

A Comparison of the Effects of Injecting Paracetamol and Transdermal Diclofenac Patch as Analgesics After Cesarean Birth

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ABSTRACT

Introduction: Pain is an inevitable outcome of any surgery and control of postoperative pain is very important to improve patient comfort and reduce morbidity. The present study aims to compare the degree of postoperative pain relief using inj paracetamol and transdermal diclofenac patch after cesarean delivery.

Materials and methods: A randomized controlled trial was done involving 200 women (100 women were involved in the transdermal diclofenac patch group and 100 women in the inj paracetamol group) to compare the efficacy of each drug as analgesia following cesarean delivery.

Results: Both the statistical and clinical observations among the 200 patients showed that 100 mg diclofenac sodium administered transdermally as a patch has equal efficacy as compared with 1000 mg of paracetamol infusion given every 8 hours.

Conclusion: Diclofenac patch and injection paracetamol as infusion have similar efficacy in providing postoperative pain relief for 24 hours after the cesarean delivery.

Keywords: Diclofenac patch, Inj paracetamol, Postoperative analgesia

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INTRODUCTION

Surgical procedures involve damage to the tissues and cause pain which is discomforting and although of short duration, is cause for concern, it subsides when the damaged tissue heals. Inadequately, postoperative pain relief contributes significantly to morbidity in the postoperative period, ensuing in the delay of patients' recovery and capability to return to daily functional activities.^{1,2} Good pain relief and early recovery are particularly important for a new mother as she is expected to take care of her newborn shortly after cesarean delivery. If not treated, the postoperative pain leads to morbidity in terms of anxiety, postpartum depression, chest infection, and chronic pain.^{2,3} Thus, effective pain relief after cesarean reduces morbidity, improves patient satisfaction, and shows better clinical outcomes.

Following cesarean sections, a variety of medications and methods have been tried, with varying degrees of success. Each medication and method has benefits and drawbacks. The opioids form an important group of medications for postoperative pain but are used in a limited manner due to fear of dependence, respiratory depression, and the possibility of secretion in breast milk. The use of TAP block using local anesthetists has also been found to be effective in a few studies.⁴ Due to their ability to reduce the need for opioids, NSAIDs like diclofenac and paracetamol have grown to be popular for treating postoperative pain.⁵ For the treatment of pain, diclofenac is accessible as a tablet, injection, suppository, and transdermal patch. Diclofenac causes side effects that are primarily related to the cardiovascular and gastrointestinal systems after injection or oral treatment. In order to reduce these side effects, diclofenac transdermal patches have been tried. These patches have increased the bioavailability, painless self-administration, maintenance of constant and stable

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Ethical approval: Ethics Committee and Scientific Committee of the institute where the study was conducted authorized the study.

CTRI Registered CTRI/2020/11/029204

Conflict of interest: None

drug levels, reduction of inter- and intra-patient variability, ease of medication termination, and maintenance of constant and stable drug levels.^{6–9}

Diclofenac patch has been studied mostly by dental surgeons after various dental surgeries¹⁰ and our surgical colleagues in hernia surgeries, and the comparison has been with the intramuscular route for the use of inj diclofenac. Our study compared the

efficacy and safety of transdermal diclofenac with inj paracetamol for postoperative analgesia following Cesarean delivery under subarachnoid block because the literature search did not reveal much clinical research works on the diclofenac patch administration after cesarean delivery.

MATERIALS AND METHODS

Type of study: Prospective open-label, parallel-group comparative study.

Place of study: Department of Obstetrics and Gynecology in the tertiary care center for six months.

Study population: Women having a cesarean at our center.

Sample size: A total of 200 women who chose a cesarean section at our center were studied (100 in each group).

Inclusion criteria: All women undergoing elective cesarean delivery at term with a singleton-term pregnancy.

Exclusion Criteria:

- Emergency cesarean delivery
- Preterm cesarean delivery
- Intraoperative complication – postpartum hemorrhage
- NSAID allergy

Methodology

The study protocol complies with the Helsinki Declaration, and it has received the Institutional Ethics Committee (IEC) approval and CTRI/2020/11/029204 registration. Purposive sampling was used in this investigator-initiated study, which was carried out with institutional support. During the preoperative time, the eligible women were told, and written informed consent was taken. They were made aware of the transdermal patch as well as the verbal rating scale (VRS) and visual analogue scale (VAS) for measuring pain. The patients were grouped into two parallel trial groups using a straightforward and equitable computer randomization process. The sealed envelope method was used for allocation concealment.

