Indian Journal of Clinical Anaesthesia 2024;11(4):557–564

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Indian Journal of Clinical Anaesthesia

Journal homepage: www.ijca.in

Original Research Article

A prospective comparitive study of transdermal patches for post operative pain management in laprotomy surgeries: efficacy and rescue analgesic requirements

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ARTICLE INFO

Article history:
Received 17-05-2024
Accepted 03-09-2024
Available online 07-11-2024

Keywords:
Fentanyl
Buprenorphine
Diclofenac
Ketoprofen
Rescue analgesia
Laparotomy surgery
Patch
Sedation
VAS

ABSTRACT

Background: The word laparotomy is derived from the Greek words lapara, meaning flank, and tomy, meaning cut. In surgical practice, this translates to a big cut in the abdomen to gain access to the peritoneal cavity. Pain continues to be a significant problem following laparotomy. Transdermal drug delivery has several advantages over oral and parenteral administration.

Aim & Objective: A randomized comparative study to evaluate and compare the efficacy of various transdermal patches (Fentanyl, Buprenorphine, Diclofenac and Ketoprofen) for post operative pain relief in laparotomy surgeries.

Materials and Methods: A total 80 patients of ASA grade I & II with age between 20-60 of either sex who were undergoing laparotomy surgery were randomly divided into 4 groups Group F (Fentanyl), Group B (Buprenorphine), Group D (Diclofenac) & Group K (Ketoprofen) using a computer-generated randomization list. Anesthetic procedure was standardized in all groups. group F received 25μg/hr Fentanyl patch, group B received 20μg/hr Buprenorphine patch, group D received 200mg Diclofenac patch and group K received 20mg Ketoprofen patch, applied postoperatively. Patients were followed for 72 hours postoperatively and pain was assessed using the visual analogue scale (VAS) and Sedation was assessed using Ramseys sedation scoring system.

Results: Group D (Diclofenac) and Group K (Ketoprofen) required more frequent rescue analgesics and daily patch replacements. Group F (Fentanyl) had the least analgesic requirements, with a single patch lasting for 72 hours. Group B (Buprenorphine) had similar duration of action, but produced more sedation as compared to Group F (Fentanyl). VAS score and pain relief were highest in Group F (Fentanyl), with minimal side effects when compared to other groups.

Conclusion: The transdermal fentanyl patch provides effective post operative analgesia with minimal side effects and lower rescue analgesic requirements over 72 hours.

1. Introduction

The word laparotomy is derived from the Greek words lapara, meaning flank, and tomy, meaning cut. In surgical practice, this translates to a big cut in the abdomen to gain access to the peritoneal cavity. The abdominal wall encloses the abdominal cavity and protects the abdominal viscera. The layers of the anterior abdominal wall which may be encountered in a laparotomy include the following from superficial to deep: skin, subcutaneous fat, fascia of Camper, fascia of Scarpa, external oblique muscle, internal oblique muscle, rectus abdominis muscle, transverse abdominis muscle, pyramidalis muscle, transversalis fascia, and peritoneum.

Pain continues to be a significant problem following laparotomy.[1,2] In this era of fast track surgery, the ERAS

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https://doi.org/10.18231/j.ijca.2024.100

(enhanced recovery after surgery) group has suggested that a multimodal rehabilitation programme with epidural analgesia, short laparotomy, early feeding and early mobilisation improve outcomes after elective colonic surgeries.[3] Emergency laparotomy is a common intra-abdominal procedure, with generally poor outcomes[4] and this group is demanding with time and resources.Pain is the most symptom experienced by a patient after surgery. Mechanical and thermal injury to tissue causes release of analgesic substances (prostaglandin, histamine, serotonin, bradykinin, 5-hydroxytriptamine, substance P) and generation of noxious stimuli that are transduced by nociceptors and transmission to the neuraxins by A delta and C nerve fibers.[5]

Post operative good analgesia improves the quality of life, reduces the morbidity and provides greater comfort, allowing for rapid recovery and early return of patients to daily routine. This can be done using non-steroidal anti-inflammatory drugs, opioids or combination.[6]

