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ORIGINAL RESEARCH ORTHOPEDIC ANESTHESIA

Patch versus pump: Evaluating efficacy, satisfaction level and safety of transdermal fentanyl patch versus intravenous morphine with PCA pump for acute postoperative pain in orthopedic surgery

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ABSTRACT

Background & objective: Transdermal Fentanyl Patches (TFP) are commonly used in chronic cancer pain management. TFP offer a sustained delivery of fentanyl, due to its high lipid solubility for efficient transdermal administration. This non-invasive analgesic method is particularly advantageous for severe postoperative pain, delivering fentanyl consistently and matching morphine's effectiveness while minimizing side effects. This study was conducted to compare the effectiveness, patient satisfaction and safety of TFP versus Patient-Controlled Analgesia (PCA) IV morphine for managing acute postoperative pain in orthopedic surgery.

Methodology: This retrospective study compares the effectiveness, satisfaction and safety of TFP versus intravenous (IV) Patient-Controlled Analgesia (PCA) morphine for managing acute postoperative pain in orthopedic surgery. Data from 114 patients who underwent orthopedic surgery at Hospital Universiti Sains Malaysia (HUSM), were analysed, with 51 receiving TFP and 63 receiving PCA morphine. Primary outcomes included mean pain scores and patient satisfaction, while the incidence of side effects e.g., nausea, vomiting, respiratory depression, itchiness, and hypotension, served as a secondary outcome.

Results: TFP demonstrated equivalent analgesic efficacy to PCA morphine. A mixed-design repeated-measures ANOVA (Greenhouse-Geisser test) indicated no significant difference in mean pain scores between TFP and PCA morphine ($P = 0.364$, $P > 0.05$). Patient satisfaction rates were similarly high, with 96% satisfaction reported for TFP. Importantly, TFP exhibited fewer side effects, observed in 6 out of 51 patients, compared to PCA morphine, which caused side effects in 12 out of 63 patients, including one case of respiratory depression.

Conclusion: TFP offers comparable efficacy and patient satisfaction in acute pain management following orthopedic surgery, amd enhanced safety with fewer reported side effects compared to PCA morphine. High patient satisfaction rates further support TFP as a viable alternative in postoperative pain management.

Abbreviations: NRS: Numerical Rating Scale, PCA: Patient-Controlled Analgesia, TFP: Transdermal Fentanyl Patches, TKR: total knee replacement.

Keywords: fentanyl; morphine; analgesia; efficacy; satisfaction; safety

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1. INTRODUCTION

In 1979, the International Association for the Study of Pain (IASP) defined pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.[1] By 2020, IASP refined this definition to encompass pain as an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage, further clarifying its complexity with six key notes and the etymology of the word pain.[1]

Effective pain management is a crucial component of postoperative care, particularly in orthopedic surgery, where patients often experience significant pain that can impede recovery. Orthopaedic surgeries, including joint replacements, fracture fixations, and spinal surgeries, are typically associated with substantial postoperative pain due to extensive tissue manipulation, bone resection, and the inflammatory response triggered by surgical trauma.[2] Scott et al. analysed 1,217 cases of total knee replacement (TKR) surgeries, finding that pain was the primary contributor to postoperative patient dissatisfaction.[2] This highlights the critical need for effective pain management strategies in orthopedic surgeries to enhance patient satisfaction and recovery outcomes.

The choice of analgesic method can profoundly impact not only pain relief but also patient safety and overall outcomes. Among the various options available, transdermal fentanyl patches (TFP) and intravenous patient-controlled analgesia (PCA) with morphine represent two widely utilized modalities.[3] Some studies concluded that both methods provided equal postoperative analgesia, reinforcing that both methods are equally effective in pain management.[3-6] However, some studies found that TFP provided better analgesia and reduced morphine consumption without additional side effects.[7-10] This suggests that TFP may enhance patient satisfaction by offering effective pain relief with a reduced side effect profile. These findings also underscore TFP's potential to reduce overall opioid consumption, addressing concerns related to opioid overuse and dependency.[7]

Esmat et al. evaluated the efficacy of TFP and transdermal melatonin compared to a placebo in 75 lumbar laminectomy patients.[11] They found significant analgesic efficacy in both the TFP and transdermal melatonin groups, with higher patient satisfaction. However, the TFP group experienced a higher incidence of nausea and vomiting, whereas the melatonin group had significant sedative effects. These findings highlight the importance of monitoring and managing side effects to optimise patient outcomes. Jang Ji Su et al. evaluated TFP for acute postoperative management in 60 laparoscopic cholecystectomy patients.[12] They found that TFP maintained higher constant concentrations than IV fentanyl without causing respiratory depression. This finding is significant as it suggests that TFP can provide effective and safe pain management in less invasive surgeries where respiratory function is a concern.

