EFFICACY OF CONVENTIONAL LOCAL ANAESTHESIA VS TWIN MIX ANAESTHESIA (ROPIVACINE & DEXAMETHASONE) FOR SURGICAL REMOVAL OF IMPACTED MANDIBULAR THIRD MOLAR: A PROSPECTIVE SPLIT MOUTH RANDOMIZED STUDY.

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ABSTRACT:

Surgical removal of mandibular impacted third molar can cause trauma to the surrounding tissues and can limit the vital activities for a significant period of time. The aim of this study was to investigate the efficacy of dexamethasone in reducing the post-operative sequelae following the mandibular third molar impaction surgeries, if used along with the local anesthetic solution. Forty patients with bilaterally symmetrical impacted mandibular third molars were included in the study. Two groups, in group A 0.5% Ropivacine 1.8ml with 1ml dexamethasone and in group B 0.5% Ropivacine 1.8ml will be used for inferior alveolar nerve block and buccal nerve block. The parameters assessed between postop 36-48 hours and postop 6^{th}-7^{th} day in this study were the postoperative mouth opening, swelling and pain. Group A (study group) patients had a better postoperative sequelae in terms of swelling, pain and mouth opening when compared to group B (control group) patients. The twin mix anaesthesia for the surgical removal of impacted mandibular third molar improved the patient's quality of life postoperatively. There was significant reduction in the postoperative pain, swelling and improved mouth opening when compared with the conventional anaesthesia.

Keywords: Ropivacine, Dexamethasone, Twinmix, Third molar impaction, Minor oral surgery, Postoperative complications.

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INTRODUCTION:

Mandibular third molar impaction surgery forms the higher proportion of minor oral surgical procedures. The complications following impaction surgery are based on the position of the impacted teeth per se; it's close proximity to vital anatomical structures and surgeon's experience. The postoperative complications most commonly related to the mandibular third molar impactions are paraesthesia, reactionary haemorrhage, swelling, pain, trismus and infection. It is also quoted in literature that increased age and removal of bone were the main reasons for postoperative complications (*Sayed N et al*., 2019).

There are various measures taken up by the surgeons in managing postoperative complications. The drugs such as Cox1 & selective cox2 inhibitors and opioids are commonly used in alleviating postoperative swelling, pain and trismus (*Akinbade AO et al*., 2018). Pre-emptive infusion of ibuprofen and steroids such as dexamethasone, prednisolone and methlyprednisolone are also used effectively in reducing the postoperatively sequelae (*Gulnahar Y and Kupeli I*, 2018, *Feslihan E and Eroglu CN*, 2019). The photomodulation therapy can be used as an alternative to steroid therapy in controlling postoperative swelling and trismus (*Feslihan E and Eroglu CN*, 2019). The pure type-1 collagen have been used in the third molar sockets which reduces the pain, trismus and also promotes bone healing at the extraction socket(*Tsai SJ et al*., 2019).

The Submucosal / intraspace / submessetric injection of steroids, commonly dexamethasone

used in relation to the surgical site improved postoperative sequelae of the patients undergoing mandibular third molar impactions. The dexamethasone also helps in the prevention of postoperative nausea and vomiting *(Grossi GB et.,* 2007*, Cardoso MM et al.,* 2013*, Sreekumar K and Sanchit Goyal,* 2015*, Muniappan Harihara Sabari et al.,* 2018*).* The dexamethasone have also been used as an adjuvant with local anaesthetics in various surgical procedures. This mixture also called twin mix anaesthesia induces rapid onset, increases the duration of nerve blockage with extended the period of effective analgesia (*Tandoc MN et al*., 2011, *Dar FA et al*., 2013, *Kumar S et al*., 2014, *Bhargava D et al*., 2016, *Engineer SR et al*., 2017, *Udit Prakash et al*., 2017)

Twinmix solution of dexamethasone and lignocaine have been used for inferior alveolar nerve block anaesthesia which aided in reducing the postoperative swelling, pain and trismus to a greater extent (*Bhargava D et al*., 2016, *Udit Prakash et al*., 2017). Local anaesthetic solution such as ropivacine provides longer duration of anaesthesia for a period of 6-9 hours. This provides the patient with comfortable immediate postoperative period and also delays the immediate requirement of rescue pain medication (*Ernberg M and Kopp S*, 2002*, El-Sharrawy E and Yagiela JA*, 2006, *Budharapu A et al.,* 2015, *Bansal V et al*., 2018).