Group I patients were given the first dose of 1000 mg paracetamol (100 mL) intravenous infusion after the completion of surgery and the injection was repeated every 08 hours for 24 hours. Following cesarean delivery, patients in Group II received a transdermal diclofenac diethylamine patch (100 mg) once daily near the upper arm. Every 6 hours throughout a 24-hour period, the severity of the pain was evaluated using the visual analogue scale (VAS) and verbal rating scale (VRS). If a patient is found to be with a VAS score >5 or VRS >2, she was given rescue pain relief with an injection of tramadol hydrochloride (50 mg) intramuscularly.

- **Postoperative analgesia endpoints:** Following a cesarean delivery, the pain was assessed using a visual analogue scale (VAS) of 0–10 points and a verbal rating scale (VRS) of 0–4 at 6, 12, 18, and 24 hours.
- **Supplementary terminal overview:** The entire amount of rescue pain medication needed.
- **Safety evaluation:** To check for any negative effects, patients were queried. If there was significant injection or patch toxicity, the participant was removed from the research and provided the required treatment.
- **Statistic interpretation:** The “student’s *t*-test” (unpaired) was used for the statistical evaluation of the results.

Observations and results:

A total of 200 patients were recruited at centers as shown below in the consort diagram (Flowchart 1).

Flowchart 1: Consort diagram

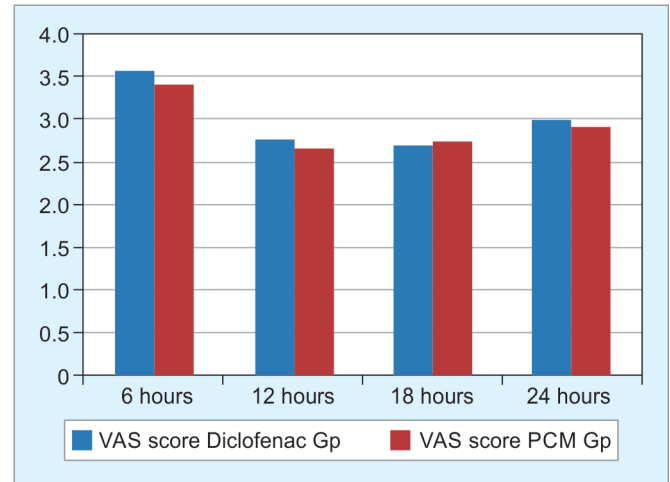
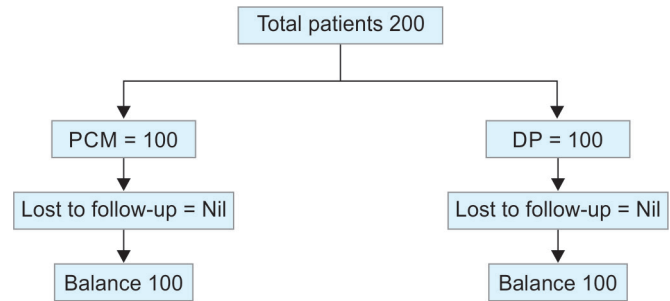


Fig. 1: Visual analogue scale at different intervals

RESULTS

Both the groups were matched by age, parity, and a common indication for the cesarean section in demographic characteristics. In two groups, postoperative pain was measured using the VAS score. After 6, 12, and 24 hours, the mean VAS score for patients in the patch group was observed to be 3.56 ± 0.26 , 2.76 ± 0.14 , 2.68 ± 0.13 , and 3.00 ± 0.19 , while the mean VAS score for patients in the paracetamol group was observed to be 3.40 ± 0.23 , 2.66 ± 0.12 , 2.73 ± 0.09 , and 2.93 ± 0.18 . This demonstrates that throughout the 24-hour observation period, the mean VAS score for both groups had only a low intensity (Fig. 1).