Regarding satisfaction with TFP, Langford et al. studied the impact of fentanyl iontophoretic transdermal systems on early postoperative mobilisation.[13] They concluded that these systems provided better mobilization compared to IV PCA morphine, reinforcing the benefits of steady analgesia for enhancing early recovery. This finding correlates with a meta-analysis of randomized controlled trials that showed TFP had a higher percent of being an excellent method of pain control and patient's satisfaction compared to PCA morphine.[14]

Despite the widespread use of both TFP and PCA morphine, there is a paucity of comparative data evaluating their relative efficacy, satisfaction and safety specifically in the context of acute postoperative pain management in orthopedic patients. Understanding the comparative effectiveness of TFP versus PCA morphine has significant implications for clinical practice. The significance of this study is to introduce TFP as an acute postoperative analgesia in orthopedic surgery. With the ongoing opioid crisis, optimizing postoperative pain management, while minimizing opioid consumption and related adverse effects is paramount. Therefore, this study aims to assess the efficacy, satisfaction and safety of the transdermal fentanyl patch compared to intravenous morphine patient-controlled analgesia for

managing acute postoperative pain in orthopedic surgery.

2. METHODOLOGY

This retrospective study utilized medical records from orthopedic patients who received TFP or intravenous PCA morphine postoperatively. With ethical approval from the Institutional Ethical Board of Universiti Sains Malaysia (USM/JEPeM/22010020), the study included data from 114 patients, who underwent orthopedic surgery at Hospital Universiti Sains Malaysia (HUSM). Exclusions were applied for patients with alcoholism, drug abuse, chronic pain, the American Society of Anesthesiologists (ASA) classification ≥ 3, and morbid obesity (Body Mass Index, BMI ≥ 35 kg/m^2), aged 18 to 65 years. Pain intensity was assessed using the Numerical Rating Scale (NRS) from 0 (no pain) to 10 (worst pain), was recorded at 12, 24, and 48 hours post-surgery, with TFP documentation starting at 12 hours due to its onset time. Rescue medications were administered for pain scores > 4. Patients with TFP received subcutaneous (SC) Oxynorm 5 mg as needed (PRN) for rescue, while PCA morphine patients received bolus based on the patients' requirement. The study also monitored and compared side effects and patient satisfaction, recorded as binary yes/no outcome after 48 hours of treatment.

2.1. Sample size

Our primary objective was to evaluate the efficacy of TFP versus PCA morphine in managing postoperative pain in orthopedic patients, measured by pain score intensity. According to Viscusi et al., the sample size was determined using G-power 3.9.1.4 for an F-test ANOVA repeated measures within factors, recommending 60 patients per group with a 10% dropout rate considered. However, we utilised the medical records from our hospital and the total patient collected within one year with 51 receiving TFP and 63 receiving PCA morphine.

2.2. Statistical analysis

Data collection and analysis were conducted using Microsoft Excel and IBM SPSS Statistics for Windows Version 24.0, with rigorous data cleaning to ensure accuracy. The data cleaning process was initiated to minimize any errors that might skew the results. All probability values are two-sided, and a level of significance of < 0.05 (P < 0.05) is considered statistically significant.

Pain intensity scores, presented as means, were analysed via repeated measures mixed ANOVA were presented for the overall population and subpopulations categorized by age, BMI, gender, surgery duration, and type. Equivalence in analgesic efficacy between the treatment groups was defined by a two-sided 95% Confidence Interval (CI) within ±1 on a 0-10 pain scale, with mean pain intensity scores graphically depicted over time. Patient satisfaction at 48 hours post-treatment was assessed by comparing the percentage of success ratings between TFP and PCA morphine recipients. Adverse event incidences were analysed descriptively.

3. RESULTS

Our retrospective analysis includes 114 patients under 65 years who underwent orthopedic surgery at Hospital USM in 2021, comparing TFP (n=51) and PCA morphine (n=63) recipients. The patient group was predominantly male (68%) versus female (32%), with no significant age variation (Table 1). Lower limb surgeries accounted for 59.6% of cases, and the majority (57.9%) had surgeries lasting between 4 to 8 hours (Table 2).

