

Analgesic Efficiency of Transdermal Patches of Fentanyl and Diclofenac in Impacted Mandibular Third Molar Surgery - A Comparative Study

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Aim: This study aimed to compare the effectiveness of fentanyl transdermal patches versus diclofenac transdermal patches in managing postoperative pain following simultaneous removal of bilaterally impacted lower third molars. **Materials and Methods:** Sixty patients undergoing bilaterally impacted lower third molar surgery were included. Postoperatively, patients were randomly assigned to receive either a fentanyl patch or a diclofenac patch. Pain intensity was assessed using a 10 cm visual analog scale (VAS) on days 1, 3, and 5 after surgery. Analgesic consumption was also recorded. **Results:** The study found that patients treated with the fentanyl transdermal patch reported significantly lower postoperative pain intensity and used fewer analgesics compared to those using diclofenac patches ($p < 0.05$). Furthermore, the duration of effective postoperative pain relief was significantly longer in the fentanyl group ($p < 0.05$). **Conclusions:** These findings suggest that the fentanyl transdermal patch provides more effective pain relief following third molar surgery compared to diclofenac transdermal patches.

Keywords: Transdermal Patches, molar surgery, diclofenac transdermal, analgesia.

1. Introduction

Extraction of impacted lower third molars is a common oral surgical procedure often associated with significant postoperative pain [1-3]. This pain has been extensively studied to evaluate various drugs and methods for effective analgesia. Despite advancements in pain management, managing moderate-to-severe acute postoperative pain remains a challenge, prompting the exploration of innovative approaches like transdermal drug delivery [4,5].

Fentanyl, a potent Schedule II opioid, has been utilized in transdermal patches since 1984. Known for its efficacy in treating severe chronic pain, fentanyl has also shown promise in managing certain types of postoperative pain. The Fentanyl Transdermal System (FTS) consists of a rectangular patch containing a high concentration of fentanyl within a gel reservoir. This patch includes a release membrane that controls the gradual absorption of the drug through the skin over a period of 72 hours, ensuring a sustained and consistent analgesic effect[6-10].

The dosage of the fentanyl patch is 25 µg per hour. Its low molecular weight, high potency, and lipid solubility facilitate rapid absorption into subcutaneous fat upon application to intact skin. From there, fentanyl is gradually released into the bloodstream, with peak plasma concentrations typically achieved between 24 and 72 hours post-application [11-14].

This comparative study highlights the potential efficacy of transdermal fentanyl patches in managing postoperative pain following lower third molar surgery.

2. Materials and methods

This preliminary comparative study was conducted at the Clinic of Oral Surgery, in saveetha dental college and hospitals. 60 adult patients aged between 18 and 36 years, all requiring bilateral surgical removal of impacted lower third molars, participated after obtaining approval from the local Ethics Committee Each patient provided informed consent before enrollment.

Randomization was achieved using sealed envelopes containing random assignments for each tooth and the postoperative pain control protocol. Both the surgical operator and patients were blinded to the use of the Fentanyl Transdermal System (FTS).

Inclusion criteria:

- Bilateral impacted lower third molars in identical positions.
- Good physical and mental health (ASA I).
- Absence of infection (pericoronitis) or prior trauma.

Exclusion criteria:

- Allergy to study medications.
- Recent use of anti-inflammatory or antimicrobial drugs.
- Pregnancy or lactation.
- History of alcohol or drug abuse.
- Lack of compliance with study procedures.

Preoperative assessments included panoramic radiographs to confirm the symmetrical position of lower third molars on both sides. Measurements of mouth opening and facial cheek diameter were recorded using standard methods.

Surgical Procedure:

Each patient underwent separate surgical extractions of position B, class 2, mesioangular impacted third molars, with approximately two weeks between procedures. All surgeries were performed under local anesthesia (2% lidocaine chloride with adrenaline 1:80,000), without sedation or premedication, by the same surgeon to minimize variability. Surgical techniques included mucoperiosteal flap elevation, bone removal, and tooth extraction, as necessary. The surgical details, including the procedure duration, were meticulously recorded.

Postoperative Regimen and Assessments:

Postoperative pain management was randomly assigned into two groups: group and control group. After the first surgery, the fentanyl transdermal patch group received a transdermal fentanyl patch (fendrop 25mcg Sun Pharmaceutical Industries Ltd) and a placebo tablet. Following the second surgery, patients received a placebo patch and an oral non-steroidal anti-inflammatory drug (Dicloplast 100mg, (Zuventus Healthcare Ltd) once daily.

Postoperative Management:

Patients were instructed to take an additional analgesic tablet when their pain reached a moderate level, and the exact time of taking each additional dose was recorded. All patients received oral amoxicillin 500 mg every 8 hours for 5 days as antimicrobial prophylaxis. They were also advised to use chlorhexidine mouth rinse twice daily for 10 days starting the day after each surgery. Standard postoperative instructions were provided to each patient.