Transdermal drug delivery has several advantages over oral and parenteral administration. It's a noninvasive adhesive skin patch which avoids gastrointestinal tract and lacks first pass metabolism, it also helps in maintaining sustained blood level of drug.[7] Steady and continuous drug delivery can avoid potential side effects associated with repeated doses, additionally it reduces dose frequency which causes increased compliance and convenience.[8] Transdermal patch applied topically penetrates skin, subcutaneous fatty tissue, muscle and finally reaches the blood stream in amounts sufficient to cause therapeutic effects without reaching higher plasma drug concentration when compared to other routes.[9,10]

Opioids are commonly used for chronic pain management in various routes.[11] Buprenorphine is a partial agonist with very affinity for opioid receptors for which it has got a long duration of action, it has a ceiling analgesic effect and if given in greater than optimum doses it increases the side effects and reduces the analgesic effect.[12] Fentanyl is a pure agonist and is more potent than morphine.[13] It has more rapid onset of action. Fentanyl doesn't appear to have active metabolites and is suitable for patients with renal dysfunction, but dose reduction should be considered.[14] Diclofenac is a non-steroidal anti-inflammatory drug which acts by inhibition of prostaglandin synthesis by blocking the activity of cyclooxygenase. Oral diclofenac carries risk of hepatic first pass metabolism and there is loss of 50% qualities of drug before it gets absorbed systemically.[15,16] Due to high plasma concentrations[17,18] after oral administration of tablet diclofenac there can be significant risk of adverse effects particularly in gastrointestinal tract and kidney.[19,20] Ketoprofen is a propionic acid derivative which has analgesic and antipyretic effects. ketoprofen transdermal patches in various doses have been found to be more effective in traumatic and nontraumatic patients without additional side effects.[21]

2. Materials and Methods

A total of 80 patients undergoing laparotomy surgery were randomly divided into four groups using a computer-generated randomization list and included in the study. The inclusion criteria were patients scheduled for laparotomy surgery, with ASA physical status I or II, of either sex, and aged between 20-60 years. The exclusion criteria were patients unwilling to provide written informed consent, those with a history of allergy to NSAIDs or opioids, patients with an active peptic ulcer within the last six months, patients with systemic diseases such as renal disease, bronchial asthma, stroke, epilepsy, hepatic failure, psychological diseases, pregnant patients, patients younger than 20 years or older than 60 years, and those with a history of alcohol or opioid abuse.

This study was a prospective, randomized, comparative single-blinded observational study. Patients in group F (Fentanyl) received a 25 μg/hr patch, those in group B (Buprenorphine) received a 20 μg/hr patch, those in group D (Diclofenac) received a 200 mg patch, and those in group K (Ketoprofen) received a 20 mg patch.

Pre anesthetic checkup was done for all the patients a day before the surgery. Routine laboratory investigations like hemoglobin concentration, platelet count, leucocyte count, blood sugar, electrocardiogram, urea, creatine, bleeding time, clotting time, blood grouping, chest Xray, serum electrolytes and liver function tests were checked. Patients were explained about VAS (Visual Analogue Score) which is a 10 cm scale having pain index from 0 to 10, in which 0 indicating no pain and 10 indicating severe to excruciating pain as shown in (Figure 1).

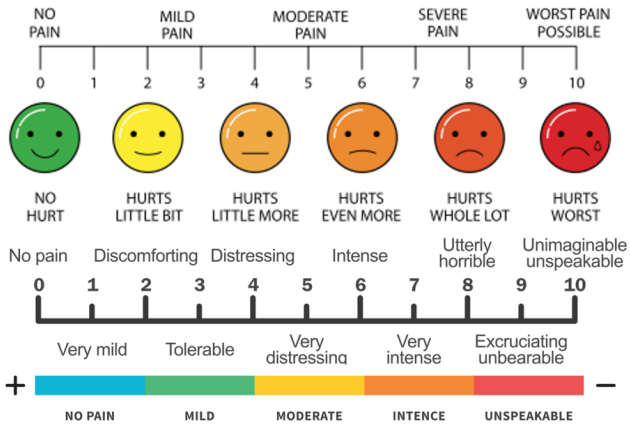


Figure 1: Visual analogue score (VAS)

Patients were taken up for surgery after adequate starvation of 8 hrs. Preoperative vitals were checked. Once shifted into the operation theatre intravenous access was

established using 18G cannula, all noninvasive monitoring's like pulse, blood pressure, saturation, respiratory rate, temperature and electrocardiogram were attached.