Our analysis revealed no significant differences in mean postoperative pain scores between patients receiving TFP and those on PCA morphine at 12, 24, and 48 hours post-surgery, as shown in Table 3. Utilizing the analytical tool of Mixed Design Repeated Measure ANOVA (Greenhouse-geisser in Test of Within Subject Effect), the results indicated no statistical significance in postoperative mean pain score differences for both

Table 1: Demographic characteristics of the study

Variables	Frequency (%)
Age (years)	
• < 30	45 (39.5)
• 30-50	34 (29.8)
• > 50	35 (30.7)
Gender	
• Male	78 (68.4)
• Female	36 (31.6)
Race	
• Malay	107 (93.9)
• Chinese	4 (3.5)
• Indian	1 (0.9)
• Others	2 (1.8)
BMI (kg/m^2)	
• < 25	52 (45.6)
• 25-29	44 (38.6)
• 30-35	18 (15.8)

Table 2: Types and durations of surgery

Variables	Frequency (%)
Types of surgery	
• Upper limb	26 (22.8)
• Lower limb	68 (59.6)
• Spine	20 (17.5)
Duration of surgery	
• < 4 Hours	40 (35.1)
• 4-8 Hours	66 (57.9)
• > 8 Hours	8 (7.0)

treatment as presented in the Table 4 (F (2.3,258 = 1.03, P-value of 0.3645 (P >0.05)). This can be further illustrated via the graph obtained from Mixed Design Repeated Measure ANOVA statistical tool as visually represented in Figure 1, comparing mean pain score obtained via NRS ruler at 12, 24 and 48 hours for both treatment of TFP and IV PCA morphine.

Analysis of patient satisfaction rates at 48 hours post orthopedic surgery revealed no significant disparity between those receiving TFP and IV PCA morphine. Among TFP recipients, 96% reported satisfaction rate, with 2 patients expressing dissatisfaction due to side effects. Conversely, 98% of IV PCA morphine recipients were satisfied, with only 1 patient dissatisfied, as detailed in Table 5 and illustrated in Figure 2.

Analysis of postoperative data reveals a higher incidence of side effects in patients receiving IV PCA morphine compared to those using the TFP, as detailed in Table 6. Specifically, twelve patients on IV PCA morphine experienced side effects, including 2 cases developing hypotension and 1 case of respiratory depression

Table 3: Comparison mean pain score between TFP and IV PCA morphine at time pre-operatively, post-operative 12, 24 and 48 hours

Time	Types of Analgesia	Mean PS	95% CI	P-value
Preoperative	TFP	2.47	2.16, 2.78	0.62
	PCA Morphine	2.36	2.08, 2.64	0.56
12 Hour	TFP	2.67	2.42, 2.91	0.49
	PCA Morphine	2.92	2.70, 3.14	0.44
24 Hour	TFP	2.78	2.55, 3.02	0.47
	PCA Morphine	2.89	2.67, 3.10	0.43
48 Hour	TFP	2.39	2.18, 2.60	0.42
	PCA Morphine	2.43	2.24, 2.62	0.38

Table 4: Mixed ANOVA test comparing TFP and IV PCA morphine in different time of pain score assessment

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Noncent. Parameter
Time	Sphericity Assumed	18.238	3	6.079	10.029	.000	30.088
	Greenhouse-Geisser	18.238	2.312	7.889	10.029	.000	23.186
	Huynh-Feldt	18.238	2.384	7.649	10.029	.000	23.915
	Lower-bound	18.238	1.000	18.238	10.029	.002	10.029
Time * TYPAN	Sphericity Assumed	1.887	3	.629	1.038	.376	3.113
	Greenhouse-Geisser	**1.887**	**2.312**	**.816**	**1.038**	**.364**	**2.399**
	Huynh-Feldt	1.887	2.384	.791	1.038	.365	2.474
	Lower-bound	1.887	1.000	1.887	1.038	.311	1.038
Error(time)	Sphericity Assumed	203.666	336	.606			
	Greenhouse-Geisser	203.666	258.923	.787			
	Huynh-Feldt	203.666	267.060	.763			
	Lower-bound	203.666	112.000	1.818			

necessitating oxygen support. In contrast, only 6 patients on TFP reported side effects, with just 1 case experiencing mild sedation. These findings suggest that TFP is a safer option in managing postoperative pain than IV PCA morphine, with fewer and less severe adverse effects.

4. DISCUSSION

Pain relief is the cornerstone of postoperative care, with effective pain control not only improving patient comfort but also enhancing early mobilisation, reducing the risk of complications, shortening hospital stays, and improving overall outcomes. Transdermal Fentanyl Patch (TFP) is a non-invasive analgesic method, compared to PCA morphine and one of the multimodal analgesia strategies. Therefore, we attempted to do a retrospective study to evaluate the efficacy, patient satisfaction, and safety of TFP versus PCA morphine in managing acute postoperative pain in orthopedic patients.

