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Comparison of the Intramuscular and Sub-mucous Postoperative Analgesic Effect of Tramadol HCL After Minor Oral Surgery

(Intramuscular and Sub-mucous Analgesic Effect of Tramadol HCL in Minor Oral Surgery)

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ABSTRACT

Aims: The study aims to test the analgesic efficacy of using 100 mg sub-mucous tramadol in comparison with 100 mg intra-muscular tramadol after minor oral surgery.

Materials and Methods: Sixty medically fit patients who anticipated to underwent minor oral surgical procedures were randomly selected and divided into three groups; group I (submucous tramadol group). group II (intra-muscular tramadol group) and group III (control group). Each group comprised 20 patients. Minor oral surgical procedures were done under aseptic conditions. After minor oral surgery each patient in group I was injected with 100 mg tramadol submucously at the site of operation immediately post-operatively , whereas each patient in group II was injected by 100 mg tramadol intra-muscularly immediately post-operatively. Patients in group III served as a negative control group. postoperatively each patient in all groups were given 500 mg amoxicillin capsules orally three times daily and 500 mg paracetamol tablets as a rescue analgesic as needed for pain . At the first post-operative day, analgesia was assessed using Visual Analog Scale (VAS) Verbal Pain Scale (VPS), patient satisfaction (PS), and total number of analgesic tablets (AT) consumed during the first post-operative day.

Results: There was a significant difference between group I and both group II and group III when postoperative analgesia was assessed by VAS, VPS, PS, and AT . Also a significant difference between group II and group III was found when postoperative analgesia was assessed using VAS, VPS.

Conclusions: SM tramadol found to be superior and more significant in reducing pain after minor oral surgical procedures than IM tramadol and control group.

Key Words: intramuscular, sub-mucous, tramadol, analgesia, minor oral surgery.

INTRODUCTION

Pain control is one factor that has permitted surgery to progress enormously. The anesthetist and the surgeon must do everything possible to eliminate postoperative pain without causing additional problems. Patients with postoperative pain are treated with various drugs in two main categories: nonsteroidal anti-inflammatory drugs (NSAIDs) and narcotic analgesics[(1)]. Non steroidal anti inflammatory drugs are the first choice of analgesics after dento-alveolar surgery [(2)]. The systemic administration of high doses of opiates has been associated with side effects ranging from pruritus, nausea, and vomiting, to sedation and respiratory depression [(3)]. Tramadol Hydrochloride is a narcotic analgesic that produces its effects through central actions. It relieves moderate to severe pain by combining synergistically week opioid and mono amino gerically mediated anti-nociceptive mechanisms [(2).] Tramadol is preferred tp narcotic analgesics because of the relative lack of some of the serious side effects such as respiratory depression seen with other opioids of comparable efficacy [(4)]. It

causes minimal dependence and tolerance and has a very low abuse potential [2] . tramadol can be administered systemically and locally. Potential advantages of locally route include no first pass drug metabolism by the liver, improved patient compliance, convenience, and comfort; and consistent analgesia [3].

Materials and Methods

This study is a randomized controlled clinical study conducted on patients who underwent minor oral surgical procedures. The study was approved by the Scientific Committee in Dentistry College, University of Mosul. A written informed consent was taken from each patient. These patients were randomly assigned into 3 groups; Group I , Group II and Group III. Each group consisted of (20) patients. Inclusion criteria any age, any gender, medically fit patients. All patients were to undergo elective minor oral surgical procedures, excluding conventional tooth extraction and dental implants. Exclusion criteria included the use of analgesics 24 hr before the treatment, history allergy to medication used in the study and pregnancy or lactation. The operations were done using standard surgical procedures by the same oral surgeon under aseptic conditions. Local anesthesia was administered using 2% xylocaine with 1:100,000 adrenaline. At the end of the surgical operations each patient in group I was injected by 100 mg tramadol hydrochloride (Trabilin, Mepha, Switzerland) sub-mucosaly at the surgical site, while patients in group II were injected by 100 tramadol hydrochloride (Trabilin, Mepha, Switzerland) I.M. Patients in group III served as a negative control group in which no tramadol was given. THE duration of the operation (from incision to last suture) was recorded. Each patient were instructed postoperatively to use ice packs at the site of operation and given the usual postoperative instructions. Postoperatively, patients in each group were given amoxil cap. 500 mg orally t.i.d. and paracetamol tablets 500 mg orally as rescue analgesic to be used only as needed for pain. At the second postoperative day the perception of pain was provided by each patient using visual analog scale (VAS), Verbal pain response (VPS), patient satisfaction(PS). Patients recorded the number and time at which they took oral paracetamol tablets consumed during the day of operation.

