



PERIOPERATIVE ANALGESIA IN PLASTIC SURGERY PROCEDURES UTILISING TRANSDERMAL BUPRENORPHINE PATCH.

Anaesthesiology

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ABSTRACT

Introduction: Buprenorphine is a semisynthetic thebaine derivative. It acts centrally and has substantially better analgesic efficacy than morphine. As a result, a low concentration in a transdermal patch is sufficient to offer pain relief. The effect of Buprenorphine is compared with other conventional analgesics and the results are evaluated. **Aim:** To assess the effectiveness of a transdermal Buprenorphine (TDB) 5mcg patch in postoperative pain management in plastic surgery patients, as well as the potential side effects and compare them to the institution's standard analgesic regimen. **Materials and Procedures:** Following ethical approval and informed agreement, patients who satisfied the inclusion criteria were randomly assigned to one of two groups of 200 individuals each. Group A: 5mcg transdermal buprenorphine patch, Group B: Paracetamol with Tramadol as usual. Analgesic potency, side effects, the need for rescue analgesia, and patient satisfaction are all assessed and compared. **Results:** From 6 hours postoperatively to 7 days, the pain score measured by VAS was considerably reduced (p value 0.0007) in group A as compared to group B. In group B, the requirement for rescue analgesia was likewise greater and lasted longer. Group A had a substantially higher satisfaction level (mean 4.45 ± 0.11) than group B (mean 3.6 ± 0.51). The expense to achieve the same pleasant post-operative time was much cheaper in group A. **Conclusion:** Transdermal buprenorphine patch 5mcg is effective in reducing postoperative pain, has a superior safety profile, a higher patient satisfaction score, requires less rescue analgesics, and is significantly less expensive than normal conventional analgesia with Paracetamol and Tramadol.

KEYWORDS

analgesia, patch, transdermal, buprenorphine

INTRODUCTION

According to estimates, 20–40% of patients who underwent surgical operations report experiencing postoperative pain, and it has a substantial impact on the patient's physical, psychological, and functional recovery [1, 2]. Effective analgesia not only promotes functional recovery but also enhances the result by promoting early physical therapy and ambulation, reducing hospital stay, lowering the likelihood of complications, and raising patient satisfaction. Consequently, surgery becomes a pleasant experience [3].

To lessen postoperative pain, analgesic medications such NSAIDs, opioids, and others are frequently given intravenously, intramuscularly, or through epidural catheters. Each agent and approach has unique benefits and drawbacks. Once placed, the transdermal buprenorphine patch has the ability to provide consistent rates of absorption via the skin, resulting in sustained pain relief.

The study's main goal is to determine if a transdermal Buprenorphine (TDB) 5mcg patch used 24 hours before surgery is beneficial in giving individuals having standard cosmetic surgery the best possible postoperative analgesia. Evaluating the analgesic's effectiveness and safety in relation to the occurrence of adverse effects such drowsiness, respiratory distress, nausea, and vomiting before and after surgery, as well as the need for breakthrough analgesia with another class of medication, such as diclofenac 75mg.

MATERIALS AND METHOD

Following approval from the institution's ethical committee, a prospective comparative study was carried out. The study was carried out from September 2020 to September 2022 in patients who were scheduled for elective plastic surgery treatments and met the inclusion criteria. All procedures were performed under general anesthesia on patients ranging in age from 18 to 65 years of either sex and with ASA PS grades I and II. Patients were separated into two groups (A and B), each with 200 patients. A TDB 5 mcg patch was applied to a relatively hairless location, preferably the upper chest, shoulder, or upper back, the day before surgery. A placebo patch was applied to a similar region in Group B.

As per institutional policy, all patients were pre-medicated the night before surgery. The anesthesia team delivered weight-adjusted doses of induction, maintenance, and reversal drugs intraoperatively. After extubation, the VAS score was calculated, and if it was greater than 40, Diclofenac (75mg IV) was administered as a rescue analgesic. In

group B, infusion paracetamol with tramadol was the predominant analgesic of choice, with injection diclofenac providing rescue analgesia, as in group A. The VAS score was calculated at six hours, twelve hours, twenty-four hours, and seven days following surgery. Nausea, vomiting, application site rash and pruritus, headache, constipation, drowsiness, and other side effects were identified and treated as needed. Overall, patient satisfaction was graded on a scale of 1 to 5, where 5 implies extremely satisfied and 1 indicates least.

