THE EFFICACY OF DICLOFENAC FOR POST CAESAREAN SECTION ANALGESIA: COMPARISON OF RECTAL AND INTRAMUSCULAR ROUTES

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ABSTRACT

Background: Despite advances in postoperative pain therapy, pain relief may still be inadequate for a substantial number of women.

Aim: The aim was to compare the analgesic efficacy of rectal and intramuscular diclofenac for post Caesarean section analgesia.

Materials and Methods: Following approval from the Hospital Ethics Committee 94 ASA I and II parturients aged 18 years and above scheduled for elective Caesarean section under spinal anaesthesia were recruited into the study. While one group of parturients received 100 mg Diclofenac suppository rectally (group R) those in the other group received 75 mg Diclofenac intramuscularly (group IM) immediately after surgery. The patients were instructed to request analgesic when they felt pain post-operatively. Pain scores were recorded using the VAS (0 to 10), (0 = no pain, 10 = the most severe pain), initially every 30 minutes for the first 2 hours, then every 2 hours from the 2nd hour to the 8th hour and every 4 hours after the 8th hour till the 24th hour.

Results: The demographic data, BMI, PCV and ASA classification between the two groups of patients were comparable; the two groups were also comparable in the haemodynamic variables (mean systolic BP, mean diastolic BP, mean MAP and mean heart rate) and in the mean SpO_2 recorded in the recovery room, $p > 0.05$ for all the variables. The time to first analgesic request in group IM was 313.2 ± 218.8 mins and in group R 314.1 ± 121.6 mins, p=0.98. There was no significant difference between the IM/R groups in the mean VAS scores of patients, the number of patients who received pentazocine at each time interval in the two groups, and the total pentazocine consumption in the two groups in 24 hours, $p>0.05$ in all the variables. There was no significant difference between the two groups in the mean satisfaction score in pain relief, $p = 0.73$, the mean satisfaction score with staff's response to patient's pain management needs, $p = 0.85$, and the mean acceptability score, $p = 0.62$.

Conclusion: Suppository diclofenac administered through the rectal route is as efficacious as intramuscular diclofenac injection for post Caesarean section analgesia with equal levels of patient satisfaction and acceptability.

Keywords: Post Caesarean section analgesia, diclofenac, rectal, intramuscular, spinal anaesthesia,

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INTRODUCTION

Despite current advances in postoperative pain therapy, pain relief may still be inadequate for a substantial number of women. The incidence of pain ranges between 9 - 33%, in the first 24 hours after Caesarean section (C-section).[1]

Pain relief after operative delivery is important because it can ameliorate or prevent the incidence of undesirable physiological and psychological consequences of pain which increases post-operative morbidity, delayed ambulation and recovery. Effective post-Caesarean section analgesia provides a smoother post-operative course, improved physical activity which enables the mother to optimally care and breast feed her baby in the immediate postpartum period. It also has great economic benefit as it promotes wound healing and early discharge from hospital.

In recent times, non-steroidal anti-inflammatory drugs (NSAIDs) have been used alongside opioids for management of post-operative pain. NSAIDs possess analgesic and anti-inflammatory properties and are well known to be effective for minor to moderate pain and, their use in combination with opioids will reduce total opioid requirements and side effects. Diclofenac administered intramuscularly has been shown to effectively decrease the amount of morphine consumed after C-

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section.[2] Similarly, rectal diclofenac has been shown to provide effective analgesia when administered after C-section and it reduced patient's opioid requirement and opioid related side effects.[3] Diclofenac has also been shown to have a comparative analgesic efficacy over pethidine and tramadol.[4,5]

This study however, was designed to compare the effectiveness of diclofenac by rectal and intramuscular routes in providing adequate analgesia after C-section under spinal anaesthesia.

MATERIALS AND METHOD

Following approval from the Hospital's Ethics Committee and an informed consent obtained, 94 ASA I and II parturients aged 18 years and above scheduled for elective C-section under spinal anaesthesia were recruited into this prospective, randomized, comparative study. Exclusion criteria included patients with ASA classes > II or who have contraindications to spinal anaesthesia, a history of peptic ulceration, gastrointestinal bleeding or bleeding diathesis, severe renal or hepatic insufficiency: severe PET, eclampsia.

The patients were randomly allocated into two groups, Groups R and IM, by random sampling. Patients in group R, received 100mg rectal diclofenac while those in group IM, received 75mg diclofenac intramuscularly, immediately after surgery. The patients were instructed to request for analgesic whenever they felt pain during the post-operative period. Preoperative fast was prescribed according to American Society of Anesthesiologists guidelines.[6]

Anaesthesia and Surgery

All the patients in groups IM and R had preanaesthetic review in the evening prior to the day of surgery. Assessment of the physical status and airway was done using the ASA and Mallampati classifications respectively. All patients observed an overnight fast (8 hours for solids and 3 hours for clear fluids).

