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Comparison Of The Effect Of Submucosal And Intra-Massetric Methyl Prednisolone On Postoperative Sequelae After Third Molar Surgery

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Abstract

Background: *The removal of lower third molars is often associated with swelling, pain, and trismus as a result of the postoperative inflammatory response, and these can have a serious impact on the patient's quality of life, as well as having financial consequences. To reduce postoperative complications, therefore, seems a logical goal, particularly if healing is not compromised, and the use of corticosteroids has gained wide acceptance. Over several decades many studies have reported the effectiveness of corticosteroids given before or just after removal of third molars in improving recovery. The method of use, however, has varied, and the most effective regimen has yet to be defined. Methyl prednisolone is a widely used CS and the main aim of this study is to evaluate the most effective route of administration.*

Materials and methods: *The aim of this study is to compare the effect of submucosal and intramassetric methyl prednisolone on postoperative sequelae after third molar surgery. A Single blinded prospective randomized clinical trial was performed. 3 groups each containing 27 patients, with a total of 81 patients were involved in this study. The groups were intra masseteric injection of methyl prednisolone (27 patients) sub mucosal injection of methyl prednisolone (27 patients) and control group (27 patients). The primary outcome variables were pain and mouth opening, whereas the secondary mouth opening was swelling. These were recorded on the first, third and seventh post operative days respectively.*

Results: *Based on this randomized controlled trial, we can interpret from the results that, On day 1, the maximum pain is registered in control group and intra masseteric followed by sub mucosal group which has the best pain tolerance. On day 3, there is a very minimal difference between the intramasseteric and sub mucosal groups. On the 7th day, sub mucosal route proves to be better route compared to the intramasseteric group by a very close margin.*

Conclusion: *Even though there is a very minimal difference between the two groups, the sub mucosal route proves to be slightly more effective than intra masseteric route in reducing the post operative sequale after surgical removal of impacted third molars.*

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I. INTRODUCTION:

Impacted third molar surgery is frequently associated with significant postoperative complications like pain, edema and trismus, regardless of surgical technique. Over the years, attempts to reduce the severity of complications have been advocated to improve patient comfort during the postoperative period.(1) The use of corticosteroids for this role has been studied and proven to have a significant benefit towards reducing the severity of postoperative sequelae.(2) It is known that corticosteroid reduces and inhibits the synthesis of inflammatory mediators, and this in turn reduces edema by reducing fluid transudation.(3) Although corticosteroids are

associated with certain adverse effects like delayed wound healing and disruption of the HPA axis, these effects are clinically insignificant with minor oral surgical procedures.(4) The use of glucocorticoids in minor oral surgical procedures has been elaborated by many studies and post operative administration of methyl prednisolone has been proved effective. But however, there is no study comparing the intra masseteric(5) and sub mucosal route of administration of methyl prednisolone post operatively, as to find out which of these routes is more effective in reducing the post operative sequalae after impacted mandibular third molar surgery.

II. MATERIALS AND METHODS:

A prospective, randomised, double blinded clinical trial that included 81 patients with impacted mandibular third molars in the Department of Oral and Maxillofacial Surgery, Saveetha Dental College, Chennai, from March 2013 to October 2013 after obtaining approval from the Ethical Committee. The inclusion criteria were patients aged 18 and above with impacted lower third molars requiring surgical removal. The exclusion criteria were patients with co-morbid illnesses like diabetics, immuno-compromised patients, hypertensive patients, pregnancy, lactating mothers, peptic ulcer, cardiovascular disease, pulmonary tuberculosis and patients currently on steroid therapy. A detailed case history was recorded, relevant clinical examination done, procedure explained and Informed consent was obtained from patients participating in the clinical trial. The patients were then randomised into two groups using a double blinded block randomisation method: -

Group 1: Intramasseteric Methylprednisolone group(n=27)

Group 2: Submucosal Methylprednisolone Group (n=27)

Group 3: control group (n=27)

Surgical extraction of impacted third molar carried out, followed by administration of 40mg of methylprednisolone intramasseterically via the trans buccal approach or submucosally near the surgical site postoperatively. Under Injection of 2% Xylocaine (1:200000) with adrenaline impacted mandibular wisdom teeth were removed after bone guttering/tooth division if required using saline cooled surgical bur, wound closure done using 2-0/3-0 silk sutures. A regime of antibiotics (Amoxicillin 500mg capsules for three days three times a day), and Analgesic (Piroxicam Dolonex-DT 20mg) twice daily for three days). The following Variables of interest were recorded - Tooth number (FDI) to be removed, along with type of impaction (mesioangular, distoangular, horizontal, vertical), postoperative swelling in millimetres, recorded on the first, third and seventh postoperative day across the largest diameter of the swelling; measured using calipers and a silk thread, postoperative pain on a 10-point Visual Analogue Scale recorded on the first, third and seventh postoperative day. The data was then analysed using Statistical Package for the Social Sciences (SPSS) 17, using a Student'st-test to compare between the two groups. The level of significance was set as $P < 0.05$.

