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CLINICAL INVESTIGATION

Comparison of Efficacy of Tapentadol Nasal Spray with Parenteral Diclofenac Sodium in Post-Operative Pain Control Following Laparoscopic Surgeries: A Prospective Randomized Controlled Trial

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ABSTRACT

Background: Pain management is a crucial aspect of post-operative care. Comparing different analgesic formulations helps determine the most effective and patient-friendly approach to reducing post-operative pain and discomfort.

Objectives: This study aims to evaluate and compare the efficacy and safety of Tapentadol nasal spray versus Diclofenac injection in managing post-operative pain following laparoscopic procedures. The study seeks to determine which formulation provides better pain relief, faster onset of action, and fewer side effects.

Methods: We conducted a comparative analysis among patients undergoing laparoscopic surgery. Group A received 22.5 mg tapentadol nasal spray in each nostril, and Group B received 75 mg intramuscular diclofenac sodium injection in the post-operative period; we monitored responses

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for 48 hours post-operatively. The study collected data on pain intensity, duration of relief, and any adverse effects.

Results: Preliminary observations suggest that Tapentadol nasal spray provides faster pain relief than Diclofenac injection ($p<0.001$). Patients reported a quicker onset of action with the nasal spray, while Diclofenac provided slower but more sustained relief. Side effects also differed between groups, with nasal irritation with Tapentadol spray and injection-site pain with Diclofenac.

Conclusion: The findings indicate that Tapentadol nasal spray provides faster pain relief than Diclofenac injection in the postoperative period. It required less rescue analgesia, and patients could use the nasal spray without supervision.

Keywords: Tapentadol, post-operative pain, visual analog scale, diclofenac sodium, laparoscopic surgery

INTRODUCTION

Nearly one-fourth of day care surgery patients experience moderate to severe postoperative pain, especially on the day of surgery, with pain levels declining over 3–4 days.[1] Although laparoscopic surgeries generally cause less overall pain compared to open surgeries, patients often report more intense early postoperative discomfort. This is due to a combination of somatic pain at the incision site and peritoneal/visceral pain resulting from phrenic nerve irritation caused by pneumoperitoneum and tissue trauma.[2] The intensity of pain in these patients is influenced by certain factors such as the duration of surgery and the pressure of the pneumoperitoneum, necessitating aggressive analgesia in the first 24 hours after surgery.[3]

Advancements in treatment modalities for control of postoperative pain, such as intraperitoneal instillation and incision site infiltration of local anaesthetic agents, and use of analgesic skin patches containing non-steroidal anti-inflammatory drugs (NSAIDs) and opioids remain the mainstay of postoperative pain management. NSAIDs, including Diclofenac and Ibuprofen, work by inhibiting cyclooxygenase and prostaglandin synthesis but are associated with gastrointestinal and renal risks.[4] Conversely, opioids like morphine, codeine, fentanyl, tramadol, and tapentadol provide effective pain relief by acting on μ-opioid receptors, though they have adverse effects such as nausea, respiratory depression, and dependency. Among opioids, tapentadol exerts its effects through both μ-opioid receptor agonism and noradrenaline reuptake inhibition. It is two- to three-fold more potent than tramadol and has a more favorable gastrointestinal side-effect profile.[5] Moreover, intranasal tapentadol offers rapid absorption, bypasses first-pass metabolism, and has a rapid onset of action with potentially fewer systemic side effects than parenteral administration, although its ease of use raises concerns about abuse.[6] In light of these factors, this study aimed to compare the efficacy of intranasal Tapentadol spray with intramuscular Diclofenac sodium for immediate postoperative pain control following laparoscopic surgeries. Moreover, it seemed logical to compare injectable Diclofenac with Tapentadol nasal spray, since the latter is likely to be as effective as parenteral injection due to rapid mucosal absorption without the pain of

an injection prick. The primary objective was to compare pain scores and rescue analgesia requirements, while the secondary objectives were to compare satisfaction scores among surgeons and patients, as well as the occurrence of side effects for both drugs. Even though both are established drugs for post-operative pain control, we hypothesized that Tapentadol nasal spray could provide better and quicker analgesia with fewer side effects.

