**Original Article** 

# Comparison of analgesic efficacy of diclofenac suppository with intramuscular diclofenac sodium in post-operative pain relief after cesarean delivery in the first 24 hours

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<sup>6</sup>Analysis/Interpretation/Discussion

<sup>2</sup> Manuscript Writing

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# **Abstract**

**Introduction:** Adequate pain relief is needed after caesarean section to assist ambulation & mother/baby bonding. Different analgesics are available for post-operative pain relief. The WHO recommends diclofenac as a first line drug in pain relief. It is available in various preparations like injections, tablets and suppositories. We compared the mean pain experienced by the women after use of intramuscular diclofenac sodium and diclofenac sodium suppositories after elective cesarean section in first 24 hours.

Materials and Methods: This RCT was done in the department of Obstetrics and Gynecology, Pakistan Ordinance Factories Hospital, affiliated with Wah Medical College, Wah Cantt. from 1st March 2018 till 30th August 2018. Total of 100 antenatal women already planned for elective caesarean section, which fulfilled inclusion criteria were selected after taking informed consent & ethical approval by employing non probability consecutive sampling. The age, parity, gestational age, weight, BMI & ASA status of all women was documented. 50 women were randomly assigned to the each group A & B. Group A was given 75 mg intramuscular diclofenac injection immediately & then 8 hrs for the first 24 hrs after caesarean section while group B was given 100 mg rectal diclofenac suppository immediately & then after 12 hrs post caesarean for the first 24 hrs. if needed, 50 mg tramadol I/V was given to the women as rescue analgesia, Visual analogue pain (VAS) score was used to assess the pain intensity of post-operative women after 24 hrs of caesarean. The number of women needing rescue analgesia in each group was also documented, & compared between the two groups.

**Results:** Data was analyzed on the SPSS version 23. The mean pain score was 3.72 with STD of 0.57 in group A (intramuscular diclofenic) while the mean pain score was 1.84 with STD of 0.68 in group B (Diclofenic Suppository). P-value was significant. 26 women (52%) in group A (I/M diclofenac group) and 20 women (40%) in group B (diclofenac suppository) needed rescue analgesia with I/V Tramadol. P value was not significant.

**Conclusion:** Rectal diclofenac suppository for pain in early post caesarean period has shown to have effective and prolonged effect in our study with infrequent need for rescue analgesia. Furthermore it avoids painful intramuscular route & shortens hospital stay. Rectal diclofenac suppository should be promoted as a post caesarean analgesic.

Keywords: Intramuscular diclofenac sodium, diclofenac sodium suppositories, elective cesarean section.

# Introduction

Almost all of the patients go through moderate to severe postoperative pain after major operative procedures.(1) Pain is a repulsive experience accompanied by tissue damage & inflammation.(2) Caesarean delivery is an operative procedure by which a baby is delivered through a surgical incision in the uterus and abdomen. It is indicated when the baby cannot be safely delivered through the vaginal route. Caesarean section(C-section) generates severe to moderate pain in the first 24-48 hours post-operative period. The prevalence of pain after c-section within 24 hrs post-operative period is from 9-33%.(3)

It needs adequate post-operative pain relief for early ambulation, shortened hospital stay and mothernewborn bonding (4). Although worrisome but it is a fact that C-section has become the commonest obstetrical procedure in private as well as public sectors from the last 3 decades due to multiple reasons. Current global caesarean section rate is 21%(5). In Pakistan the caesarean section rate has increased from 14% in 2012-2013 to 27.7% in 2017-18 Consequently there is an increased need for effective post caesarean analgesia. The newer developments in anaesthesia techniques, new suture materials & antibiotics have overcome the risks of haemorrhage and sepsis to a large extent but adequate post caesarean pain control and its other deleterious long term consequences is still a question mark. Multiple methods have been used to relieve post caesarean pain like epidural, transversus abdominis block, injection of local anaesthetic agent into the wound, opiods and nonsteroidal anti-inflammatory drugs (NSAIDs) worldwide. The choice of analgesic depends upon the institutional protocols, availability, financial concern & the patient's choice. The novel analgesic techniques are not uniformly available especially in developing countries. Opiod derivatives (pentazocine/tramadol) & NSAID's are widely used in post caesarean pain relief in low resource countries. Opiods can cause respiratory depression, confusion, nausea/vomiting & dependency. Tramadol, an analogue of codeine acts on descending pain pathways in the central nervous system through eu-opiod receptor & inhibitis norepinephrine and serotonin reuptake.

