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ORIGINAL ARTICLE

Effect of Submucosal Injection of Tramadol on Postoperative Complications after Third Molar Surgery

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ABSTRACT

Objective: To determine the effectiveness of submucosal application of tramadol for acute postoperative pain, swelling and trismus.

Material and Methods: A total of 84 patients having age between 18 to 35 years with irrespective of gender and require impacted mandibular 3rd molar extractions were included in study whereas patients with pericoronitis, periapical infection or lesions with respect to impacted 3rd molars, opposing traumatic occlusion or impinging upper 3rd molars or pregnant and lactating women were excluded in study. Subjects were distributed in two groups by port (chit) method i.e., Group A (Tramadol Group) with 42 patients and group B (sterile normal saline group) with 42 patients. Postoperative pain, swelling and trismus were recorded on Day 1, 2, 3 and 7

Results: Male patients were 25 (59.5%) and 25 (59.5%) and female patients were17 (40.5%) and 17 (40.5%) with mean age of25.7±4.7 (18-35) years and 26.5±4.9 (18-35) years in group A (Tramadol Group) and group B (Sterile Normal Saline Group) respectively. Post-operative findings in both groups were significantly different, group A (Tramadol Group) is better from group B (Sterile Normal Saline Group) in terms of post-operative pain, swelling and trismus.

Conclusion: Submucosal Tramadol is more effective, safe and reliable than sterile normal saline in patients after third molar surgery.

Keywords: Effectiveness, Submucosal, Tramadol, Facial pain, Third Molar

INTRODUCTION

Enhanced postoperative pain care after oral surgery may contribute to a speedier comeback in areas of lifestyle and oral function. Pain management after oral surgery is a critical element in lowering panic and stress in individuals.[1, 2]

Wisdom tooth extraction surgery is one of the most common dental surgical operations, and it is linked with moderate-to-severe discomfort. The effectiveness of local anesthetic begins to wane within 3-5 hours following surgery, and discomfort approaches its peak. [3, 4] Third molar tooth extractions are frequently done on a day-to-day basis. Inflammation, swelling, trismus, and discomfort are all common side effects of these operations.[5]

Non-opioid medications [non-steroidal anti-inflammatory drugs (NSAIDs), paracetamol (acetaminophen), metamizole], opioids, and adjuvants are the three primary pharmacological types used to treat pain (antidepressants, anticonvulsants and local anesthetics).[6]

The numerous administration methods are divided into two categories: enteral (sublingual, pe roral, and rectal) and parenteral (intravenous) (intravascular, intramuscular, subcutaneous and inhalation). [6]

Tramadol hydrochloride is a synthetic opioid medication that acts centrally. Tramadol, although being classed as a weaker opioid in terms of analgesic characteristics, has a dual action, acting as both an opioid and a non-opioid. It also inhibits serotonin and nor epinephrine re-uptake, which lowers the propagation of pain sensations.[7] Tramadol's major mode of action is agonism of -opioid receptors (-OR) and suppression of monoamine reuptake, which inhibits the reuptake of monoamines produced from nerve terminals such as norepinephrine and serotonin.[8] Tramadol inhibits pain transmission in the central nervous system by blocking monoamine reuptake.[9]

Various studies have shown that tramadol is a suitable analgesic for post-extraction pain treatment with few adverse consequences and offers long-lasting analgesia, demonstrating its superiority over ketorolac.[10-11] Earlier authors said that tramadol injection as an adjuvant to articaine had no local adverse effects at the site of administration, but our study indicated that tramadol injection prolongs anaesthetic effect and improves postoperative pain control.[12]

Tramadol, once submucosally administered locally, gives enough analgesic impact for prolonged periods of time, therefore multiple local injection of tramadol are not necessary during treatment. [13] Although there is evidence that orally given tramadol is efficacious, few research have assessed its analgesic effectiveness. The impact of tramadol submucosal injection following surgical removal of the third molar on pain, swelling, and mouth opening must be assessed.

METHODOLOGY

This randomized controlled trial with non probability consecutive sampling technique was conducted in Department of Oral and Maxillofacial Surgery, Liaquat University of Medical and Health Sciences, Jamshoro/Hyderabad from 1st January 2021 to 31st December 2021.

A total of 84 patients were designated into two groups.