In the diclofenac group, the mean pain score according to the VRS score was 1.60 ± 0.09 , 1.06 ± 0.46 , 1.03 ± 0.03 , and 1.40 ± 0.09 at 6, 12, 18, and 24 hours, respectively. Subsequently, at 6, 12, 18, and 24 hours, the mean VRS score for the paracetamol group was 1.53 ± 0.09 , 1.03 ± 0.03 , and 1.37 ± 0.06 , respectively (Fig. 2). No patient had any side effects necessitating the stoppage of the treatment.

DISCUSSION

The surgical procedures lead to intense inflammation of the surgical site and lead to pain in the postoperative period which may become the nemesis of many surgeons. Various NSAID's (Both inj paracetamol and inj diclofenac) have been used for a long duration for pain relief after the completion of the surgical procedure.

Diclofenac patch effectiveness for postoperative pain reduction following major general surgery was investigated in research consisting of 100 patients by Vinod et al. They found that outstanding efficacy was seen in 34 patients, good efficacy

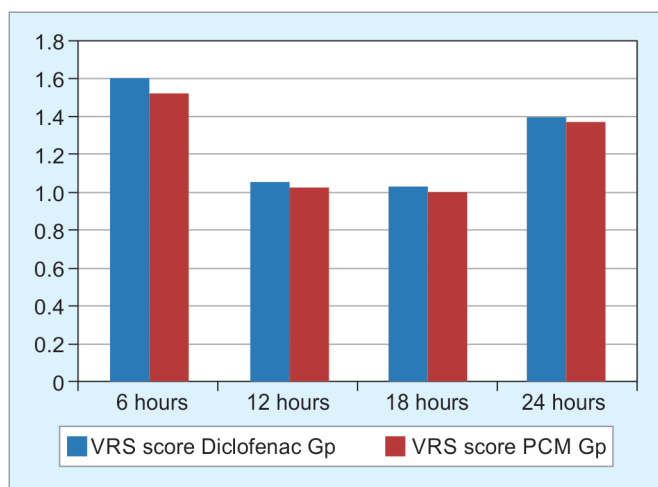


Fig. 2: Verbal rating scale at different intervals

in 38 patients, fair efficacy in only 27 patients, and poor efficacy in 1 patient. In 66 patients, they observed that rescue analgesic was being used. About 57%, 65%, and 72% of patients got pain relief after 12 hours, 24 hours, and 48 hours of applying the transdermal patch.⁷ This is in contrast to our study in which we received excellent analgesia in all the patients in both the groups. None of the patients in our study required rescue analgesics.

Transdermal diclofenac patch is a suitable analgesic approach for the management of mild-to-moderate pain following surgery, according to Selvi et al.'s research on dental patients, and this approach shows little systemic side effects.¹⁰ In patients undergoing endoscopic gynecologic surgery, Alessandri et al. compared pain relief with standard analgesic and standard analgesic plus transdermal patch and found that diclofenac transdermal patch aids standard analgesic treatment in pain relief and may also shorten the length of hospital stay for patients undergoing laparoscopic benign gynecologic surgery.¹¹ Similar to this study, According to Krishna,¹² using a single 100 mg transdermal diclofenac patch intraoperatively is just as effective as taking a single 75 mg intramuscular dosage of diclofenac to treat postoperative pain, with less serious side effects.¹²

CONCLUSION

The transdermal diclofenac patch seems to be showing potential as an analgesic modality for the efficient management of pain after cesarean delivery. The efficacy is similar to the commonly used analgesic—inj paracetamol. However, bigger and multicentric clinical trials with a larger sample are needed before the real scope of the transdermal diclofenac patch for cesarean delivery can be defined.

Declarations

- i. Funding: None
- ii. Conflicts of interest/Competing interests: None
- iii. Ethics approval: Institutional Ethical Committee approval taken
- iv. Consent to participate: Consent was taken from all participants

- v. Consent for publication: Consent taken
- vi. Availability of data and material: Available
- vii. Code availability: NA
- viii. Authors' contributions: as follows
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Drafting and manuscript revision: Sushil Chawla, KG Vivek, Dr Anuj Sharma, CH Anupama
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