III. RESULTS:

Among the 81 patients involved in this study, 45 were males and 36 were females.

Table 1

SEX - GROUPS Cross tabulation					
Count					
		GROUPS			
		SUBMUCOSAL	CONTROL	INTRAMASSETERIC	Total
SEX	MALE	15	11	19	45
	FEMALE	12	16	8	36
Total		27	27	27	81

Table 2

	N	Minimum	Maximum	Mean	Std. Deviation
AGE	81	20	58	28.83	7.169
Valid N (listwise)	81				

The mean age of patients who underwent this study is 28.83 years.

Table 3

AGE			
GROUPS	Mean	N	Std. Deviation
SUBMUCOSAL	28.67	27	6.754
CONTROL	30.48	27	9.521
INTRAMASSETERIC	27.33	27	4.086
Total	28.83	81	7.169

PAIN

Table 4 shows the mean pain scores in day 1, day 3 and day 7 respectively. On day 1, the maximum pain is registered in control group (7.33) and intra masseteric (6.11) followed by sub mucosal group which has the best pain tolerance (5.74) on day 1. On day 3, there is a very minimal difference between the intramasseteric (2.96) and sub mucosal groups(3.07). On the 7th day, sub mucosal route proves to be better route compared to the intramasseteric group by a very close margin. However, it is evident that both the sub mucosal and intra masseteric routes are better than the control group in controlling pain. ANOVA and post hoc tests were used. Based on post hoc test, there is no difference between sub mucosal and intra masseteric administration of methyl prednisolone on all three post operative days ($P<0.05$). However, there is a statistically significant difference, between control and other two groups on all 3 days for pain control.

Table 4

		N	Mean	Std. Deviation
PAIN DAY 1	SUBMUCOSAL	27	5.74	1.163
	CONTROL	27	7.33	1.240
	INTRAMASSETERIC	27	6.11	.892
	Total	81	6.40	1.291
PAIN DAY3	SUBMUCOSAL	27	3.07	1.035
	CONTROL	27	4.74	1.289
	INTRAMASSETERIC	27	2.96	.898
	Total	81	3.59	1.349
PAIN DAY 7	SUBMUCOSAL	27	.74	.594
	CONTROL	27	2.07	.917
	INTRAMASSETERIC	27	.81	.622
	Total	81	1.21	.945

Table 5
ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
PAIN DAY 1	Between Groups	37.506	2	18.753	15.260	.000
	Within Groups	95.852	78	1.229		
	Total	133.358	80			
PAIN DAY3	Between Groups	53.556	2	26.778	22.703	.000
	Within Groups	92.000	78	1.179		
	Total	145.556	80			
PAIN DAY 7	Between Groups	30.321	2	15.160	28.764	.000
	Within Groups	41.111	78	.527		
	Total	71.432	80			

IV. DISCUSSION:

A third molar is considered to be impacted when its eruption into normal functional occlusion is interfered with by the bone lying above, other teeth, or soft tissue and if it does not fully erupt by approximately 20 years of age, which is the expected age of eruption of the 3rd molar.(6) According to Andreasen JO (1997), the most commonly impacted tooth is the 3rd molar, with an incidence of approximately 18-32%.(7) Based on the angulation of the lower 3rd molar in relation to the lower 2nd molar, Winter (1926) gave a classification for impaction as mesioangular, distoangular, horizontal and vertical.(8) Another classification scheme was given by Pell & Gregory, based on the relationship of the 3rd molar with the ramus of the mandible and the 2nd molar→ *Class I*: Sufficient space is present between the distal aspect of the 2nd molar and the anterior border of ascending ramus, for the third molar to erupt into, *Class II*: The space between the distal aspect of the 2nd molar and the anterior border of the ascending ramus is lesser than the mesiodistal width of the 3rd molar; hence the distal aspect of the 3rd molar crown is covered with bone from the ramus & *Class III*: There is total lack of space; hence the 3rd molar is completely covered by bone from the ramus. According to the level of eruption of the 3rd molar, it can be classified into levels A, B and C by Padhye et al.(9) *Level A*: The highest portion of the 3rd molar is higher or at the same level of the 2nd molar occlusally. *Level B*: the highest portion of the 3rd molar is below the occlusal plane, but above the cervical line of the 2nd molar. *Level C*: The highest portion of the 3rd molar is even below the cervical line of the 2nd molar.

