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Comparative Evaluation of the Efficacy of two Different Pre-emptive Analgesic agents following Dental Implant Placement-A Prospective Clinical Trial

Guy Patrick Sandou[1*], Priya Lochana Gajendran[2], Thiyaneswaran Nesappan[3]

[1]Deaprtment of Implantology, Saveetha academy of implant dentistry, Saveetha Dental College and Research Institute, SIMATS, Chennai, India

[2]Deaprtment of Periodontology and oral Implantology, Saveetha academy of Implant Dentistry, Saveetha Dental College and Research Institute, SIMATS, Chennai, India

[3]Deaprtment of Maxillofacial Prosthodontics and Oral Implantology, Saveetha academy of Implant Dentistry, Saveetha Dental College and Research Institute, SIMATS, Chennai, India

ABSTRACT

Background of the study: Pre-emptive analgesia are analgesics that are given before painful stimuli occur in order to relieve postoperative pain. During the intraoperative surgical process, dental implant placement is associated with a fear of pain. Pre-emptive analgesia can help to reduce or prevent postoperative pain amplification

Aim: This prospective randomized double blinded trial was planned to compare the efficacy of two pre-emptive analgesics in patients undergoing stage 1 dental implant surgery.

Material and methods: A total of 60 systematically healthy patients undergoing dental implant placement were included in the study. Group 1 consisted of 30 patients who were administered preoperative and postoperative Ketorol-Dt. In group 2 30 patients was administered preoperative and postoperative zerodol-p. Visual analog scale scores were recorded postoperatively immediately following the surgery and at 3 days postoperatively.

Results: When comparing the VAS scores at day 0 between the group 1 and 2 the results were not statistically significant. When comparing the VAS score on day 3 between the group 1and 2 the results were statistically significant. When comparing the vas score at day 0 and day 3 the results were highly statistically significant.

Conclusion: The present study suggests that pre-emptive ketorol-dt was superior in post-operative pain reduction when compared to Zerodol-p.

Key words: Analgesic, Dental implants, VAS score, Postoperative pain, Pre emptive analgesic

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Corresponding author: Guy Patrick Sandou
e-mail ✉ :drpatrickdental@gmail.com
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INTRODUCTION

Oral surgical operations, including the insertion of dental implants, can cause postoperative discomfort and swelling.The use of dental implants has brought a new age in dentistry. Dental implants are still a very popular treatment for treating single or multiple edentulism, and their use has gradually expanded in recent decades [1]. Though anaesthetic agents can effectively control intraoperative pain [2] postoperative pain is still a possibility with dental surgery [3,4]. Patients can experience varying levels of postoperative pain following dental implant insertion surgery. The release of inflammatory mediators causes pain and swelling, which are typical side effects of surgical trauma [5]. Despite the predictable effectiveness of dental implants, patients' compliance with implant treatment is hampered by postoperative pain and swelling [6]. As a result, efforts should be taken to avoid the risks that come with tissue damage following implant insertion in order to increase the patient's quality of life [7].

Pain is a factor that is difficult to separate from dental care [1]. Their mere presence can trigger a slew of negative reactions such as fear and anxiety, which can jeopardize the safety of seeking care [8]. Surgical procedures, especially implantology procedures, were also among the dental procedures that elicited the most fear associated with the possibility of pain [9]. The concept of preemptive analgesia (PA) to scale back the postoperative pain was supported by a series of experimental animal studies [10], which demonstrated central systema nervosum plasticity and sensitization after nociception. The PA has as

fundamentals the administration of analgesics before the onset of painful stimuli, so as to scale back or prevent postoperative pain (hyperalgesia), also on reduce the analgesic dose required within the postoperative period in comparison to the dose used alone, after the occurrence of the pain stimulus [11,12]. Blockages with local anesthetics, non-steroidal anti-inflammatory drugs (NSAIDs), and opioids are three types of analgesic drugs that are used individually or in combination for this function [10,13].

