

*Full Length Research Paper*

# Comparative analysis of diclofenac suppository and intramuscular morphine for post-cesarean pain management

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A proper post-cesarean section (CS) pain relieving method results in early mobilization and better early maternal–fetal interaction. Many different methods have already been suggested for analgesic purposes after CS delivery. The known standard method is the intramuscular injection of morphine; however, in our medical center, administration of the diclofenac suppository has been the practice of choice. The aim of this study is to compare the efficacy of the two methods on relieving the post-CS pain. In a clinical trial, 120 parturient women were recruited after CS in Taleghani Hospital of Tabriz during an 18-month period (2006 to 2007). They were randomized into two equal groups: Receiving either diclofenac suppository (3\*100 mg in 24 h post-surgery) (group D) or intramuscular (IM) morphine (3\*10 mg in 24 h post-surgery) (group M). The pain level was evaluated according to Visual Analogue Score (VAS) on 8, 16 and 24 h post-cesarean for each patient. The mean age ( $26.98 \pm 5.85$  vs.  $27.15 \pm 5.08$  years), gravidity ( $2.13 \pm 1.27$  vs.  $2.00 \pm 1.15$ ), parity ( $0.95 \pm 1.05$  vs.  $0.87 \pm 0.98$  years), and the gestational age ( $38.98 \pm 1.43$  vs.  $38.35 \pm 2.55$  weeks) were compared in groups D and M respectively ( $p > 0.05$ ). The mean pain severity score was significantly lower in group D for every three readings ( $p < 0.001$ ). The mean reduction of the pain score was also higher in the same group ( $p < 0.05$ ). No major complications were observed in either group. The current study showed that the diclofenac suppository is considerably more efficient than IM morphine in relieving post-CS pain.

**Key words:** Cesarean section, pain, morphine, diclofenac.

## INTRODUCTION

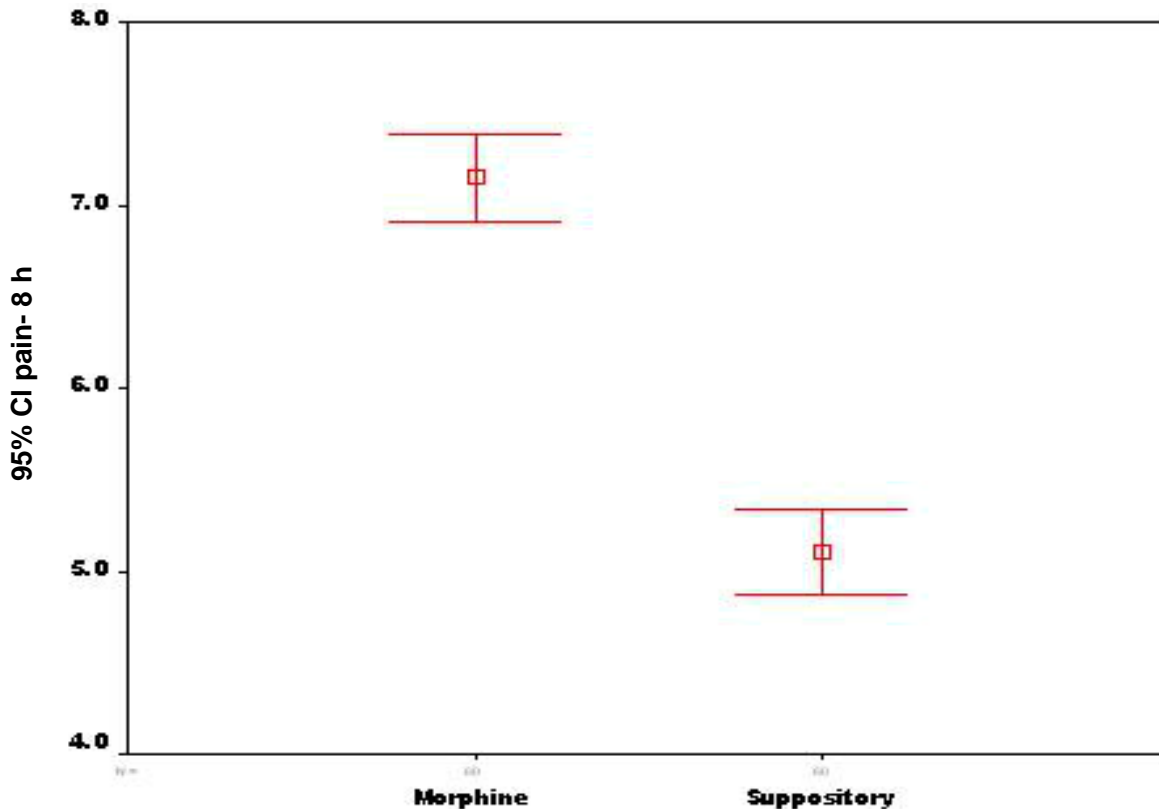
Cesarean section rate is increasingly rising. In the U.S. in 2002, it has reached 1.26%. There is no detailed information available about the prevalence of cesarean section in Iran, but it seems to be equal to, or even higher than this rate in our society. The most common reasons mentioned for cesarean section include primarily a history of previous cesarean section, and then dystocia, fetal distress, etc (Gabbe et al., 2001).