The inclusion criteria were

1. Patient who underwent elective plastic surgery procedures belonging to the age group 18 and above.
2. Patients with American Society of Anaesthesiology grade I and II.
3. Procedure under general anaesthesia and those requiring minimum 7 days of postoperative in hospital care.

The exclusion criteria were

1. Pregnant patients and patients with significant history of cardiopulmonary, cerebrovascular, neuromuscular diseases, cerebral or kidney dysfunctions.
2. Patients with active peptic ulcer disease, gastrointestinal bleeding or psychiatric disorders.
3. Patients with long term history of analgesic intake.

Statistical Analysis

The statistical analysis was performed using windows 10 Excel student's paired t-test.

RESULTS

The average age of patients in group A was 34.7 years with a standard deviation of 9.72 years, while the average age of patients in group B was 36.80 years with a standard deviation of 10.11 years. In group A, 44% of the patients were female, while in group B, 47.5% of the patients were female. In group A, there were 122 patients with an ASA Physical Status (ASAPS) of class I, while in group B there were 109 patients with an ASAPS of class I. There was no statistically significant difference between the two groups in terms of age, sex, and ASA PS grade. Table 1

Table 1- Shows The Profile Of Study Population

Parameters	Group A(n=200)	Group B(n=200)	p- value
Age (mean±SD)	34.87±9.72	36.80±10.11	0.0523
Gender			1.000
Male	88(44.00%)	95(47.50%)	
Female	112(56.00%)	105(52.50%)	

ASA PS I/II	122/78 (61%/39%)	109/91 (54.5%/45.5%)	0.0778
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The study found that postoperative complications were more common in group B, with 20% of patients experiencing complications, compared to 10% of patients in group A. Nausea was the most common complication and was more prevalent in group B (12.50%) than in group A (10.00%). However, the difference in the prevalence of complications between the two groups was not statistically significant, with a p-value greater than 0.05. Table 2

Table 2 Showing Postoperative Complications

Complications	Group A		Group B		P-Value
	Number	Percentage	Number	Percentage	
Nausea	17	8.50	29	14.50	0.98
Vomiting	7	3.50	19	9.50	0.87
Constipation	0	0	0	0	-
Application site rash	0	0	0	0	-
Head ache	0	0	0	0	-
No complications	180	90	160	80	0.68

Pain scores at rest were assessed using a Visual Analog Scale (VAS) with a range of 0 to 100 (100mm scale). The study found that pain scores were significantly lower in group A compared to group B for the first 7 days after surgery, starting from 6 hours postoperatively (p value = 0.0007). The average pain score in group A decreased from 35 on day 1 to 10 on day 7, while the average pain score in group B decreased from 55 on day 1 to 15 on day 7.

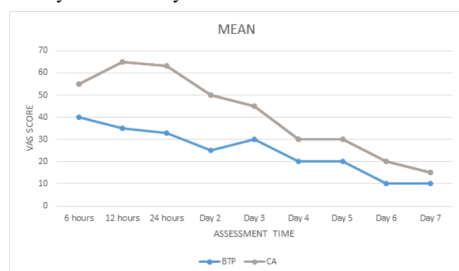


Chart 1 . Comparing VAS Scores Of The Two Groups. BTPp-Buprenorphine Transdermal Patch; CA- Conventional Analgesia; VAS; Visual Analogue Scale.

The amount of rescue analgesia (additional pain relief) needed by the patients in the first 24 hours after surgery was measured and compared between the groups. The results showed that group B patients needed more rescue analgesia (125±52.08 mg) than group A patients (75±37.25 mg), and this difference was statistically significant at all-time intervals. On the second day after surgery, group B patients still needed some rescue analgesia (37±12.83 mg), while group A patients did not need any. On the fourth day after surgery, both groups did not need any rescue analgesia. The chart 2 below illustrates the difference in analgesia requirement of the two groups over time, which was statistically significant at all the time intervals.

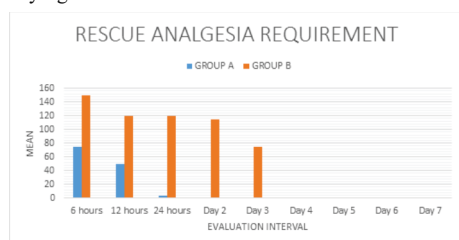


Chart 2 Postoperative Analgesia Requirement (amount In Mg).

