ISSN: 2581-5989
PubMed - National Library of Medicine - ID: 101738774

International Journal of Dental Science and Innovative Research (IJDSIR)

IJDSIR : Dental Publication Service

Available Online at: www.ijdsir.com

Volume – 4, Issue – 6, November - 2021, Page No. : 01 - 07

Comparison of Submucosal injection of dexamethasone and methylprednisolone for the control of postoperative sequelae after apicectomy in maxillary teeth: Randomized controlled trial

[1]Abid Majeed Rather, [2]Umer Mukhtar, [3]Amit Thakur, [4]Ejaz Ahmad Mokhtar

[1-4]Department of Oral Health Sciences, PGIMER Chandigarh- 160012

Corresponding Author: Ejaz Ahmad Mokhtar, Senior Resident, Department of Oral Health Sciences, PGIMER Chandigarh- 160012

Citation of this Article: Abid Majeed Rather, Umer Mukhtar, Amit Thakur, Ejaz Ahmad Mokhtar ,"Comparison of Submucosal injection of dexamethasone and methylprednisolone for the control of postoperative sequelae after apicectomy in maxillary teeth: Randomized controlled trial", IJDSIR- November - 2021, Vol. – 4, Issue - 6, P. No. 01 – 07.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Pain, swelling, and trismus are the most common undesirable symptoms seen after periradicular surgeries. These post op sequelae can significantly affect the individual's quality of life. Thus, management of these postop sequelae is important to increase the success of treatment. The purpose of this study was to compare the effects of the preoperative submucosal administration of equivalent doses of two commonly used steroids on these postoperative sequelae. A randomized double blinded controlled clinical trial involving 40 subjects who underwent apicectomy in the maxillary tooth region was conducted from august 2017 to august 2018. Periradicular lesions involving maximum of three teeth were included. The participants were allocated randomly to two groups: The (DM Group) dexamethasone group received 8 mg dexamethasone and (MP Group) methylprednisolone group received 40 mg methylprednisolone dissolved in 2ml saline by administration through submucosal injections preoperatively. Each participant was assessed for, swelling, postoperative pain, trismus and amount of rescue analgesic medication taken. Submucosal injection of dexamethasone was found to be superior to methylprednisolone in terms of the reduction in swelling and amount of rescue analgesic medication taken. Thus, the preoperative submucosal use of steroids can be considered an effective, safe, and simple therapeutic strategy to reduce post op swelling, pain, and trismus after periradicular surgeries

Keywords: Apicectomy, Methylprednisolone, Dexamethasone

Introduction

Apicectomy refers to the surgical removal of periapical or periradicular lesion around the tooth root that cannot be resolved by itself or with an orthograde endodontic approach. It is the last resort to save a tooth when

conventional endodontic retreatment is not possible or is associated with therapeutic risks[1]. It is the standard endodontic surgical procedure to maintain a tooth with significant periapical lesion that cannot be treated with conventional endodontic re-treatment. It is one of the most common endo surgical procedure performed. Even a proper surgical technique in oral cavity can cause considerable pain, swelling, and trismus due to abundant loose connective tissue and high blood supply. These postoperative effects can cause great distress, and irritation in the postoperative period that will compromises quality of life (QOL). Thus, proper management of these post op is important for highly cognizant and extremely busy generation of today. Thus we, are obligated to render better control of this postoperative discomfort for patients undergoing apical radicular surgeries[2].

Corticosteroids have been used to control postoperative inflammation and swelling after third molar surgery for several decades. They reduce the swelling by decreasing the oedema due to surgery due to their anti-inflammatory effect however, their direct role in reducing postop pain and trismus are controversial[3].

