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## Comparison of the analgesic effects of paracetamol and tramadol in lumbar disc surgery

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**Background/aim:** To compare the postoperative analgesic efficacy and side effects of paracetamol and tramadol in patients undergoing lumbar disc surgery.

**Materials and methods:** Group P (paracetamol group) was given 1 g of paracetamol intravenously 30 min before the end of the operation and 1 g each day at 6-h intervals. Group T (tramadol group) was given 1.5 mg/kg of tramadol as a loading dose and patient-controlled analgesia for 1 day. Hemodynamic parameters, modified Aldrete score, Ramsay sedation scale score, patient satisfaction scale (PSS) score, visual analog scale (VAS) score, nausea/vomiting scale score, and additional analgesic needs/times were recorded.

**Results:** PSS scores were significantly higher in Group T ( $P < 0.05$ ). The total analgesic consumption was significantly higher in Group P. There were no significant differences in the VAS scores at any time points. Twenty-one patients in Group P and 8 patients in Group T needed additional analgesia ( $P < 0.05$ ). The first additional analgesic time was earlier in Group P, and pain was more evident at the 15th minute and at hours 2 and 6 ( $P < 0.05$ ).

**Conclusion:** Paracetamol alone was not able to provide effective analgesia. Tramadol was more effective in the treatment of postoperative pain after lumbar disc surgery.

**Key words:** Paracetamol, tramadol, postoperative analgesia

### 1. Introduction

Despite developments in the pathophysiology and treatment of pain, increased knowledge of pain management, the availability of new drugs, and complex drug delivery systems, the pain management of many patients after surgery remains inadequate. Studies have shown that successful postoperative analgesia after surgery prevents many side effects of pain, such as the inability to breathe at ease, the increase in the workload of the cardiovascular system, the development of thromboembolic events due to a delay in the mobilization of patient, and the increase in stress response due to the activation of the sympathetic nervous and neuroendocrine systems (1,2). Inadequate treatment of acute pain is the most common cause of chronic pain after surgery. The aim after surgery is to ensure that organ functioning returns to normal quickly by controlling pain as soon as possible (3).

Today it is possible to achieve successful postoperative analgesia by selecting appropriate methods/routes of

administration, agents, dosages, and dosage ranges. Opioids are the most widely used group of drugs in the treatment of postoperative pain due to their strong analgesic activities. However, opioid-related nausea, vomiting, pruritus, urinary retention, respiratory depression, sedation, and central nervous system depression have accelerated the search for analgesic drugs with better pain relief efficacy and fewer side effects (4).

Research has reported gastric irritation, erosion, bleeding, and inhibition of platelet aggregation with nonsteroidal antiinflammatory drugs (NSAIDs), in addition to adverse effects on the secretion of uric acid and bleeding (5), thereby restricting their use. Side effects, such as systemic toxicity and prolonged sensory and motor responses, have also been reported with local anesthetic drugs used to provide pain control (6). Tramadol, a weak, effective synthetic opioid, has been shown to have relatively few side effects compared to other opioids, and its abuse or addiction potential is negligible (7). Paracetamol is a

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reliable NSAID with few side effects. It is available in a ready-to-use form suitable for infusion intravenously (i.v.) and can be used for postoperative mild and moderate pain. Research has also demonstrated that it has a very good safety profile at therapeutic doses (8).

This study aimed to compare the postoperative analgesia efficacy and side effects of paracetamol with those of tramadol in patients undergoing lumbar disc surgery.

## 2. Materials and methods

Sixty patients aged 18–70 years and classified as ASA I–II who were scheduled for elective lumbar disc surgery under general anesthesia were selected for the study after obtaining the approval of the patients and the local ethics committee. The study was planned as a randomized prospective one. Patients who could not use a patient-controlled analgesia (PCA) device, who had severe liver and kidney disease, who were obese (body mass index of  $\geq 30$  kg/height [m<sup>2</sup>]), or who had drug allergies or a history of drug abuse were excluded from the study. The patients were randomly divided into two groups (Group P [paracetamol] and Group T [tramadol];  $n = 30$  in each). The day before the surgery, the patients were informed about the prospective drugs, the PCA, and the visual analog scale (VAS) that would be used in their pain assessment. All the patients were given famotidine (40 mg) and diazepam (10 mg) orally at 2200 hours the night before the surgery as routine premedication.