Cost effectiveness was estimated for achieving similar comfortable pain score. During the study period, the cost of single patch of 5-mcg buprenorphine was Rs 520 (used for seven days), that of conventional therapy was Rs 320 on an average per dose, and per day it will be not less than Rs 700. This implies that there is a saving of Rs 1580 even if we consider neglecting the rescue analgesia, which is used in both the groups.

Another outcome that was measured and compared between the groups was the satisfaction of the patients with their pain management.

The patients were asked to rate their satisfaction on a scale of 1 to 5, where 1 means very dissatisfied and 5 means very satisfied. The results showed that group A patients were more satisfied (mean 4.45±0.11) than group B patients (mean 3.6±0.51), and this difference was statistically significant. The chart 3 below shows the distribution of satisfaction scores in the two groups.

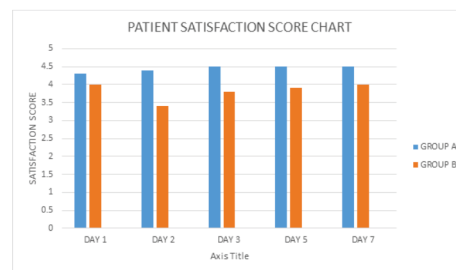


Chart 3 – Patient Satisfaction Score

DISCUSSION

The use of transdermal Buprenorphine patch for postoperative analgesia is compared with conventional combination of paracetamol with or without tramadol (whenever indicated). It is observed in this study that the group with buprenorphine patch had lower pain score, lesser incidence of complications, fewer dose of rescue analgesia, and better satisfaction scores in comparison with patients receiving conventional analgesia regimen. A patient's post-operative discomfort is caused by a variety of factors. Inflammation, microfractures, nerve irritability, tissue stress, ischemia, and other factors are all present. These elements, either together or separately, may result in pain that has both nociceptive and neuropathic components. A multimodal analgesic approach is the current gold standard of therapy to address all these concerns [5]. A powerful opioid with central action, Buprenorphine also has partial mu agonist and kappa and delta antagonist properties [6]. Its duration of action is prolonged by slower dissociation and strong affinity for the mu receptor.

Buprenorphine is safely excreted through hepatic metabolism, making transdermal Buprenorphine an option for older patients with renal impairment. Additionally, a single application of the drug had a longer duration of action for more than 5 days due to continuous drug delivery, a relatively stable plasma concentration, fewer side effects, and greater compliance [7]. Chronic non-malignant and malignant pain are well-established uses for TDB [8, 9]. There are, however, very few data on the use of TDB in patients undergoing cosmetic surgery, and there is no comparison of the two with a typical analgesic regimen.

We have successfully achieved considerable productive outcomes in patients undergoing a wide range of treatments such as skin grafting, locoregional and microvascular flap surgeries, liposuction, and extremity reconstructive surgeries such as tendon transfer and nerve grafting. Similar research on knee replacement, lumbar disc prolapse surgery, and abdominal surgery are abundant [4, 6, 10, 11]. TDB resulted in higher patient satisfaction as well as safer perioperative analgesia. Similarly, the current study found a substantial postoperative VAS score, higher patient satisfaction, fewer side effects, and improved compliance when compared to a typical analgesic regimen that included acetaminophen and tramadol. In patients having open gynaecological procedures, Setti et colleagues discovered that the use of rescue analgesia was inversely associated to TDB dose [13], with IV Morphine and Ketorolac used as rescue analgesics. A large postmarketing monitoring analysis of 13179 individuals showed that they have a low incidence of nausea (4%), vomiting (1.6%), and constipation (1.0%), which is similar to our data, however the decreased incidence was not statistically significant [14].

CONCLUSION

It is clearly demonstrated in this study that TDB provides a safe, effective, persistent and predictable analgesia in postoperative patients undergoing routine plastic surgery procedures. Lesser adverse effects, cost effectiveness and better patient satisfaction score compared to conventional analgesics makes TDB a superior option to routine analgesia protocols. There is sustainable reduction in requirement of rescue analgesia and hence preventing associated potential nephrotoxicity, hepatotoxicity and dependency.

