Original Article

Comparative Evaluation Of The Effectiveness Of Dexamethasone And Adrenaline With 2% Lignocaine For Pterygomandibular Nerve Blocks: A Randomized Controlled Clinical Study

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Abstract:

Background and Aim: Dexamethasone, a glucocorticoid, has been used in local anesthetics as an additive for various locoregional nerve blocks. Although, its use in the dental field has not been unexplored and concealed. The current study was conducted to evaluate and compare the calibre of anesthesia, their hemodynamic response, vasoconstrictive effects, and control of pain while administering pterygomandibular nerve blocks using 2% Lignocaine hydrochloride solution with Dexamethasone(4mg/ml) with that of the standard 2% Lignocaine hydrochloride solution and Adrenaline bitartrate (1:80000).

Materials and Methods: This triple-blind randomized controlled study included 80 healthy subjects, aged between 18-45 years with an indication for surgical removal of impacted mandibular third molars. With the aid of a computer-generated sequence, the subjects were arbitrarily assigned into 2 groups (40/group)- Group 1: patients administered with 2% Lignocaine hydrochloride and Dexamethasone Sodium Phosphate (4mg/ml) solution, and Group 2: patients administered with 2% Lignocaine hydrochloride with Adrenaline bitartrate (Adr) 1: 80,000 (12.5 µgm/ml) solution. The variables were assessed based on their time of onset, depth (pain) and duration of anesthesia, systolic, diastolic, and mean arterial blood pressures, heart rate, and blood loss.

Results: Statistically significant difference ($P<0.05$) was noticed for the onset (shorter onset in Group 1) and duration of action (prolonged in group 1) and number of analgesics required (less in grp 1). Statistically non-significant difference between 2 groups ($P>0.05$) for pain, blood loss, cardiovascular variables (systolic, diastolic and mean arterial blood pressures and heart rate) at various intervals was noted.

Conclusion: Dexamethasone added to Lignocaine shortens onset, prolongs duration of action and yields better control of post-operative pain as compared to Lignocaine with Adr. Vasoconstrictive properties, hemodynamic variables and intra-op pain control were comparable.

Keywords: adrenaline, dexamethasone, lignocaine, local anaesthetics, pterygomandibular nerve block

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Introduction:

Pain and inflammation are inevitable responses of living tissues to any surgical trauma as it results in the release of inflammatory mediators that enervates the peripheral nociceptors, eventually resulting in hyperalgesia and patient discomfort[1]. Pain control is an important aspect of patient management and involves the usage of individual drugs, and multimodal analgesics singly or in combinations, with or without LA agents.

Corticosteroids are important adjuncts to surgery since they suppress inflammatory mediators, thereby reducing post-surgical oedema. Conventionally, systemic corticosteroids are administered (pre/intra/post operatively) post the evulsion of impacted mandibular wisdom teeth surgically aimed to reduce the post-operative outcome such as swelling, trismus, and pain. Thoren H et al. determined through a retrospective study correlating the ramification of perioperative glucocorticosteroids on surgical wound healing that there was no higher risk of interference in the healing of bone with doses equivalent to 30 mg or less of dexamethasone[2]. Grossi GB et al. comparatively assessed the effects of dexamethasone injected submucosally in the doses of 4mg and 8 mg on the postoperative distress following wisdom tooth surgery and ascertained that the difference between the two dosage regimens was statistically not significant[3].

Dexamethasone, a synthetic glucocorticoid has a half-life of 36–54 hours as they have 20-30 times more potent anti-inflammatory action in contrast to cortisol. It has been recommended as a single-dose therapy for controlling post-surgical inflammatory sequelae in the maxillofacial region[4]. Bhargava et al have demonstrated the effectiveness of Twin Mix (1.8 ml of 2 % lignocaine with 1:200,000 epinephrine + 1 ml of 4 mg dexamethasone inj.) injected into pterygomandibular space (intra-space administration), reducing the postoperative outcome following mandibular wisdom tooth removal. It was also determined that the admixture reduced the latency and prolonged the duration of anesthesia[5]. Administration of intra-space twin mix has been proven to be efficient to the conventional methods of steroid administration[4] Based on the above, the current study was intended to comparatively assess the efficacy of 2% Lignocaine with Dexamethasone sodium phosphate (4mg) and 2% Lignocaine with Adrenaline bitartrate (1:80000 ie 12.5 µgm/ml) for pterygomandibular nerve blocks in the surgical removal of impacted mandibular wisdom teeth. In accordance with the **null hypothesis** of the study tested, the efficacy of Dexamethasone with 2% Lignocaine when compared with Adrenaline with 2% Lignocaine in the surgical evulsion of impacted mandibular wisdom teeth, showed no difference in their outcome variables- the quality of anaesthesia, vasoconstriction effects, hemodynamic response and pain control.

Materials and Method:

This randomized controlled triple-blind (operator, subject, and observer) study was performed in the Dept. of Oral and Maxillofacial Surgery at a recognized dental college. The formula used to calculate the sample size (n) is:

$$n= 2 (Z\alpha +Z\beta)^2 [s]^2 /d^2$$

Wherein:

Zα: z variate of α error i.e. a constant with a value 1.96,

Zβ: having a value of 0.84.

Hence, from the literature, the mean and standard deviation was contemplated, and almost 40 subjects per group were determined. The ethical clearance was obtained from the Institutional Ethics Committee.