The induction of general anesthesia (i.v.) was achieved with propofol (2.5 mg/kg) and a 1  $\mu$ g/kg remifentanyl bolus dose and maintained with 2% sevoflurane, 50%/50% O<sub>2</sub>-air, and remifentanyl (0.1  $\mu$ g kg<sup>-1</sup> min<sup>-1</sup>) in an intravenous infusion. Neuromuscular block was induced by 0.2 mg/kg cisatracurium administered i.v. and maintained with 0.03 mg/kg cisatracurium administered i.v. Group P received 1 g of paracetamol i.v. 30 min before the end of the operation and 1 g at 6-h intervals for 1e day. Group T was given 1.5 mg/kg tramadol as a loading dose in the reanimation unit via the PCA, and a bolus dose of 20 mg was administered i.v. for 1 day. The lockout time limit was 20 min and the 4-h limit was 200 mg. Both groups were given 10 mg metoclopramide i.v. with the analgesics.

The modified Aldrete score (MAS) was used to evaluate patients at the end of the operation. Those who had adequate spontaneous breathing were extubated in the operating room and monitored at 1-min intervals after the first 5 min and then at 5-min intervals for 1 h in the recovery room. Monitoring was performed by routine ECG, pulse oximetry, and noninvasive blood pressure measurement. The patients' heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), peripheral oxygen saturation (SpO<sub>2</sub>) (only in the reanimation unit

for 1 h), respiratory rate, fever, Ramsay sedation scale (RSS) score, patient satisfaction scale (PSS) score, VAS, nausea/vomiting scale (NVS) score, and side effects were evaluated at 15, 30, 45, and 60 min in the reanimation unit and at 2, 4, 6, 12, and 24 h in the neurosurgical unit in the postoperative period. Intramuscular diclofenac (75 mg) was given as an additional analgesic to those whose VAS score was  $>3$ .

Bradycardia was defined as a HR of less than 45 beats/min and treated with 0.5 mg of atropine. A 20% drop in preoperatively measured SBP was defined as hypotension and treated with 5-mg doses of ephedrine, administered i.v. A 20% increase was defined as hypertension and treated with 100 mg of perlinganit i.v.

### 2.1. Statistical analysis

SPSS 10.0 for Windows was used in the evaluation of the findings in the statistical analysis. Student's t-test was used to compare quantitative data, for intergroup comparisons of data showing a normal distribution, and for descriptive statistics (mean, standard deviation) in the evaluation of the study parameters. A Bonferroni corrected Mann–Whitney U-test was used in intragroup comparisons of parameters not showing a normal distribution. A paired sample t-test was used in intragroup comparisons of normally distributed parameters. A Bonferroni-corrected Wilcoxon-signed rank test was used for intragroup comparisons of parameters showing a normal distribution. A chi-square test was used to compare qualitative data. In the Bonferroni-corrected tests,  $P < 0.01$  was considered significant, whereas  $P < 0.05$  was considered significant in the other tests. Data are expressed as mean  $\pm$  standard deviation.

## 3. Results

No statistically significant difference was observed between the two groups when the 60 patients included in the study were evaluated in terms of demographic characteristics such as age and sex, weight, height, and duration of the surgery (Table 1).

When their hemodynamic parameters were evaluated, there were no statistically significant differences in the patients' HR, SBP, DBP, respiratory rates, or SpO<sub>2</sub> values according to the measurement time in the intragroup comparison. In the intragroup comparison of the RSS scores, there was no significant difference at any time other than minute 15, with RSS scores significantly higher in Group T at this time point. In the intragroup evaluation of the MAS score, there was no significant difference at any time point except minute 30. At that time, there was a significant increase in the MAS score in Group P ( $P < 0.05$ ).

