

## **Abstract**

**Background:** Pain is one of the debilitating events in the postoperative period after caesarean section, as such, optimal postoperative analgesia is required to make the event a tolerable and satisfying experience. Two major groups of analgesics are commonly employed to that purpose, the opioids and the non-steroidal anti-inflammatory drugs (NSAIDs). Diclofenac is one of the commonly used NSAIDs and can be delivered through several routes including the oral, rectal and topical (patch, cream) routes. The use of the diclofenac patch has not been extensively studied despite obvious advantages which include offering adequate analgesia in the postoperative period, and elimination of some of the side effects known to be associated with other routes of diclofenac administration and the traditional opioids like pentazocine. There is a paucity of studies directly comparing the analgesic effects of diclofenac patch as against intramuscular pentazocine.

**Objective:** To compare the effectiveness of transdermal diclofenac patch and intramuscular pentazocine in providing postoperative analgesia after caesarean section.

**Test and Subjects:** This was a double blind randomized, non -inferiority controlled study performed at the obstetric complex of Nnamdi Azikiwe University Teaching Hospital, Nnewi, in the region of Nigeria. Ethical approval was obtained before commencing the study. Eligible and consenting women who presented for lower segment caesarean section were the case subjects. Randomization was done by computer generated random numbers. Spinal anaesthesia was administered by the senior registrar anaesthetist. Group 1 patients were given intramuscular pentazocine 30mg every 4 hours and placebo patch applied every 12 hours, from within 30 minutes after completion of surgery while group 2 patients received topical application of the diclofenac patch on the anterior abdominal wall about 5cm from the

operation site and reapplied every 12 hours and an injection of 1ml of water for injection (placebo for pentazocine) every 4 hours. All interventions were for a total of 48 hours. Postoperative pain was assessed using the visual analogue scale (VAS) score at the 2<sup>nd</sup>, 6<sup>th</sup>, 10<sup>th</sup>, 16<sup>th</sup>, 24<sup>th</sup> and 48<sup>th</sup> hour. Additional doses of intramuscular pentazocine 30mg were used as rescue analgesia if VAS >8. Other outcome measures such as adverse effect profile and timing of initiation of breast feeding were also monitored.

The result was analyzed using the Statistical Package for Social Sciences (SPSS) version 23 (IBM Corp 2015). (IBM Corp 2015). Data was presented in tables and charts, while continuous data like age were summarized with mean and standard deviation. Categorical variables like educational status were summarized using proportions and percentages. Test of association of categorical variables were analyzed using Chi-square tests where appropriate while continuous data was analyzed using unpaired T-test if parametric or Mann Whitney if non-parametric. The statistical significance was inferred at P value <0.05.

**Results:** A total number of 120 patients participated in the study with 60 patients in each arm of the study. There was no statistical difference in the mean pain scores between the two arms of the study at different point of monitoring;  $p = 0.949$  at the 2<sup>nd</sup> hour post operatively and  $p = 0.5$  at the 16<sup>th</sup> hour postoperatively. Patient satisfaction was better in the pentazocine group with 30 patients indicating excellent satisfaction level, however this difference was not statistically significant when comparing the two groups. There was a statistical difference in the duration from surgery to bowel sounds on auscultation, with the diclofenac patch group showing shorter durations. ( $p = 0.001$ ). Furthermore, maternal side effect such as dizziness and excessive sleep in the newborn were significantly higher in the pentazocine group ( $p = 0.001$ ).

**Conclusion/Recommendation:** There was comparable analgesic efficacy in both the pentazocine and diclofenac patch group, though the pentazocine group had lower pain scores overall, this difference was not statistically significant. Moreover, the diclofenac patch group was associated with fewer side effects. The diclofenac patch group should be considered as a viable option in postoperative analgesia after cesarean section.

## Flow chart

### Enrollment

Assessed for eligibility (n= 141 )

Excluded (n= 18 )

- ♦ Not meeting inclusion criteria (n= 10)
- ♦ Declined to participate (n= 8)

Randomized (n= 123)

### Allocation

Allocated to intervention (n= 62)

- ♦ Received allocated intervention (n=60)
- ♦ Did not receive allocated intervention (n=2)
  - Cancelled surgery (n=2 )

Allocated to intervention (n=61 )

- ♦ Received allocated intervention (n= 60)
- ♦ Did not receive allocated intervention (n=1)
  - Cancelled surgery (n=1 )

Lost to follow-up (n=0 )

- Non-compliance(n=0)

### Follow-Up

Lost to follow-up (n= 0)

- Non-compliance(n=0)

### Analysis

Analysed (n= 60)

- ♦ Excluded from analysis(n=0 )

Analysed (n=60)

- ♦ Excluded from analysis (n= 0)

# Complications of the treatment

Complications of the medications	Diclofenac (n=60)	Pentazocine (n=60)	X <sup>2</sup>	P value
Drowsiness	-	14(23.33)	7.963	0.001
Nausea	-	-		
Rash	-	-		
Respiratory distress	-	-		
Excessive Sleeping in newborn	-	7(11.67)	7.434	0.001

## **Outcome measures**

- a. Primary outcome measure was mean visual analogue score.
- b. Secondary outcome measures included patient need for rescue analgesia, maternal side effect profile, patient satisfaction and timing of initiation of breastfeeding.