EFFECT OF CO-ADMINISTERED PREDNISOLONE AND DICLOFENAC POTASSIUM IN REDUCING POSTOPERATIVE TRISMUS AFTER IMPACTED LOWER THIRD MOLAR SURGERY

Zahid Qayyum[1], Zafar Ali khan[2], Fahimuddin[3], Prof Muhammad Saeed[4], Muhammad Ishfaq[5], Khadim Shah[3]

[1]Oral and Maxillofacial Surgery Department, Khyber Girls Medical College, Hayatabad, Peshawar, Pakistan

[2]Oral and Maxillofacial Surgery Department, College of Dentistry, University of Jouf, KSA

[3]Oral and Maxillofacial Surgery, Khyber Girls Medical College, Hayatabad, Peshawar, Pakistan

[4]Bakhtawar Amin Medical College, Mattital road northern Bypass, Multan, Pakistan

[5]King Khalid University College of Dentistry, Abha, KSA

ABSTRACT

Objective: *To determine the effect of adding a combination of oral Diclofenac Potassium with an intramuscular dose of Prednisolone preoperatively to minimize postoperative trismus after the surgical removal of the lower third molar tooth.*

Materials and Methods: *A total of 160 patients undergoing surgical removal of their impacted lower third molar tooth were randomized into 2 experimental groups; Group A (50mg Diclofenac Potassium oral and 40mg Prednisolone administered intramuscularly one hour before surgery) and Group B (40mg of intramuscular Prednisolone administered one hour before surgery). In this randomized control trial,both groups were prescribed the combination of Paracetamol and codeine as analgesics postoperatively for 48 hours. The maximum inter incisal distance was measured immediately before and 48 hours after surgery.*

Results: *Mean preoperative maximum inter incisial opening in Group A and Group B were 48.28±5.12 and 47.51±5.18 respectively. On postoperative second day the Mean maximum inter incisial opening in Group A was 34.49±3.73mm when compared to 27.71±5.48 in Group B.The mean postoperative trismus in Group A and Group B were 13.79±6.39mm and 19.95±7.07mm respectively. The mean difference in post operative trismus was 6.160mm which was statistically significant at a 99% confidence interval ($p<0.01$).*

Conclusion: *Preemptive medication with a combination of Prednisolone-Diclofenac Potassium was more effective in reducing postoperative trismus compared to Prednisolone alone.*

Keywords: *Lower mandibular third molar , Prednisolone, Diclofenac Potassium, postoperative trismus, Preemptive analgesia*

INTRODUCTION

Surgical removal of a lower third molar tooth is generally followed by side effects such as post-operative pain, swelling and trismus[1]. Of these, swelling and trismus are shown to significantly affect the quality of life of patients, especially in the first postoperative week following third molar surgery[2].

Preemptive medications are a well-accepted protocol in third molar surgery with proven benefits. Steroids, being the most commonly used preoperatively, are proven to reduce postoperative complica-

Correspondence:
Dr. Fahimuddin
BDS, FCPS, CHPE, Associate Professor Oral and Maxillofacial Surgery, Khyber Girls Medical College, Hayatabad, Peshawar, Pakistan
Email: fahim79pk@yahoo.com
Contact: +923338737733

tions. A meta-analysis on the use of corticosteroids showed a significant correlation between their use and reduction of postoperative swelling and trismus, but no additional benefit in reducing post-operative pain was shown[3]. Much research has 'combined non-steroidal anti-inflammatory (NSAIDs) agents with corticosteroids pre-operatively to enhance the anti-inflammatory effect with the added advantage of pain control[1]. Interestingly, combining steroids with NSAIDs demonstrated a better effect on reducing post-operative swelling than the use of NSAIDs alone, but reduction in postoperative trismus was inconsistent[1,4,5,6]. Most publications in literature are focused on assessing the combined effect of steroids and NSAIDs in comparison to NSAIDs alone, rather than with steroid alone groups. Studies on preemptive combination of NSAIDs and steroids versus steroids alone are limited. Most available studies that evaluate the effect of of this drug combination in post-operative trismus have been done with smaller sample sizes[6]. Therefore, this randomized control trial aims to evaluate premedication with combined intramuscular prednisolone and oral Diclofenac Potassium on reducing post-operative trismus in comparison to Prednisolone only.