Follow-up Evaluation:

Each patient was assessed 24 hours after surgery during a follow-up visit. Postoperative pain levels were evaluated using a 100 mm visual analog scale (VAS) ranging from "no pain" at the left end to "extremely severe pain" at the right end. The same examiner, who conducted preoperative assessments, measured clinical outcomes during follow-up, including trismus (mouth opening) and facial edema. Differences between preoperative (baseline) and postoperative (24 hours) measurements were recorded.

Statistical Analysis:

Data analysis was performed using SPSS version 20.0 (SPSS Inc., Chicago, IL, USA). The normality of the data distribution was assessed using the Shapiro-Wilk test. Differences between the two treatment groups were analyzed using either the Wilcoxon signed-rank test for paired samples or the paired t-test, based on the normality of the data. Categorical variables were analyzed using the χ^2 test. Statistical significance was set at $p < 0.05$.

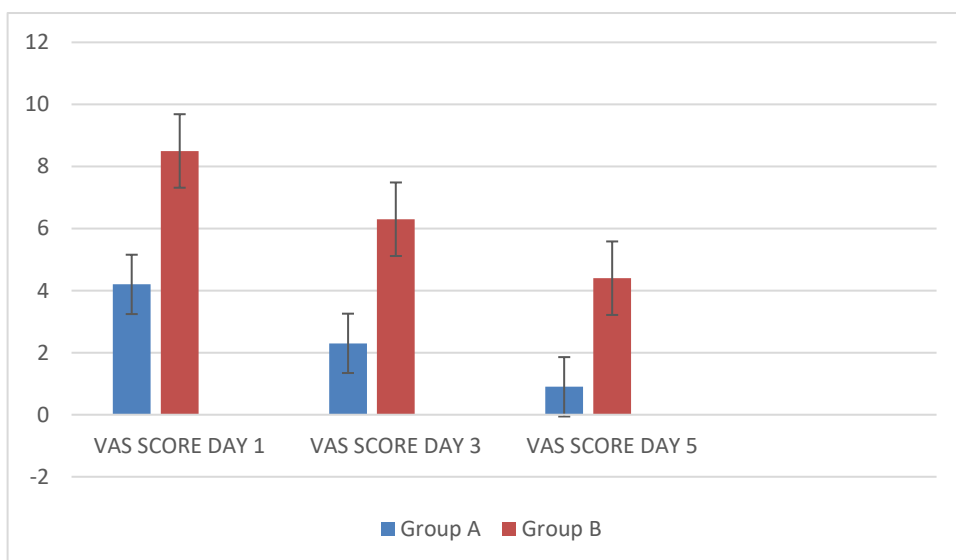
3. Results:

Data from a total of 60 patients (32 females and 28 males) were analyzed, with a mean age of 23.8 ± 7.3 years. There were no statistically significant differences between the study groups in terms of surgical duration during both sessions. All patients had an uneventful postoperative recovery.

Pain Management Outcomes:

Patients who received a fentanyl transdermal patch reported significantly less postoperative pain compared to those who received only a non-steroidal anti-inflammatory drug, as assessed by the Visual Analog Scale (VAS) after 24 hours. This difference was statistically significant.

VARIABLES	GROUP A	GROUP B	P- VALUE
VAS SCORE ON DAY 1	4.2 ± 0.62	8.4 ± 0.43	0.005*
VAS SCORE ON DAY 3	2.3 ± 1.03	6.7 ± 1.9	0.003*
VAS SCORE ON DAY 5	0.9 ± 1.6	4.4 ± 12.3	0.004*



Swelling and trismus:

There were no statistically significant differences between the groups in terms of postoperative facial swelling and trismus.

4. Discussion:

Postoperative pain significantly impacts patient quality of life following lower third molar surgery, with patients often rating it as the most troublesome symptom. While numerous studies have explored various analgesics for pain control over time, there remains a gap in evaluating the effectiveness of the fentanyl transdermal patch specifically for acute postoperative pain management in this context [15-16]. FTS, proven effective in chronic pain management, is theorized to be beneficial for patients with severe trismus or gastrointestinal issues like ulcers, though there is limited literature on its use for acute postoperative pain after lower third molar surgery [17-18].

Adverse events associated with transdermal fentanyl use include therapeutic misuse and abuse, characterized by intentional misuse for euphoric purposes or, rarely, for suicidal reasons [19, 20]. These incidents may lead to serious side effects such as skin irritation, nausea, fever, headaches, and potentially life-threatening respiratory depression. Temperature elevations from external sources can also increase fentanyl absorption, potentially causing an overdose.

In our study, patients were thoroughly informed about the procedure and monitored closely, with a few cases of nausea reported during movement, promptly managed upon cessation of activity. Other side effects were minimal [21, 22].

The choice of application site for FTS is crucial, considering variations in skin thickness and permeability across different body areas. The upper arm was selected as the application site in our study after careful examination.

5. Conclusion:

In conclusion, our preliminary findings suggest that FTS effectively manages postoperative pain after lower third molar surgery with good tolerability. However, larger clinical trials are warranted to establish its standard use in acute pain management following oral surgery.

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