Anesthetic procedures were standardized across all groups, including premedication, induction, and maintenance protocols. Patients were premedicated with glycopyrrolate 0.01 mg/kg, ondansetron 0.1 mg/kg, midazolam 0.05 mg/kg, and fentanyl 100 μg. After preoxygenation with 100% oxygen for 3 minutes, general anesthesia was induced with propofol 2 mg/kg. Once sufficient mask ventilation was established, patients were paralyzed with vecuronium 0.1 mg/kg and oxygenated for an additional 2 minutes.

Direct laryngoscopy was performed, and after visualization of the vocal cords, tracheal intubation was completed using an endotracheal tube. The cuff was inflated with air through the pilot balloon, and correct placement of the tube was confirmed with a capnogram. The tube was fixed after ensuring bilateral air entry.

Patients were placed on a ventilator in volume control mode, and anesthesia was maintained with a mixture of 50% oxygen and nitrous oxide, sevoflurane (MAC 1 to 1.2), and vecuronium as a muscle relaxant at a rate of 0.02 mg/kg infusion. Depending on the duration of surgery, an arterial line was placed in some patients for invasive arterial blood pressure monitoring.

Upon completion of the surgical procedure, patients were extubated using a combination of neostigmine (0.05 mg/kg) and glycopyrrolate (0.01 mg/kg) for reversal of neuromuscular blockade. Patients were then shifted to the recovery room, where continuous monitoring of vital signs, including pulse oximetry, blood pressure, and electrocardiogram, was conducted. Once the vital parameters were confirmed to be within normal ranges, a transdermal patch was applied to a clean, hair-free area on the upper arm, chest, or back. The type of transdermal patch applied was determined randomly using a computer-generated randomization list. In addition to their routine medications, patients were provided with inj. tramadol SOS, to be administered if they reported pain, as it would take some time for the peak therapeutic levels of the transdermal patches to be reached.

Pain was assessed using the Visual Analog Scale (VAS), and sedation was evaluated using Ramsay's Sedation Scale as shown in (Figure 2).

Continuous hemodynamic monitoring was conducted throughout the postoperative period. Pain was assessed using the Visual Analog Scale (VAS) at specific intervals: hourly for the first 4 hours, every 4 hours for the next 24 hours, and then every 12 hours up to 72 hours postoperatively. If the VAS score exceeded 5, rescue analgesia was administered. The time until the first requirement for rescue analgesia was documented, along with the total number of transdermal patches and rescue analgesic doses required within the first 72 hours.

RAMSAY SEDATION SCALE

Score	Level of Sedation
1	Patient is anxious and agitated or restless, or both
2	Patient is co-operative, oriented, and tranquil
3	Patient responds to commands only
4	Patient exhibits brisk response to light tactile stimuli or loud auditory stimulus
5	Patient exhibits sluggish response to light tactile stimuli or loud auditory stimulus
6	Patient exhibits no response

Figure 2: Ramsay sedation scale

Side effects such as nausea, vomiting, pruritus, sedation, and respiratory depression were closely monitored and recorded. The level of sedation was also assessed during this period using Ramsay's Sedation Scale.

2.1. Statistical analysis

Sample size calculation:

$$N = \frac{(Z_{\alpha/2}+Z_{1-\beta})^2\, 2\sigma^2}{d^2}$$

Standard deviation (σ)	0.750
Expected difference (Δ)	1.100
Significance level (α)	0.050
Power (1-β)	0.950
Drop-out	10%
Sample size	20
Sample size (with drop-out)	23

Data from all groups were collected and statistically compared using ANOVA. Statistically significant differences between the groups were determined with a significance level (α) of 0.05 and a study power of 95%.

3. Results

A total of 80 patients were randomly divided into 4 groups. Males were 49 and females were 31. The demographic profile of patients was comparable between 4 groups and found no statistically significant difference ($p > 0.05$) as shown in (Table 1).

3.1. Visual analog scale (VAS) scores

The standard deviation of VAS scores was recorded for each study group. The mean VAS score immediately after surgery (0 hours) showed no significant difference between the groups. However, differences were observed at subsequent time points as detailed in (Graphs 1 and 2 and Tables 2 and 3 . The statistical test used to compare VAS scores among the groups was ANOVA (Analysis of Variance), followed by post-hoc pairwise comparisons to determine specific differences between groups.