Pain assessment: pain was assessed using:

1. Visual analog scale (VAS): A 100 point scale was used to assess pain. It consists of an interval scale range from 0 to 100 (0 represents no pain) to 100 (represents intolerable pain).

2. Verbal pain response (VPS):
A four point pain scale ranges from 0 to 3. 0: no pain; 1: mild pain; 2: moderate pain; 3: severe pain

3. Patient satisfaction(PS):
If the patient experienced pain more than that he suspected it was considered as not satisfied, whereas if the patient experienced pain less than that he suspected it was considered as satisfied.

4. Number of analgesic tablets (AT):
Patients were instructed to record the total number of analgesic tablets (paracetamol) administered during the 24 hours after surgical operation.

Statistical Analysis

Data were loaded on Pentium IV computer and analyzed using IBM Statistical Package for Social Sciences (SPSS) Program Version 19.0**.** Analysis included descriptive statistics (frequency and percentages for non–parametric data, and mean and standard deviation for parametric data); and analytical statistics (Mann–Whitney Test for non–parametric data, and independent sample Student's t–test for parametric ones). Differences between groups were considered statistically significant when $p < 0.05$ level.

RESULTS

Distribution of the sample according to age is illustrated in Table (1) and Figure (1). The mean ages of the patients participated in this study were 25.30, 25.10 and 23.10 years for group I, group II and group III, respectively (Table 1 and Figure 1).

1. VAS:
Seventy five percent of SM tramadol group (group I) scored 0–25 pain assessment, whereas 25% of patients in this group scored 26–50 pain score In IM tramadol group (group II), 30% of patients had 0–25 pain score and 55% of the treated

patients' score was 26–50, 10% of patients in this group had 51-76 and 5% scored 76-100. In the control group, 60% of the patients had 26–50 score, 30% 51–75 score and 10% 76–100 score. There was a significant difference between group I and group II (0.003), and also a significant difference between group I and group III (p=0.000), and a significant difference between group II and group III (p= 0.010) (Table and 2 Figure 2).

2. VPS:
Sixty percent of group I represented no pain, 35% mild, 5% moderate. Ten percent of group II expressed no pain, 45% mild, 25% moderate, 20% severe. Whereas 10% of group III represented mild pain, 70% moderate, 20% severe There was a significant difference between group I and group II (p= 0.000), and also a significant difference between group I and group III (p= 0.000), and group II and group III (p= 0.031).Table 3and Figure 3.

3. PS:
Ninety five percent of patients in group I were satisfied, while 60% of patients in group II and 50% in the control group were satisfied There was a significant difference between the group I and group II and between group I and group III (p= 0.009 and 0.002 respectively), whereas there was no significant difference between group II and control group (P=0.530). Table 4and Figure 4.

4. AT:
There was a significant difference between the group I and group II and between group I and group III (p= 0.004 and 0.000 respectively), whereas there was no significant difference between group II and control group (P=0.332). Table 5 and Figure 5.

DISCUSSION

Analgesia improves the quality of life, reduces morbidity and provides greater comfort, allowing for rapid recovery and early return of patients to daily activities [(5)]. Analgesia can be established by the administration of analgesic drugs systemically or locally. The administration of analgesic drugs locally at the site of tissue injury is done to maximize drug level at the site of action and minimize systemic exposure [(6)]. In the present study tramadol which is a suitable and safe analgesic for the relief of postoperative pain was used either systemically or locally.