Following adequate preload of fluid with ringers lactate and while observing asepsis, spinal anaesthesia was instituted in a sitting position, using a 25 gauge Whitacre needle through the midline approach, at the L3/L4 inter-vertebral space, with a 21 G hypodermic needle acting as a guide. On confirmation of correct placement (by free flow of cerebrospinal fluid), the attending anaesthetist injected 2 ml (10 mg) of 0.5% hyperbaric bupivacaine plus 0.5 ml (25 µg) fentanyl citrate USP, intrathecally. The needle was removed and light sterile dressing applied over the puncture site. The parturient was immediately returned to the supine position, with a 15° left lateral displacement of the gravid uterus. Both groups had the same standard technique of surgery – Pfannenstiel incision, exteriorization of the uterus and repair of layers were carried out during the surgery. Parturients in Group IM received intramuscular (100 mg) diclofenac sodium (Olfen, Mepha Switzerland) in the upper, outer quadrant of the gluteus muscle, at the end of surgery. The surgeon administered the rectal diclofenac sodium (100 mg) suppository (LOFNAC, Bliss GVS Pharma Ltd), to the R group.

Postoperative data were recorded by another Anaesthetist who was blinded to the patient's group. The main outcome measures investigated were the mean VAS score of patients, number of patients who received pentazocine at each time interval, analgesic consumption, haemodynamic variables in the recovery room, satisfaction and acceptability of pain relief. Pain scores were recorded using the VAS: from 0 to 10 (0 = no pain, 10 = the most severe pain), initially every 30 minutes for the first 2 hours, then every 2 hours from the 2nd hour to the 8th hour and every 4 hours after the 8th hour till the 24th hour. Intravenous pentazocine 30

mg was given for rescue analgesia when VAS ≥ 4. Patient's satisfaction with postoperative pain management was assessed at the 24th hour postoperatively, with a 2-item, 5 point Likert pain scale:
0 = no pain relief
1 = a little pain relief
2 = moderate pain relief
3 = a lot of pain relief
4 = complete pain relief.

Maximum score in the items tested was 8 and the least was 0. The two items tested were:

1. How satisfied are you with pain relief.
2. How satisfied are you with staff's response to your pain management needs.

STATISTICS

All data collected were fed into a spread sheet and analyzed using the Statistical Package for Social Sciences (SPSS) version 17.0 software (SPSS, Chicago, IL, USA) for windows. Results were presented in tables and figures and expressed as mean and standard deviation and number of patients/percentage. A $p < 0.05$, was significant.

RESULTS

Six patients (6.4%) were excluded from the study (three from each group) because they could not participate through the study while 88 (93.6%) of them completed the study.
The two groups were comparable in demographic data in this study, $p > 0.05$ for all the variables (Table I).

There was no significant difference between the IM/R groups in the time to first analgesic request p=0.98, number of analgesic requests p=0.41 and total analgesic consumption p=0.55, in 24 hours (Table II).

The two groups were comparable in the haemodynamic variables (mean systolic BP, mean diastolic BP, mean MAP and mean heart rate) in the recovery room, $p > 0.05$ for all the variables. There was no significant difference in the mean SpO_2 between the two groups, $p > 0.05$.

There was no significant difference between the IM/R groups in the mean VAS scores of patients, $p > 0.05$ (Table III). The number of patients who received pentazocine at each time interval in the two groups was also not significantly different, $p > 0.05$ (Table IV). The total pentazocine consumption in the two groups in 24 hours did not differ significantly, $p = 0.55$.

There was no significant difference between the two groups in the mean satisfaction score in pain relief, p=0.73, the mean satisfaction score with staff's response to patient's pain management needs, p=0.85, and the mean acceptability score, p=0.62.

DISCUSSION

The study compared the analgesic efficacy of rectal and intramuscular diclofenac for post Caesarean section analgesia after spinal anaesthesia.

The VAS score in this present study was not significantly different between the two groups, throughout the study period. Unlike this present study Bourlert[2] and, Jakkrid and Yuen[7] compared study groups that received intramuscular diclofenac and placebo control groups. Bourlert[2] did not record any significant difference in VAS score all through the study period, between his study and control groups. This could be due to the fact that only a single dose of the study drug, (75mg intramuscular diclofenac injection) was administered even though both groups received baseline post-operative analgesic in the form of morphine, by IM bolus and PCA. Jakkrid and Yuen[7] however recorded significant difference between their study and control groups up to the 24th hour. This finding could be explained from the fact that their study group received 150 mg intramuscular diclofenac injection in 2 doses

while the control group did not receive any diclofenac.