Several studies have been conducted about the best

methods of pain relief after cesarean delivery and various methods have been mentioned such as PCA (patient controlled analgesia), intramuscular and oral opioids. So far, several studies have been conducted to compare these methods (Gabbe et al., 2001; Cunningham et al., 2005; Farhud et al., 1986; Nichols and Humenich, 2000). In the textbooks, the use of intramuscular meperidine and morphine is the one that has been recommended as the proven method (Scott et al., 2003).

On the other hand, the use of diclofenac suppositories is the method commonly used in Taleghani Hospital for post-CS pain relief, but its effectiveness is not yet approved. In a study, these suppositories have been used with intrathecal morphine (Fuller et al., 1990).

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**Figure 1.** Pain score of patient in diclofenac suppository group and intramuscular morphine group at 8 h after caesarean section.

The aim of this study is to compare the method routinely used in Taleghani Medical Center (100 mg diclofenac suppositories, one rectal every 8 h) with the method recommended in the book of *Williams* (intramuscular morphine 10 mg every 8 h); so that, if its effectiveness proven, recommendations should be provided to hospital officials to change the method of pain relief after cesarean section, to thereby satisfy most patients.

## METHODS AND MATERIALS

In a clinical trial conducted on 120 women with cesarean delivery in Taleghani Hospital of Tabriz during 2005 to 2006, the effect of diclofenac suppository and intramuscular morphine in relieving after cesarean pain was evaluated. In this study, 120 pregnant women were randomly selected from among the patients delivered by cesarean section in this Center and were randomized into two groups.

In this study, 60 women were treated for post-CS pain control by diclofenac suppositories (one rectal every 8 h). The other 60 women were treated with intramuscular morphine injections of 10 mg every 8 h.

These treatments started after the patients transferred to the ward. The two groups were matched in terms of age, gravidity, parity and gestational age.

Patient's pain score was evaluated and recorded based on single dimension self report scale (visual analogue scale, VAS) in 8, 16

and 24 h after surgery and before the next dose of medication. The person recording the pain scores was blinded to the grouping of the patients. Finally, the pain score at times mentioned and its changes were compared in the two groups through two inquiry phases. It should be noted that none of the individuals under study had any background physical or mental disease. Due to ethical considerations and non-exclusion of patients from postoperative pain control, selecting a control group and placebo receiver was not possible.

A visual analogue scale (VAS) is a measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured. For example, the amount of pain that a patient feels ranges across a continuum from none to an extreme amount of pain. From the patient's perspective, this spectrum appears continuous  $\pm$  their pain does not take discrete jumps, as a categorization of none, mild, moderate and severe would suggest. It was to capture this idea of an underlying continuum that the VAS was devised.

Operationally, a VAS is usually a horizontal line, 100 mm in length, anchored by word descriptors at each end, as illustrated in Figure 1. The patient marks on the line, the point that they feel represents their perception of their current state.

The VAS score is determined by measuring in millimeters from the left hand end of the line to the point that the patient marks.

