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Effect of Submucosal Application of Tramadol on Postoperative Pain after Single Dental Implant Placement: A Randomised Double-Blind Controlled Trial

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Abstract: ***This study aimed to evaluate the effectiveness of the submucosal application of tramadol, for acute postoperative facial pain, following the single implant placement in the mandibular posterior region. This prospective, double-blind, randomized placebo-controlled study included 40 ASA I-II patients undergoing single mandibular implant placement under local anaesthesia. Following the surgical procedure, patients were randomly divided into two groups; Group T (1 mg/kg in 2ml tramadol) and Group S (2-mL saline). Treatments were applied submucosally after surgery at implant site. Pain after implant placement was evaluated using a visual analog scale (VAS) 1, 2, 4, 6, 12, 24, and 48 h postoperatively. The time at which the first analgesic drug was taken, the total analgesic dose used, and adverse tissue reactions were also evaluated. In group T, postoperative VAS scores were significantly lower compared to that in group S (p < 0.05). This study demonstrated that post-operative submucosal application of tramadol is an effective method for reducing acute post-operative facial pain after implant placement surgery.***

Keywords: Tramadol, implant placement, Postoperative analgesia

1. Introduction

Implant placement is now the most frequently performed dental surgical procedure for the rehabilitation of teeth. The placement of a dental implant is usually associated with medium to severe pain. The pain may result inbothe surgical insult as well as due to the inflammatory process, which peaks after 48–72 hours post-surgery. General patient factors that exacerbate post-operative pain includes, anxiety levels, gender, and smoking status, and other factors, include bone graftingtechniques, implants number, posterior implant placement, excessive heat generation due to surgical bur during drilling, extensive surgical flaps, and over-torquing of the implant. Between 3–5 h after surgery, the efficacy of local anesthesia declines and pain reaches its maximum level, so the management of postoperative pain after implant placement is very much necessary to provide relief to the patient. Post-operative pain management is very important for the high success rates and levels of patient satisfaction.[1-6]

Surprisingly, there is less literature available about the role of pre-and post-operative analgesic medication for treatment outcome and patient satisfaction after implant placement.

Tramadol is one of the most common centrally-acting synthetic opioids used for the management of pain. It has a dual mechanism of action i.e. it acts both as an opioid agonistas well as anaminergic (noradrenaline and serotonin reuptake inhibitor) drug. Tramadol at an equianalgesic dose is more potent and causes less adverse effects as compared to other opioids. Its dose for management of dental pain ranges from 50-100mg every 4-6 hours with a maximum dose of 400mg per day. The common side effects seen after tramadol include nausea, vomiting, constipation, respiratory depression, somnolence, and dizziness. It has less effect on GIT functions, less risk of causing respiratory depression, and less seizure risk as compared to other prototypes of opioids. Thus, Opioids having both central and peripheral effects have been seen to be more efficient in severe pain management conditions and thus can be a good option for pain management after implant surgery[7-10].

Therefore, for many years researchers have aimed to identify a moreeffective analgesic for application after dental implant placement. The purpose of this study was to evaluate the effectiveness of the submucosal application of tramadol, for acute postoperative facial pain, following the placement of a dental implant

2. Materials & Methods

This comparative study was conducted from August 2019 to August 2020. It was arandomized, double-blind, placebo-controlled trial. A total of 40 patients with age <18 years, weight< 100 kg of either sex who underwent single dental implant placement in the posterior mandibular arch.Participantswere enrolled from the outpatients, who reported at the unit of oral and maxillofacial surgery MNDAV Solan dental college and hospital.Patients were classified as ASA I-II using the guidelines of the American Society of Anaesthesiology. The Ethics Committee approval was obtained from the appropriate institution andinformed consent was obtained from all participants.Patients allergic to tramadol, use of sedatives, alcohol, or analgesic drugs 24 h before treatment, placement of multiple implants and the use of more than three ampules of local anaesthesia during the procedure were excluded from the study.

