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Post-operative analgesic efficacy of transdermal fentanyl patch in patients undergoing total laparoscopic hysterectomy

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Abstract
The aim of the study: Determine if transdermal fentanyl patches (TFP) at a dose of 25 g/hour, given 10-12 hours before surgery, are more effective than intravenous analgesics at reducing postoperative pain after total laparoscopic hysterectomy (TLH) (1).
Materials and Techniques: We enrolled sixty patients scheduled for elective TLH under general anesthesia. After the surgery, we randomly assigned the subjects to receive intravenous tramadol 50 mg-100 mg and TFP (1, 2) at a rate of 25 g/hour. Over the course of 48 hours, patients were assessed every 8 hours (3).
Findings: The TFP group experienced a decrease in the numerical rating scale ratings for pain during activity and at rest over a 48-hour period (1). Although there were statistical improvements in the ambulation and nausea/vomiting (3) scores, there was no meaningful difference between the groups. There was no statistically significant difference in the groups' sedation scores, which were modest. (1, 2)
In Conclusion: In the first 48 hours following TLH surgery, TFP (25 µg/hour) can effectively lower pain scores when given 10-12 hours prior to surgery. (1, 2)

Keywords: Matrix transdermal delivery system (3), fentanyl, analgesia, complete laparoscopic hysterectomy