Methylprednisolone and dexamethasone, are the most commonly used steroids in dentoalveolar surgical procedures to control postoperative inflammation and swelling due to their dominant glucocorticoid and minimal sodium retention activity. Even they are very advantageous as concluded by numerous studies[4-6] still there is a lack of knowledge regarding their dosage, route of administration, and duration of treatment. This is due to primarily due to lack of good controlled clinical trials and use of non-standardized parameters for studies. There are studies that both advocate and oppose the use of 8mg of dexamethasone. Methylprednisolone at doses of 20 mg, 40 mg, 80 mg, and 125 mg has also been used in different Surgical procedures[2]. The superiority of one drug over the other has not been advocated properly, hence a study that should compare the equivalent doses of these two steroids might provide insights into these controversies.

The purpose of this study was to compare the effects of the preoperative submucosal administration of methylprednisolone 40 mg and dexamethasone 8 mg in terms of postoperative sequelae after mandibular third molar surgery.

Materials & methods

This comparative study was conducted from august 2017 to august 2018. It was a, double-blind, randomized controlled trial. A total of 40 patients with age 18-60 years, weight < 100 kg of either sex who underwent apicectomy in the maxillary arch were enrolled from the outpatients, who reported at the unit of oral and maxillofacial surgery MNDAV dental college and hospital Solan. The Ethics Committee approval was obtained from the appropriate institution and Informed consent was obtained from all participants. Patients allergic to dexamethasone or methylprednisolone, periradicular lesions extending more than three teeth, pregnant, breast feeding mothers and medically compromised were excluded from the study. The 40 patients were randomly assigned in one of the two groups.

1. Dexamethasone Group=(n=20)
2. Methylprednisolone Group = (n=30).

Computer generated list for randomisation was prepared and opaque sealed envelopes were used for the allocation of patients in the respective groups.

Evaluation of efficacy

The preoperative mouth opening, facial measurements and pain by VAS was done. Mouth opening was measured as the maximum distance between the incisal

edges of the upper and lower central incisors with help of ruler. Facial swelling was measured with thread by using four reference points: tragus, gonion (angle of the mandible), outer cantus of eye and the corner of the mouth. It was calculated as the sum of the two diagonals made between these reference points(a-b+c-d) figure 1[7].

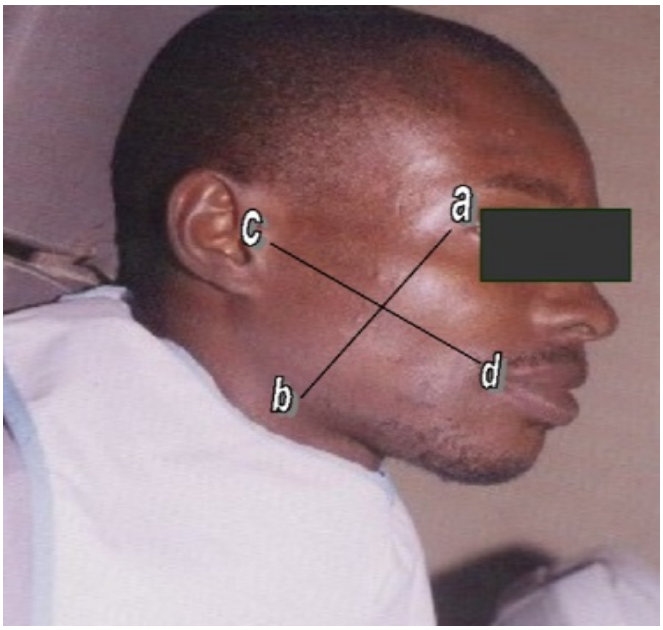


Fig. 1: Tape-measuring method for evaluation of facial swelling. (a–b) Distance between the outer canthus of the eye and angle of the mandible. (c–d) Distance between the tragus and outer corner of the mouth[7].

The 2-mL volume of solutions containing either of the intervention drugs was prepared by nurse and placed in sterile disposable syringes. Both the surgeon and the patients were blinded to the specific solution used. After local anaesthesia, the interventional drug was infiltrated into the submucosal tissues both on the buccal and the palatal side with respect to site of lesion in all participants. The apicectomy was performed by the same surgeon in all cases, by using the standard technique using a bur and air-driven hand-piece for removing bone and root apex and a retrograde filling with MTA was done followed by the primary closure of the surgical wound with a 3–0 vicryl suture. Routine postoperative instructions along with regular antibiotics, and chlorhexidine rinses, were prescribed. For postop pain management, the patient was advised to take a tablet of Aceclofenac 75 mg and were advised to note the total number of rescue tablets taken over 7 days.

