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Post-Operative Pain Relief Using Transdermal Buprenorphine Patch or Transdermal Fentanyl Patch in Lower Limb Surgeries: A Comparative Study

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ABSTRACT
Adequate pain management is a challenge to the pain physician as there are many adverse psychological and physiological effects associated with it. Hence, effective analgesia in this population is essential to accelerate functional recovery and enable patients to return to their normal activity more quickly after rehabilitation. Written and informed consent was taken from the patient, patients satisfying the inclusion and exclusion criteria were randomly allocated, using a computer-generated random number table and sealed envelope technique, to one of the following two groups of patients. **Group A:** This group received Buprenorphine patch (10mcg/hr). **Group B:** This group received Fentanyl patch of (25mcg/hr). When Sedation score was compared between two groups at different time intervals, p value was <0.05 and so the results were statistically significant.

INTRODUCTION

Patients undergoing lower limb surgeries are known to experience severe degrees of pain in the post-operative period. Persistent, intense pain activates secondary mechanisms both at the periphery and within the central nervous system that cause allodynia, hyperalgesia and hyperapathia that can diminish normal functioning and may lead to chronic pain[1]. Adequate pain management is a challenge to the pain physician as there are many adverse psychological and physiological effects associated with it[2]. Hence, effective analgesia in this population is essential to accelerate functional recovery and enable patients to return to their normal activity more quickly after rehabilitation. Although many methods are available for post-operative pain management, newer approaches are constantly being investigated. Usually, post-operative analgesia includes NSAIDs or opioid drugs like morphine and fentanyl taken intravenously, intramuscularly or per-orally. Recent times have witnessed the introduction of a newer modality of therapy: transdermal patches containing opioids for pain relief. Although its use is more prevalent in treating patients experiencing severe cancer pain, studies are now being conducted to popularize it for post-operative analgesia. Buprenorphine and fentanyl are two such opioid analgesics available as transdermal patches that are being used for their analgesic effects in the post-operative period. Buprenorphine is a non-selective mixed agonist-antagonist opioid receptor modulator, acting as a partial agonist of the μ receptor, an antagonist of the and the d-receptors, d-receptor. Its active metabolite norbuprenorphine, acts as a strong agonist at the d-receptors[3]. It has physicochemical properties, including a low molecular weight and high analgesic potency that makes it an excellent compound for transdermal drug delivery. The new technology of transdermal buprenorphine (TDB) is an advanced system that contains the active drug incorporated into a polymer matrix, which is at the same time the adhesive layer. The patch precisely controls the rate of drug delivery and produces stable plasma concentrations within 48 hours of the first application. Patch adhesion analysis shows the appropriateness of the seven-day application period[4,5]. Fentanyl is a pure μ-opioid receptor agonist known for its analgesic and sedative effects. It bypasses the first pass metabolism in the liver and hence has high bioavailability. Moreover, owing to the high lipophilic action, it is an ideal agent for transdermal delivery and it achieves a large volume of distribution. The transdermal patch provides consistent diffusion of fentanyl over a 72-hour period[6]. The purpose of this study is to find out which transdermal opioid analgesic among the two is more efficacious in terms of postoperative analgesia and which one has a better side effect profile.

MATERIALS AND METHODS

It is a prospective, randomized single blind study in patients of age group 18-60 years and of American Society of Anesthesiologists (ASA) physical status I and physical status II posted for elective lower extremity surgery.

Study Design: Prospective, randomized single blind study.

Sample Size: 90 with each group having 45 patients

Inclusion Criteria:

- Age-18-60 years of either sex.
- Patients belonging to ASA -Grade I and II.
- Patients undergoing elective lower limb surgeries.

Exclusion Criteria:

- Patients with history of drug abuse or alcohol abuse.
- Patients with known allergy to fentanyl and buprenorphine.
- Patients on antidepressants, antipsychotics, anxiolytics and anticonvulsants.
- Patients' refusal for the procedure.

We planned to conduct a prospective randomized single blind comparative study involving adult patients undergoing major lower limb surgery under spinal anaesthesia. Written and informed consent was taken from the patient, patients satisfying the inclusion and exclusion criteria were randomly allocated, using a computer- generated random number table and sealed envelope technique, to one of the following two groups of patients.

- **Group A:** This group received Buprenorphine patch (10mcg/hr).
- **Group B:** This group received Fentanyl patch of (25mcg/hr).

Drug patches were applied to patients 12 hours before proposed surgery in both groups after noting baseline hemodynamic parameter. Patients were premedicated with Antacids and Anxiolytics i.e., Tab Ranitidine 150 mg po and Tab Alprazolam 0.5mg PO HS under strict aseptic precautions 25g Quincke's Babcock spinal needle was inserted in L3-L4 and 0.5% (H) bupivacaine was injected. Adequate block was achieved. Analgesia was assessed using visual analogue score, Ramsay Sedation Score (RSS) 40 and hemodynamic parameters respectively for next 3 days 12 hourly. Hemodynamic parameters and any adverse effects were also noted if any. Injection diclofenac (75mg IV) was used as a rescue analgesic in patient complaining of inadequate pain relief.