Pre-emptive analgesia has been achieved using Nonsteroidal anti-inflammatory medications (NSAIDs) [7,14]. The cyclooxygenase enzyme is inhibited by NSAIDs, which reduces peripheral and central prostaglandin activity [15]. As a result, the exposure to noxious stimuli by peripheral and central sensitization is reduced [16]. Because of these features, NSAIDs may be used as a pre-emptive analgesia during a surgical operation in the hopes of reducing discomfort [7,17]. The aim of this study was to test and compare the efficacy of pre-emptive administration of Ketorol-dt and zerodol P 1 hour before surgery for stage 1 dental implants in the management of postoperative pain.

MATERIALS AND METHODS

This study was conducted from August 2020 to December 2020 in the Department of Implantology, Saveetha dental college and Hospital, Chennai. The following inclusion criteria were considered 1) Systemically healthy patients (ASA I or II) with no medical illnesses were included in the study. 2) Absence of current pain or presence of any active oral inflammatory process. 3) no usage of analgesics in the three weeks prior to the study; 4) no continuous use of steroid and non-steroidal anti-inflammatory drugs; 6) implants with a diameter of 3.75 to 5mm mm and a length of 10 to 13 mm; 7) presence of compatible bone.

Pregnant or lactating mothers, those taking medicine that may alter pain perception, those with a history of allergy or intolerance to the medications used in the study, and those with a history of alcohol or substance abuse were all excluded.

Sixty systematically healthy patients were selected, and were randomly divided into two groups, 30 in each group. Group 1 consisted of 30 patients who were administered preoperative and postoperative Ketorol-Dt. In group2 30 patients were administered preoperative and postoperative zerodol-p. VAS scores were statistically recorded and tabulated.

The treatment groups were randomly assigned using a sequential stratified randomization method that included the use of opaque envelopes with the treatment groups' identifications (groups I and II). The envelopes were then sealed and scrambled before being numbered in order. A new numbering envelope was opened for each new participant in the research.

Instructions for the analysis and data collection

Prior to surgery, all patients in consultation received specific guidelines for correctly filling out forms and using the visual equivalent scale (VAS) [18] for postoperative pain assessment. If they had any doubts, they were advised to contact the operator. Following the randomization protocols, the participants were given a medicine capsule from Group I or a medicine capsule from Group II, to be taken 1 hour before surgery. Participants filled out a visual analogue scale (VAS) to indicate whether or not they were in pain. This scale measures 10 cm in length and is divided into five equivalent segments, with one end representing no pain and the other representing extreme pain. Both participants finished the registry on the third day after surgery. In addition, if rescue VAS (3rd day post-surgery) Pre-emptive analgesia medication was needed, the registration was done at the time of taking the medication in relation to the time elapsed after the surgery.

The statistical analysis and the graph were done using SPSS software v 25. For descriptive interventions, the variables of interest were reported (mean, standard deviation and CI). A paired t test was used to compare pain sensitivity over time (VAS 1 hour and 72 hours) between the two groups (Ketorol-dt and zerodol P) (Figure 1).

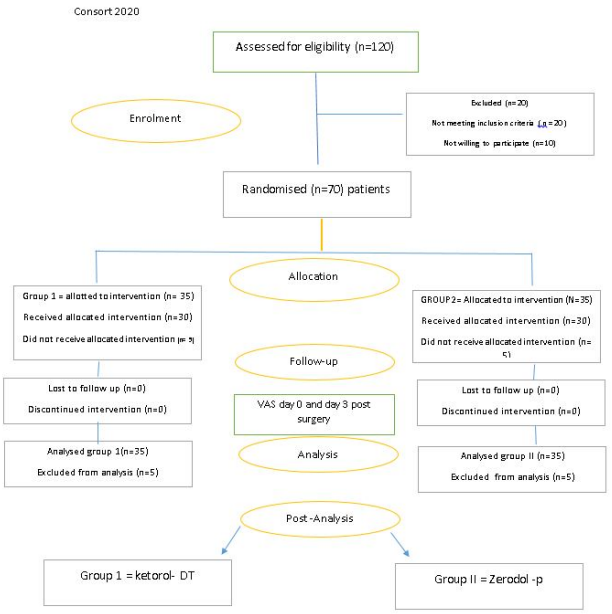

Figure 1: Flow diagram based on CONSORT guidelines.