Table 1: Demographic profile of patients

Characteristics	Group F	Group B	Group D	Group K	P -Value
Age in years	40.8 ± 9.2	40.3 ± 9.7	39.5 ± 10.5	38.6 ± 11.4	P > 0.05
Sex (M / F)	12/8	14/6	10/10	13/7	P > 0.05
ASA Grade I/II	14/6	13/7	12/8	15/5	P > 0.05
Weight	50.3 ± 10.7	48.6 ± 12.8	52.7 ± 8.3	51.1 ± 9.9	P > 0.05
Heart rate	87.1 ± 7.4	88.7 ± 8.3	86.4 ± 8.8	84.2 ± 10.5	P > 0.05
SBP	126.5 ± 4.8	126.7 ± 8.3	121.6 ± 11	122.2 ± 6.2	P > 0.05
DBP	82.4 ± 7	81 ± 7.6	83.2 ± 6.2	80.8 ± 8.2	P > 0.05

Table 2: Mean VAS among the groups

Time (Hours)	Group D	Group B	Group F	Group K
1	2	3	3	1
2	2	3	3	1
3	0	2	2	0
4	0	1	2	0
8	0	0	0	0
12	2	0	0	0
16	3	0	0	2
20	3.5	0	0	3
24	2	2	2	1
36	2	3	2	3
48	5	4	3.5	4.5
60	3	2	4	3
72	5	3	1	4

Table 3: Summary of VAS scores and statistical comparisons

Time	Group F vs Group D	Group F vs Group B	Group F vs Group K
1 Hour	p = 0.0032 (Significant)	p = 0.7055 (Not significant)	p = 0.0002 (Significant)
2 Hours	p = 0.0494 (Significant)	p = 0.8206 (Not significant)	p = 0.0082 (Significant)
3 Hours	p = 0.0065 (Significant)	p = 0.5967 (Not significant)	p = 0.0052 (Significant)
4 Hours	p = 0.0032 (Significant)	p = 0.1306 (Not significant)	p = 0.0065 (Significant)
8 Hours	p = 0.0413 (Significant)	p = 0.0696 (Not significant)	p = 0.0494 (Significant)
12 Hours	p = 0.0005 (Significant)	p = 0.5453 (Not significant)	p = 0.0821 (Not significant)
16 Hours	p = 0.0002 (Significant)	p = 0.9397 (Not significant)	p = 0.0002 (Significant)
20 Hours	p = 0.0002 (Significant)	p = 0.2568 (Not significant)	p = 0.0002 (Significant)
24 Hours	p = 0.9397 (Not significant)	p = 0.1988 (Not significant)	p = 0.0102 (Significant)
36 Hours	p = 0.8206 (Not significant)	p = 0.0494 (Significant)	p = 0.0012 (Significant)
48 Hours	p = 0.0065 (Significant)	p = 0.1509 (Not significant)	p = 0.0284 (Significant)
60 Hours	p = 0.2265 (Not significant)	p = 0.0005 (Significant)	p = 0.2265 (Not significant)
72 Hours	p = 0.0002 (Significant)	p = 0.0002 (Significant)	p = 0.0002 (Significant

3.2. Interpretation of results

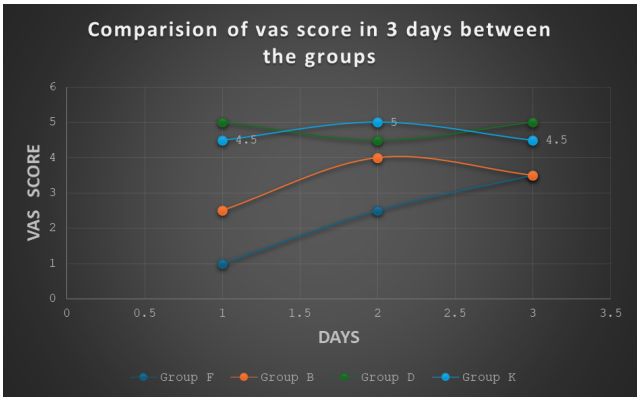
1. Group F vs D: Significant differences at most time points (1, 2, 3, 4, 8, 12, 16, 20, 48, 72) indicate that Group F (Fentanyl) had lower VAS scores compared to Group D (Diclofenac).
2. Group F vs B: Significant differences were noted at 36, 60, and 72 hours, with Group F showing better pain control compared to Group B (Buprenorphine) at these times.
3. Group F vs K: Significant differences observed at multiple time points (1, 2, 3, 4, 8, 16, 20, 24, 36, 48, 72) suggest that Group F provided more consistent pain relief compared to Group K (Ketoprofen).