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During surgery, all patients were placed in the semi-supine position. Patient important vitals i.e heart rate, blood pressure, and peripheral oxygen saturation were monitored. The local inferior dental nerve block was obtained using 4 % articaine HCl with 1:100,000 epinephrine HCl (Ultracaine D-S Forte; Aventis, Bridgewater, NJ, USA) and its efficacy was assessed by verbal questioning for subjective symptoms and gentle probing of the buccal and lingual surfaces of the arch at the implant placement site.

After the implant placement, patients were randomly divided into two groups: Group T (Tramadol) (1 mg/kg tramadol diluted with saline to 2 mL) and Group S(Saline) (2-mL saline). The 2-mL volume of solutions was prepared by an anaesthetic nurse and placed in sterile disposable syringes. Both the surgeon and the patients were blinded to the specific solution used. After implant placement, the surgeon applied the solution to the implant site submucosally. The time at which the local anaesthesia was applied was defined as time 0and the total implant placement timewas also recorded.

The post-surgery mean blood pressure, heart rate, peripheral oxygen saturation were recorded at 20-min intervals and Patients were questioned about sideeffects (burning sensation, nausea, vomiting, constipation, dizziness,and constipation) after the procedure.

Post-operative was evaluated using a visual analog scale (VAS); patients were asked to score overall pain at 1, 2, 4, 6, 12, 24 and 48 hrs using the VAS. Patients were also asked to record the time and amount of analgesic taken after implant placement; total analgesic consumption during the first 48 h was also recorded. Data charts were collected from patients at the end of the follow-up period.

The data were analyzed using the SPSS for Windows software package (ver. 16.0; SPSS Inc., Chicago, IL, USA). Descriptive statistics (mean, standard deviation, frequency) were obtained by using an independent t-test and Fisher exact test, and the chi-squared test was used to compare groups.

3. Results

A total of 40 patients were included in this study (20 in each group). The distribution of patients among groups is shown in Table 1. There were no significant group differences in grouping variables. No complications were associated with the procedure. The VAS scores of the control group (Group S) 1, 2, 4, 6 and 12 h postoperatively, were significantly higher compared to the Tramadol group (group T) ($p<0.05$). There were no significant group differences in VAS scores at 24 and 48 h postoperatively ($p>0.05$). The first analgesic was taken significantly later in the tramadol group as compared to the control group ($p = 0.0001$). Total analgesic intake in the control group was significantly higher as compared to the tramadol group ($p=0.0001$; Table 1).

There were no significant group differences in side-effects (nausea, vomiting, burning, dizziness and constipation; (Table 2). Mean blood pressure, heart rate and peripheral oxygen saturation are displayed in Table 3. Although there were differences in mean blood pressure and heart rate between 0 and 40 min,in the groups but these differences were not clinically significant ($p>0.05$) Table (3)

4. Discussion

Following implant surgery, medium-severe pain occurs during the early postoperative stage. To improve patient satisfaction after dental implant surgical procedures, postoperative pain should be reduced. Several studies have assessed the effectiveness of tramadol application for analgesia after surgery, but few have evaluated submucosal application. Atef et al. found less need for postoperative analgesia after submucosal tramadol was administered after pediatric tonsillectomy[11].Bourne et al. found, a combination of tramadol and acetaminophen tablets highly potent analgesia after orthopedic pain[12]. Collins et al.in a study evaluated the efficacy of tramadol for pain management after dentoalveolar operations the results of the study showed that tramadol was successful in complete pain relief [13]. Pozos AJ et al. studied the analgesic effects of tramadol, in both local and systemical administration. He found tramadol applied into the surgical site after the extraction of the impacted third molar under local anaesthesiaextends the duration of anaesthesia and improved the quality of postoperative analgesia[14]. Isıordia Espinoza MA et al. in a comparative study, combinations of 10- mg oral ketorolac and 50-mg submucosal tramadol, and 10-mg oral ketorolac and saline, administered 30 min before the impacted third molar surgery found combination tramadol treatment was more effective in reducing post-operative pain and the total amount of analgesic required[15].Another comparative, prospective, randomized double-blind study, by Pozoset al. compared preoperative and postoperative 100-mg intramuscular tramadol. Preoperative tramadol was more effective in reducing postoperative pain [16]. Isıordia Espinoza et al. in a double-blind, randomized, placebo-controlled, study evaluated the effect of submucous tramadol as an adjuvant of mepivacaine in inferior alveolar nerve block and concluded that submucous tramadol increased the anesthetic efficacy of mepivacaine of soft tissue in inferior alveolar nerve block[17]. Cecchetti et al. also found submucosal tramadol injection after third molar surgery increased postoperative analgesia,but did not extend anesthetic action duration[18]. In the present study, VAS scores at 1, 2, 4, 6 and 12 h were significantly lower, first analgesic intake was significantly later, and total analgesic intake was significantly lower, in the tramadol group compared to controls. This could be due to the high concentration of tramadol during the initial post-operative hours as compared to the control group. Adverse effects were comparable in both the groups with nasea, vomiting and dizziness seen more in the tramadol group, as these are common side effects with opioid usage.