RESULTS

The study has involved 60 systemically healthy patients of both genders who required stage 1 implant placement. Mean ± S.D of age in group 1 was 36.4 ± 10.9 and group 2 was 41.43 ± 11.2. Both the groups had 14 males and 16

females. The Mean ± S.D VAS score for day 0 was 6.07 ± 2.28 in group I and 5.03 ± 2.4 in group II. The Mean ± S.D VAS score for day 3 in group 2 was 6.4 ± 2.6 (Table1). On comparing the VAS 0 on group1 and group2, the result was not statistically significant.(p-value=0.064)Similarly while comparing the VAS score of day 3 in group 1 and 2 ,the results were not significant(p-value=0.018).On the other hand, comparing the VAS score of (VAS0 and VAS 3 in group1) they were statistically significant(p-value=0.001) .The same way the vas scores of VAS0 and VAS3 in group 2 were statistically significant(p-value=0.001) (Table 2) (Figures 2-5).

Table 1: Table represents the gender, Mean ± S.D of Age, VAS day 0 and VAS day 3.

Parameters	Group 1 Mean ± S.D	Group 2 Mean ± S.D
Age	36.4 ± 10.9	41.43 ± 11.2
Gender	Male- 14; Female- 16	Male- 14; Female- 16
VAS day 0	6.07 ± 2.28	5.03 ± 2.4
VAS day 3	7.8 ± 2.4	6.4 ± 2.6

Table 2: Table represents the p value of that data on comparing the VAS scale.

Parameters	p value
Comparing	0.064
VAS 0 group 1 & VAS 0 group2	
Comparing	0.018
VAS 3 group 1 & VAS 3 group2	
Comparing	0.001
VAS 0 group 1 & VAS 3 group1	
Comparing	0.001
VAS 0 group 2 & VAS 3 group2	

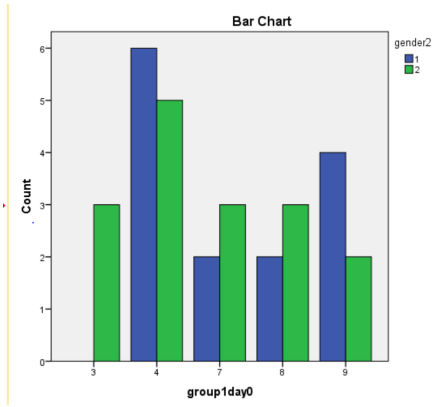

Figure 2: Bar graph representing the VAS pain scale in group 1 day 0 scores ranging from 3-9 majority of male and female pts had a score of 4.

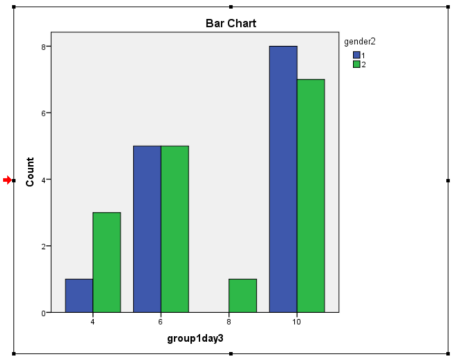

Figure 3: bar Graph representing the VAS pain scale in group 1 day 3.

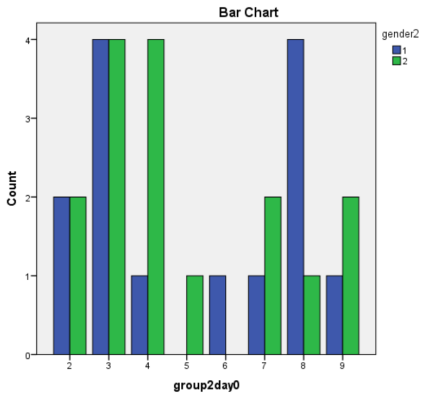

Figure 4: Bar graph representing VAS pain scale in group 2 days 0.

