



## To compare efficacy of Diclofenac by intramuscular route and rectal route in post surgical pain.

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**ABSTRACT... Objective:** This study was carried out in Lahore General Hospital, Lahore to test the results of Intramuscular vs Suppository form of Diclofenac Sodium on the severity of post-surgical pain in patients who underwent Cesarean delivery under Subarachnoid Block. **Study Design:** Randomized Study. **Setting:** Lahore General Hospital, Lahore. **Period:** April 2019 to September 2019. **Material & Methods:** This was a double-blind run on 100 patients who underwent for cesarean delivery irrespective of any indication for the procedure. The pain sufferers had been randomly divided into 2 groups. The group A: who received Diclofenac Sodium in the form of suppository and Group B: who received intramuscular Diclofenac Sodium? The pain severity was assessed using VAS scale at categorically unique times. Data was then analyzed using SPSS 23 version and the results were compiled in the form of mean and percentage. **Results:** The mean age (Years) of patients was (25.27±6.07). There was a big statistical difference between the 2 groups regarding pain score after the intervention (p=0.018). **Conclusion:** To reaffirm the effectiveness of Diclofenac for Post-Caesarean section, the physique part (Suppository) is established to hold advantages over the contractile organ (muscles).

**Key words:** Contractile Organ, Diclofenac, Learning, Protected, Tertiary care.

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### INTRODUCTION

Post-operative pain is predictable after any major surgery due to surgical trauma and manipulation of tissues.<sup>1</sup>

Pain management has a vital role in countless surgical techniques. In case of Cesarean delivery, it has more implication due to several psychological and social factors like initiation of breast feeding for optimizing bonding between mother and the baby. A number of studies have recorded the incidence of reasonable to severe post-operative pain counting almost over 80%.<sup>2,3</sup> The longer duration of persistence of such pain is not only consistent with other post-operative complications but also with stress reactions resulting in lengthening in post-operative restoration time and delays in hospital discharges and resumption of daily routine activities. Such clinical and psychological effects (short term and long term) increase morbidity and mortality with

negative impact on quality of life. Negative clinical outcomes in response to ineffective postoperative pain controls include discomfort, hemodynamic compromise, pneumonia, deep vein thrombosis, pulmonary embolism, myocardial infarction, delayed wound healing, disturbed sleep and depression.<sup>4</sup> Pain management plays a necessary role in reducing mortality and morbidity owing to postoperative complications.<sup>5</sup> Uncontrolled pain leads to increased hospital stay and hence increased use of hospital resources.

Effective pain management has an important role to play in low segment cesarean sections as it helps in early communication of mother with the newborn and initiation of infant feeding.<sup>6,7</sup> Opioid analgesics for post-op pain relief are gaining numbers, but on the other hand it ends up with dangerous after effects like CNS depression and altered GI motility.<sup>8</sup> Recently physicians have focused on Non-steroidal anti-inflammatory

drugs (NSAID) for pain relief because of various anticipated problems associated with opioids.<sup>9,10</sup>

Diclofenac is amongst the NSAIDs class of medicine having an effective post-operative pain relief resulting in lowering postoperative narcotic demands.<sup>11-15</sup> The consequences of previous studies are variable pertaining to the post cesarean pain reduction via use of diclofenac either by intramuscular route or in suppository form. A study of sixty patients receiving analgesics who underwent low segment cesarean section, had been divided into three groups; one who used paracetamol alone, second; who used diclofenac only, and the third group used their combination. These were investigated and the outcomes confirmed that patients who were given a combination of diclofenac and paracetamol needed less opioids than those who were given paracetamol alone.<sup>16</sup>

In another study of parturients requiring elective cesarean delivery under spinal anesthesia, postoperative analgesic effects of diclofenac and/or paracetamol were evaluated. Diclofenac given after cesarean delivery had effective pain relief with significantly higher morphine-sparing effects.<sup>17</sup>

Effective pain relief is significant in mothers who underwent cesarean delivery to enhance the power of self-care, ensuing early discharge and resuming routine activities. We conducted this study in Lahore General Hospital, Lahore to address the disparities regarding efficaciousness of painkiller and diclofenac especially by different routes of administration.

## MATERIAL & METHODS

It was a randomized, double-blind trial of 100 patients who were brought to the tertiary care hospital for cesarean delivery irrespective of any indication.

Following patients were included in the study:

1. Age between 17-40 years.
2. ASA I and II class of American Society of Anesthesiologists Physical Status Classification.

3. Term pregnancy.

Following patients were excluded from the study:

1. Having an allergic history to Paracetamol and NSAIDS (Diclofenac)
2. ASA III-VI class of American Society of Anesthesiologists Physical Status Classification.
3. General Anesthesia.