Patient self–report is the most accurate and reliable indicator of the existence and intensity of pain and any resultant distress [(7)] . Self–report measurement tools such as adjective or numerical rating scale or VAS can assist the patient in quantifying and characterizing the pain. Assessment of the patient pain is a crucial part of initial evaluation to estimate analgesic requirement [(8)] . In this study VAS and VPS had been used to describe the intensity of pain. PS and the consumption of paracetamol tablets 500 mg for pain relief was also used as an indirect measure of the analgesic response to SC and IM tramadol treatments over the 24 hr postoperative period.

This study found a significant difference between SC tramadol group and both IM tramadol and control groups as assessed by VAS and VPS indicating a superior effect of SC tramadol than IM tramadol in producing analgesia, also a significant difference between IM tramadol and control groups was found in regard to VAS and VPS. This is in agreement with some other studies who found that local submucous tramadol administration is effective in reducing pain [(9)] and[10) (11) 3)]. A study conducted by Amaury et al [(12)] found that the administration of 50 mg tramadol either systemically (IM) and/or locally suppressed the pain in comparison to the control group. However, in contrast to the present study there was no difference between the systemic and local administration of tramadol for the pain intensity values. The reduced pain following SC administration of tramadol may be explained by the ability of tramadol to produce a local anesthetic effect at the site ofoperation(comparison of local anaesthetic effects of tramadol with prilocaine for minor surgical procedures. Comparison of local anaesthetic effects of tramadol with prilocaine for minor surgical procedures. Altunkaya, H., Ozer, Y., Kargi, E. and Babuccu, O. (2003) Br. J. Anaesth. 90, 320-322) [(13)] and [(12)].

Regarding PS and AT the present study demonstrated that There was a significant difference between the SC tramadol group and both IM and control groups. Also indicating a better postoperative analgesic effect of SC tramadol than IM tramadol. Whereas there was no significant difference between IM tramadol group and control group in this respect. This is in agreement with a study done by [(10)] found that following septoplasty operations submucosal tramadol reduces intravenous opioid consumption and increases patient satisfaction. [(11)]also found that subcutaneous wound infiltration with tramadol reduces postoperative opioid consumption following pyelolithotomy [(11)].

CONCLUSIONS

Postoperative administration of SM 100 mg tramadol at the site of operation found to be superior and more significant than both 100 tramadol administered IM and the control group in reducing postoperative pain following minor oral surgical procedures as assessed by VAS, VPS, PS and AT. Whereas a significant difference between IM tramadol group and the control group was found regarding the degree of postoperative analgesia as assessed by VAS and VPS. But there was no significant difference between IM tramadol group and the control group in PS and in the total number of paracetamol tablet intake post operatively.

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Table (1): Mean, standard deviation, minimum and maximum age of patients (years) in different groups

Group	No.	Mean	SD	Minimum	Maximum
Submucous Tramadol	20	25.30	6.860	18	45
Intramuscular Tramadol	20	25.10	6.172	19	45
Control (No Tramadol)	20	23.10	3.538	18	29

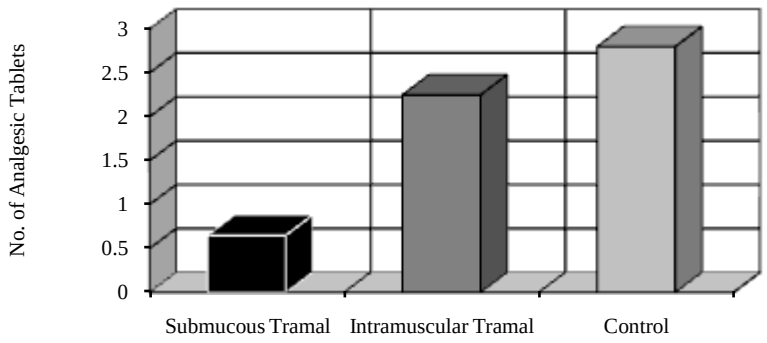

Figure (1): Mean age of patients (years) in different groups

Table (2): Distribution of the samples and the level of significance according to visual analog scale of different groups