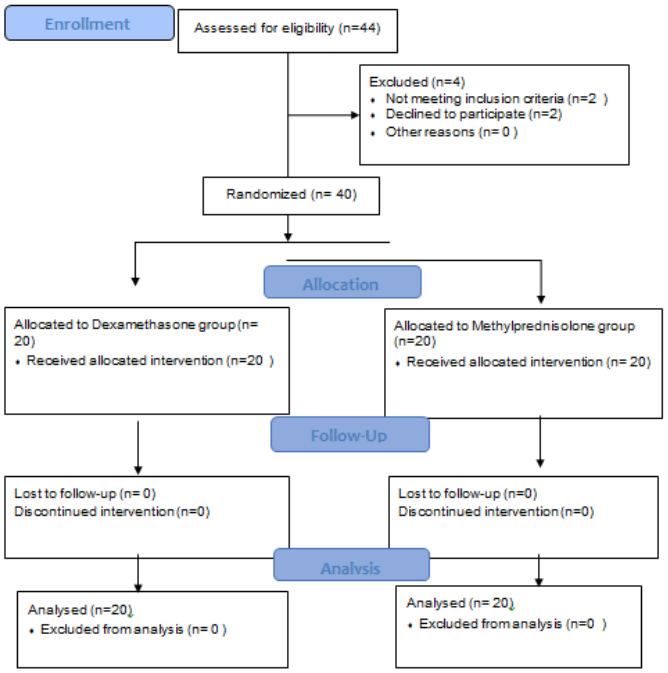
Facial swelling and trismus were recorded on days 2 and 7 postoperative using the same method as described above.

Pain was measured on a 10-cm visual analogue scale (VAS)with 0 on extreme left denoting no pain and 100 on extreme right denoting ‘worst pain’. The patient was asked to mark the intensity of pain on a VAS each day for 7 days by giving pain dairy to patients.

Patients were questioned about side effects (burning sensation, nausea, vomiting, constipation, dizziness, somnolence and hallucinations) after the procedure.

Observations and results

Consort flow diagram



Statistical Analysis

The results were analysed by using graph pad prism 9 and SPSS version 22version (Chicago, IL). Longitudinal variables across the two groups by were analysed by two

way anova with Sidak's test for post hoc analysis. Categorical data was analysed by Pearson chi-square test using SPSS software version 22(Chicago, IL)

p value less than 0.05 was considered to be significant.

Results

A total of 48 patients fulfilled the inclusion criteria. Of these 48 patients, eight were excluded. Forty patients requiring the periradicular surgery were included in the study; 18 were males and 22 were females, and their mean age was 37.8 years in DM group and 37.55 in MP group.

The patients were randomized to the dexamethasone 8 mg group (DM group, n = 20), and methylprednisolone 40 mg group (MP group, n = 20). Patient participation and the reasons for withdrawal are summarized in (Fig. 2). The baseline characteristics of the subjects in the three treatment groups and given in Table 1.

The duration of the procedure ranged from 50 to 60 min. There were no cases of wound infection, dehiscence, or any other postoperative complication. Mean preoperative mouth opening was 45.5 mm in both the groups. A reduction in mouth opening was noted on day 2 postoperatively in all of the groups as depicted in table no. Mouth opening had almost returned to normal in all three groups on day 7 post- operative (Table 2).

There was statistically significant increase in facial swelling at day 2 in methylprednisolone group (259.7±5.4) as compared to DM group (243.1±5.8) (P <0.001). However, on day 7 postoperative, swelling persisted mildly in the two intervention groups, with greater swelling in the MP group as compared to the DM group which was statistically non-significant. (Table 3).