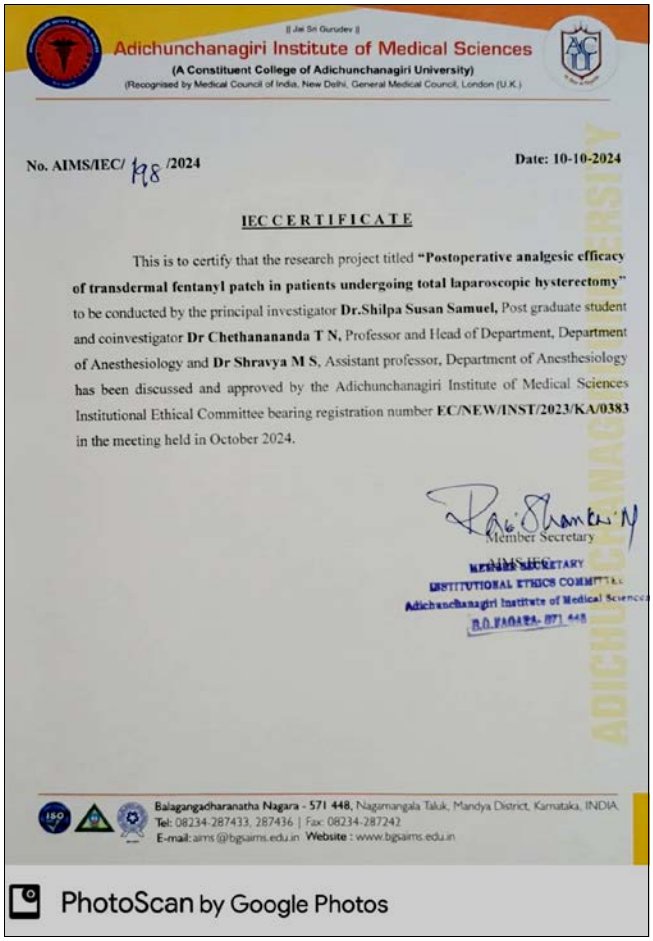
Introduction

Introduction Compared to traditional abdominal hysterectomy, total laparoscopic hysterectomy (TLH), a common gynecological treatment, has many advantages, such as lower postoperative morbidity, shorter hospital stays, and faster recovery. TLH can happen during surgery, along with incisional pain. Some of the conditions that can cause this are pneumoperitoneum, abdominal cavity stretching, leftover blood in the abdomen, and pelvic area dissection. A study conducted by Singh and Govil in 2021 [24] using data from the fourth National Family Health Survey (NFHS 4) found that the incidence rate of hysterectomy surgeries in India was 3.2% of women in the 15-49 age range. Additionally, compared to patients undergoing more invasive surgeries, individuals receiving laparoscopic procedures-which are thought to be less painful-were found to experience higher levels of postoperative discomfort and receive less pain treatment. Even though TLH is a minimally invasive laparoscopic operation, managing postoperative pain following the treatment is often challenging, leading to increased opiate intake and delayed hospital discharge [1]. Inadequate pain relief is frequently cited as the most prevalent complaint, and postoperative pain management remains a significant concern in surgical care. The best pain treatment techniques should be economical, safe, simple to use, and effective. However, maintaining proper pain management while reducing adverse effects is still quite difficult. The traditional approach to treating postoperative pain has been intravenous patient-controlled analgesia (IV-PCA) using tramadol, fentanyl, morphine, or meperidine [1]. Fentanyl patches are designed to administer the drug at a consistent rate between 25 and 100 µg/h. After the first application, fentanyl forms a depot in the epidermis' outermost layers, which progressively raises serum levels. Peak plasma levels are usually reached in 12 to 24 hours. Up to three days may pass before the analgesic effect wears off. It's important to understand, though, that fentanyl concentrations are typically higher in the first 24 hours and fall in the days that follow as the concentration gradient between the skin and patch narrows. A rise in body temperature may hasten the absorption of fentanyl, even though local blood flow has no effect on its distribution. Following an intravenous injection, the plasma level and clearance were similar. Researchers first presented this technique in 1987 to treat chronic cancer pain, and since then, they have studied its application to acute postoperative pain.

Early studies on how well and safely TFP works for this purpose only looked at side effects, rescue painkiller use, and pain scores. TFP is not appropriate for treating acute pain because of its generally sluggish onset, which reaches a plateau in 15 hours [3]. [1, 2] The μ-opioid receptor is the primary target of the synthetic opioid agonist fentanyl. Given that it is 100 times more effective than morphine, an identical amount of analgesia would require an estimated conversion ratio of 1 to 100. It is ideally suited for transdermal distribution due to its low molecular weight, high potency, and lipid solubility [1]. Fentanyl can significantly impact brain areas that are essential for analgesia once it has been absorbed and entered the bloodstream. Mu-opioid receptor activation produces analgesia and stimulates parts of the brain linked to addictive potential. Given that fentanyl must saturate the epidermis for better absorption, it takes around 12 to 16 hours for the drug to reach the therapeutic index, but it can be detected in serum 1 to 2 hours after initial injection. With a 90% bioavailability, the transdermal method skips the liver's first-pass metabolism of fentanyl. This approach lets smaller doses of the drug be used, which lowers the risk of side effects. Because cytochrome P450 (CYP34A) enzymes change fentanyl into inactive metabolites, drugs that raise or lower cytochrome P450 will change how the drug is broken down [1]. Among the many clinical benefits of fentanyl patches are reduced drowsiness and improved patient comfort. There is a limited incidence of serious side effects, including nausea, vomiting, or respiratory depression, and patients stay calm, relaxed, and easily awake even though their sedation scores may be somewhat higher. Incisional and visceral pain peaked 30 minutes after surgery and then gradually decreased. Furthermore, fentanyl's continuous release mechanism makes sure that patients get more consistent pain relief after surgery, which lowers the risk of breakthrough pain and the need for extra painkillers. Over the course of the 72-hour postoperative period, visceral discomfort continuously outweighed incisional pain. However, shoulder discomfort was less severe on the day of surgery and peaked 24 hours after the procedure [1]. To sum up, transdermal fentanyl patches show promise as a postoperative analgesic following laparoscopic hysterectomy. They improve patient comfort and recuperation by providing longer-lasting, more effective pain management with fewer adverse effects than alternative techniques. Integrating transdermal fentanyl into pain management strategies is a promising way to improve patient outcomes and speed up recovery for at-risk patient populations, especially given the ongoing need for improved postoperative care. This study looked at how well two different ways of managing pain during a total laparoscopic hysterectomy worked: giving patients an intravenous injection of 50-100 mg of tramadol after surgery [2] and putting on a transdermal fentanyl patch (25 μg/hour) 10-12 hours before surgery [2].