The aim of this study is to assess the efficacy of a novel twinmix solution (4mg dexamethasone with 0.5%ropivacine) in alleviating the postoperative morbidity associated with the mandibular third molar impactions.

MATERIALS AND METHODS:

The prospective split mouth randomized study was performed in the Department of Oral & Maxillofacial Surgery, SRM Dental College, Ramapuram, Chennai, after procuring approval from the Institutional Review Board (SRMDC/IRB/2018/MDS/No.407). Patients with bilaterally symmetrical impacted third molars of the mandible, with the age group of 18-45 years were included in this study. Patients with symptoms of pericoronal or periapical infection, systemic co-morbidities and known allergic reactions were excluded from the study. Preoperative blood investigations such as complete blood count, bleeding time as well as clotting time were assessed for all the patients. The test dose for ropivacine and lidocaine were given to every patient 72 hours prior the surgical procedure. On the study side (Group A) 1.8ml 0.5% ropivacine with 1ml dexamethasone(4mg) was used for inferior alveolar nerve block (direct technique) while conventional LA (2% lidocaine with adrenaline 1:80000) was used on the control side (Group B), which were randomised by simple randomisation method. The study details, surgical procedure and the follow-up protocols were explained to the patients. Informed consent was obtained from all the patients. To avoid bias all the impaction surgeries were performed by a single operator and clinical parameters were assessed by a blinded investigator. Postoperatively patients in both the groups were prescribed with same antibiotics and analgesics (Amoxicillin 500mg TDS, Metronidazole 400mg TDS, Paracetamol 325mg with Aceclofenac 100mg BD).

Parameter And Assessment Scale:

1. Pain was assessed using Visual analogue scale (VAS).
2. Maximal interincisal distance was measured using a scale in millimeters to assess the mouth opening.
3. Fixed reference points in the face were used to assess the swelling given by *Gogulanathan et al*., 2015 (Fig:1).

A - The posterior most point on the tragus.

B - The lateral canthus of the eye.

C - The lateral most point on the angle of the mouth.

D - The soft tissue pogonion.

E - The inferior most point on the mandibular angle.

AC, AD and BE linear measurements were measured and the swelling score was obtained using the formula AC+AD+BE.

Fig 3: MEASUREMENT OF SWELLING

Review Protocol:

The parameters were measured preoperatively, postoperative 36-48 hours and postoperative 7th day.

STATISTICAL ANALYSIS:

The Normality tests, Kolmogorov-Smirnov and Shapiro-Wilks tests results reveal the study followed normal distribution. Therefore, to analyse the data, parametric test were applied. Paired T test was used to compare the mean values recorded for VAS score, mouth opening, swelling recorded in all the angles included in the study. The analysis of data was done using SPSS (IBM SPSS Statistics for Windows, Version 26.0, Armonk, NY: IBM Corp. Released 2019). Significance level was fixed as 5% ($\alpha = 0.05$). P-value <0.05 is considered to be statistically significant.

RESULTS:

Total of 40 patients; 20 males and 20 females with an average age of 26.92±6.91 years (Table 1) (age range 18 – 45 years) were assessed for postoperative swelling, pain and mouth opening following the surgical removal of third molars in the mandible. Inferior alveolar nerve block as well as buccal nerve block on all the 80 interventions were adequate and successful without any requirement for re-anaesthesia. Patient's recovery from the local anaesthetic effect was complete in all the patients without any neurological deficit.

Table 1: Age distribution among the study participants

Age distribution (in years)	**Study participants**
17-26	52.5%
27-36	37.5%
37-46	10.0%
Mean	26.92
Standard deviation	6.91

The mean postoperative pain score between 36-48 hours in group A and B were 2.25±1.16 and 5.3±1.09 respectively which was significant statistically (p-value 0.031) and postoperative 7th day in group A and group B were 0.10±1.0 and 1.10±0.77 (Table 2) respectively which was statistically insignificant (p-value 0.248).