MATERIAL AND METHODS

This prospective randomized, single-blind interventional study with an allocation ratio of 1:1 was conducted in a tertiary care centre after receiving approval from the institutional ethics committee (Ethics committee letter no. BREC/23/TH-Surgery/01) and CTRI registration (CTRI/2023/10/058950, dated 21 October 2023, accessible at https://ctri.nic.in/). We obtained written informed consent from all patients, with permission to use their data for research and educational purposes. We conducted the study in accordance with Good Clinical Practice guidelines and the principles of the Declaration of Helsinki (2013).

Over two years (January 2023 to January 2025), 84 patients were assessed for eligibility, and 60 met the inclusion criteria and were enrolled. We allocated patients to the study or control group using computer-generated simple random numbers. After randomisation, 30 patients each were allotted to Group A (Tapentadol nasal spray) and Group B (Diclofenac sodium injection), as shown in the Consolidated Standards of Reporting Trials (CONSORT) flow diagram (Figure 1).

The patients undergoing routine laparoscopic abdominal surgeries such as appendicectomy, cholecystectomy, and hernia repair with American Society of Anaesthesiologists grade I and II and aged over 18 years were included in the study. Patients undergoing emergency surgeries, open laparotomy or conversion from laparoscopic to open procedures, multiple surgeries in one admission, those with known drug allergies, or those who refused participation were excluded. In Group A, patients received Tapentadol nasal spray by inserting the bottle tip into one nostril while closing the other, directing the spray toward the lateral nasal wall, and administering one puff (22.5 mg) in each nostril while patients were instructed to breathe gently with their head held upright. Intramuscular gluteal injections of Diclofenac sodium at a dose of 75 mg were administered to group B patients.

Preoperatively, a detailed history was taken, a physical examination was performed, and necessary preoperative investigations were done. The patients were also briefed about the surgical procedure, anaesthesia plan, and postoperative pain management, and were familiarized with the Visual Analog Scale (VAS) for pain assessment. All patients undergoing general anaesthesia received intravenous fentanyl at a dose of 2 µg/kg during induction of anaesthesia, followed by supplemental doses of 0.5 µg/kg every hour intraoperatively, administered intermittently as required to maintain adequate analgesia. All patients also received 1 g of intravenous paracetamol before closure of port sites. At the end of surgery, all patients received a local infiltration of 0.5% Lignocaine at the port sites. The initial dose of analgesic as per the allocated group was given in the immediate postoperative period. Thereafter, predetermined analgesia was given to both groups at 8-hour intervals and was labeled as the first, second, and third dose. VAS scores were recorded before giving analgesia and at 10, 30, and 60 minutes after each dose. VAS score of 0-1 was considered

pain relief. In case of persistent pain (pain score >4) in either group, an additional dose of Diclofenac sodium 75 mg IM was given as rescue analgesia. Postoperative monitoring included regular pain assessment using a 10-cm VAS (supplemented by the Wong-Baker face scale) and measurement of vital parameters (pulse, blood pressure, respiratory rate, and oxygen saturation). Because most patients were discharged by the first post-operative day, we recorded analgesic doses for the first 24 hours after surgery. The adverse effects such as rash, itching, pain/hematoma at injection site, nausea, vomiting, sedation, and respiratory depression (respiratory rate<8/min) were recorded in both groups.

All the patients, as well as attending surgeons, were asked to grade their satisfaction with the patient's pain control using a Likert scale, and it was categorized as "good"(score 4-5), "fair" (score 3), and "unsatisfactory" (score