The standard deviation of VAS scores showed no significant differences between the groups immediately after surgery (0 hours). At 2, 4, and 8 hours, the mean VAS scores were lower for groups D and K, as initially NSAIDs worked faster than the opioids in groups F and B. At 12 hours, VAS scores began to decrease for groups F and B as the opioid patches took effect, and all patients felt comfortable. However, by 16 hours, VAS scores started to rise in groups D and K, particularly in group D, while groups F and B remained comfortable.

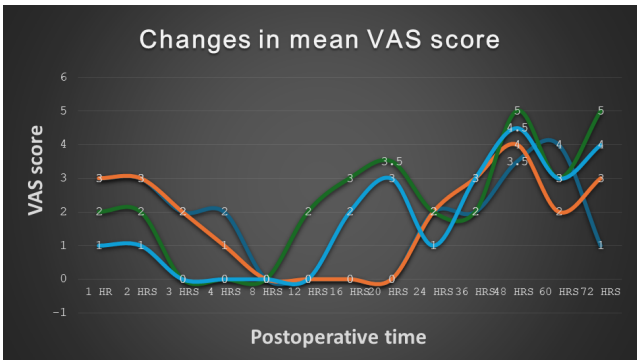
At 20 hours, 15 patients in group D and 10 in group K needed rescue analgesia, while those in groups F and B did not. To manage pain better, new patches were applied for groups D and K, and this process continued for 72 hours. At 24 hours, 10 patients in group K and 5 in group D needed rescue analgesics, while patients in groups F and B remained comfortable. By 48 hours, 13 patients in group B and 9 in group F required rescue analgesia, but the patches were still effective, as fentanyl lasts for 3 days and buprenorphine for 7 days.

By 60 hours, nearly all patients in group B and around 5 in group F needed rescue analgesia

Patients in Group F (Fentanyl) experienced more consistent pain control compared to those in the other groups. The mean VAS score was consistently lowest in Group F across all time intervals, indicating superior pain management.



Graph 1: VAS score comparison between the groups



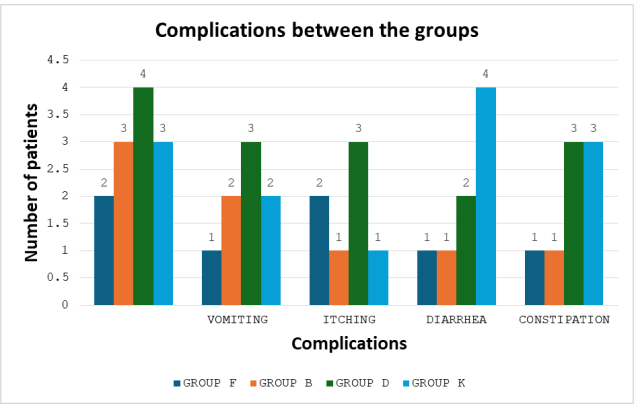
Graph 2: VAS score 1st hour to 72 hours postoperatively

3.3. Incidence of complications and adverse drug reactions

The incidence of complications and adverse drug reactions associated with the transdermal patches varied among the different study groups. The observed complications included nausea, vomiting, itching, diarrhea, and constipation. The distribution of these adverse events is summarized below and illustrated in (Graph 3).

1. **Nausea**: The highest incidence of nausea was observed in Group D, while Group F reported the lowest incidence.
2. **Vomiting**: Group D experienced the highest rates of vomiting, whereas Group F had the lowest.
3. **Diarrhea**: The highest incidence of diarrhoea was reported in Group K.
4. **Constipation and Itching**: Data for constipation and itching are also shown in (Graph 3).

Overall, the frequency of complications was minimal in Group F compared to the other groups. This indicates that the transdermal patch used in Group F was associated with fewer adverse effects overall.