Statistical analysis

Ethical approval and informed consent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No. AIMS/IEC/ 78 /2024 Date: 10-10-2024

IEC CERTIFICATE

This is to certify that the research project titled **"Postoperative analgesic efficacy of transdermal fentanyl patch in patients undergoing total laparoscopic hysterectomy"** to be conducted by the principal investigator **Dr.Shilpa Susan Samuel,** Post graduate student and coinvestigator **Dr Chethanananda T N,** Professor and Head of Department, Department of Anesthesiology and **Dr Shravya M S,** Assistant professor, Department of Anesthesiology has been discussed and approved by the Adichunchanagiri Institute of Medical Sciences Institutional Ethical Committee bearing registration number **EC/NEW/INST/2023/KA/0383** in the meeting held in October 2024.

Member Secretary

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Statistical details

Table 1: Pain score and time of rescue analgesia

Description	Group I.V.	Group TFP	p-value
Mean pain scores	4.67±1.18	3.80±0.12	0.012
Mean interval of rescue analgesia (minutes)	345.50±33.34	58.10±12.88	<0.0001

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

Formula used

Σ1	Standard deviation of group 1
Σ2	Standard deviation of group 2
Σ	Average standard deviation
D	The minimum difference in the values which will make clinically relevant impact (to be decided by the clinician),

S. No	Alpha error	Z(1-α/2): Z score for the alpha error chosen	1-beta (power)	Z(1-β): Z score for the power chosen	Σ1	Σ2	Σ	D	Sample size calculated	Sample size (round figure)
1	5.00%	1.959963985	80.00%	0.841621234	33.3400	12.8800	23.1100	25	13.41397658	14
2	1.00%	2.575829304	80.00%	0.841621234	33.3400	12.8800	23.1100	25	19.95971539	20

3	5.00%	1.959963985	90.00%	1.281551566	33.3400	12.8800	23.1100	25	17.9575088	18
4	1.00%	2.575829304	90.00%	1.281551566	33.3400	12.8800	23.1100	25	25.42932977	26
5	5.00%	1.959963985	95.00%	1.644853627	33.3400	12.8800	23.1100	25	22.20835861	23
6	1.00%	2.575829304	95.00%	1.644853627	33.3400	12.8800	23.1100	25	30.44495421	31
7	5.00%	1.959963985	99.00%	2.326347874	33.3400	12.8800	23.1100	25	31.39911452	32
8	1.00%	2.575829304	99.00%	2.326347874	33.3400	12.8800	23.1100	25	41.07030015	42

Results: The study included 60 participants in total (n = 10 in the fentanyl group (F) and 10 in the tramadol group (T)) [1]. Patients in the tramadol group were 45.4±6.7 years old, whereas those in the fentanyl group were 48.1±9.7 years old. Both groups' BMI, length of anesthesia for surgery, and ASA grading were completed (Table 1).

Table 2: Study groups' demographic data comparison

Comparing the groups	Group F	Group T	P value
Age (In years)	49.2±6.2	56.0±5.3	0.05
ASA (I:II)	11:12	19:18	0.07
BMI	25.4±4.2	25.1±3.7	0.03
Duration of Anaesthesia	2.02 hrs±0.45	1.96 hrs±0.36	0.79

Table 3: Group-to-group comparison of parameters at various time points

	6 hours		P Value	12 hours		P Value	24 hours		P Value	48 hours		P Value
	Group F	Group T		Group F	Group T		Group F	Group T		Group F	Group T	
Pain rating for pain severity	3.87±0.819	6.87±0.937	<0.001	2.23±0.626	5.10±0.548	<0.001	1.53±1.167	3.53±0.507	<0.001	0.00±0.00	3.47±0.507	<0.001
Ambulation Score	1.98±0.740	1.23±0.430	<0.001	2.53±0.507	1.55±0.900	<0.001	3.00±0.00	2.00±0.640	<0.001	3.00±0.000	3.00±0.407	<0.009
Sedation score	1.767±0.858	2.067±0.583	0.119	0.700±0.837	0.300±0.46	0.01	0.300±0.466	0.733±0.450	<0.001	0.00±0.00	0.05±0.00	<0.010
Nausea / Vomiting Score	0.467±0.507	2.933±0.254	<0.001	0.200±0.407	0.167±0.379	<0.001	0.167±0.379	1.00±0.00	<0.001	0.00±0.00	0.06±0.54	0.115