Table 2: Descriptive statistics of VAS score during the time intervals among study groups

Intervals	**Group A**		**Group B**	
	Mean	**S.D**	**Mean**	**S.D**
Post operative 36-48 hours	2.25	1.16	5.3	1.09
POST OP 6TH - 7TH DAY	0.10	1.0	1.10	0.77

Table 2a: Comparison of mean difference of VAS during the post operative 36-48 hours among the study groups

Paired Samples Test

Post operative 36-48 hrs	Paired Differences					T	df	P-value
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Group A – Group B	-3.10000	1.10477	.17468	-3.45332	-2.74668	-17.747	39	0.031

Table 2b: Comparison of mean difference of VAS during the post operative 7 days among the study groups

Paired Samples Test

Post operative 7 days	Paired Differences					t	Df	P-value
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Group A- Group B	-1.00000	.75107	.11875	-1.24020	-.75980	-8.421	39	.248

The mean preoperative mouth opening in group A & B were 43.7±5.96 & 43.67±5.94 respectively. The mean postoperative mouth opening between 36-48 hours and postoperative 7th day in group A was 37.07±6.98 and 43.30±6.01 and in group B was 26.45±6.86 and 39.92±6.40 respectively (Table 3) which was statistically significant (p-value <0.001).

Table 3: Descriptive statistics of mouth opening during the time intervals among study groups

Intervals	**Group A**		**Group B**	
	Mean	**S.D**	**Mean**	**S.D**
Pre operative	43.7	5.96	43.67	5.94
Post operative 36-48 hours	37.07	6.98	26.45	6.86
POST OP 6TH - 7TH DAY	43.30	6.01	39.92	6.40

Table 3a: Comparison of mean difference of mouth opening during the post operative 36-48 hours among the study groups

Paired Samples Test

	Paired Differences					t	Df	P-value
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Group A-Group B	11.11765	5.40911	.92765	9.23032	13.00497	11.985	33	<0.001

Table 3b: Comparison of mean difference of mouth opening during the post operative 7 days among the study group

Paired Samples Test

	Paired Differences					t	Df	P-value
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Group A-Group B	3.85294	2.87236	<0.001	2.85073	4.85515	7.822	33	<0.001

The mean preoperative facial measurements in group A & B were 38.05±2.55 & 37.78±3.24 respectively. The mean postoperative swelling between 36-48 hours and postoperative 7th day in group A was 38.80±2.54 and 38.07±2.55 and in group B was 40.37±2.85 and 38.48±2.76 respectively (Table 4) which was significant statistically (p-value <0.001).

Table 4: Descriptive statistics of assessment of swelling during the time intervals among study groups

Intervals	Group A		Group B	
	Mean	S.D	Mean	S.D
Pre operative	38.05	2.55	37.78	3.24
Post operative 36-48 hours	38.80	2.54	40.37	2.85
POST OP 6TH - 7TH DAY	38.07	2.55	38.48	2.76

Table 4a: Comparison of mean difference of swelling during the post operative 36-48 hours among the study groups

Paired Samples Test

	Paired Differences					t	df	P-value
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Group A-Group B	-1.56750	.88561	<0.001	-1.85073	-1.28427	-11.194	39	<0.001

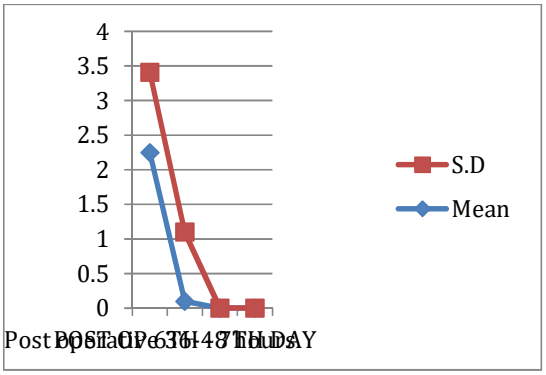
Table 4b: Comparison of mean difference of swelling during the post operative 7 days among the study group