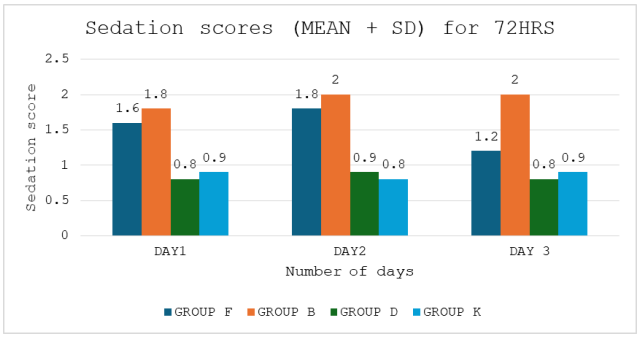


Graph 3: Complications between the groups

Ramseys Sedation score was comparable between the groups as patients in group F and group B were comfortable as compared to patients in group D and group K who had minimum or no sedation. In group B sedation was more over a period of 3 days and patients were comfortable as compared to other groups as shown in (Graph 4). The P-value for ANOVA test comparing the mean sedation scores among the four groups over time is approximately 1.709.

4. Discussion

Laparotomy is considered one of the most painful surgical procedure, providing effective analgesia and making the patient comfortable post operatively is the onus for all anaesthesiologists. Noxious stimuli like surgical incision produces excitatory changes in central nervous system and sensitize them to subsequent input. Once sensitization is established, pain response is accentuated and pain is felt following sub noxious stimulation. It has been proven that if adequate analgesia is given intraoperatively development of central sensitization is blocked and



Graph 4: Sedation scores

subsequent post operative analgesia becomes profound. Pain at movement remains a significant issue following emergency laparotomies. Opioids remain the mainstay of pain management following these surgeries. The choice of pain management is not linked to the time of surgery, patient factors including ASA physical grading and p-Possum scores. Worldwide emergency laparotomies are associated with poor outcomes and prolonged hospital stay.[22,23] There is a lack of standardised protocol for this vulnerable group and there is a need to develop an enhanced recovery programme for these patients.[24] A comprehensive bundle including preoperative optimisation, surgical intervention and postoperative care can potentially improve outcomes in this group of patients and needs attention.[25]

In laparotomy patients analgesia can be administered as boluses or continuous epidural infusion or patient controlled systems like PCA (patient controlled analgesia). The use of adhesive skin patches to deliver drugs systematically and are safe and convenient for post operative analgesia is new technique and for than fentanyl, buprenorphine, diclofenac and ketoprofen are most commonly used. Transdermal drug delivery system is preferable to parental and oral drug delivery methods as it avoids multiple dosing and skin punctures. It allows continuous drug delivery to plasma without first pass metabolism thereby avoiding peaks and troughs in plasma levels of the drug. Decreases incidence of breakthrough pain by providing sustained pain relief and thereby decreases the requirement of rescue analgesics.

Fentanyl patches are designed to deliver fentanyl at constant rate ranging from 25 to 100 μg/hr. after initial application a depot of fentanyl forms in the upper skin layers and serum fentanyl concentrations increasing gradually and maximum plasma concentration achieved between 12-24 hrs. Analgesic effect lasts up to 3 days. Concentrations are found to be higher in first 24hrs and decrease on 2^{nd} and 3^{rd} day due to decreasing concentration gradient between patch and skin. Fentanyl delivery is not affected by local blood supply. Increase in body temperature causes increase in absorption rate.[26,27]

Buprenorphine is a semi synthetic opioid analgesic. It is partial agonist at the mu opioid receptor and its analgesic efficacy is comparable with the usual doses of other opioids such as pentazocine, morphine and pethidine.[27,28] Buprenorphine patches are available in three different strengths in India namely 5, 10 and 20 μg/hr.[29] Patches with higher strengths have proportionately larger area and usually last for 7 days.