Table 4: Pain rating for pain severity

Post OP duration	Group	Mean ±SD	Difference in Mean	SE	P value
6hours	F	3.87±0.819	-3.00	0.150	<0.001
	T	6.87±0.937		0.1711	
12 hours	F	2.23±0.626	-2.87	0.114	<0.001
	T	5.10±0.548		0.1000	
24 hours	F	1.53±1.167	-2.00	0.213	<0.001
	T	3.53±0.507		0.092	
48 hours	F	0.00±0.00	-3.47	0.000	<0.001
	T	3.47±0.507		0.0926	

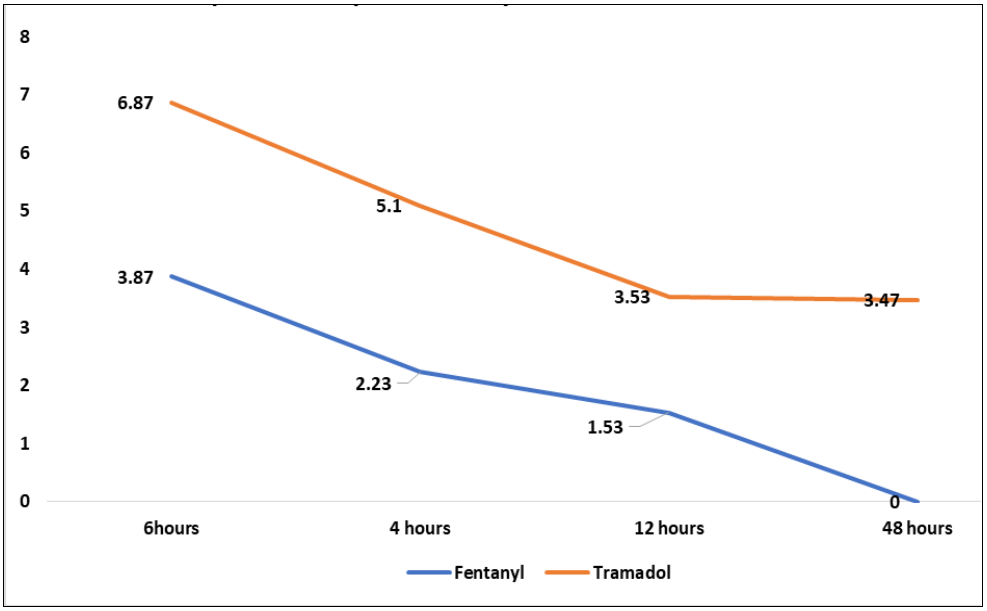

Fig 1: Comparision of pain severity score at different time intervals

We later evaluated the intensity of the pain in both groups at 6-, 12-, and 24-hour intervals. Group F experienced less severe pain, with a mean difference of 3 between the two groups. For the first 24 hours, group F experienced less severe pain, and over the following 24 hours, the difference in severity decreased.

Table 5: Ambulation Score

Post OP duration	Group	Mean	Difference in Mean	SE	P value
6 hours	F	1.98±0.740	0.1562	0.1562	<0.001
	T	1.23±0.430			
12 hours	F	2.53±0.507	0.1886	0.1886	<0.001
	T	1.55±0.900			
24 hours	F	3.00±0.00	0.1168	0.1168	<0.001
	T	2.00±0.640			
48 hours	F	3.00±0.000	0.0743	0.0743	0.009
	T	3.00±0.407			

Both groups' ambulation scores were evaluated at the same intervals of 6, 12, 24, and 48 hours, and the results indicated that Group F had higher ambulation than Group T.