Paired Samples Test

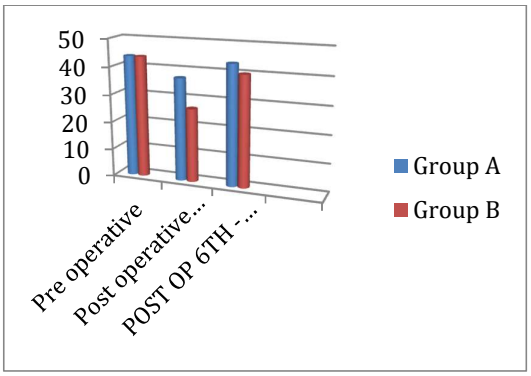
	Paired Differences					t	Df	P-value
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Group A-Group B	-.41000	.70340	.11122	-.63496	-.18504	-3.686	39	0.001

When comparing both the groups, group A (study group) patients had a better postoperative sequelae in terms of swelling, pain and mouth opening. The group A patients showed decreased pain in their immediate postoperative period when compared to group B patients, which was statistically significant and on the 7th postoperative day the pain score was almost similar in both the group (Graph 1). In terms of postoperative mouth opening (Graph 2) and swelling (Graph 3), group A patients showed reduced swelling and increased mouth opening on 2nd and 7th postoperative day when compared to group B patients, which were statistically significant.

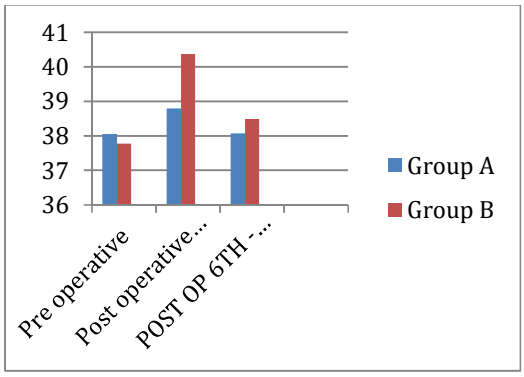
Graph 1: Comparison of VAS score among the study group



Graph 2: Comparison of mean difference of mouth opening among the study group



Graph 3: Comparison of mean difference of swelling among the study group



DISCUSSION:

The patients undergoing mandibular third molar impactions usually have an unpleasant postoperative period. The main reason for this is the various complications associated with these surgeries. Although the complication list is abounding and self-limiting; trismus, pain and swelling are the three main complications which interfere with the quality of patient's life postoperatively.

Various pharmacologic and nonpharmacologic measures have been in use to overcome the foresaid issues. These include physical measures like application of cold pack, use of accupressure for pain control, pharmacologic preparations including systemic steroids, trypsin-chymotrypsin combinations, bromalein and anti-inflammatory agents of NSAIDs. Most of these are given through systemic routes and are affected by factors of drug absorption and metabolism. The benefits of these drugs are side-lined with adverse effects such as gastric irritation, GI bleeding, nausea and vomiting.

Use of local steroids aided in reducing the issues with systemic absorption and associated complications. Apart from this, considering the steroid given as a pre-emptive drug along with the local anaesthesia in close proximity to the site of injury, the possibility that the anti-inflammatory effect starts before the onset of tissue injury leading to more profound effect on controlling the tissue injury induced inflammatory postoperative complications (*Grossi GB et al.*, 2007, *Sreekumar K and Sanchit Goyal*, 2015, *Muniappan Harihara Sabari et al.*, 2018)

Grossi GB et al., 2007 used submucosal injection of 4mg & 8mg dexamethasone in their study and reported that there was no difference in result between these two dosage regimens. Both the dosage showed good control of postoperative edema, pain and increased the mouth opening in all the patients.

Sreekumar K and Sanchit Goyal, 2015, *Muniappan Harihara Sabari et al*., 2018, reported the use of dexamethasone as an intraspace and intra massetric injection respectively and established the benefits of these techniques. In their studies, results showed reduced postoperative swelling, pain and trismus on the 2nd postoperative day.