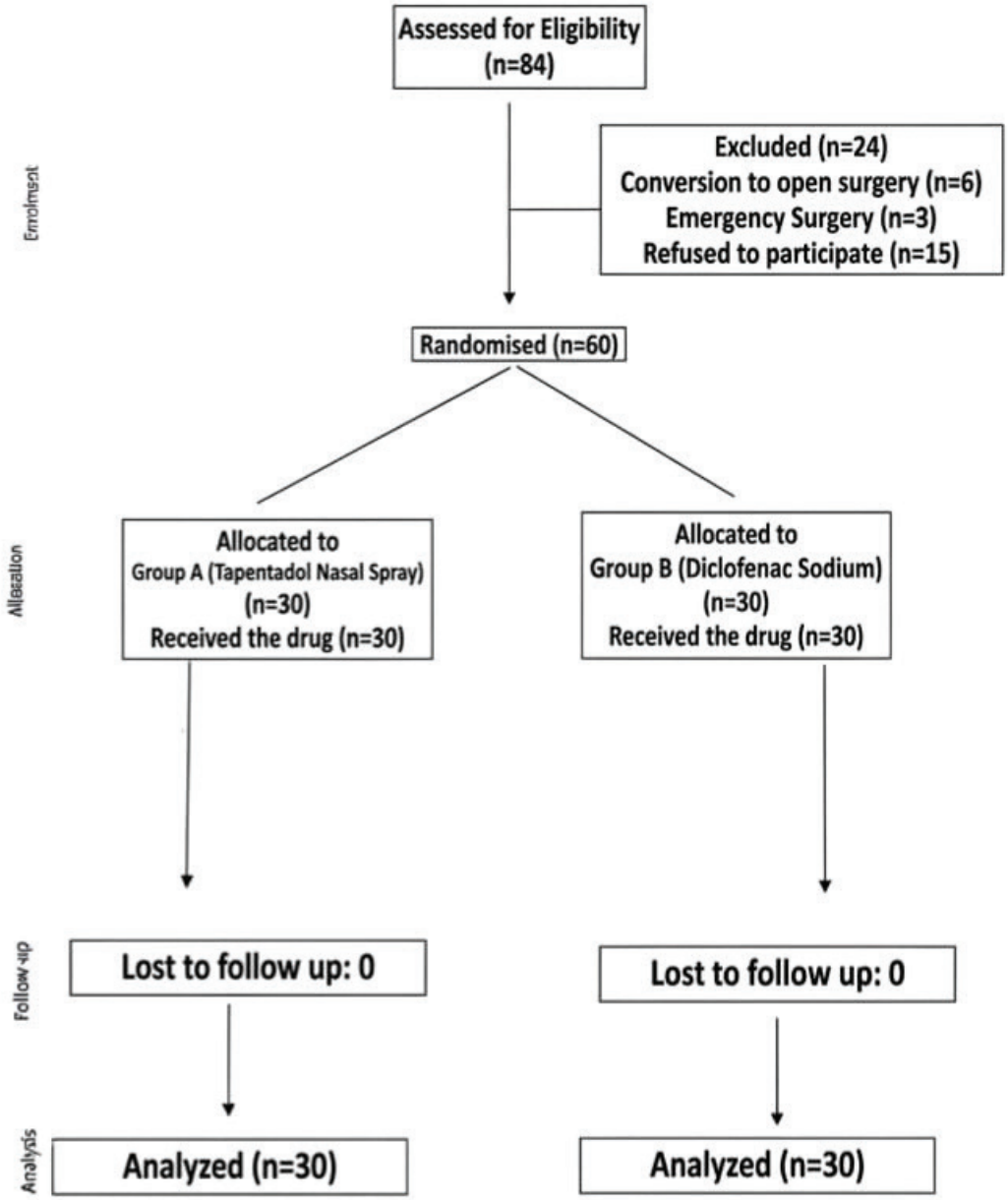


Figure 1: Consolidated standards of reporting trials (CONSORT) diagram.

1-2) at the time of discharge. We recorded the duration of hospital stay. Follow-up at one week included the number of analgesic doses (Tapentadol nasal spray/tablet, Diclofenac) taken after discharge.

The sample size was calculated using the Kelsey formula for comparison of two proportions. Based on Chaudhary et al.[7], the incidence of pain relief was 28% in the NSAID group and 64% in the Tramadol group. Assuming a two-sided alpha error of 5% and a study power of 80%, and considering equal group allocation (1:1 ratio), the values used for calculation were: $P_0 = 0.28$; $P_1 = 0.64$; $Z_{\alpha/2} = 1.96$; $Z_{1-\beta} = 0.84$; $\overline{P} = (P_0 + P_1)/2 = 0.46$; $\overline{q} = (1-\overline{P}) = 0.54$.

Using the formula, $n = [(Z_{\alpha/2} + Z_{1-\beta})2 * 2* \overline{P} * \overline{q}] / (P_1 - P_0)^2$, the required sample size was calculated as 60, with 30 patients in each group.

Data were entered into MS Excel and analysed using SPSS Version 26.0 2022. Categorical variables were expressed as proportions, while continuous variables were expressed as means and standard deviations if normal or as median and interquartile range if not. The chi-square test was used to assess statistically significant differences between two or more groups for categorical variables. We compared normally distributed continuous variables between two groups using an independent t-test, and non-normally distributed continuous variables between two groups using the Mann-Whitney test. We compared normally distributed continuous variables within a single time interval using a paired t-test. A p-value of less than 0.05 was considered statistically significant.