Limitations

The study does not randomise between different surgical procedures.

The analgesia requirement in various procedures vary according to extent of dissection, method of repair, various modifications, flap design and closure technique to name a few.

Conflict of Interest: None

REFERENCES

1. H.J. Gerbershagen, S. Aduckathil, A.J.M. Van Wijck, et al. Pain intensity on the first day after surgery: a prospective cohort study comparing 179 surgical procedures. *Anesthesiology*, 118 (2013), pp. 934-944
2. Baratta JL, Gandhi K, Viscusi ER. Perioperative pain management for total knee arthroplasty. *J Surg Orthop Adv* 2014;23:22–36.
3. Barrington JW, Halaszynski TM, Sinatra RS, et al. Perioperative pain management in hip and knee replacement surgery. *Am J Orthop (Belle Mead NJ)* 2014;43(4 suppl):S1–6.
4. Tang J, Fan J, Yao Y, Cai W, Yin G, Zhou W. Application of a buprenorphine transdermal patch for the perioperative analgesia in patients who underwent simple lumbar discectomy. *Medicine (Baltimore)*. 2017 May;96(20):e6844. doi: 10.1097/MD.00000000000006844. PMID: 28514299; PMCID: PMC5440136.
5. Barker JC, Joshi GP, Janis JE. Basics and Best Practices of Multimodal Pain Management for the Plastic Surgeon. *Plast Reconstr Surg Glob Open*. 2020 May 26;8(5):e2833. doi: 10.1097/GOX.0000000000002833. PMID: 33154874; PMCID: PMC7605865.
6. Kumar S, Chaudhary AK, Singh PK, Verma R, Chandra G, Bhatia VK, Singh D, Bogra J. Transdermal Buprenorphine Patches for Postoperative Pain Control in Abdominal Surgery. *J Clin Diagn Res*. 2016 Jun;10(6):UC05-8. doi: 10.7860/JCDR/2016/18152.7982. Epub 2016 Jun 1. PMID: 27504383; PMCID: PMC4963743.
7. Desai SN, Badiger SV, Tokur SB, Naik PA. Safety and efficacy of transdermal buprenorphine versus oral tramadol for the treatment of post-operative pain following surgery for fracture neck of femur: a prospective, randomised clinical study. *Indian J Anaesth* 2017;61:225e9.
8. Davis MP. Twelve reasons for considering buprenorphine as a frontline analgesic in the management of pain. *J Support Oncol* 2012;10:209e19.
9. Likar R. Transdermal buprenorphine in the management of persistent pain e safety aspects. *Ther Clin Risk Manag* 2006;2:115e25
10. Londhe S, Patwardhan M, Shah R, Oak M. Efficacy and Safety of Buprenorphine Transdermal Patch for Immediate Postoperative Analgesia After Total Knee Arthroplasty Surgery. *J Arthroplasty*. 2020 Jun;35(6S):S178-S181. doi: 10.1016/j.arth.2020.02.015. Epub 2020 Feb 13. PMID: 32201109.
11. Yadav M, Mohan CL, Srikanth I, Raj ER, Gopinath R, Chandrasekhar P. Effect of preoperative application of buprenorphine transdermal patch on analgesic requirement in postoperative period in hip and knee replacement surgeries. *J Anaesthesiol Clin Pharmacol*. 2019 Jan-Mar;35(1):124-128. doi: 10.4103/joacp.JOACP_13_17. PMID: 31057254; PMCID: PMC6495615.
12. Arshad Z, Prakash R, Gautam S, Kumar S. Comparison between transdermal buprenorphine and transdermal fentanyl for postoperative pain relief after major abdominal surgeries. *J Clin Diagn Res* 2015;9:UC01e4.
13. Setti T, Sanfilippo F, Leykin Y. Transdermal buprenorphine for postoperative pain control in gynecological surgery: a prospective randomized study. *Curr Med Res Opin* 2012;28:1597e608.
14. Norbert Griessinger, Reinhard Sittl & Rudolf Likar (2005) Transdermal buprenorphine in clinical practice – a post-marketing surveillance study in 13-179 patients, *Current Medical Research and Opinion*, 21:8, 1147-1156, DOI: 10.1185/030079905X5331