Unlike in this present study, Zahiri et al[4] compared suppository diclofenac and pethidine for post Caesarean section analgesia. The VAS in their study was significantly less in the diclofenac group throughout the study period. In this present study, the VAS was not significantly different. The difference observed between this present study and that of Zahiri et al[4] could be attributed to the dose and frequency of diclofenac administration. The study group in the research by Zahiri et al[4] received 100 mg diclofenac suppository immediately after surgery and then 100 mg 8 hourly compared to a control group that received pethidine.

When compared to researchers that used only single doses of diclofenac in their studies, it is noted that the VAS in this present study was not significantly different between the IM and R groups in the 24-hour study period. Although Bourlert[2] used a placebo arm in the research, the VAS was not significantly different throughout his study period, unlike the study by Joshi et al[5] that recorded significantly less VAS score in the diclofenac group than the tramadol group. The observed difference may have arisen due to the relatively short study period of 10 hours. Moreover, the study compared diclofenac with tramadol, which is a synthetic opioid with moderate analgesic effect.

The number of patients that received pentazocine in the IM/R Groups in this present study at the various time intervals did not differ significantly. However, relatively less number of patients in the IM group required rescue analgesic at the various time intervals, than the R group. This outcome is different from that of Jakkrid and Yuen[7] who recorded significant difference in the number of patients that requested rescue analgesic between their study and control groups, p=0.003. This difference can be attributed to the fact that unlike this study they compared diclofenac with placebo control groups who were predisposed to greater analgesic needs.

Unlike this present study, Bourlert[2] recorded significant difference in rescue drug consumption between the study and control groups. This result by Bourlert[2] was because the control group was a placebo group and so demanded more rescue analgesic.

The frequency of pentazocine consumption, in this study showed that the mean number of times analgesic request was made in a 24-hour period was not significantly different between the two groups of patients. By the 12th hour, while 42 (95.5%) patients in the IM Group had received pentazocine, 44 (100%) patients in the R Group had done so. In other words, 2 (4.45%) patients in the IM group had not received rescue analgesic as at the 12th hour. This can be attributed to early and steady peak plasma concentration and duration of action of 12 hours of diclofenac, in the IM Group. The study by Jakkrid and Yuen[7] also showed that as at the 12th hour, 2 (5%) patients in their study group had not requested rescue analgesic.

The time to first analgesic request, was not significantly different in the two groups in this present study, though it was marginally less in the IM group. This could be attributed to the fact that the onset of action of diclofenac via the intramuscular route is 28.37 ± 11.61 mins, which is not much different from that administered through the rectal route as demonstrated by Adarsh et al.[8] The time to first analgesic request in this present study was shorter than that of the diclofenac group (18 hours 58 mins) demonstrated by Dennis et al[9]. The mean time to first analgesic request was longer in their research because they used intrathecal morphine which has a longer duration of action (4 -24 hours) than fentanyl, used in this present study.

Postoperatively in the recovery room the patients demonstrated comparable haemodynamics. The results reveal that all the variables did not show any significant

difference between the two groups. Following spinal anaesthesia some degree of haemodynamic instability can occur as a result of the temporary sympathectomy. However, after Caesarean section, in the recovery room, the blood pressure and heart rate would begin to normalize as the effect of spinal anaesthesia wears off. In this study the blood pressure and heart rate did not show any abnormal variation. Although the pain of surgery could also precipitate elevations of blood pressure, there was no pain (VAS score of 0 in both groups) throughout stay in the recovery room and this could be attributed to post Caesarean section analgesia provided by diclofenac and any residual analgesic effect of spinal anaesthesia. The results in this study are similar to that of Ebrahim et al[11] which demonstrated stable haemodynamics in the recovery room.

There was no significant difference in the mean satisfaction score between the IM and R Groups, both to pain relief and staff's response to patient's pain management needs. Twenty seven (61.4%) patients in the IM Group and 30 (68.2%) in the R Group scored satisfaction to pain relief as 'moderate pain relief', while 30 (68.2%) patients in the IM Group and 28 (63.6%) in the R Group scored satisfaction to staff's response to patient's pain management needs as 'moderately satisfied'. In the study by Zahiri et al[4] 70.8% of women in the study group rated their method of pain relief as good.

Regarding acceptability, 79.6% of the women in the IM group and 72% in the R group considered this method of pain relief as acceptable to them. There was no significant difference between the two groups in terms of acceptability of method of pain relief.

CONCLUSION

This study shows that diclofenac suppository, administered through the rectal route is as efficacious as diclofenac injection administered via the intramuscular route for post C/S analgesia after spinal anaesthesia. Both routes provided equal extension of time to first rescue analgesic, comparable haemodynamics and opioid sparing effects. The level of patient satisfaction and acceptability in both groups were essentially the same.

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