The PSS score was significantly higher in Group T ( $P < 0.05$ ). When all the times were compared between the

**Table 1.** Demographic and clinical characteristics of patients administered paracetamol or tramadol.

	Paracetamol (n = 30)	Tramadol (n = 30)
Age (years)	48.1 ± 14.1	43.8 ± 9.8
Weight (kg)	75.3 ± 14.5	77.3 ± 14.6
Body mass index (kg/m <sup>2</sup> )	27.4 ± 4.2	26.7 ± 4.0
Duration of surgery (min)	83.1 ± 19.8	74.1 ± 23.1
Amount of bleeding (mL)	184.7 ± 84.4	151.7 ± 73.8

Data are presented as mean ± standard deviation. No significant differences were observed among groups.

two groups, there was no significant difference in the VAS score. The total analgesic consumption was significantly higher in Group P (21 patients in Group P vs. 8 in Group T;  $P < 0.05$ ). In addition, the time to the first analgesic was earlier in Group P, especially at minute 15 and at hours 2 and 6 (Table 2).

There was no significant difference between the groups when the NVS score was evaluated. In terms of side effects, a dry mouth was the most common side effect in Group T (reported in 43.3% of patients). The incidence of a dry mouth in Group P was 20%, and this difference was statistically significant ( $P < 0.05$ ; Table 2).

#### 4. Discussion

Postoperative pain is an acute type of pain that begins with surgical trauma and gradually decreases with tissue healing. Postoperative pain treatment is an important part of patient follow-up after surgery in anesthesia practice. There are differences between the effectiveness of analgesics depending on the location of the pain, the type of the pain, and the advantages and disadvantages of each method of pain relief. Thus, studies of the analgesic efficacy of various drugs are important. In this study, the VAS score and side effect profile of paracetamol were similar to those of tramadol, with additional analgesia needed in both groups undergoing lumbar disc surgery. However, the patient satisfaction was lower with paracetamol than with tramadol, and paracetamol alone did not provide adequate postoperative analgesia.

Paracetamol is the preferred analgesic in the treatment of postoperative mild and moderate pain. Although the mechanism underlying the action of paracetamol is not yet fully understood, it is believed to act primarily by inhibiting the central cyclooxygenase (COX-3) pathway of the central nervous system and by an indirect interaction with the serotonergic system (9). Paracetamol is available in ready-to-use 1-g intravenous forms, and these were used

**Table 2.** Postanesthesia care unit evaluation (1-h observation period).

	Paracetamol group (n = 30)	Tramadol group (n = 30)
VAS		
15 min after surgery	3.6 ± 2.4	
30 min after surgery	3.4 ± 2.3	3.1 ± 1.3
45 min after surgery	3.6 ± 2.3	3.1 ± 1.2
1 h after surgery	3.3 ± 2.0	3.2 ± 1.3
Nausea and vomiting scale		3.0 ± 1.2
15 min after surgery	0.1 ± 0.3	
30 min after surgery	0.0 ± 0.01	0.1 ± 0.3
45 min after surgery	0.1 ± 0.4	0.0 ± 0.0
1 h after surgery	0.0 ± 0.0	0.1 ± 0.3
Patient satisfaction scale		0.0 ± 0.0
15 min after surgery	1.4 ± 0.6*	1.8 ± 0.6
30 min after surgery	1.8 ± 0.6	1.9 ± 0.5
45 min after surgery	1.8 ± 0.6	2.0 ± 0.5
1 h after surgery	1.9 ± 0.5	1.9 ± 0.5
Dry mouth	5**	13
Additional analgesic requirement	21***	8

Data are presented as means ± SD or as absolute numbers.

\* $P < 0.05$  versus tramadol group; \*\* $P < 0.05$  versus tramadol group; \*\*\* $P < 0.001$  versus tramadol group.

in the current study. They are widely used because they save time for nurses by shortening the time for preparation and administration of the drug and decrease direct costs by requiring less supplementary products (e.g., PCA pumps, infusion bags, batteries). In addition to its ready-to-use intravenous preparation, paracetamol reduces the risk of contamination and dosage errors by medical staff. The onset of analgesic action with paracetamol administered i.v. is also faster than an equivalent dose of oral paracetamol, and it has higher activity and a longer lasting analgesic effect. Thus, paracetamol administered i.v. has become an indispensable analgesic agent, used in combination with other drugs, for balanced analgesia to control postoperative pain and reduce side effects.