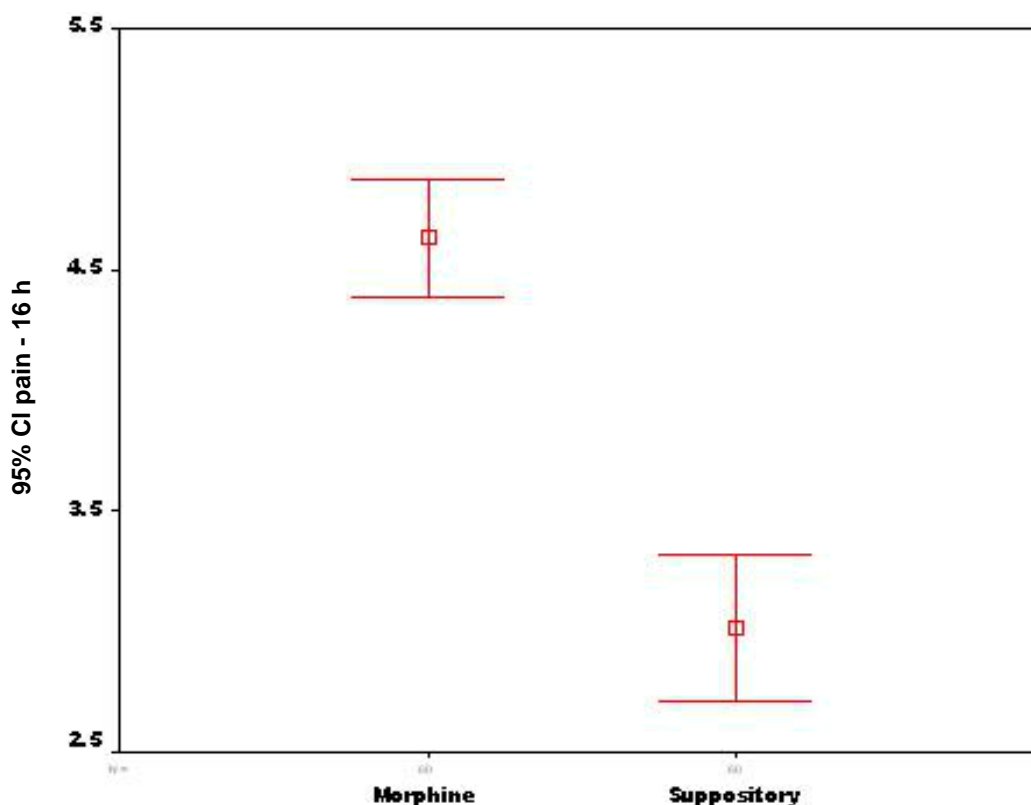
## Ethical considerations

Before the inclusion of the patient in the study, treatment method,

**Table 1.** Characteristic finding in diclofenac suppository group and intramuscular morphine group.

Parameter	Diclofenac suppository group (n = 60)	Intramuscular morphine group (n = 60)	p-value*
Age (year)	28.15 ± 5.08	26.98 ± 5.85	0.868
Gestational age (week)	38.35 ± 2.55	38.98 ± 1.43	0.097
Gravidity	2.00 ± 1.15	2.13 ± 1.27	0.547
Parity	0.87 ± 0.98	0.95 ± 1.05	0.654
History of previous caesarean section	21 (35%)	21 (35%)	1

\*, p < 0.05 was significant.



**Figure 2.** Pain score of patient in diclofenac suppository group and intramuscular morphine group at 16 h after caesarean section.

possible complications and benefits were explained, and the patients were included in this study with the full knowledge and written consent.

Variables examined include age, gravidity, parity, number of previous cesarean sections, gestational age, and pain score based on VAS in 8, 16 and 24 h after cesarean were the major complications.

## RESULTS

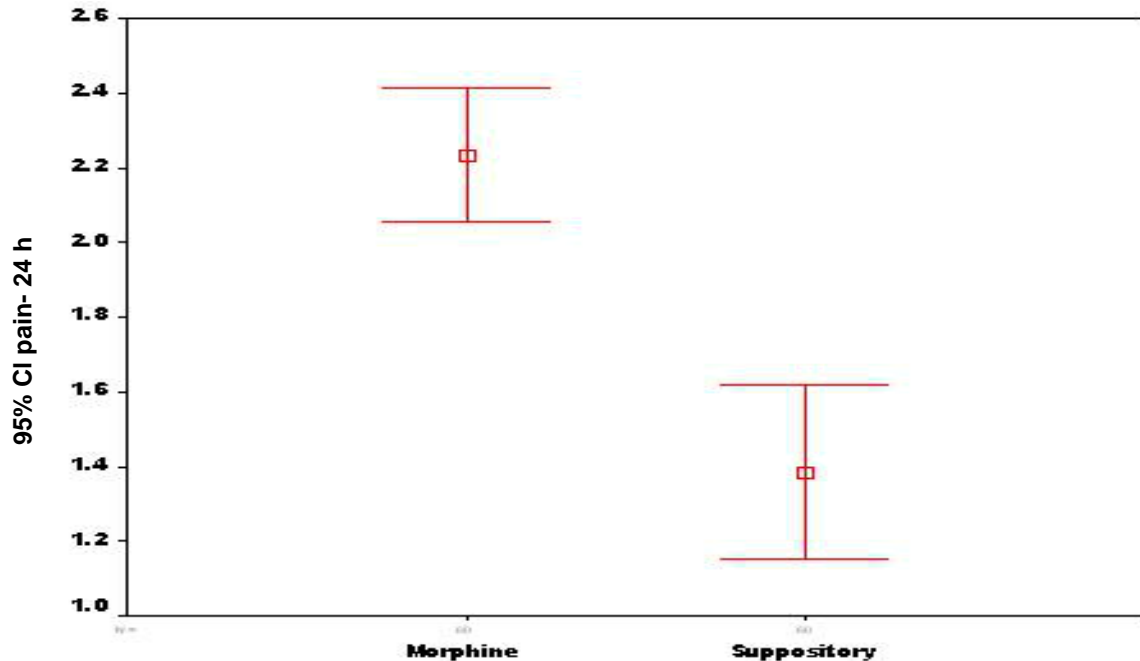
General specifications of the patients in the two groups are summarized and compared in Table 1.