It causes less respiratory depression and GIT effects than with other opiods but can cause seizures, if interacts with similar drugs (7). It is secreted into the breast milk & can affect the baby.(8)

Surgery causes inflammation & pain. NSAIDs are useful in postoperative pain as they inhibit the production of prostaglandins by inhibition of cyclooxygenase(COX) isoenzyme (9). NSAIDs can reduce the need of opiod in 40-70% cases (8). American Society of Anaesthesiologists suggest that NSAIDs should be the first line drug in postoperative pain relief. (10)

Diclofenac is the most effective of all NSAIDs.. It acts by blocking both COX1 & COX2 -isoenzymes (11). It has additional actions which makes it the most effective among other NSAIDs. There is evidence that it reduces leukotrienes by inhibition of lipoxygenase pathways & may also block phospholipase A2 (7). Diclofenac effectiveness as post caesarean analgesic is due to reduction of pain from uterine contractions.(12)

Its use is safe for short period (within a week), without its side effects like bleeding predisposition & irritation at injection site but should be avoided in people with bleeding diasthesis, gastric ulcers, cardiovascular & renal diseases. Its use avoids opiod side effects with more than equivalent efficacy in post-operative pain control. It is available in injection, tablets, transdermal gel and suppository form. it is not found in clostrum so the baby is spared from its effects (7).

In our setup we use diclofenac intramuscular injections as post caesarean analgesic in first 24-48 hours but intramuscular route of administration is painful.

Diclofenac suppository appear to be more effective, safer & less painful when compared to intramuscular diclofenac.(1) Although mechanism of action of both the drugs are same but use of rectal suppository is less invasive & easy to administer. It is easily available and cost effective.

In this study, the primary objective was to compare the mean pain score after use of intramuscular diclofenac and rectal diclofenac sodium suppository post elective caesarean section in the first 24 hour period.

The second objective was to compare the number of women needing rescue analgesia in both groups for 24 hours.

# **Materials and Methods**

This randomized control trial was conducted in the department of Obstetrics & Gynaecology in Pakistan Ordinance Factories Hospital, affiliated with Wah Medical College, Wah Cantt. after approval from the ethical committee from 1.3.2018 - 30.8.2018. Sample size was calculated by WHO sample size calculator. This gave the level of significance of 5% & statistical power of 95% to the study. Sampling was done by non-probability consecutive sampling. Total of 100 women, already planned for caesarean section (for obstetric reasons), who met the inclusion criteria were selected for the study after taking their informed consent.

### **Inclusion Criteria:**

- Women from 15 to 40 years of age admitted for lower segment cesarean section under spinal anesthesia.
- American society of anesthesiologist (ASA) status I and II.
- Full term pregnancy with single fetus.

### **Exclusion Criteria:**

- ASA status III or severe medical disease i.e., uncontrolled hypertension diabetes, renal insufficiency, bleeding diasthesis, GIT problems.
- Women with allergic reaction to NSAIDS
- Preclampsia.
- Women taking long term analgesics.
- Any complications during cesarean section i.e., (bladder or intestinal injuries).

They were randomized into group A & B by allotting random numbers generated by the computer. All women received spinal anaesthesia before undergoing caesarean section.