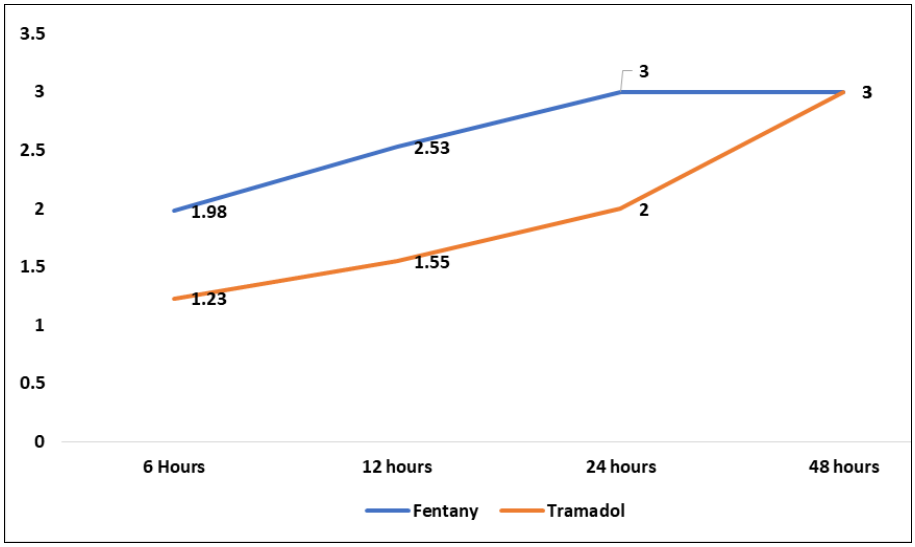

Fig 2: Comparision of Ambulation score at different time intervals

Table 6: Sedation score

Post OP duration	Group	Mean	Difference in Mean	SE	P value
6hours	F	1.767±0.858	-0.300	0.1895	0.119
	T	2.067±0.583			
12 hours	F	0.700±0.837	-0.633	0.2420	0.01
	T	1.333±1.028			
24 hours	F	0.300±0.466	-0.433	0.1183	<0.001
	T	0.733±0.450			
48 hours	F	0.000±0.00	-0.500	0.0928	<0.001
	T	0.500±0.500			

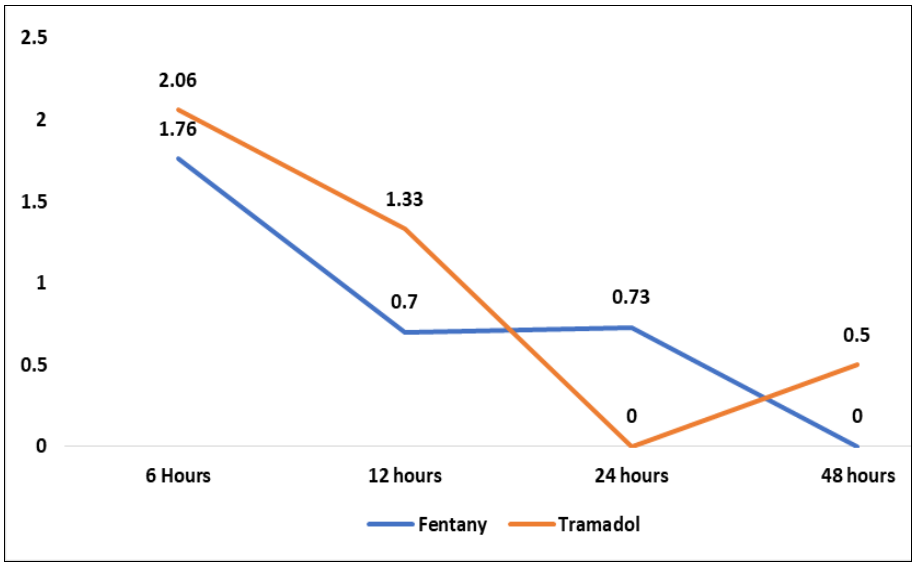

Fig 3: Comparision between sedation score at different time interval

Group F experienced less sedation than group T, according to sedation scores measured at intervals of 6, 12, 24, and 48 hours. By 48 hours, group F's drowsiness had completely subsided; however, group T was still somewhat sedated.