The study was conducted at Lahore General Hospital after obtaining permission from the hospital ethical committee (PGMI/LGH/AMC; ARTICLE/RESEARCH No. 17-23). After obtaining informed written consent from the patient and getting included in the study, the patients underwent Cesarean section under subarachnoid block. The regional anesthesia was given by using a 27G spinal needle and with identical approach (in sitting position at L2-3, L3-L4 or L4-L5 space) and drugs, Marcaine (Bupivacaine SP percentage 0.5%). The vital signs were continuously monitored during whole surgery and in the post-anesthesia care unit. Meanwhile, in post-anesthesia care, post-operative pain in all patients was evaluated by using Visual Analogue Score (VAS) 17. For all patients with significant pain, medicine was given for pain relief. Patients were randomly divided into 2 groups. One group received the diclofenac sodium in intramuscular form and the other group in suppository form. If the pain was not relieved with diclofenac by either route, rescue medications were given (opioids, paracetamol etc). The Intensity and length of pain was evaluated with the aid of Visual Analogue Score (VAS) score at 0 hrs, 2 hrs, 4 hrs, 6 hrs, 12 hrs and 24hrs postoperatively. The data was analyzed using SPSS version 23 and was reproduced in the form of mean and percentages. Chi-square was applied to calculate the P-value.

## RESULTS

The necessary demographic characteristics were found similar in both the groups. The necessary medical and obstetric parameters are shown in Table-I & II.

Parameters	Rectal Route	Intramuscular Route	Statistical Test	P-Value
Maternal weight (Kg)	74.63 ± 9.07	76.76 ± 8.12	-1.232	0.221
Gestational age at delivery (wks)	38.42 ± 1.34	37.90 ± 1.50	-1.826	0.071
<b>N (%)</b>	<b>N (%)</b>	<b>Fisher's Exact Test</b>		
Booked	42(84.0)	44 (88.0)	0.219	0.640
Unbooked	8(16.0)	6(12.0)		
Primigravida	11(22.0)	13(26.0)	0.271	0.603
Multigravida	39(78.0)	37(74.0)		

Table-I. Clinical and obstetric characteristics of respondents.

	Rectal n (%)	Intramuscular n (%)	Statistical Test	P-Value
No of patients who were administered rescue analgesia	13(43.86%)	18(58.14%)	$\chi^2=1.57$	0.21
Total number of doses of rescue analgesic agent administered	18(42.03%)	22(57.97%)		
Mean ± SD	1.44 ± 0.52	1.42 ± 0.63	t =2.35	0.027
Median	1	1		
Range	1	2		
Time interval between post-operative analgesia and rescue analgesia (hrs)				
Mean ± SD	4.39 ± 2.78	3.92 ± 2.52	t =-0.29	0.77
Median	4.0	3.5		
Range	9.67	10.25		
Relief of pain				
Yes	30(84.8)	28(78.8)	$\chi^2=0.257$	0.612
No	3(15.2)	5(21.2)		

Table-II. Rescue analgesia.  
t - Independent t test,  $\chi^2$  - Chi-square test

	Rectal	Intramuscular	T-test	P-Value
<b>6 hours post op</b>				
Mean ± SD	5.52 ± 1.46	5.58 ± 1.82	0.15	0.88
Median	5	4		
Range	7	9		
<b>12 hours post op</b>				
Mean ± SD	5.12 ± 1.56	5.52 ± 1.39	1.08	0.28
Median	4	4		
Range	7	8		
<b>18 hours post op</b>				
Mean ± SD	4.24 ± 1.50	4.79 ± 1.29	1.58	0.12
Median	3	4		
Range	5	5		
<b>24 hours post op</b>				
Mean ± SD	3.88 ± 1.90	4.76 ± 1.75	1.95	0.06
Median	3	4		
Range	10	5		

Table-III. Pain score comparison.

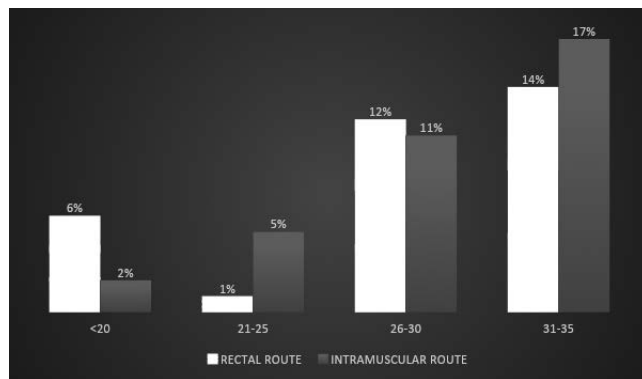


Figure-1. Age distribution.