Table 1: Comparison of Rescue Analgesia Between Group B and Group F

		Group B		Group F				
		Group B	Group B	Group F	Group F	Total	Chi-square value	p value
Rescue analgesia (Y/N)	N	39	86.7%	45	100.0%	84	6.429	0.026 (Significant,
	Y	6	13.3%	0	0.0%	6		p<0.05)
Total		45	100.0%	45	100.0%	90		

Table 2: Comparison of Adverse Effects Between Group B and Group F

		Group B		Group F				
		Group B	Group B	Group F	Group F	Total	Chi-square value	p value
Adverse effects (Y/N)	N	37	82.2%	36	80.0%	74	0.304	0.581(Not significant,
	Y	8	17.8%	9	20.0%	16		p>0.05)
Total		45	100.0%	45	100.0%	90		

Table 3: Comparison of VAS Between Group B and Group F

	Group B		Group F			
	Mean	SD	Mean	SD	Z	p-value
VAS_POD 1 12 Hourly	3.64	0.48	3.38	0.49	-2.516	0.012
VAS_POD 1 24 Hourly	4.00	0.00	3.00	0.00	-9.434	0.001
VAS_POD 2 12 Hourly	4.64	0.48	2.47	0.50	-8.475	0.001
VAS_POD 2 24 Hourly	5.00	0.00	2.00	0.00	-9.434	0.001
VAS_POD 3 12 Hourly	5.64	0.48	2.00	0.00	-8.936	0.001
VAS_POD 3 24 Hourly	6.00	0.00	2.00	0.00	-9.434	0.001

Table 4: Comparison of Sedation Score Between Group B and Group F

			Group B		Group F			
			Mean	SD	Mean	SD	Z	p-value
SEDATION SCORE_POD Hourly	1	12	2.00	0.00	1.64	0.001	-4.387	0.001
SEDATION SCORE_POD Hourly	1	24	1.82	0.39	1.58	0.012	-2.516	0.012
SEDATION SCORE_POD Hourly	2	12	1.67	0.48	1.47	0.050	-1.904	0.050
SEDATION SCORE_POD Hourly	2	24	1.98	0.15	1.33	0.001	-6.397	0.001
SEDATION SCORE_POD Hourly	3	12	1.69	0.47	1.18	0.001	-4.865	0.001
SEDATION SCORE_POD Hourly	3	24	1.62	0.49	1.00	0.001	-6.340	0.001

RESULTS AND DISCUSSIONS

6 out of 45 patients required Rescue Analgesia in Group B and no patients required Rescue Analgesia in Group F. When two groups were compared, p value was 0.026 which is statistically significant (Table 1). 8 out of 45 patients in Group B and 9 out of 45 patients in Group F experienced adverse effects. When both the groups were compared, p value was 0.581 which is statistically insignificant (Table 2). When VAS score was compared between two groups at different time intervals, p value was <0.05 and so the results were statistically significant (Table 3). When Sedation score was compared between two groups at different time intervals, p value was <0.05 and so the results were statistically significant (Table 4).

The patients were allotted into two groups. As it was a single blinded study, only the patient did not know which group they belonged to. Further they were categorized into either group B which received transdermal buprenorphine patch and group F which received transdermal fentanyl patch. During the pre-anaesthetic evaluation, all the patients were taught the visual analogue scale (VAS) and how to identify adverse reactions e.g. erythema rashes if any occurred. Pre-operative VAS score was noted respective patch was then applied onto a clean, hairless, dry area on the upper chest/back. If there was no area free of hair, then the hair over the chest was clipped with scissors and the patch was firmly held over the skin for 30 seconds. Patients were educated on the care to be taken while on the patch and a patient information leaflet was also provided. Comparison of the age between the two groups showed that the age in both the groups were similar and so the result was statistically not significant[7]. Comparison of Gender between two groups showed no statistical significance between both the groups. The comparison of the postoperative VAS scores was done every 12 hourly for 3 consecutive days and the result was statistically significant with Group Fentanyl having lower VAS scores compared to Group Buprenorphine on all the 3 days[8]. On the second and third postoperative days, there was a statistically significant difference in the VAS scores with Group Fentanyl having relatively lower scores compared to group Buprenorphine having higher scores throughout the day. This concludes that transdermal fentanyl takes around 16-18 hours to reach maximum serum concentrations and has better analgesic effect when compared to buprenorphine. Also on comparison of baselines VAS scores on day 1, 2 and 3, the VAS scores were significantly increasing in Group Buprenorphine compared to Group Fentanyl which suggests that Fentanyl is more effective in controlling Post op surgical pain. The findings of our study were in accordance with the studies done by Z. Arshad, R. Prakash and S. Gautam, in which they found that mean VAS scores were significantly lower in the fentanyl group when compared to the buprenorphine group on

postoperative days 1, 2 and 3[9]. On the second postoperative day, two patients and on third postoperative day, four patients required inj. diclofenac 75mg I/V from group Buprenorphine as rescue analgesic compared to none in group Fentanyl. This corresponds with good postoperative pain relief with transdermal fentanyl patch[10]. The findings of our study were in accordance with the studies done by Z. Arshad, R. Prakash and S. Gautam, in which they found that the need for rescue analgesia was higher in the buprenorphine group (6 out of 30) when compared to the fentanyl group (0 out of 30). Comparison of the Ramsay sedation score between the two groups showed that there was statistically significant change or drop in Ramsay sedation score in Group Fentanyl compared to Group Buprenorphine. Despite of fall, Ramsay sedation scores were higher in Group Buprenorphine compared to Group Fentanyl. All patients in both groups were calm, comfortable and easily arousable throughout the study and none of them showed excessive sedation.

CONCLUSION

Based on the findings of our the study we conclude that for post-operative pain relief using Fentanyl 25 mcg/hr administered 12 hr prior to surgery provides better and effective analgesia, when compared to transdermal buprenorphine 10 mcg/hr with minimal side effects.

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