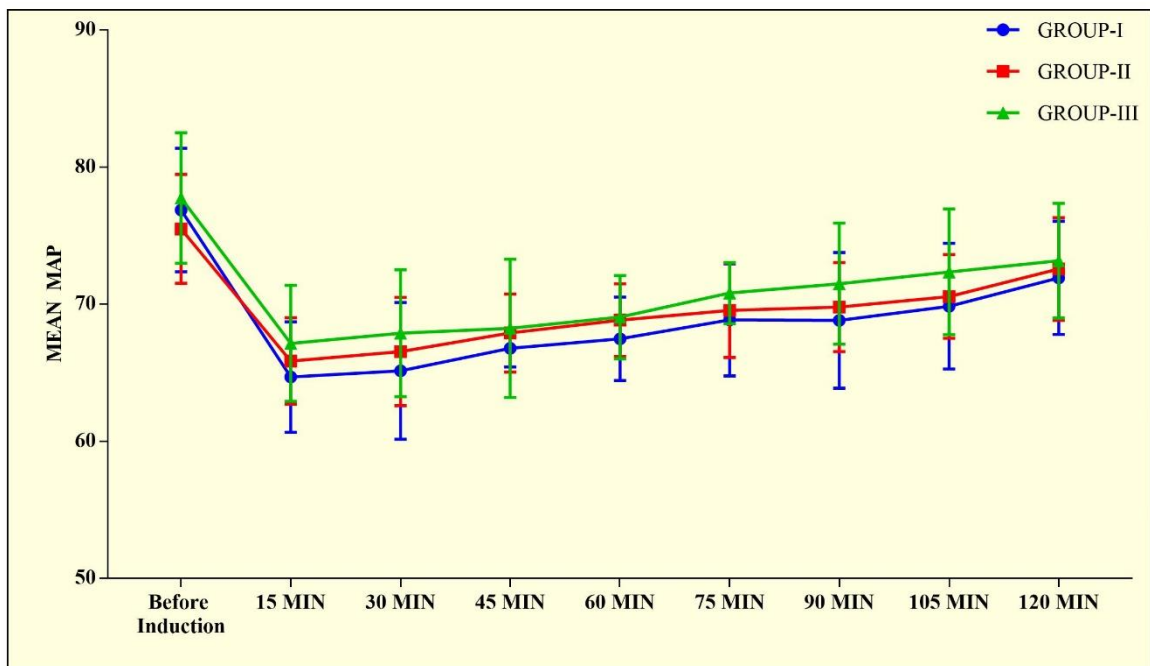
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400 **Figure 2:** Mean Pulse Rate in beats per minute between three groups

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403 **Figure 3:** Mean Arterial Pressure in mm of Hg between three groups