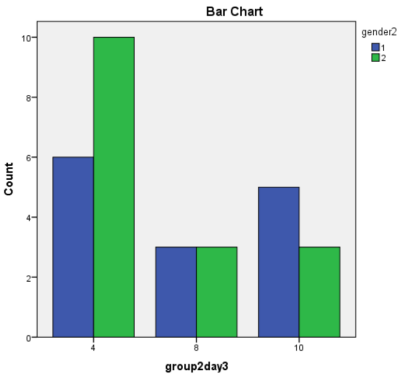

Figure 5: Bar graph representing VAS pain scale in group 2 days 3.

DISCUSSION

The present study evaluated the efficacy of Ketorol DT and Zerodol P in patients undergoing single implant surgery and suggested that the medication protocol is effective for preventing pain and swelling following the surgical procedure. From the present study ketorol-dt shows better reduction in pain when compared with zerodol-p. The statistical data was represented in Table 1 and Table 2. Pictographic representation of the VAS score data is depicted in Figures 2-5. To eliminate the risk of bias CONSORT guidelines [19] were followed (Figure 1).

In this context, our finding is supported by previous study. Patients undergoing posterior lumbar spinal fusion were randomized into three groups (n=32) in a prospective, double-blinded randomized controlled trial. Each patient underwent an injection of parecoxib, ketorolac, or a placebo 30 minutes before the incision. At the postanesthesia treatment unit, both the ketorolac and parecoxib groups reduced early postoperative pain significantly more than the control group (p 0.05) [20].

A similar study done by Neha et al on the efficacy of sublingual Piroxicam as a pre-emptive analgesic agent in patients undergoing single implant surgery. A prospective triple-blind placebo-controlled trial that involved 40 patients was randomly allocated to two groups. Group I - sublingual Piroxicam and Group II - placebo. The pain level was measured using visual analog ratings at 1 hour, 6 hours, 1, 3, and 5 days after surgery. At all-time intervals, mean scores were higher in controls as compared with the cases [21].

Systematic review verified that several clinical trials were conducted seeking to prove the efficacy of pre-emotive analgesics in the clinical practice exhibiting controversial results [6]. Contradicting to this context Meta et al demonstrated a parallel Randomised Control Trial on 30 participants of multiple implants with two groups. Ketorolac vs ketorolac + betamethasone were considered as 2 groups and were administered 2 hours before surgery and post-operative pain was elucidated by VAS pain scale and found out no significant difference between ketorolac vs ketorolac + betamethasone on 3 to 14 day post-operative assessment was found [21].

Preoperative administration of Dexketoprofen Trometamol on pain and swelling was studied in 100 patients with single implant treatment and were randomly assigned in test groups I- cases II-Placebo (vitamin C). The study was completed by 83 patients out of a total of 100. (There were 8 dropouts in the PLACEBO group and 9 in the DKT group). During the immediate postoperative phase, patients who received DKT indicated less pain severity. At 48 hours, the DKT group's inflammatory reaction was lower than the control groups, but bleeding was higher. In none of the groups, there were any other complications. Finally, the results suggested that preemptive administration of 25 mg soluble DKT 15 minutes before implant surgery will reduce the incidence of acute postoperative discomfort [11].

The current study could act as a key starting point for future research aimed at learning more about the use of ketorol DT and Zerodol P as pre-emptive analgesics in implant surgeries. Prospective multicentric trials in diverse populations with various surgical and dosing procedures are needed to validate these findings and develop a reliable procedure for pain management in dental implant surgeries.

The limitations of this study are VAS scoring was done only on day 0 and day 3. Patients BMI, psychological status, site of implant placement was not considered. Future studies should focus on the impact of sociocultural, environmental, and psychological influences on pain, as well as the effects of sex on factors that hinder the production of pain or keep it from being unbearable. Further long term studies with proper follow up is required.

CONCLUSION

The present study suggests that pre-emptive ketorol-dt was superior in post-operative pain reduction when compared to zerodol-p. Our results indicate that preoperative Ketorol DT is more effective than postoperative Zerodol P in controlling postoperative pain and swelling following surgical implant placement.

CLINICAL SIGNIFICANCE

Pre-emptive analgesia is a drug used to prevent sensitization during a surgical operation. Immediate postoperative discomfort can be minimized, and the production of chronic pain can be avoided, thanks to this "protective" effect on the nociceptive system.

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