The total mean VAS score for pain was 12.6 for the DM group, and 21.9 for the MP group (Table 4). On day 1, the mean VAS score was 38.05 in the DM group, and 39.30 in the MP group; however, there was no statistically significant difference between any of the groups. On day 3, also non-significant difference between the VAS mean scores was seen between DM and MP groups (P = 0.2). On day 4, the difference in mean VAS score between the DM and MP groups was statistically significant (P = 0.041). There was, however, significant difference in the total amount of rescue analgesics consumed between the two groups (P = 0.019) table no. 5.

Discussion

Pain, swelling, and trismus are the most common postoperative sequelae after periradicular surgeries. One cannot can happily accept these symptoms even for the short period of time because these symptoms causes serious irritation and alters quality of life[2,4] So the drugs that can decrease these postoperative symptoms must be used regularly to prevent discomfort and irritation to the patients. Corticosteroids represent one such class of drugs that can be used to prevent these undesirable effects in postoperative period. They work by inducing the synthesis of endogenous proteins, that blocks the activation of phospholipase A2. This inhibits the synthesis of inflammatory mediators e.g. prostaglandins, leukotrienes, and thromboxane's that decreases fluid transudation and oedema. The decreased oedema indirectly reduces pain and trismus. Many authors studies have studied that the corticosteroid administration cause reduction in postoperative complications after surgical procedures[5,6]. However, inconsistencies occur in optimum dosing and route of administration of these drugs. According to different classification of corticosteroid 4 mg of methylprednisolone is equivalent to 0.75 mg of dexamethasone according to their potency[6].

Positive outcomes have been seen with the use of Methylprednisolone at various dosages (20 mg to 125 mg) through different routes of administration. Milles and Desjardins et al. found decrease in swelling after third

molar surgery with a single preoperative dose of 20 mg of methylprednisolone[8]. Similarly, Sisk and Bonnington ton, also found in their study the reduction in swelling, pain, and trismus following mandibular third molar extraction with preoperative use of 125 mg methylprednisolone given intravenously[9]. Huffman in a comparative study seen the effects of intravenous administration of 40 mg and 125 mg of methylprednisolone after surgical removal impacted lower third molar found that the increased dose reduced swelling more, but the the difference was not statistically significant[10].

The optimal dose and route of administration of dexamethasone prior to dentoalveolar surgery also remains unclear. Filho et al. evaluated the effects of two different concentrations of dexamethasone (4 mg and 8 mg) on postoperative discomfort following the surgical extraction mandibular third molars in 30 patients. Results of the study showed that 8mg dexamethasone promoted a greater reduction of symptoms as compared to 4 mg of dexamethasone[11]. In contrast, Grossi et al. in a similar study involving 61 patients, stated that increasing the dose of dexamethasone to 8 mg provided no further benefit in reducing postoperative edema[12]

Postoperative sequelae i.e. pain and swelling reaches, maximum levels around 48–72 h after surgery. The physiological cortisol levels released in the body are not potent enough to decrease the inflammatory sequelae after surgical trauma, stress and fever. Increased concentration of the cortisol above the physiological levels about (from 2 to 10 times the daily replacement) are needed to counteract the inflammatory mediators, and that can only be achieved by external use of corticosteroids. In our study, we used the enhanced dose levels of steroids and that too preoperatively in order to avoid the complications of prolonged steroid use. The maximum reduction in swelling was seen in the DM group on day 2 postoperative. Increased swelling was seen at 48 h in the MP group when compared to the DM group. This could be explained in part by the fact that the half-life of methylprednisolone is 12 h to 36 h, while that of dexamethasone is 36 h to 54 h. Thus, methylprednisolone loses its effect on the second day because of a shorter duration of action. On the seventh postoperative day, swelling measurements were close to baseline values in all three groups. These findings are consistent with the results of previous studies [1,3,5,7-10.]