In clinical studies, the efficacy of paracetamol alone in the treatment of mild-to-moderate postoperative pain and its place in combination treatment were investigated (10–12). Studies of combination treatment showed that paracetamol has an opioid-reducing effect and that it significantly reduces the patient's need for total opioids, thereby increasing the patient's overall satisfaction with the analgesic therapy (10,13). In the current study, we found

that patient satisfaction was lower in the group that received postoperative analgesia with paracetamol and that the need for supplemental analgesia was higher in these patients undergoing lumbar disc surgery. Korkmaz et al. compared the effects of paracetamol, metamizol, and lornoxicam on postoperative pain and morphine consumption in 80 patients undergoing lumbar disc surgery (14). They reported that postoperative analgesia was effective with paracetamol and metamizol but lornoxicam was not sufficient in pain treatment and that morphine consumption was not significantly different between the groups. Studies have investigated the selection of appropriate analgesics according to the type of surgery (minor vs. major) and the site of the surgery in postoperative pain management. Studies to reduce opioid-related side effects and to provide effective postoperative analgesia are ongoing. Paracetamol stands out among nonopioid analgesics due its effective analgesia and reduced side effect profile. However, many recent studies have reported adverse effects of paracetamol on postoperative pain and morphine consumption after surgery (15–18). Tunali et al. compared the postoperative analgesic effect of paracetamol and dextetoprofen and reported that dextetoprofen provides better analgesia (15). In a similar study, Mowafi et al. compared the analgesic effect of paracetamol and lornoxicam in patients undergoing lower abdominal surgery and presented results in favor of lornoxicam (19). We also found a need for additional analgesics in a greater number of patients (Group P: n = 21, Group T: n = 8) and an earlier (15 min, 2 h, and 6 h) need for analgesia in Group P, although there was no significant difference in terms of the VAS scores between the two groups when we compared paracetamol and tramadol. When we examined the VAS values between the two groups, they were higher in Group P, although not significantly so. We think that this may explain the need for higher levels of supplementary analgesics in Group P. The high patient satisfaction in Group T also supports this idea.

Tramadol is a centrally acting synthetic analgesic, which is structurally similar to opioid derivatives. It is an analogue of 4-phenylpiperidin codeine and is part of the aminocyclohexanol group. As tramadol has a safe side effect profile, it does not require monitoring, unlike strong opioids. It can also be used in noncooperative patients and does not require special training of staff (20). For these reasons, its clinical use is widespread.

Many studies have investigated tramadol's pain-killing efficacy, side effect profile, and usefulness for different types of pain. A recent study compared the postoperative pain relief provided by paracetamol and tramadol in children after adenotonsillectomy and reported that paracetamol showed similar analgesic effects and provided early recovery (21). Another study reported that a tramadol/acetaminophen combination was superior to propoxyphene/acetaminophen in postoperative wound pain treatment (22). In the current study, we did not find a significant difference in the postoperative VAS scores of the patients in Group P compared to those in Group T. However, the greater need for additional analgesia in Group P may explain the lack of a significant difference between the VAS scores of the two groups. Tramadol was administered to patients by PCA in Group T. Therefore, patients analgesic needs were met quickly without the need for additional analgesic, whereas in Group P, patients did not have adequate analgesia with paracetamol. Thus, need for additional analgesic may have been increased in this group. Further studies with larger patient groups may produce different results.

In postoperative pain treatment, the administration of drugs with side effects that require interventions and disrupt the patient's vital functions increase costs and require additional staff, all of which limit their use. Recent studies showed that paracetamol is an analgesic with few side effects, a wide dosage range, and easy use (16,23). Tramadol is an opioid with few side effects also and it is thought to have good analgesic activity (24). In our study, we did not find a significant difference between the two groups in terms of the most common side effects. The most frequent side effect was a dry mouth, and this was significantly more common in Group T. However, as the patient satisfaction scale was significantly higher in this group, we concluded that patients did not find a dry mouth a distressing problem.

In conclusion, the postoperative VAS values with paracetamol were similar to those with tramadol in patients undergoing lumbar disc surgery. However, the patients in the paracetamol group had increased additional analgesic requirements. There were no significant differences in the side effect profiles of paracetamol and tramadol. Paracetamol alone was not able to provide effective analgesia, and tramadol was more effective in the treatment of postoperative pain after lumbar disc surgery.

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