Group	VAS	Frequency	Percent
Submucous Tramadol	**0–25**	15	75.0
	26–50	5	25.0
	51–75	0	0.0
	76–100	0	0.0
Intramuscular Tramadol	**0–25**	6	30.0
	26–50	11	55.0
	51–75	2	10.0
	76–100	1	5.0
Control (No Tramadol)	**0–25**	0	0.0
	26–50	12	60.0
	51–75	6	30.0
	76–100	2	10.0
Mann–Whitney Test: • Submucous Tramadol vs. Intramuscular Tramadol: U= 102.500, p= 0.003 (Significant). • Submucous Tramadol vs. Control: U= 30.000, p= 0.000 (Significant). • Intramuscular Tramadol vs. Control: U= 115.000, p= 0.010 (Significant).			

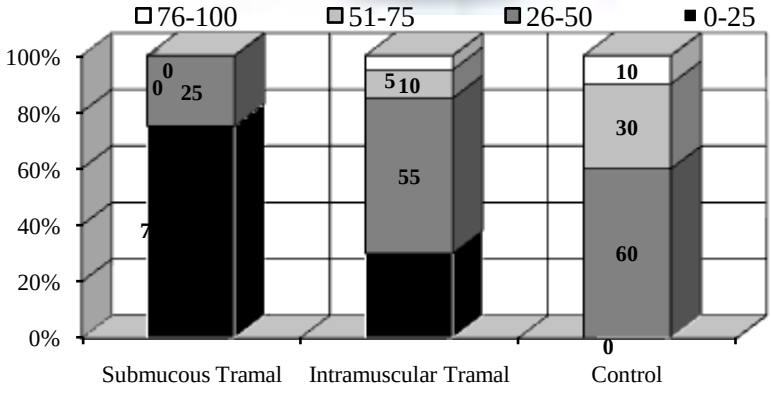

Figure (2): percent of the samples and the level of significance according to visual analog scale of different groups

Table (3): Distribution of the sample and level of significance according toverbal pain scale of different groups

Group	VPS	Frequency	Percent
Submucous Tramadol	No Pain	12	60.0
	Mild	7	35.0
	Moderate	1	5.0
	Severe	0	0.0
Intramuscular Tramadol	No Pain	2	10.0
	Mild	9	45.0
	Moderate	5	25.0
	Severe	4	20.0
Control (No Tramadol)	No Pain	0	0.0
	Mild	2	10.0
	Moderate	14	70.0
	Severe	4	20.0

Mann–Whitney Test:

- Submucous Tramadol vs. Intramuscular Tramadol:
  U= 71.000, p= 0.000 (Significant).
- Submucous Tramadol vs. Control:
  U= 16.000, p= 0.000 (Significant).
- Intramuscular Tramadol vs. Control:
  U= 126.000, p= 0.031 (Significant).

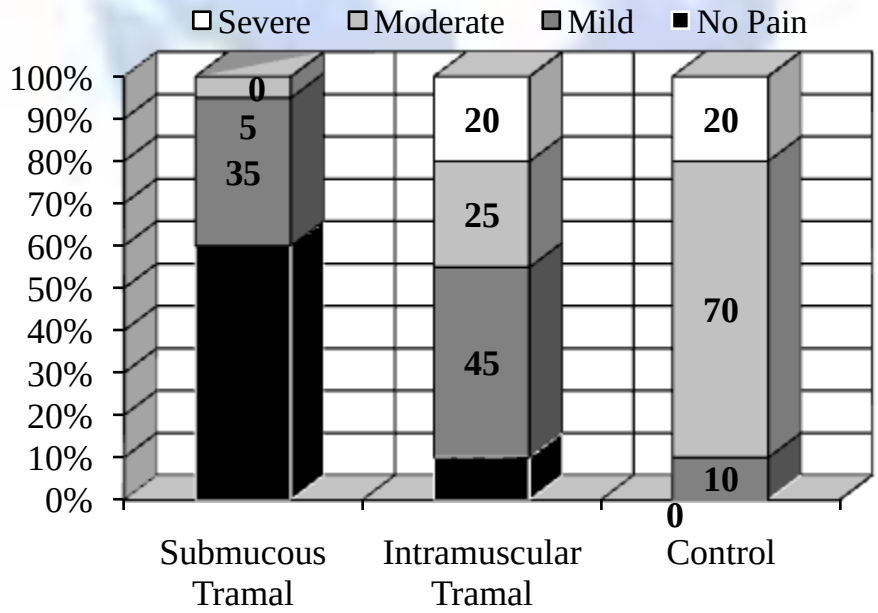

Figure (3): percent of the samples according to visual analog scale of different groups