Pain scores in 8, 16 and 24 h after cesarean in the two

groups are shown in Figures 1 to 3.

The mean pain scores at the times mentioned are summarized and compared in Table 2. The mean pain was reduced from  $5.1 \pm 0.09$  to  $1.38 \pm 0.09$  in diclofenac group, and from  $7.15 \pm 0.94$  to  $2.23 \pm 0.07$  in intramuscular morphine group.

As observed in all three times of evaluation, the mean pain is significantly lower in the group receiving diclofenac suppositories. The mean pain reduction between different measurement times in the two groups are summarized and compared in Table 3. As observed, the mean pain reduction between different measurement times is significantly higher in the group receiving



**Figure 3.** Pain score rate of patient in diclofenac suppository group and intramuscular morphine group at 24 h after caesarean section.

**Table 2.** Mean pain score  $\psi$  after caesarean section in diclofenac suppository group and intramuscular morphine group.

Parameter	Diclofenac suppository group (n = 60)	Intramuscular morphine group (n = 60)	p-value*
8 h after surgery	5.1 $\pm$ 0.90	7.15 $\pm$ 0.94	<0.001
16 h after surgery	3.02 $\pm$ 1.17	4.63 $\pm$ 0.94	<0.001
24 h after surgery	1.38 $\pm$ 0.90	2.23 $\pm$ 0.70	<0.001

\*, p < 0.05 was significant;  $\psi$  pain score evaluated by VAS

**Table 3.** Mean pain score  $\psi$  reduction rate after caesarean section in diclofenac suppository group and intramuscular morphine group.

Parameter	Diclofenac suppository group (n = 60)	Intramuscular morphine group (n = 60)	p-value*
8 - 16 h after surgery	2.52 $\pm$ 0.70	2.08 $\pm$ 0.83	0.002
8 - 24 h after surgery	4.92 $\pm$ 0.77	3.72 $\pm$ 0.80	<0.001
16 - 24 h after surgery	2.40 $\pm$ 0.64	1.63 $\pm$ 0.80	<0.001

\*, p < 0.05 was significant;  $\psi$  pain score evaluated by VAS.

diclofenac suppositories. No major or significant complication was observed during hospitalization in the two groups and none of the patients were excluded from the study.

## DISCUSSION

Narcotics, due to their potential and serious complication

that may be pursued, are always used cautiously in patients after surgery; therefore, one of the objectives of all studies is to find an alternative to reduce or eliminate opioid dose (Juneja et al., 1991; Rosen et al., 1983; Fuller et al., 1990; Bush et al., 1994; Luthman et al., 1994; Engel et al., 1989; Power et al., 1990).

In this study, we compared two methods of post-CS pain relief used in Taleghani Hospital of Tabriz. In one method, intramuscular morphine is used for this method

as recommended in most references. In the second method, only diclofenac suppositories are used. As far as we have studied, no similar study has been conducted in this area and this is the first study.

In order to assess the pain intensity, VAS was used, the efficiency of which has already been approved by various studies for this purpose.

The current results indicate that the mean pain score in 8, 16 and 24 h after CS in the group receiving diclofenac suppositories (100 mg every 8 h) was significantly lower than that in the group receiving intramuscular morphine (10 mg every 8 h) (All p-values were less than 0.001).