Table 7: Nausea / Vomiting Score

Post OP duration	Group	Mean	Difference in Mean	SE	P value
6hours	F	0.467±0.507	-2.466	0.103	<0.001
	T	2.933±0.254			
12 hours	F	0.200±0.407	-1.133	0.114	<0.001
	T	1.333±0.479			
24 hours	F	0.167±0.379	-0.833	0.069	<0.001
	T	1.000±0.00			
48 hours	F	0.000±0.00	-0.066	0.046	0.115
	T	0.06±0.54			

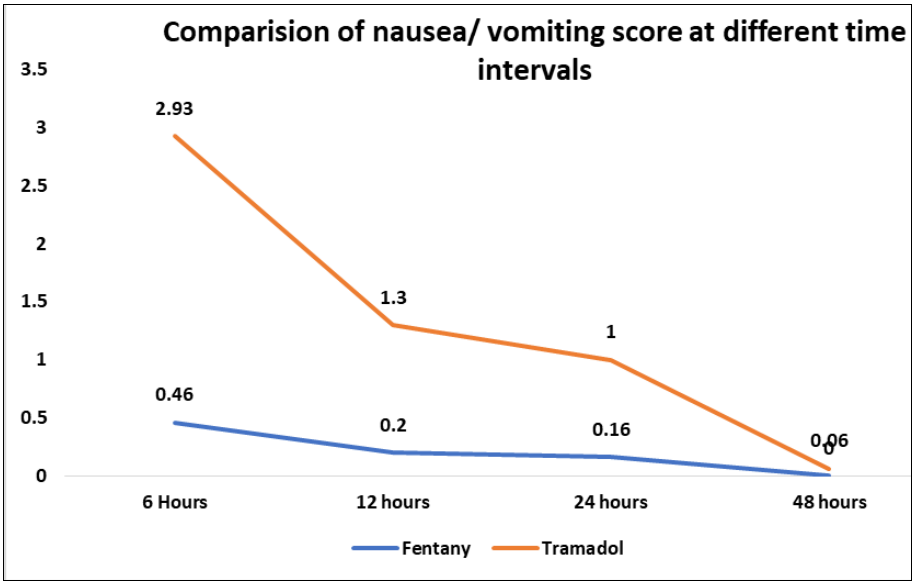

Fig 4: Comparision of nausea/ vomiting score at different time intervals

When the nausea and vomiting scores of the two groups were compared, it was shown that group F had a statistically lower score six, twelve, and twenty-four hours after surgery. At 48 hours, there was little difference.

In this cohort study, sixty patients who chose to have a total laparoscopic hysterectomy under general anesthesia were included. The surgery took place at the Adichunchanagiri Institute of Medical Sciences and Research Center between November 2024 and January 2025. The participants were divided into two groups, F and T, at random. Ten to twelve hours before general anesthesia, Group F got TFP (25 µg/hour) applied to the anterior chest wall using a self-adhesive substance [1, 2]. Group T received 50-100 mg of intravenous tramadol BD for the treatment of post-operative pain, with their approval. Each study participant acquired written informed consent. The study looked at 60 women between the ages of 40 and 55 who were scheduled to have a total laparoscopic hysterectomy under general anesthesia. These women were classified as Grade I or II by the American Society of Anesthesiologists. We used a computer to randomly assign patients into two groups of thirty each. People who had an opioid addiction or allergy in the past, as well as people with lung, liver, heart, or kidney problems, who chose not to go under general anesthesia or who were taking painkillers for a long time, were not allowed to participate in the study. The study used specific instruments for data collection. We assessed the patients at 6, 12, 24, and 48 hours. A numeric rating scale (NRS) was used to measure the intensity of the pain. We also recorded ambulation, sedation, and nausea/vomiting (N/V) scores for each group [2]. We enrolled 60 patients who met the inclusion criteria and were undergoing elective TLH under general anesthesia after obtaining institutional ethics committee approval and written informed consent from participants. • The participants signed the ethical committee consent documentation after being fully informed about the study. • It was not possible to achieve double blinding in the study for both patients and all participating staff, but our sampling, statistical evaluation, and medical history collection were completely blinded to treatment group designations [1]. All participants underwent total laparoscopic hysterectomy at the Adichunchanagiri Institute of Medical Sciences and Research Center between November 2024 and January 2025. Ten to twelve hours before the general anesthesia, Group F got TFP (25 µg/hour) applied with a self-adhesive to the anterior chest wall. Group T received 50-100 mg of intravenous tramadol for the treatment of post-operative pain. At 6, 12, 24, and 48 hours, the patients underwent assessments. A numeric rating scale (NRS) was used to gauge the severity of the pain. Both groups also underwent sedation, nausea/vomiting (N/V) grading, and ambulation [1, 2].