- Group A (Tramadol Group): 100 mg/2 ml tramadol (TRAMAL 100 Grunenthal Ltd Pharmaceutical, Pakistan) = 42 patients.
- Group B (Sterile Normal Saline Group): Sterile 2 ml of 0.9% normal saline Ostaka (Made in Pakistan) = 42 patients.

Inclusion Criteria:

- Either gender.
- Patients' age between 18 and 35 years.
- Patients who required impacted mandibular 3rd molar extractions.
- Pell and Gregory class 2, position B.
- Winters mesioangular position.

Exclusion Criteria:

- Patients with pericoronitis, periapical infection or lesions with respect to impacted 3rd molars.
- Opposing traumatic occlusion or impinging upper 3rd molars.
- Pregnant and lactating women.

Data Collection Procedure: The study was performed after approval of research ethics committee of the university. The impacted third molars were diagnosed by clinical examination and radiographs like OPG and periapical radiographs.

All data was entered in the Performa and procedures were described to the patients. Under aseptic, all surgical extractions were done under local anesthesia by giving conventional inferior alveolar nerve block, also anesthetizing lingual nerve and long buccal nerve by xylocaine 2% with epinephrine 1:100000 (Medicaine Hunos, Co, Ltd Korea). Incision was given with sterile surgical blade no. 15 carbon steel company name (Feather safety razor Co, Ltd Japan).

The envelop flap was raised along with releasing incision for all cases, followed by reflection of mucoperiosteum with periosteal elevator than bone was removed with slow hand piece round head bur under constant irrigation with sterile 0.9% normal saline (Ostaka made in Pakistan). Then tooth was lifted, after the removal of tooth any sharp bone was smoothen by bone filer and irrigation was done with normal saline then suturing was done with vicryl 3-0 (Johnson and Johnson made in USA).

In 42 patient's injection tramadol 100 mg/2 ml (TRAMAL 100 Grunenthal Ltd Pharmaceutical, Pakistan) was given submucosally and remaining 42 patients receive sterile 2 ml of 0.9% normal saline Ostaka (Made in Pakistan). As a standardized postoperative treatment, Augmentin 625mg orally every 8 hours for 5 days was given to avoid any surgical infection.. A dose of 400 mg ibuprofen (Brufen) was prescribed as a rescue drug for moderate and severe postoperative pain as per need. All patients were reviewed postoperatively on Day 1, 2, 3 and 7 for pain, swelling and trismus. All data was recorded on Performa. The Wong-Baker FACES Pain Rating Scale was used to measure pain. Swelling was graded in millimeters from the angle of the mandible to the menton (ranging from 2mm to 8mm).Trismus was distributed as Mild/grade I (35–26 mm), Moderate/grade II (25–16 mm), Severe/grade III (15-0 mm)

Data Analysis Procedure: The data was entered in the statistical package for the social sciences (SPSS) V:21 for categorical variable, frequency and percentages were calculated by chi-square test with the confidence interval of 95% and P value equal to or less than 05 was used to compare the efficacy of Injection tramadol 100mg/2ml and sterile 2ml of 0.9% normal saline.

RESULTS

In this study male and female were equal in both groups; 25 (59.5%) and 25 (59.5%) patients were male and 17 (40.5%) and 17 (40.5%) patients were female in group A and group B. for age estimation all enrolled patients were grouped as; in 18-25years 22 (52.4%)and 15 (35.7%) patients, in 26-30years 13 (31.0%)and 17 (40.5%)patients and in 31-35years 7 (16.7%)and 10 (23.8%) patients in group A and group B respectively. Distribution of age and gender is shown in table 1.

In terms of postoperative pain from day 1 to 7, group A (Tramadol) shows better results as compare to group B (Normal Saline). And on day 7 none of the patients of tramadol group experience any sort of pain as per Wong Baker FACES pain rating scale. Detailed findings of postoperative pain are shown in table 2.

On all postoperative days grade 1 to 4 swelling was better controlled in group A as compare to group B, as tabulated in table 3.

Postoperative trismus results were seen greatly in favor of group A as compare to group B. Trismus at day 3 and day 7 was almost normal in all patients of group A as compare to group B. Table 4 shows detailed results for trismus.