O'Hanlon et al. (1996) showed in their study that non-steroidal anti-inflammatory drugs (NSAIDs) can effectively reduce post-CS pain and the need for narcotic analgesics. Burns et al. (1991) and Perttunen et al. (1992) had shown in other studies that the use of NSAIDs in this group of patients decreases the need for opioids by 40 to 70%. Cardoso et al. (1998) showed in a study, that adding diclofenac to small doses of intrathecal morphine can effectively reduce the level of post-CS pain control and decrease the need for narcotics. Dennis et al. (1995) showed in their study that use of diclofenac suppositories after CS extends the administration time of the first next analgesic from 14 to 20 h. In a study, Siddik et al. (2001) showed that use of diclofenac suppositories 100 mg every 8 h is very effective in relieving the pain after CS and reducing the need for opioids. Also, Olofsson et al. (2000) showed in their study that administration of 150 mg diclofenac suppositories during the first 24 h after CS may decrease the need for opioids by 39% (20). Lim et al. (2000) compared the analgesic effect of diclofenac suppositories (100 mg single dose) with spinal anesthesia (ropivacaine) after delivery. In this study, usage rate of narcotics was significantly lower in the first group (Lim et al., 2001).

As observed in all of these studies, diclofenac suppositories have been referred to be effective in decreasing the need for opioids and reducing post-CS pain; but what distinguishes our study from the others is that in one of the study groups during the first 24 h after CS, we only used diclofenac suppositories (Opiate-sparing = 100%). So, this conclusion is of considerable importance.

One of the restrictions of similar studies is the lack of assessment of the basic pain level before the administration of analgesics which is due to violation of the ethical considerations. To eliminate this restricting factor, we also compared pain relief scores in the two groups during assessment times. The result of this comparison showed that during all times of comparison, the pain relief score in the group treated by diclofenac suppositories was significantly higher than that in the second group.

In our study, significant complications were observed neither in the group receiving diclofenac suppository nor in the group receiving intramuscular morphine. A possible

reason would be the low dose of morphine used; but what is important, as mentioned earlier, was the elimination of the need for opioids in the first group.

In some previous studies, it has been suggested that the use of NSAIDs (including diclofenac) may cause bleeding during or after surgery, excretion of drugs and metabolites in breast milk; patent ductus arteriosus (PDA) remaining open in infant, reduction of postpartum uterine contractility and the need for auxiliary drugs (such as methergine), and increased gastrointestinal, renal and cardiovascular complications (Kitterman, 1980; Rorarius et al., 1993; Pérez et al., 1995; Sia et al., 1997; Valanne et al., 1987).

Sia et al. (1997) showed that administration of diclofenac, even before surgery, does not increase the risk of complications. Valanne (1987) showed that there is no significant difference in terms of bleeding causing complications between the group receiving diclofenac and control group. Isel (1990) in his study concluded that most of the systemic complications arising from the use of NSAIDs do not initiate during their short-term prescription (Kitterman, 1980).

Rorarius et al. (1985) in a study showed that no major complications will be caused by the recommended doses.

Al-Waili (2001) in a study showed that intramuscular injection of diclofenac after cesarean section significantly reduces pain and the need for opioid without any complications.

Even in case of any possible side effects of diclofenac administration after delivery, the dosage and method recommended by the current study (post-CS administration of diclofenac suppositories after the patient's arrival to the ward) minimize the possibility of their incidence and even eliminate them. Furthermore, the rate of drug excretion in breast milk is not to the extent to cause significant adverse effects infant (Bush et al., 1994).

Diclofenac (including its suppository form) is a cheap and easily accessible drug with low complication (Al-Waili, 2001). Furthermore, reduced need for opioids and, hence, reduction of their costs and expenses due to their possible complications using this drug, justify the use of diclofenac suppositories in this group of patients as a reasonable method. Additionally, it should be noted that inappropriate pain control in post-CS patients may lead to delayed discharge and increased hospital costs (Snell and Hicks, 2006). Regarding the results obtained, it is recommended to conduct additional studies to investigate the effects of combination therapy of diclofenac and narcotic analgesics, and also more studies to examine the appropriate times for postoperative administration of analgesics on pregnant women after cesarean section.

## Conclusion

The use of diclofenac suppositories in post-CS patients, compared to the common method, e.g. intramuscular

injection of morphine, causes better pain relief and hence, increases patient satisfaction. According to the results of the present study, the use of diclofenac suppositories in post-CS patients is recommended as an alternative to intramuscular injection of morphine.

To achieve more conclusive results in this regard, further studies are recommended to be conducted with larger sample size. Also, a study of the role of combination therapy of NSAIDs, regarding their synergistic role or their mutual additive effects using diclofenac suppositories can be helpful in achieving better therapeutic results.

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