MATERIALS AND METHODS

The randomized control trial was conducted at the Department of Oral & Maxillofacial Surgery at the Nishtar Institute of Dentistry, Multan- Pakistan. The necessary approval was obtained from the ethical committee of the same institute. The study included 160 patients with impacted lower third molars, who were treated within a six months' period. Patients were randomly assigned to Group A (combination group) or Group B (steroid only group) with 80 cases in each group. Allocation to treatment was performed by a non-clinical staff member who used a blind technique with sealed envelopes that were opened only on the day of surgery.

Patients requiring surgical removal of impacted mandibular third molars from both genders, aged between 20 and 45 years with optimal mouth opening (35-55mm) fulfilled the inclusion criteria. Mesioangular and vertical impactions were selected with a difficulty level 1A according to Pell and Gregory classification (Pell and Gregory, 1933). All patients were otherwise healthy with no known allergies. Patients with active infections or other pathologies associated with the lower third molar teeth were excluded. Written informed consent was obtained prior to surgery and premedication.

Group A (combination group) received a combination of Prednisolone 40mg given intramuscularly (I/M) and Diclofenac Potassium (50mg) orally one hour before the procedure. Group B (steroid only) received Prednisolone 40mg (I/M) one hour before procedure. Both patients received Co-Codamol tablets (Paracetamol 500 mg with Codeine Phosphate 15 mg) 2 tablets every 6 hours, by the clock for the first 48 hours). Both groups received only 1 dose of preoperative Co-Amoxiclav, orally 1 hour before surgery. In case of suspected Penicillin allergy, 600 mg Clindamycin was used.

Surgical procedure involved elevation and reflection of an adequate buccal mucoperiosteal flap under local anesthesia (2% Lidocaine Hydrochloride with 1:100,000 Adrenaline). Buccal and distal bone was removed and the tooth was sectioned when necessary to facilitate delivery. Following complete removal, surgical site was irrigated with normal saline (0.9%). Next, the flap was repositioned and sutured. A single surgeon (first author) performed all these surgical procedures. All the patients were instructed to place a hot pack on the side of the surgery with instructions to engage in mouth opening exercises, twice daily.

The mouth opening measurement was done by the same operator on the (first author) 2nd day after surgery. The maximum inter-incisal opening (MIO) was measured between the right maxillary and mandibular central incisor teeth with an electronic caliper. Trismus was calculated as the difference between preoperative MIO and postoperative MIO on day 2. The outcome of both treatment modalities in term of the difference in the mean was calculated.

Data analysis was performed using SPSS version 19.0 (IBM SPSS). Mean±SD was calculated for postoperative trismus. Frequency and percentages were calculated for categorical variables like gender and t-test was applied to see the significant level for effect (mean post operative MIO and mean trismus) between the two treatment modalities. A 95% confidence interval with a level of confidence of 0.01 was used for the difference in postoperative trismus.

Table 1: Age and Gender Distribution of Patients

		Group A	Group B
No of Operated Patients		**80**	80
Gender	(Male)	50 (62.5%)	46(57.5%)
	(Female)	30(37.5%)	34(42.5%)
Mean age(Mean ±sd)		24.91(±4.23)	24.59(±4.09)
Age Range		20-45 years	

Group A: Combination Group (Diclofenac and Prednisolone)
Group B: Steroid Only Group (Prednisolone Alone)

Table 2: Comparison of Pre and Postoperative Findings of Patients

	Group A	Group B	P value
No of Operated Patients	**80**	80	P<0.01
Preop MIO (mean ±sd)	48.25 (±5.12)	47.41 (±5.18)	
Postop MIO (mean ±sd)	34.49 (±3.73)	27.71 (±5.48)	
Mean Trismus (Difference in MIO)	13.79 (±6.39)	19.95 (±7.07)	

Group A: Combination Group (Diclofenac and Prednisolone)
Group B: Steroid Only Group (Prednisolone Alone)

RESULTS

Among 160 study patients, group A consisted of 50 males and 30 females with the mean age of 24.91±4.23 years. Group B included 46 males and 34 females with the mean age 24.59±4.09 (table1). Age range in this study was 20-45years with most patients (N=107, 63%) being between ages of 20 to 25 years. All patients accepted that they complied with the postoperative instructions as advised.