The transdermal route represents a novel drug delivery mechanism for NSAIDs, offering an alternative to traditional oral and other forms of administration. This method allows for the steady absorption of the drug through the skin, where it diffuses into the capillaries and achieves systemic absorption. This steady, controlled release of the medication aligns with therapeutic goals by maintaining consistent drug levels in the bloodstream, potentially improving efficacy and reducing the risk of adverse effects associated with fluctuating drug concentrations.[30,31] Diclofenac retards prostaglandin synthesis by inhibiting cyclooxygenase-1 COX-1 and COX-2 with relative equipotency, whereas ketoprofen, other than inhibiting COX, also inhibits the lipoxygenase pathway of the arachidonic acid cascade, thereby reducing the synthesis of leukotrienes. It is a potent inhibitor of bradykinin and prevents the release of lysosomal enzymes by stabilizing the lysosomal membranes against osmotic damage, thus decreasing inflammatory reactions.[32] Osterwalder et al. (2002) studied the absorption and distribution of ketoprofen following patch application in patients undergoing knee arthroscopy or endoscopic carpal ligament release. They found that ketoprofen, when applied topically, penetrates the skin and reaches subcutaneous and intra-articular tissues at significantly higher concentrations than in the plasma. This localized delivery achieves the desired therapeutic effect while maintaining plasma levels low enough to prevent systemic adverse effects.[33]

Our findings are consistent with those reported by Vladimir S. Todorvic et al. who evaluated the efficacy of fentanyl transdermal patches in third molar surgery. Their study concluded that the fentanyl transdermal system significantly reduced postoperative pain following third molar extraction.[34] Similarly, Arshad et al. conducted a comparative study between transdermal buprenorphine and transdermal fentanyl for postoperative pain relief after major abdominal surgeries. They found that the VAS scores for pain were significantly lower in the fentanyl group compared to the buprenorphine group from day 1 to day 3.[35] Verma et al. compared the efficacy of single-dose transdermal patches of diclofenac (100 mg) and ketoprofen (20 mg) for postoperative analgesia following lower limb orthopedic surgery under spinal anesthesia. They found that both diclofenac and ketoprofen patches were effective for pain relief. However, patients in the diclofenac group required more rescue analgesics compared to those in the ketoprofen group. These findings are consistent with our results as well.[36]

The incidence of complications and adverse drug reactions varied among the study groups, with nausea and vomiting being most frequent in Group diclofenac, and the lowest rates observed in Group fentanyl. Diarrhoea was most common in Group ketoprofen. Overall, the data suggest that the fentanyl group experienced the fewest complications, indicating its relative safety compared to the other transdermal patches used in this study.

The buprenorphine patch offers extended pain relief compared to fentanyl, diclofenac, and ketoprofen patches, but the fentanyl patch is more effective as an analgesic. Patients using fentanyl and buprenorphine patches were generally calm, comfortable, and easily arousable throughout the study. While sedation scores were slightly higher in the buprenorphine group compared to the fentanyl group, no sedation was observed in the diclofenac and ketoprofen groups. Additionally, the need for rescue analgesics and incidence of side effects were notably lower in the fentanyl group compared to the other patches.

5. Conclusion

The transdermal patches of fentanyl 25μg/hr, buprenorphine 20μg/hr, diclofenac 200mg & ketoprofen 20mg were all safe and provided effective for post operative pain relief in laparotomy patients. Fentanyl transdermal patches (25 μg/hr) are the most effective and safest option for postoperative pain management in laparotomy patients, significantly reducing the need for rescue analgesics compared to other transdermal patches. Diclofenac and ketoprofen patches, which last about 24 hours, require more frequent replacements and have higher side effect profiles. Buprenorphine patches offer a cost-effective, long-term solution but are associated with more adverse effects. For settings with restricted access to narcotics, such as secondary health centers or private clinics, NSAID patches like diclofenac and ketoprofen are viable alternatives. However, for patients undergoing surgery in tertiary centers, fentanyl patches provide superior pain relief and are preferred for their efficacy and safety.

6. Limitations of the Study

The study's sample size was limited, and the follow-up duration was short, which restricts the ability to generalize the findings to a larger population. Additionally, the study relied on subjective score values reported by the patients, making it susceptible to participant bias that could not be fully controlled.

7. Financial Implications

The patients are managed according to the protocol laid down for the management of the patient. There are no financial implications. There was no financial support or sponsorship.

8. Conflict of Interest

There are no conflicts of interest.

9. Ethical and Legal Consideration

A patient information and consent was given to the patients in their local language, all their queries were satisfactorily answered and when they were willing to participate, signature of the patient or her husband/guardian was obtained and only after that study was initiated.

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Cite this article: Gollamudi U. A prospective comparitive study of transdermal patches for post operative pain management in laprotomy surgeries: efficacy and rescue analgesic requirements. *Indian J Clin Anaesth* 2024;11(4):557-564.