RESULTS

All 60 patients completed the study, as described in the Consolidated Standards of Reporting Trials (CONSORT) flow diagram (Figure 1). Both groups were comparable in demographic and clinical profile (Table 1).

Table 1: Demographic and Clinical Profiles of the study population

Demographic and clinical profile	Group A Tapentadol (n=30)	Group B Diclofenac Sodium (n=30)	*p*-value
Age (years) (mean ± SD)	42.03 ± 14.92	47.13 ± 13.36	0.169
Male/Female (n)	8/22	13/17	0.176
BMI (kg/Sqm) (mean ± SD)	23.55 ± 3.72	24.81 ± 3.57	0.186
Laparoscopic procedures LC/LA/TEP* (n)	24/3/3	18/5/7	0.138
Duration of surgery (min) (mean ± SD)	63.67 ±19.20	73.00 ± 46.49	0.316

Independent t-test and chi square test

**LC - Laparoscopic cholecystectomy, LA - Laparoscopic appendicectomy, TEP –Totally extra-peritoneal hernia repair (Laparoscopic hernia repair)*

Table 2: Comparison of time taken for pain relief after drug administration

Dose	Time taken for pain relief	Group A Tapentadol (n=30)	Group B Diclofenac Sodium (n=30)	*p*-value
1st dose	<10 mins	17 (56.66%)	3 (10%)	<0.001
	<30 mins	13 (43.33%)	22 (73.33%)	
	<60 mins	0 (0%)	5 (16.66%)	
2nd dose	<10 mins	21 (70%)	2 (6.66%)	<0.001
	<30 mins	9 (30%)	25 (83.33%)	
	<60 mins	0 (0%)	3 (10%)	
3rd dose	<10 mins	22 (73.33%)	2 (6.66%)	<0.001
	<30 mins	8 (26.66%)	26 (86.66%)	
	<60 mins	0 (0%)	1 (3.33%)	
	No relief	0 (0%)	1 (3.33%)	

Chi-square test

Table 3: Distribution of cases according to number of rescue analgesic dose requirement

Number of rescue analgesic doses required	Group A Tapentadol (n=30)	Group B Diclofenac Sodium (n=30)	*p*-value
One	1 (3.33%)	3 (9.99%)	0.605
Two	1(3.33%)	2(6.66%)	
Three	1(3.33%)	1(3.33%)	
None	27 (90.00%)	24 (80.00%)	

In the post-operative period, 10% of patients in group A and 20% in group B had a VAS score of 4 or more and needed rescue analgesia, and the difference was not statistically significant (p=0.278) [Table 3].

Among local side effects, the majority of Group A patients experienced burning in the nasal cavity, whereas most of Group B patients experienced local pain at the site of injection. Nasal burning in patients receiving tapentadol increased with each subsequent dose. After zero dose, 40% of patients reported a burning sensation in the nose, increasing to 93.33% with the second and third doses.

Table 4: Comparison of patient's and surgeon's satisfaction score using Likert scale

	Group A (Tapentadol)			Group B (Diclofenac Sodium)			*p*-value
Likert scale scores	Good (4-5)	Fair (3)	Unsatisfactory (1-2)	Good (4-5)	Fair (3)	Unsatisfactory (1-2)	
Patient's satisfaction (n)	13 (43.33%)	16 (53.33%)	01 (3.33%)	3 (10%)	27 (90%)	00 (0%)	0.007
Surgeon's satisfaction (n)	14 (46.66%)	15 (50%)	01 (3.33%)	04 (13.33%)	24 (80%)	2 (6.66%)	0.019

Likert scale (scores 1-5): 4-5 (good);3 (fair); 1-2 (unsatisfactory)

Table 5: Comparison of number of analgesic doses required after discharge

Number of analgesic doses required after discharge	Group A Tapentadol (n=30)	Group B Diclofenac Sodium (n=30)	*p*-value
None	26 (86.67%)	5 (16.67%)	
1-3 doses	4 (13.33%)	4 (13.33%)	<0.001
3-5 doses	0 (%)	21(70%)	

We assessed patient and surgeon satisfaction scores using a Likert scale at discharge. In the Tapentadol group, 43.33% of patients reported good satisfaction, compared with only 10% in the Diclofenac group; this difference was statistically significant. Similarly, 46.66% of surgeons rated their satisfaction as good in the Tapentadol group, compared with only 13.33% in the Diclofenac group, indicating a significant difference (p=0.019). [Table 4]

More than 85% of the patients in Tapentadol Group required no additional analgesics after discharge, compared to only 15% in Diclofenac Group and the difference was highly significant (P<0.001) [Table 5].