Each group contained 50 women. Group A women received 75 mg intramuscular diclofenac sodium immediately after surgery and then every 8 hrs for 24 hrs. Group B received 100 mg diclofenac sodium

suppository just after surgery and then after 12 hours for 24 hrs. If any of the women developed severe pain, she was given intravenous tramadol 50 mg as rescue analgesic. Visual Analogue Scale (VAS) was used for evaluation of pain intensity (0-no pain & 10cm -worst pain) after 24 hrs post caesarean and was plotted in the proforma.

The data was analyzed by using SPSS version 23. The continuous variables like age, weight, gestational age and pain score were presented as means ± standard deviation (SD). The student t-test was used to compare the continuous variables between the two groups. The categorical data such as parity and ASA was expressed as frequencies and percentages. Age, parity, gestational age, ASA and BMI were used for stratification. Post stratification independent student t test was applied. P value <0.05 was considered statistically significant. The number of women needing rescue analgesia in both the groups were noted and documented.

# Results

Overall sample of (N=100) women were included in the study; sample was further divided into two groups. Sample of 50 women was taken in each group respectively, Group A: intramuscular diclofenic injection & Group B: Diclofenic Suppository Descriptive statistics of both groups are shown in Table-1. In group-A minimum and maximum weight of women was 66 Kg & 94 Kg respectively with mean weight of 84.62 Kg(STD of 5.76). Minimum and maximum BMI in group-A was 24.80 &36.40 respectively with mean BMI as 32.18 (STD of 3.16). In group-B minimum and maximum weight of women was 65 Kg & 94 Kg respectively with mean weight of 84.84 Kg(STD of 7.27). Minimum and maximum BMI in group-B was 24.70 &36.70 respectively with mean BMI being 31.13 (STD of 3.57).

Table 1: Descriptive Statistics of Age, Gestational-Age, Weight & BMI of both groups, N=100

		Minimum	Maximum	Mean	Std. Deviation
Age of patient	Group A	18	34	26.34	3.69561
	В	18	34	25.3	3.47733
Gestational Age of Patient	Group A	35	42	37.82	1.79216
	В	35	41	37.7	1.59399
Weight of Patient	Group A	66	94	84.62	5.76014
_	В	65	94	81.84	7.27972
BMI of Patient	Group A	24.8	36.4	32.182	3.16032
	В	24.7	36.7	31.134	3.57472

Table 2: Independent Sample T-Test comparing of pain scores in both groups, N=100

	Mean	Std. Deviation	Std. Error Mean	P-Value
Group A: Intramuscular Diclofenic injection	3.7200	.57286	.08101	0.001
Group B: Diclofenic Suppository	1.8400	.68094	.09630	

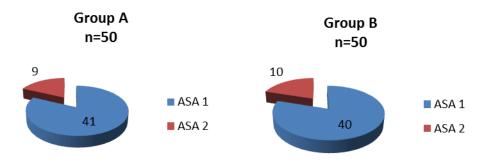


Figure 1: Frequency Statistics of ASA Category in both Groups (A&B), N = 100

Independent sample T-test is utilized to compare the both groups (Table-2). In group A (intramuscular diclofenic injection group) the mean pain score is 3.72 with STD of 0.57. In group B (Diclofenic Suppository Group) the mean pain score is 1.84 with STD of 0.68. P-value is significant. (Table 2) `

Post Stratification comparison of Pain score in both groups is shown in Table 3. In group A (I/M

diclofenac group) 26(52%) women and 20(40%) women in group B (rectal diclofenac suppository group) needed rescue analgesia with I/V Tramadol. Less number of women needed rescue analgesia in rectal suppository group than the I/M diclofenac group but the difference was not statistically significant.