The indications of 3rd molar surgery usually are localized pain, pericoronitis, odontogenic abscess, trismus, distal caries, periodontal pocket in relation to the second molar, development of follicular cysts and crowding of lower incisors; hence they need to be frequently extracted to prevent these signs. The surgical extraction of the third molar involves the usual steps that are- mucoperiosteal flap elevation, ostectomy, tooth sectioning, root removal once luxated, removal of any sharp bony spicule or pathologic condition if present, debridement and wound closure. The postoperative course after surgical extraction of third molars can be complicated. It produces a significant degree of trauma to the soft tissues and bony structures of the oral cavity, hence resulting in a significant inflammatory reaction. This results in signs and symptoms of pain, edema and limited mouth opening due to muscle spasm. According to Grossi et al (2007), trismus, pain and swelling are the most common postoperative complaints that may affect the quality of life in a patient up to several days after the procedure.(10) Serious infections and permanent nerve damage occurred at a very low rate, but they were considered as the most severe complications after third molar surgery. Baqain et al (2008) did a study estimating the frequency and risk factors for developing postoperative morbidity after 3rd molar extraction.(11) He concluded that the postoperative morbidity increases with increasing age, deeper level of impaction, longer procedures and the impaction side differing from the handedness of the operator. Hence, patient related factors, operator related factors and anatomic factors play a role in postoperative complications after 3rd molar surgery. Chi H Bui et al (2003) talks about the types, frequencies and risk factors for complications after third molar extraction in a retrospective cohort study.(12) The authors found that the overall complication rate was 4.6%. The operative and inflammatory complication rates were 2.2 and 7.5% respectively. Complications were generally minor (91.9%) and were managed non-operatively on an outpatient basis. Major complications (8.1%) were mostly inferior alveolar nerve injuries. All nerve injuries except 1, resolved within 1 year. These postoperative sequelae may be reduced by both medication and non-medication methods. Peri-operative corticosteroid administration inhibits body's inflammatory response to trauma. A recent meta-analysis suggested that post-operative administration of corticosteroids reduce inflammatory symptoms upto 7 days after surgery.(13) Cryotherapy, compression and soft laser application can be used to minimize tissue injury after third molar extraction. Introduction of Piezosurgery in 1988 has also produced wonders in 3rd molar surgery, although it may be time consuming. Pre-operative antibiotic administration also plays a role in reducing postoperative morbidity after 3rd molar surgery. Peri-operative corticosteroid administration inhibits body's inflammatory response to trauma. A recent meta-analysis suggested that post-operative administration of corticosteroids reduce inflammatory symptoms upto 7 days after 3rd molar surgery. They can also be used post-surgically, after an orthognathic surgery, open reduction of trauma cases, etc. The local technique is convenient for the surgeon, as the injection is given in close proximity to the operative field, and also for the patient, as there is no extra pain, since the injection is given in the anesthetized area. The glucocorticoids widely used are dexamethasone (per oral), dexamethasone sodium phosphate (intravenous & intramuscular), dexamethasone acetate (intramuscular), methylprednisolone(per oral), methylprednisolone acetate and methylprednisolone sodium succinate (intravenous & intramuscular). Due to its anti-inflammatory effect, Methylprednisolone, which is an intermediate acting corticosteroid, can inhibit the inflammatory symptoms postoperatively, hence causing a reduction of edema, trismus and pain. The major advantage is the localized injection of the drug, which is convenient to both the operator and the patient, especially because it is being injected into an already anaesthetized area. Moreover, many clinical studies have been done comparing the effects of different routes of administration of dexamethasone, on postoperative sequelae after 3rd molar surgery, but only a couple of clinical studies have evaluated the effect of Methylprednisolone on postoperative morbidity after 3rd molar surgery. Hence this study may be helpful in comparing the effects of