Table: 1. Patients distribution according to gender and age (n=84)

Gender & Age	Group A Frequency (%)	Group B Frequency (%)	P-Value
Male	25 (59.5%)	25 (59.5%)	1.000
Female	17 (40.5%)	17 (40.5%)	
Age 18-25	22 (52.4%)	15 (35.7%)	0.303
Age 26-30	13 (31.0%)	17 (40.5%)	
Age 31-35	7 (16.7%)	10 (23.8%)	

Table: 2. Patients distribution according to postoperative pain (N=84

	Wong Baker FACES Scale	Group A	Group B	P-Value
Pain at Day 1		Frequency (%)	Frequency (%)	
	Hurts Little Bit (2)	9 (21.4%)	2 (4.8%)	< 0.001
	Hurts Little More (4)	14 (33.3%)	4 (9.5%)	
	Hurts Even More (6)	12 (28.6%)	6 (14.3%)	
	Hurts Whole Lot (8)	5 (11.9%)	16 (38.1%)	
	Hurts Worst (10)	2 (4.8%)	14 (33.3%)	
Pain at Day 2	No Hurt (0)	9 (21.4%)	1 (2.4%)	< 0.001
	Hurts Little Bit (2)	17 (40.5%)	3 (7.1%)	
	Hurts Little More (4)	11 (26.2%)	7 (16.7%)	
	Hurts Even More (6)	3 (7.1%)	11 (26.2%)	
	Hurts Whole Lot (8)	2 (4.8%)	14 (33.3%)	
	Hurts Worst (10)	0 (0.0%)	6 (14.3%)	
Pain at Day 3	No Hurt (0)	28 (66.7%)	2 (4.8%)	< 0.001
	Hurts Little Bit (2)	10 (23.8%)	5 (11.9%)	
	Hurts Little More (4)	4 (9.5%)	21 (50.0%)	
	Hurts Even More (6)	0 (0.0%)	9 (21.4%)	
	Hurts Whole Lot (8)	0 (0.0%)	4 (9.5%)	
	Hurts Worst (10)	0 (0.0%)	1 (2.4%)	
Pain at Day 7	No Hurt (0)	42 (100.0%)	34 (81.0%)	0.003
	Hurts Little Bit (2)	0 (0.0%)	8 (19.0%)	

Table: 3. Patients distribution according to postoperative swelling (N=84)

	Swelling Grade	Group A	Group B	P-Value
Swelling at Day 1		Frequency (%)	Frequency (%)	
	Grade 1 (2 mm) or less)	18 (42.9%)	7 (16.7%)	0.010
	Grade 2 (2-4 mm) indent	19 (45.2%)	18 (42.9%)	
	Grade 3 (4-6 mm) pit is noticeably deep	4 (9.5%)	13 (31.0%)	
	Grade 4 (6-8 mm) pit is very deep	1 (2.4%)	4 (9.5%)	
Swelling at Day 2	Grade 1 (2 mm) or less)	23 (54.8%)	8 (19.0%)	< 0.001
	Grade 2 (2-4 mm) indent	17 (40.5%)	18 (42.9%)	
	Grade 3 (4-6 mm) pit is noticeably deep	1 (2.4%)	12 (28.6%)	
	Grade 4 (6-8 mm) pit is very deep	1 (2.4%)	4 (9.5%)	
Swelling at Day 3	Grade 1 (2 mm) or less)	39 (92.9%)	23 (54.8%)	< 0.001
	Grade 2 (2-4 mm) indent	2 (4.8%)	15 (35.7%)	
	Grade 3 (4-6 mm) pit is noticeably deep	1 (2.4%)	4 (9.5%)	
Swelling at Day 7	Grade 1 (2 mm) or less)	42 (100.0%)	41 (97.6%)	0.314
	Grade 2 (2-4 mm) indent	0 (0.0%)	1 (2.4%)	

Table: 4. Patients distribution according to postoperative trismus (N=84)