There was less decrease in mouth opening or trismus in both the groups in early postoperative days. The trismus as well as swelling returned to baseline levels on seventh postoperative day in both the groups, indicating that the maximum action of drugs was within the first 3 days after surgery. This defines their role in preventing trismus after dentoalveolar surgeries. whether preventing trismus is the direct effect or is a consequence of reduced swelling by steroids, needs to be verified.

Usage of corticosteroids for the prevention of postoperative pain is controversial. Some authors have advocated the increase in tissue tense after increased swelling that then lead to postoperative pain due to tissue tension. Thus, steroids indirectly reduce the postoperative pain by decreasing the facial swelling. In the present study VAS pain scores were low with the use of dexamethasone as compared to methylprednisolone, which was statistically significant on 3rd postoperative day. This could be due to more decrease in swelling by the dexamethasone as compared to methylprednisolone that decreased tissue tension and thus postoperative pain.

All the preferred route of administration (Intravenous, per-oral, intramuscular, and submucosal routes) have been used with variable results for these steroids. In the present study, we advocated the use of the submucosal

route for its genuine advantages viz painless injection, repository effect, avoidance of an additional injection site, and minimized systemic effects. The safety and ease with which the submucosal injection can be administered for routine use should be drawn to the attention of general dental practitioners, who are often not well versed with the intravenous technique.

There is a lack of knowledge regarding the choice of the type of steroid or the optimum dose to be used for the management of post-operative sequelae after periradicular surgeries. Both the drugs showed similar potency and efficacy in reducing pain and trismus while facial swelling was decreased more in dexamethasone group patients, as the former showed a significant reduction in swelling on the second postoperative day due to higher t half as compared to methylprednisolone. A study with a larger sample size is needed to better compare the efficacy of these two types of steroid drugs to be used for management of postop sequelae.

In conclusion, the submucosal injection of 8 mg dexamethasone is an effective and potent therapeutic drug that decreases swelling and post-op pain when given submucosally at the injection site after the apicectomy procedures. It provides a very simple, non-invasive, painless, and cost-effective therapeutic measure for management of moderate and severe pain.

Table 1: Baseline characteristics

	Dexamethaosne Group N=20	Methylprednisolne Group N=20	P Value
Sex N (%)			
Male	9 (45%)	10(50%)	
Female	11(55%)	10(50%)	
Age years mean ± SD	37.8±9.58	37.5±9.44	0.95

Table 2: Mouth opening reduction or trismus mean ± SD values (millimetres)

Fallow up day	Dexamethaosne Group	Methylprednisolne Group	P Value
Preoperative (day0) mean ± SD values	45.5±1.5	45.5±1.5	0.9
Postoperative (day2)mean ± SD values	41.40± 0.9	41.15±1.2	0.6
Postoperative (day7)mean ± SD values	45.1±1.5	44.7±1.5	0.25

Table 3: Facial Swelling Measurements mean ± SD values (millimetres)

Fallow up day	Dexamethaosne Group	Methylprednisolne Group	P Value
Preoperative (day0) mean ± SD values	235.2±4.4	235.4±4.05	0.9
Postoperative (day2)mean ± SD values	243.1±5.8	259.7±5.4	<0.0001
Postoperative (day7)mean ± SD values	239.3±4.31	239.45±4.32	0.99

Table 4: Vas scores on the postoperative days 1,3,4, AND 7 mean ± SD values (millimetres)

Fallow up day	Dexamethaosne Group	Methylprednisolne Group	P VALUE
Day 1 mean ± SD values	38.05±3.98	39.30±3.6	0.69
Day 3 mean ± SD values	29.30±2.7	31.4±4.3	0.2
Day 4mean ± SD values	19.40±5.1	28.6±4.4	<0.0001
Day 7mean ± SD values	12.5±3.34	14.35±4.3	0.3

Table 5: Amount of rescue analgesic medication taken

Group	Mean± SD	P value
Dexamethaosne Group	8.25± 0.96	0.02
Methylprednisolne Group	9.25± 1.55	

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