DISCUSSION

The key finding of our study was that tapentadol nasal spray provided faster pain relief than intramuscular diclofenac injection. This difference was statistically significant for all four doses (p<0.001). In the available literature, only one similar study compared tapentadol nasal spray with intramuscular diclofenac and also showed superiority of tapentadol nasal spray.[8] It is possibly because of higher bioavailability of tapentadol due to bypass of first-pass metabolism and quicker absorption of tapentadol through the nasal route due to rich vascularity of the nasal submucosa, which led to rapid pain relief.[9] Apart from providing early pain relief compared to injection

diclofenac, tapentadol nasal spray has the edge as it can be used unsupervised as needed after demonstrating the patient for one or two times, thus providing patient-controlled analgesia. In contrast, injectable diclofenac sodium always needs a trained healthcare professional for its administration.

In the available literature, various studies have compared the effectiveness of Tapentadol with other conventional analgesics using VAS scores. Most of these studies show that Tapentadol nasal spray is better than other analgesics.[8,9,10,11]

In our study, patients receiving Tapentadol nasal spray required rescue analgesia less often, and previous studies have reported similar findings.[10,12] Consistent with the existing literature, nasal irritation after first instillation and nausea are the main side effects of intranasal tapentadol; the latter is self-limiting and does not require discontinuation of the drug.[13,14] In contrast to Kamble et al.[13], which reported that nasal irritation after the first dose subsides with subsequent doses, the incidence increased to as high as 90% after the second and third doses in the present study (p<0.001).

At discharge, both surgeon and patient satisfaction scores were significantly better in the Tapentadol nasal spray group (p=0.019 and 0.007, respectively), possibly due to the convenience of administration and quicker, better pain relief. However, 3.33% of patients receiving Tapentadol nasal spray were dissatisfied because of intense local burning sensations in the nostrils. Similarly, 6.66% of surgeons were not satisfied in the Diclofenac group due to delayed pain relief. Although previous studies mention the ease of administration of Tapentadol nasal spray, none have assessed satisfaction scores. One study reported that most patients (97.98%) preferred nasal spray over the injectable route for post-operative analgesia.[14]

At one-week follow-up, the total number of analgesic doses required after discharge was significantly lower in the Tapentadol group than in the Diclofenac group (p <0.001), indicating better efficacy of the former drug.

The strengths of the present study include the first comparison of the effectiveness of Tapentadol nasal spray with Diclofenac sodium intramuscular injection for post-operative pain relief, with analysis of local and systemic side effects, and objective assessment of satisfaction among patients and surgeons regarding drug efficacy. In future, research can be focused on evaluating long-term adverse effects and abuse potential of the nasal formulation of Tapentadol.

The limitations of the present study were that patients belonged to a single surgical centre undergoing limited laparoscopic surgical procedures. Further, multicentre studies including a wide variety of open/laparoscopic surgical procedures are warranted to validate the findings of the present study.

CONCLUSION

Tapentadol nasal spray provides faster postoperative pain relief than diclofenac sodium injection. It also contributes to higher patient and surgeon satisfaction and does not require a trained healthcare professional for administration. While recovery outcomes and side effects are comparable, nasal burning is more common with the nasal spray.

AUTHORS' CONTRIBUTIONS

Conceptualization and design: SM

Literature search: PG, M, HG, MS

Data collection: PG, M, HG, MS

Data analysis: PG

Manuscript drafting and critical revision: SM, RK, MSingh, PK

Proofreading and approval of the manuscript: SM, RK, MSingh, PK

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DECLARATION OF CONFLICTS OF INTEREST

There are no conflicts of interest to declare.

ETHICAL CLEARANCE

Approved by the Institutional Ethics Committee of Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences, Rohtak, Haryana, India (No: BREC/23/TH-Surgery/01); Approval date: August 4, 2023.

The study was registered with the Clinical Trials Registry – India.

(CTRI No: CTRI/2023/10/058950)

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