5. Conclusion

Submucosal tramadol represents an effective, safe and reliable method of reducing postoperative acute facial pain after implant placement surgery. However, further studies with more participants are required to evaluate the efficacy of submucosal tramadol after dental implant placement surgery.

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Table 1: Patient characteristics, total surgery time, visual analog scale (VAS) score, analgesic intake

	Group T	Group S		
	Mean ± SD	Mean ± SD	Test Value	*p*
Weight (kg)	64.15 ± 4.998	64.70±6.760	-.293	.771
AGE	40.45±10.303	43.10±12.096	-.746	.460
ASA Grade	1.00±0.000	1.00±0.000		
Total Surgery Time (min)	52.85±4.771	53.30±5.814	-.268	.790
VAS 1h	19.85±7.379	63.30±6.216	-20.139	.000
VAS 2h	12.45±3.634	36.90±17.134	-6.243	.000
VAS 4h	13.50±7.302	31.65±16.429	-4.515	.000
VAS 6h	16.10±9.072	33.20±16.440	-4.073	.000
VAS 12h	26.30±16.287	24.00±6.867	.582	.564
VAS 24h	31.95±16.894	33.80±16.305	-.352	.727
VAS 48h	29.30±16.099	30.80±15.602	-.299	.766
Initial Analgesic Intake	4.7±1.69	1.85±0.81	6.8	.000
Total Analgesic Intake	2.95±0.76	4.7±0.92	-6.5	.000

Independent T-test
Fischer exact test

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Table 2: Side effects

Side Effects		Group T n (%)	Groups n (%)	Test value	p
Nausea	Absent	16	19	2.057	0.151
	Present	4	1		
Vomiting	Absent	18	20	2.105	0.147
	Present	2	0		
Burning Sensation	Absent	18	18	0.000	1.000
	Present	2	2		
Dizziness	Absent	17	20	3.243	0.072
	Present	3	0		
Constipation	Absent	19	20	1.026	0.311
	Present	1	0		

Chi-Square Test

Table 3: Vital signs of Groups

	Group S Group T			
	Mean ± SD	Mean ± SD	Test Value	*p*
MBP 0 min	61.65±1.899	62.15±1.981	-.815	.420
MBP 20 min	61.90±1.373	62.10±1.774	-.399	.692
MBP 40 min	60.90±1.071	61.75±1.650	-1.932	.061
MBP 60 min	63.90±2.469	61.95±1.791	2.859	.007
HR 0 min	73.60±3.545	73.25±3.401	.319	.752
HR 20 min	74.30±2.342	72.70±3.197	1.806	.079
HR 40 min	75.40±2.981	73.35±3.392	2.030	.049
HR 60 min	73.35±2.870	73.55±3.154	-.210	.835
Spo2 0 min	97.20±1.322	97.35±.745	-.442	.661
Spo2 20 min	96.90±1.165	97.20±.768	-.961	.342
Spo2 40 min	96.65±1.631	97.30±.865	-1.575	.124
Spo2 60 min	96.40±1.698	97.15±.875	-1.756	.087

Independent T-test
Fischer exact test

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