Table 3: Post Stratification comparison of Pain score in both groups, N=100

Variables		Study Groups	N	Mean	Std. Dev	P-Value
Age	15-20 yrs	Intramuscular Diclofenic injection Group		4.3333	0.57735	0.002
		Diclofenic Suppository Group	3	2	0	
	21-30 yrs	Intramuscular Diclofenic injection Group	39	3.7436	0.54858	0.001
		Diclofenic Suppository Group	42	1.8571	0.71811	
	31-40 yrs	Intramuscular Diclofenic injection Group	8	3.375	0.51755	0.001
		Diclofenic Suppository Group	5	1.6	0.54772	
ASA	Group-1	Intramuscular Diclofenic injection Group	41	3.7073	0.55874	0.001
		Diclofenic Suppository Group	40	1.825	0.71208	
	Group-2	Intramuscular Diclofenic injection Group	9	3.7778	0.66667	0.001
		Diclofenic Suppository Group	10	1.9	0.567	
Gestational Age	< 37 weeks	Intramuscular Diclofenic injection Group	13	3.7692	0.43853	0.001
		Diclofenic Suppository Group	13	1.8462	0.68874	
	37-40	Intramuscular Diclofenic injection Group	30	3.7333	0.63968	0.001
	weeks	Diclofenic Suppository Group	33	1.8788	0.69631	
	40 weeks	Intramuscular Diclofenic injection Group	7	3.5714	0.53452	0.001
		Diclofenic Suppository Group	4	1.5	0.57735	
BMI	<25 Kg/m2	Intramuscular Diclofenic injection Group	2	4	.00000b	-
		Diclofenic Suppository Group	2	1	.00000b	
	25-30	Intramuscular Diclofenic injection Group	11	3.6364	0.50452	0.001
	Kg/m2	Diclofenic Suppository Group	20	1.75	0.63867	

	30.1-35	Intramuscular Diclofenic injection Group	25	3.72	0.61373	0.001
Kg/m2 >35 Kg/m2		Diclofenic Suppository Group	18	2.1111	0.6764	
		Intramuscular Diclofenic injection Group	12	3.75	0.62158	0.001
		Diclofenic Suppository Group	10	1.7	0.67495	
Parity Group 1	Group 1	Intramuscular Diclofenic injection Group	6	4	0.63246	0.001
Group 2 Group 3		Diclofenic Suppository Group	5	2	0	
		Intramuscular Diclofenic injection Group	28	3.7143	0.46004	0.001
		Diclofenic Suppository Group	32	1.875	0.70711	
		Intramuscular Diclofenic injection Group	12	3.6667	0.7785	0.001
		Diclofenic Suppository Group	10	1.6	0.84327	
	Group 4	Intramuscular Diclofenic injection Group	4	3.5	0.57735	0.007
		Diclofenic Suppository Group	3	2	0	

Out of 4 patients in the category of BMI <25 Kg/m<sup>2</sup> in group A (intramuscular diclofenic injection group) mean pain score of 2 patients was 4.00 with STD of 0.00 and in group B (Diclofenic Suppository Group) the mean pain score of 2 patients was 1.00 with STD of 0.00. P-value is significant. Out of 31 patients in the category of BMI 25-30Kg/m<sup>2</sup> in group A (intramuscular diclofenic injection group) mean pain score of 11 patients was 3.64 with STD of 0.50 and in group B (Diclofenic Suppository Group) the mean pain score of 20 patients was 1.75 with STD of 0.64. Pvalue is significant. Out of 43 patients in the category of BMI 30.1-35Kg/m<sup>2</sup> in group A (intramuscular diclofenic injection group) mean pain score of 25 patients was 3.72 with STD of 0.61 and in group B (Diclofenic Suppository Group) the mean pain score of 18 patients was 2.11 with STD of 0.68. P-value is significant. Out of 22 patients in the category of BMI >35Kg/m<sup>2</sup> in group A (intramuscular diclofenic injection group) mean pain score of 12 patients was 3.75 with STD of 0.62 and in group B (Diclofenic Suppository Group) the mean pain score of 10 patients was 1.70 with STD of 0.67 P-value is significant. (Table-3)