When the nausea and vomiting scores of the two groups were compared, it was shown that group F had a statistically lower score six, twelve, and twenty-four hours after surgery. At 48 hours, there was little difference.

Discussion: Although laparoscopic hysterectomy is less intrusive than open surgery, it still causes significant pain

after the procedure; therefore, having adequate analgesia is essential. One of anesthesiologists' main responsibilities is still to control pain following such treatments, particularly to lessen discomfort and aid in the patient's recuperation. Painful inputs from surgical wounds trigger excitatory reactions, making the central nervous system more susceptible to subsequent stimuli. After central sensitization, the reflexes to pain intensify, and even small stimuli can cause severe suffering. According to research, preventing this sensitization with adequate intraoperative analgesia can improve postoperative pain management. After laparoscopic hysterectomies, discomfort during movement is still an issue, especially in the early postoperative period. For the treatment of postoperative pain, opioids-especially transdermal fentanyl patches-are essential. The choice of analgesia is based on the patient's particular circumstances, including their physical state and any comorbidities, rather than the timing of the surgery. While opioids are essential for managing pain following surgery, there are currently no established protocols to guide their management, which leads to less than ideal results and prolonged hospital stays for many patients. Therefore, improving patient outcomes in this population requires developing a more efficient recovery regimen. To reduce complications and hasten recovery, a comprehensive approach that includes preoperative optimization, intraoperative management, and postoperative care is needed. Transdermal fentanyl patches are becoming more widely recognized for their capacity to provide long-lasting, efficient analgesia following surgery with minimal adverse effects. By enabling continuous drug delivery, these patches offer a safe and practical way to control pain. This technique eliminates the need for repeated doses and avoids pain variations that come with parenteral or oral administration. One of the best things about transdermal delivery is that it keeps the rate of fentanyl absorption through the skin constant. This keeps plasma concentrations stable and avoids first-pass metabolism. The design of fentanyl patches ensures a steady release of the drug, ranging from 25 to 100 g/h. Following the first application, fentanyl forms a depot in the epidermis, which progressively raises serum concentrations. Peak plasma levels are typically reached in 12 to 24 hours. Up to three days may pass before the analgesic effect wears off. However, it should be noted that fentanyl levels are often higher in the first 24 hours and progressively decrease in the days that follow as the concentration gradient between the skin and the patch decreases. Increased body temperature may improve fentanyl absorption, even though local blood flow has no discernible impact on fentanyl distribution. Transdermal fentanyl is a safe and efficient way to treat postoperative pain. With a low incidence of side effects, fentanyl has been shown to be very successful in reducing postoperative pain following laparoscopic hysterectomy when compared to other opioids. Compared to patients receiving oral or intravenous opioids, research has demonstrated that patients utilizing fentanyl patches experience less postoperative pain and need fewer rescue analgesics. Fentanyl patches offer several clinical benefits, including reduced sedation and improved patient comfort. Although some patients may have slightly higher degrees of sedation, most stay relaxed, comfortable, and easily awake, and there is little chance of serious side effects, including nausea, vomiting, or respiratory depression. The study concludes that the transdermal fentanyl patch (TFP) provides better pain relief than IV Tramadol for patients undergoing total laparoscopic hysterectomy (TLH), particularly in the immediate postoperative phase. Furthermore, fentanyl's continuous release mechanism makes sure that patients get more consistent pain relief after surgery, which lowers the risk of breakthrough pain and the need for extra painkillers. Because of this, a transdermal fentanyl patch is better than intravenous tramadol for managing pain after a total laparoscopic hysterectomy because it reduces pain severity, makes it easier to walk, and has fewer undesirable side effects. These benefits will in turn contribute to a more favorable surgical outcome. Additionally, patients receiving fentanyl had superior ambulation scores at all assessment times, reflecting better mobility and recovery. Significantly lower rates of nausea and vomiting were observed in the fentanyl group, suggesting a favorable profile of side effects.

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