	Trismus	Group A	Group B	P-Value
Trismus at Day 1		Frequency (%)	Frequency (%)	
	Mild (26-35 mm)	32 (76.2%)	22 (52.4%)	0.049
	Moderate (16-25 mm)	9 (21.4%)	15 (35.7%)	
	Severe (0-15 mm)	1 (2.4%)	5 (11.9%)	
Trismus at Day 2	Mild (26-35 mm)	33 (78.6%)	25 (59.5%)	0.102
	Moderate (16-25 mm)	8 (19.0%)	12 (28.6%)	
	Severe (0-15 mm)	1 (2.4%)	5 (11.9%)	
Trismus at Day 3	Mild (26-35 mm)	41 (97.6%)	35 (83.3%)	0.080
	Moderate (16-25 mm)	1 (2.4%)	6 (14.3%)	
	Severe (0-15 mm)	0 (0.0%)	1 (2.4%)	
Trismus at Day 7	Mild (26-35 mm)	42 (100.0%)	41 (97.6%)	0.314
	Moderate (16-25 mm)	0 (0.0%)	1 (2.4%)	

DISCUSSION

The more frequent ambulatory treatment performed by oral and maxillofacial surgeons is third molar surgery, which is an essential

element of the activity in a maxillofacial surgery department.[14] Pain, trismus and swelling are almost universal post-operative complication after third molar surgery. The rate of post-operative complication is increasing day by day. As a result, this investigation was conducted in Jamshoro's tertiary care hospital to determine the efficacy of tramadol submucosal administration for intense postoperative pain, swelling, and trismus. Study findings will be helpful for future use of tramadol to relief or to subside postoperative sequelae after third molar extraction including facial pain, swelling and trismus.

In this study, both groups i.e., group A (Tramadol Group) and group B (Sterile Normal Saline Group) have equal proportion of male 25 (59.5%) and female 17 (40.5%) with male to female ratio of 1.47:1. Mean age of patients was 25.7±4.7 (18-35) years and 26.5±4.9 (18-35) years in group A and group B respectively. Similarly, majority of the patients were in age group of 18-25years followed by 26-30years and 31-35years with non-significant difference (p-value =0.303). Iqbal AM et al[15] also reported the higher male proportion 53.3% with male to female ratio of 1.14:1 and mean age of 27.78 years. Gönül O[16] reported the mean age of 24.80 ± 2.524 and 23.93 ± 2.828 years in tramadol and sterile normal saline group respectively. Similar other studies also reported the higher male patients with third molar surgery with age ranging from 20 to 35 years.[17-18] All similar studies are reporting that young male adults are mostly go through third molar surgery.

The first day after the surgery, all patients of both group reported the pain, but level of pain was significantly (p-value =< 0.001) low in tramadol group as compared to sterile normal saline group. In terms of the Wong baker FACES pain scale, the current study found that the p values are statistically significant post-surgical removal at days 1 to 7, indicating a substantial disparity in pain score over those time periods. Iqbal AM[15], Gönül O[16] and Panchal KV[19] reported the significant lower postoperative pain score sin the tramadol group as compared to sterile normal saline. All these findings were in support of present study. A study conducted by De Pedro-Munoz A[20] stated that effectiveness of submucosal tramadol is 57%. Tramadol is preferable to other opioids since it has less major adverse effects, such as respiratory depression.[20]

Tramadol's enhanced analgesic efficacy when applied submucosally is most likely owing to the accomplishment of a larger drug concentration at the wounded area without loss, as a result of its body distribution and excretion.

On day 1 swelling grade was low, grade 1 in 18 (42.9%) patients in tramadol group whereas only 7 (16.7%) patients were reported in grade 1 from sterile normal saline group with significant difference (p-value =0.010). Similarly, trismus severity was low, mild in 32 (76.2%) patients in tramadol group whereas 22 (52.4%) patients were reported mild trismus from sterile normal saline group with significant difference (p-value =0.049). Better results were noticed for tramadol group in terms of swelling and trismus on 2nd and 3rd postoperative days. Swelling and trismus grade was similar in both groups on day 7, grade 1 in 42 (100.0%) and 41 (97.6%) patients in tramadol and sterile normal saline group respectively with non-significant difference (p-value = 0.314).

Submucosal tramadol is more successful in managing pain and swelling following impacted third molar surgery, according to the majority of studies. However, more research is needed to confirm the effectiveness of submucosal tramadol following dental or surgical operations.

CONCLUSION

It was concluded from the study that submucosal Tramadol is more effective, safe and reliable than sterile normal saline in patients after third molar surgery. Tramadol is significantly associated with decreased rate of post-operative pain, swelling and trismus as compared to sterile normal saline.

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