## DISCUSSION

Our results showed that highest demand for analgesia was in the 31-35 age group, in this age group 14% of the patients were given analgesia by the rectal route and 17% by the intramuscular route. In the age group of 26-30 years 12% required analgesia by the rectal route and 11% by the intramuscular route and in the age group of patients less than 20 years the patients who were administered analgesia by the rectal route were 6% and 2% by the intramuscular route. The least requirement for analgesia was in the 21-25 age group where only 1% were administered analgesia by the rectal route and 5% by the intramuscular route. These results were contradictory to the guidelines published by the American college of surgeons according to which the requirements for analgesia decreases with the advancement in age<sup>18</sup>, this might be explained because of the fact that our study was conducted in a different population and small sample size might be another factor.

In our study, the mean maternal weight in kilograms of patients who were administered analgesia by the rectal route was  $74.63 \pm 9.07$  and those who were administered analgesia by the intramuscular route was  $76.76 \pm 8.12$ , thus both the groups had almost equal distribution of weight which was helpful in comparing both the groups as stated by Sandra et al. according to which dose requirements increase in proportion to the increase in weight of patients.<sup>19</sup> We also compared the gestational age of patients of patients in weeks of those patients who required analgesia, the mean for those who

were administered analgesia by the rectal route was  $38.42 \pm 1.34$  and for those who were administered analgesia by the intramuscular route was  $37.90 \pm 1.50$ . Our results were similar to those reported by Adebayo et al. according to which gestational age was a strong mediator for analgesia requirements in post cesarean section patients.<sup>20</sup> The percentage of booked patients who were given rectal analgesia were 84% and who were un booked were 16%, those requiring intramuscular analgesia were 44% booked and 12% un booked, thus majority of population in our study who was administered analgesia either rectal or intramuscular being booked for cesarean section before delivery. Similar to our study Peter et al. devised a questionnaire to predict acute pain after cesarean section.<sup>21</sup> We found that those patients who were given rectal analgesia 22% were primigravida and 78% were multigravida, those given by the intramuscular route were 26% primigravida and 74% were multigravida, thus multigravida patients were more responsive to both types of analgesia, consistent with our findings.

In our study, 43.86% of the patients in the rectal group required rescue analgesia as compared to the intramuscular group in which 58.14% of the patients required rescue analgesia and the mean for total number of doses for rescue analgesia in the rectal group was  $1.44 \pm 0.52$  and the mean for total number of doses of rescue analgesia in the intramuscular group was  $1.42 \pm 0.63$ . Our results were somewhat similar to those of Lakshmi EY al. according to which analgesia by the rectal route improves quality and has longer duration.<sup>22</sup> The mean for time interval between postoperative analgesia and rescue analgesia for those who were administered analgesia by the rectal route was  $4.39 \pm 2.78$  hours as compared to the mean time for rescue analgesia by the intramuscular route,  $3.92 \pm 2.52$  hours, these results show that rectal route increases the time duration of analgesia as compared to the intramuscular route. Our results were consistent with those of Heidari et al. according to which analgesia administered by the rectal route had better relief of pain as compared to the analgesia administered by the intramuscular route.<sup>24</sup> We

found that 84.8% of the patients said that they had relief of pain after administration of analgesia by the rectal route and 78.8% of the patients had relief of pain after analgesia administration by the intramuscular route, again consistent with the findings of Heidari et al.<sup>23</sup>

The mean for the pain score after 6 hours post op by the rectal route was  $5.52 \pm 1.46$  and by the intramuscular route was  $5.58 \pm 1.82$ , after 12 hours post op by the rectal route was  $5.12 \pm 1.56$  and by the intramuscular route was  $5.52 \pm 1.39$ , after 18 hours the mean for post op pain by the rectal route was  $4.24 \pm 1.50$  and by the intramuscular route was  $4.79 \pm 1.29$  and after 24 hours the mean for post op pain score by the rectal route was  $3.88 \pm 1.90$  and by the intramuscular route was  $4.76 \pm 1.75$ . Our findings were consistent with those of McEwan et al. who reported that the codeine drug was absorbed rapidly by the rectal route but the plasma peak level was relatively lower and was achieved at the same time with both routes.<sup>24</sup>

Our study had a few limitations, firstly it was a single center study conducted in a similar type of ethnic population, we need a multi-center study with diverse ethnic populations to verify our results. Secondly, the sample size was small, we need a large sample size to verify our findings.

## CONCLUSION

In a nutshell, the majority of patients who were given analgesia either by the rectal or intramuscular route were in the 31-35 age group, more rescue doses were required to control pain in case of analgesia by the intramuscular route and rectal route was more effective in controlling pain as compared to the intramuscular route of analgesia.





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3	M. Imran Hassan Khan	Discussion review, Limitations, Final approval.	
4	Fareed Naeem	Statistical analysis, Final approval of manuscript.	
5	Salman Shakeel	Statistical analysis, Final approval of manuscript.	