Though lidocaine is the common anaesthetic agent used, the primary issue is the reduced duration of action which is often complete by the end of the surgical procedure. Addition of ropivacaine to the twinmix prolonged the duration of sensory anaesthesia in the initial postoperative phase reducing the patient postoperative discomfort. Though the reported half-life of the drug is only 6-8 hours, subjective sensory analgesia reported to last up to 12 to 18 hours which includes the major immediate postoperative phase of inflammation. This has been reported in other studies where the sensory analgesia were reported till 19 hours (*Anantanarayanan P et al*., 2013)

El-Sharrawy E and Yagiela JA, 2006, compared the different concentrations of ropivacine in inferior alveolar nerve block in their study. The inference from this study showed that 0.5% and 0.75% of ropivacine had similar results with rapid onset, prolonged duration of anaesthesia and 6±0.4 hours of postoperative analgesia.

When local anaesthetic agents were alkanized, their onset time was shortened, duration of action was increased, incidence of pain on injection was decreased, postoperative comfort of the patient was improved. LA is soluble in water and it appears to be in a balanced state between a basic non-ionized form and ionized form. The uncharged or non-ionized form of local anaesthetic is also lipid soluble, thus it penetrates through the nerve membrane and neural sheath. The sodium channel is bound by the ionized or charged form of LA and this binding prevents impulse generation. Rapid onset is achieved by modifying the pH to a more basic solution. The onset of action is enhanced and duration is prolonged by the addition of dexamethasone to the local anaesthetic solution because of their vasoconstriction action and the increased inhibitory activity on the nociceptive C-fibers of the potassium channels. The pH of the twinmix was increased from 4.5 to 5.5 by the addition of dexamethasone, thereby the quantity of free base present in the local anaesthetic solution was increased, onset time was shortened, duration of action was increased, incidence of pain on injection was decreased, postoperative comfort and quality of the patient's life was improved (*Udit Prakash et al*., 2017)

Dar FA et al., 2013, *Kumar S et al*., 2014, reported the use of ropivacine and ropivacine with dexamethasone in brachial plexus nerve block. In these studies, they have established the beneficial effects of ropivacine with dexamethasone which showed prolonged duration of anaesthesia and postoperative analgesia when compared with local anaesthetic solution alone.

The main concern while using glucocorticoids would be impairment in the postoperative wound healing. *Thoren et al*., 2009, in his study established that the perioperative use of 30mg dexamethasone would not hinder the bone healing process.

In our study, the study group patients who received 0.5% ropivacine with dexamethasone showed reduced swelling and trismus between 36-48 hours postoperatively and on the 7th postoperative day which were statistically significant and the postoperative pain score was statistically significant between 36-48 hours.

Udit Prakash et al., 2017, in their study compared the efficacy of 2% lignocaine with dexamethasone and 2% lignocaine alone for impacted mandibular third molar surgeries. They reported results similar to our study; the postoperative pain, trismus and swelling was reduced in the study group when compared to control group on 1st, 3rd and 7th postoperative day.

Results from our study showed that the usage of twinmix anaesthesia i.e., 0.5% ropivacine with dexamethasone in the inferior alveolar nerve block improved the postoperative quality and comfort of life by reducing the pain, swelling and trismus.

The recovery of the patients were absolutely uneventful in the group which received twinmix anaesthesia. Though there are few detriments such as hyperglycemia, impaired wound healing, adrenal suppression and infections associated with corticosteroids, the dosage which we have used in our study was a single minimal dose which would not cause the above mentioned complications. So the twinmix anaesthesia can be used with absolute safety in the mandibular third molar impaction surgeries (*Udit Prakash et al*., 2017).

CONCLUSION:

The twinmix anaesthetic solution comprising of 0.5% ropivacaine with dexamethasone yielded promising results by reducing the postoperative swelling, pain and trismus, thereby improving the patient's comfort and quality of life postoperatively. This effective synergistic combination could be considered as an alternative to a stand-alone anaesthetic agent being

administered for majority of the minor oral surgical procedures.

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