submucosal and intramasseteric routes of administration of Methylprednisolone and the route of choice can be decided. Overall, there is a reduction in severity of postoperative sequalae following corticosteroid administration after third molar surgery irrespective of method of administration. Various methods of administration have been reported, including oral**,** intramuscular, local intramuscular - Intramasseteric and submucosal. Administration timings of the drugs also varied among different studies as in preoperative**,** intraoperative and postoperative. The more novel methods of submucosal administration and intramasseteric administration of the drug are appealing to any dental surgeon due to the local site of administration of the drug. Local site drug administration is postulated to improve the efficacy of drug activity. Also, a parenteral administration is preferred to avoid first pass metabolism of the drug. As the onset of inflammation occurs after a few hours of traumatic injury, a postoperative administration of corticosteroid can be done. There was no statistically significant difference between the submucosal and intramasseteric groups in postoperative outcomes of pain (VAS scale), swelling and trismus. However, there was a statistically significant difference when these 2 groups were compared to the control group. Postoperative pain, swelling and trismus were more in the control group when compared to the other 2 groups. The removal of lower third molars is still the most common surgical procedure done by oral and maxillofacial surgeons. It is often associated with swelling, pain, and trismus as a result of the postoperative inflammatory response, and these can have a serious impact on the patient's quality of life, as well as having financial consequences. To reduce postoperative complications, therefore, seems a logical goal, particularly if healing is not compromised, and the use of corticosteroids has gained wide acceptance. These agents act by inhibiting the body's inflammatory response to injury through various mechanisms, with a reduction of fluid transudation and therefore oedema. Over several decades many studies have reported the effectiveness of corticosteroids given before or just after removal of third molars in improving recovery. The administration of corticosteroids in different dosage forms has proven effective to control pain, inflammation,and trismus. Corticosteroids inhibit inflammation mediators that trigger vascular exudate and edema. They also have some analgesic effects derived from their anti-inflammatory action and prostaglandin-inhibiting capacity. The most commonly used corticosteroids are dexamethasone and methyl prednisolone, but the route administration of the drug as to find out which is the most effective route, still remains a question, so the aim of this study is to compare the effect of submucosal and intramassetric methyl prednisolone on postoperative sequelae after third molar surgery. The various routes of administration that have been commonly used are, oral, sub mucosal, intra venous, intra muscular and intra masseteric routes.

Based on this randomized controlled trial, we can interpret from the results that on day 1, the maximum pain is registered in control group (7.33) and intra masseteric (6.11) followed by sub mucosal group which has the best pain tolerance (5.74) on day 1. On day 3, there is a very minimal difference between the intramasseteric (2.96) and sub mucosal groups (3.07). On the 7^{th} day, sub mucosal route proves to be better route compared to the intramasseteric group by a very close margin. However, it is evident that both the sub mucosal and intra masseteric routes are better than the control group in controlling pain and considering mouth opening, only on the first post operative day, there exists a statistically significant difference between the three experimental groups. There is no statistical significance between day 3 and day 7. Based on ANOVA and post hoc tests, statistical significance exists between sub mucosal and control group p (P=0.003) and between intra masseteric and control (P=0.026. However, there is no difference between S/M and I/M on day 1. And the secondary outcome swelling, only on the first post operative day, there exists a statistically significant difference between the three experimental groups. There is no statistical significance between day 3 and day 7. Based on ANOVA and post hoc tests, statistical significance exists between sub mucosal and control group p (P=0.003) and between intra masseteric and control (P=0.026). However, there is no difference between S/M and I/M on day 1. Therefore it is very evident that corticosteroids play a great role in reducing the post operativesequale after third molar surgery.

V. CONCLUSION:

Even though there is a very minimal difference between the two groups, the sub mucosal route proves to be slightly more effective than intra masseteric route in reducing the post operative sequelae after surgical removal of impacted third molars. It is the final desire of every doctor, clinician, physician, or surgeon, to ensure the total rehabilitation, alleviation of symptoms and improvement in comfort and satisfaction following any treatment or medical procedure. Keeping this in mind, the surgical techniques and postoperative medication should as soon as possible alleviate postoperative discomfort for patients undergoing third molar surgery. It is possible, with the administration of methyl prednisolone, in either routes of administration to reduce the incidence and severity of postsurgical pain and swelling following this minor oral surgical procedure.

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