Out of 11 patients in the category of parity 1 in group A (intramuscular diclofenic injection group) mean pain score of 6 patients was 4.00 with STD of 0.63 and in group B (Diclofenic Suppository Group) the mean pain score of 5 patients was 2.00 with STD of 0.00. P-value is significant. Out of 60 patients in the category of parity 2 in group A (intramuscular diclofenic injection group) mean pain score of 28 patients was 3.71 with STD of 0.46 and in group B (Diclofenic Suppository Group) the mean pain score of 32 patients was 1.88 with STD of 0.71. P-value is significant. Out of 22 patients in the category of parity 3 in group A (intramuscular diclofenic injection group) mean pain score of 12 patients was 3.67 with STD of 0.78 and in

group B (Diclofenic Suppository Group) the mean pain score of 10 patients was 1.60 with STD of 0.84. P-value is significant. Out of 7 patients in the category of parity 4 in group A (intramuscular diclofenic injection group) mean pain score of 4 patients was 3.5 with STD of 0.58 and in group B (Diclofenic Suppository Group) the mean pain score of 3 patients was 2.00 with STD of 0.00. P-value is significant (Table 3).

# Discussion

In our study ,the mean level of post-operative pain after 24 hrs using the visual analogue scale (VAS) experienced by the women is less in diclofenac suppository group than the intramuscular diclofenac group.(1.8 versus 3.7) and the difference is found to be statistically significant moreover less women in the rectal diclofenac group needed rescue analgesia than the I/M diclofenac group (40% versus 52%).Our findings are similar to other such studies.(4,13) Ootutoaja conducted a study in which he assessed pain scores in both rectal and I/M diclofenac group after 6,12, 18 & 24 hours(every 6 hrs) and pain intensity in rectal group was less than that of I/M group throughout 24 hrs though the difference was not significant. In his study, like our study, less no of women needed rescue analgesia in the rectal group 12(42.86%) vs 16(57.14%)

Our findings are also similar to the study of Rashid et al who concluded that rectal diclofenac is useful in relieving caesarean pain post operatively & assessed its effect after 12, 18 & 24 hours post caesarean.

Kayomugisha(14) compared the effect of diclofenac suppository & I/M diclofenac injection on post-operative pain after inguinal herniorraphy & found rectal suppository superior to I/M injection in pain control. This could be because the absorption rate of

suppository is slower and effect is prolonged than the intramuscular administration. While the study done by Onuorah (2) found that diclofenac suppository and I/M injection are equally efficacious in providing post operative pain relief. Akhavanakbari et al compared analgesic effect of diclofenac, acetaminophen and indomethacin suppositories at 12 and 24 hrs post caesarean and found least pain score in diclofenac suppository group (15). They used 50mg diclofenac suppository 6 hrs in 24 hrs which is equivalent to our dosage of diclofenac suppository (100mg 12 hrly). Findings of our study & similar such studies also prove diclofenac as an effective analgesic. Our findings of less number of women needing rescue analgesia in rectal group is similar to other studies of Dahl et al (16)& Munishankaret al(17).In other such studies, various variables like patient satisfaction, time of discharge & no of times, rescue analgesia needed has been studied in the diclofenac suppository and I/M diclofenac groups . All data favoured diclofenac rectal suppository group as being better analgesic than the I/M diclofenac group. (18,19,20). Moreover women needing elective caesarean section should also be well informed about available options of postoperative analysics in that health facility before the procedure (20). It improves the woman's, satisfaction, compliance and gives her the freedom to choose particularly when unacquainted analgesic technique or route is being used and individual woman's post analgesic caesarean plan should be documented.21

# Conclusion

Rectal diclofenac suppository for pain in early post caesarean period has shown to have effective and prolonged effect in our study with infrequent need for rescue analgesia . Furthermore it avoids painful intramuscular route & shortens hospital stay. Rectal diclofenac suppository should be promoted as a post caesarean analgesic .

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