Table (4): Distribution of the samples and the level of significance according to patients' satisfaction of different groups

Group	Satisfaction	Frequency	Percent
Submucous Tramadol	**Not Satisfied**	1	5.0
	Satisfied	19	95.0
Intramuscular Tramadol	**Not Satisfied**	8	40.0
	Satisfied	12	60.0
Control (No Tramadol)	**Not Satisfied**	10	50.0
	Satisfied	10	50.0

Mann–Whitney Test:

- Submucous Tramadol vs. Intramuscular Tramadol:
  U= 130.000, p= 0.009 (Significant).
- Submucous Tramadol vs. Control:
  U= 110.000, p= 0.002 (Significant).
- Intramuscular Tramadol vs. Control:
  U= 180.000, p= 0.530 (Not Significant).

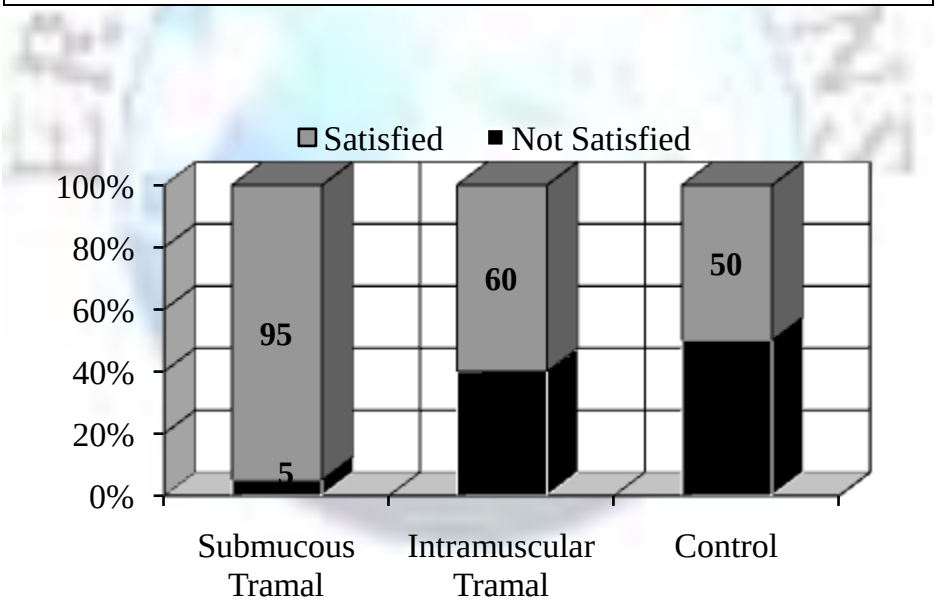

Figure (4): Percent of the samples according to patients' satisfaction of different groups

postoperative analgesics of different groups

Table (No. of Analgesic Tablets)

Table (5): Mean. standard deviation of the number of postoperative analgesics

Group	No.	Mean	SD
Submucous Tramadol	20	0.65	1.182
Intramuscular Tramadol	20	2.25	1.997
Control (No Tramadol)	20	2.80	1.508
Student's t–test: • Submucous Tramadol vs. Intramuscular Tramadol: t= –3.084, p= 0.004 (Significant). • Submucous Tramadol vs. Control: t= –5.018, p= 0.000 (Significant). • Intramuscular Tramadol vs. Control: t= –0.983, p= 0.332 (Not Significant).			

Figure (5) Number of postoperative analgesics in different groups