Mean preoperative maximum inter incisial opening in Group A and Group B were 48.28±5.12 and 47.51±5.18 respectively. On postoperative second day the Mean MIO in Group A was 34.49±3.73mm when compared to 27.71±5.48 in Group B (table 2). The results confirmed a mouth opening in Group A patients compared to Group B. Trismus was calculated as the difference of MIO before and after surgery in each group. Mean postoperative trismus after treatment in Group A was 13.79±6.398 mm while in Group B was 19.95±7.07 (P<0.01), (table 2). The mean difference in post-operative trismus of the two groups was 6.16 mm which was statistically significant (p<0.01).

DISCUSSION

Trismus is considered as the single most important variable demonstrating the complete assessment of postoperative inflammatory response after third molar surgery[7]. Our study evaluated the effect of preoperative co-administration of IM Prednisolone and oral Diclofanic Pottassium (DK) compared to IM Prednisolone only in the post-operative trismus after lower third molar surgery. The results showed that the combination of Prednisolone with Diclofanic Pottassium (DK) was significantly superior in reducing post-operative trismus. Similar research on the post-operative effect of a steroid and NSAID combination compared with a steroid alone is limited. Buyukkurt et al, in their study combined Prednisolone and Diclofanic Pottassium (DK), but this was administered in the immediate post-operative stage and significant improvement in reduction of mouth opening post surgically was seen[6].

Most of the published research on combined premedication with an NSAID and steroids compared single treatment with a NSAID, rather than with a steroid alone.[1,4,5] Bamgbose et al, in 2005 and 2006, compared the combined treatment of dexamethasone and Diclofanic Pottassium (DK) with Diclofanic Pottassium (DK) alone. In both studies, they found a significant benefit in reducing pain and swelling but had no profound effect on post-operative trismus[1,5]. An interesting randomized control trial with four arms was performed by Moore in 2005[8]. The investigators analyzed the effect of oral Refecoxib with IV placebo, IV Dexamethasone with oral placebo, Oral Refecoxib and IV Dexamethasone combination and two placebos oral and IV. Interestingly, they

found that the patients who received Refecoxib and Dexamethasone combination fared better in respect to post-operative pain and trismus. This study showed a clear benefit of combining a steroid and a NSAID over a steroid or NSAID alone for reducing post-operative trismus after a lower third molar tooth surgery.

Prednisolone is a corticosteroid is more potent than hydrocortisone and has a low mineralocorticoid action. Its IM route provides long action with less gastric irritation with only a single dose preoperatively[9]. To obtain better anti-inflammatory results and to avoid the rebound effect on swelling, a supplementary IM or oral dose of Prednisolone may be added post-operatively[10]. Such limited dosing of preemptive steroids has less effect on adrenal suppression in healthy patients.[11,12]

Diclofenac Potassium has a moderate anti-inflammatory action with mild to moderate analgesic effect including suppression of postoperative pain, swelling and trismus[6] (Buyukkurt MC, 2006). Its oral route is better tolerated with least complications with a single dose.[1] Therefore, oral administration is preferred. DK is a well-studied medication in many third molar studies with better symptom control than other NSAIDs of similar action[13]. Adverse effects of controlled dosing specially in combination with a steroid has not been reported in healthy individuals[3]. Thus, the combination of Diclofenac and Prednisolone is well suited as premedication to reduce postoperative trismus after third molar surgery. We believe that our study provides good evidence to prove that the combined use of IM 40 mg Prednisolone and oral 50mg DK gives good control on postoperative trismus after lower third molar surgery.

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