Data from 114 orthopedic patients who received either TFP or IV PCA morphine post-operatively in 2021 were analysed. Our study revealed variations based on the type and duration of surgeries. However, according to a prior study by Arefayne et. al., the site of surgery, incision size, and duration did not significantly influence postoperative pain intensity in orthopedic surgeries.[15]

The efficacy of pain relief is a critical parameter in postoperative management. Our analysis revealed no significant differences in mean postoperative pain scores between patients receiving TFP and those on intravenous PCA morphine. This finding is parallel to previous research that established a baseline equivalence in pain relief between transdermal systems and PCA morphine.[4,5] If both modalities delivered effective postoperative analgesia in orthopedic surgery, we would reinforce the viability of TFP as an alternative to PCA morphine. This is because other studies, like those by Abrisham et al. and Maleh et al., have shown that TFP provides better analgesia compared to placebo patches with additional postoperative PCA morphine in TKR and oesophageal cancer surgeries, respectively.[7,9] These studies underscore TFP's superior efficacy in certain surgical contexts, making it a viable alternative for achieving effective pain management with potentially reduced morphine consumption. This also aligns with our observation that TFP patients experienced steady pain control with fewer fluctuations. This can be attributed to the continuous release of fentanyl, which maintains stable plasma levels and pharmacokinetic profile compared to intravenous route.

Patient satisfaction is a crucial outcome measure for postoperative pain management. Our data suggest that patients using TFP reported 96% satisfaction levels, potentially due to the convenience of the patch and the steady pain control it provides. This is corroborated by studies like those by Hall et al. and Langford et al., which found higher patient satisfaction with transdermal systems due to their non-invasive nature and consistent pain relief.[6,13] The need for rescue analgesics is an important indicator of the primary analgesic regimen's adequacy. In our study, 11 patients in the TFP group required multiple doses of oral Oxynorm (5 mg) for breakthrough pain within 48 hours. This finding suggests that while TFP provides effective baseline analgesia, additional pain control measures are necessary for managing breakthrough pain. The requirement for rescue analgesics highlights the need for a multimodal approach to pain management, integrating TFP with other analgesics to address breakthrough pain effectively.

Opioid-related side effects are a major concern in postoperative pain management. Our study found that patients on PCA morphine reported higher incidence of side effects compared to those on TFP. This is consistent with existing literature by Coluzzi et al. indicating that intravenous opioids, due to their systemic peaks, are more likely to cause such side effects.[4] However, TFP is not without risks. The primary concern with fentanyl patches is the potential for overdose, especially if patches are improperly applied or multiple patches are used simultaneously. Moreover, patients with high opioid tolerance may not achieve adequate pain control with standard TFP dosages, necessitating careful patient selection and monitoring. Our findings also suggested a few TFP-reported side effects compared to PCA morphine. Esmat et al. discovered that both TFP and transdermal melatonin provided significant analgesia; however, TFP was linked to a higher incidence of nausea and vomiting.[11] This indicates that although TFP may mitigate fewer side effects relative to PCA morphine, it still presents its own set of adverse effects, emphasizing the need for vigilant patient monitoring and management.

5. LIMITATIONS

Despite the robust findings of this study, several limitations must be acknowledged. Firstly, the retrospective nature of this study inherently limits the ability to control for all potential confounding variables. Differences in patient demographics, surgical procedures, and postoperative care protocols may have influenced the outcomes, thereby affecting the generalisability of the findings. Consequently, the lack of randomised control in patient selection could lead to confounding factors that might influence the outcomes.

Secondly, the data may be subject to documentation biases and inaccuracies. Inconsistencies were noted in

the documentation of total morphine administration for patients receiving PCA morphine, with poor records of rescue doses. Future studies should incorporate long-term follow-up to fully understand the implications of these analgesic methods on patient recovery. Future studies with larger and more varied cohorts are necessary to validate these results. Lastly, the side effects profile of each analgesic method was documented based on clinical observations and patient self-reports entered in the records, which may not capture all adverse events.

6. CONCLUSION

In conclusion, while transdermal fentanyl patches (TFP) are rarely utilised for acute postoperative pain in orthopedic surgery, patient-controlled analgesia (PCA) morphine remains the standard. TFP demonstrates comparable analgesic efficacy and patient satisfaction to PCA morphine, with the added benefit of fewer side effects profile.

7. Data availability

The numerical data generated during this research is available with the authors.

8. Conflict of interest

The study utilised the hospital resources only, and no external or industry funding was involved.

9. Ethical considerations

Formal ethical approval was obtained from the Institutional Ethical Board of Universiti Sains Malaysia (USM/JEPeM/22010020).

10. Author's contribution

All authors took part in the conduct of the study and preparation of the manuscript. All authors approve the final draft of the manuscript for publishing.

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