Patients in the age range of 18 to 45 years, reporting to the maxillofacial surgery OPD for surgical extraction of impacted mandibular wisdom teeth and consenting to be a part of this study, were enrolled for the study. A complete medical history was taken and routine hematological and radiological investigations were prescribed. After ascertaining that the patient belonged to ASA-I, had no history of drug allergy were used in this research, or any active infection currently, the molar to be extracted was moderately difficult (5-7, as per Pederson's Difficulty Index[6]) and consented to be a part of this study, he/she was randomly allocated to one of the 2 groups by computer generated sequence. Child-bearing mothers, nursing mothers, patients with a past history of cardiovascular or other medical ailments, or any contraindication and/or drug interaction with Dexamethasone/ Adrenaline, apprehensive patients,

any illness or medication in the past week were excluded.

For the test group/ Group 1: 1ml of Dexamethasone sodium phosphate (4mg/ml) was mixed with 2ml of plain 2% lignocaine just prior to the surgical procedure. The control group (Group 2) was administered with standard solution of 2% Lignocaine with Adrenaline 1:80,000. The surgical procedure was conducted by a single standardized operator and the variables were noted and measured by a single observer, both blinded. All surgical procedures were carried out using Pterygomandibular nerve blocks after ascertaining negative aspiration of blood.

The outcome variables assessed were, i) calibre of anesthesia (onset, duration, and depth) ii) vasoconstrictive effects/ blood loss, iii) hemodynamic variables i.e., SBP, DBP, MABP, and HR, and iv) post-operative pain control. The onset of anesthesia, determined in seconds, is defined as the time interval from the time of administration of local anesthetic to the first tingling sensation experienced by the subject on the labium inferious oris. Duration, determined in minutes, was recorded from the time of the first sensation of paraesthesia on the labium inferious oris until the first prescriptive rescue analgesic was consumed by the subject. Depth of anesthesia was a measure of intra-operative pain control assessed using a visual analogue scale (VAS). The vasoconstrictive effects were estimated from the loss of blood volume which was calculated as the difference in weights of the gauze pieces used preoperatively and postoperatively and the difference in the volume of used saline and suction jar collection. SBP, DBP, MABP, and HR were determined until LA injection and periodical at intervals of 5mins, 10mins, 15mins, 30mins, and 45mins using a multiparameter monitor (Intellivue MX 400, Philips, with more than 95% accuracy).

Statistical Procedures:

MS Office Excel Sheet (v 2019, Microsoft Redmond Campus, Redmond, Washington, United States) was used for compiling information and was subsequently evaluated applying a Statistical package for social sciences (SPSS v 26.0, IBM). Descriptive data including frequencies and percentages for categorical data, mean & standard deviation for numerical data have been illustrated.

Parametric tests were used to compare the demographic data. T-test was used for inter-group comparison. The chi-square test was applied to compare the frequencies of the categories of variables with groups.
The Shapiro-Wilk test was applied to check the normality of numerical data. Since data for outcome variables did not follow a normal curve, the Mann-Whitney U test was applied for inter-group comparison.

For all the statistical tests, the power to study was given as 80%, by keeping α error (false positive) at 5% and β error (false negative) at 20%, and $P<0.05$ was considered to be statistically significant.

Results:

The mean age of the subjects was 31.8± 5.412 (Min-18, Max 44). There were 31(38.8%) females, and 49 (61.3%), male subjects in this study.
On inter-group comparison, the mean age of the subjects was considered to be statistically non-significant ($P>0.05$), while ruling out any confounding effect of age. Similarly, for prevalence of sex of the subjects obtained was not statistically significant ($P>0.05$).

Table 1 shows the inter-group comparison of amount of solution injected, number of injections, Onset, duration, depth, vasoconstrictive effects and post-op pain control

Table 2 shows the inter group comparison of hemodynamic variables

Discussion:

From the systematic review and meta-analysis conducted by Markiewicz MR et al, it is evident that the administration of steroids clinically reduces post-operative edema and improves the range of motion after the surgical evulsion of the wisdom tooth, thereby reducing postoperative morbidity[7]. Bhargava et al conducted a pilot study to analyze the effectiveness of intra-space administration (pterygomandibular) of Twin Mix (1.8 ml 2 % lignocaine with 1:200,000

epinephrine + 1 ml of 4 mg dexamethasone) along with 2 % lignocaine with 1:200,000 epinephrine for surgical extraction of mandibular third molars[5]. The study deduced that the inclusion of Dexamethasone improved both the comfort postoperatively, and also shortened the inception and the period of the soft tissue anesthesia. Further, it was shown that the post-operative comfort with Twin mix was comparable to other routes of steroid administration[4]. UV Spectrometry confirmed the chemical stability of Twin mix [8]. The study on absorption of dexamethasone systemically after intra-space vs intra muscular administration showed statistically no significant difference in plasma concentration of venous blood using high performance liquid chromatography[9,10]. Noss C et al through their systematic review, affirmed the safety of perineural usage of dexamethasone[11].

In the present study, a freshly prepared mixture of 1ml Dexamethasone sodium phosphate (4mg) and 2% lignocaine was comparatively evaluated with the standard Adrenaline (12.5μgm/ml) and 2% lignocaine 1:80000 for pterygomandibular nerve blocks to examine the quality of anesthesia, its hemodynamic alterations, surgical blood loss and intra and post-operative pain control.

Onset of LA action showed a highly significant difference(p=0.000) with a Mean of 196.50 sec for grp1, and 283.88 sec for grp2; (Table 1). This was consistent with the results from other studies[4,5,12]. The decreased onset of action with Dexamethasone as an additive has been explained on the basis of vasoconstrictive action, alkalinization of LA solution (rendering more unionised entities, RN) and increasing the inhibitory activity of potassium channels on C-fibres[5].

Duration of action showed a highly significant difference (p=0.000) with a Mean of 183.75min for grp 1, and 109.95 min for grp2; (Table 1). This was also consistent with previously reported studies for pterygomandibular blocks as well as upper and lower extremity nerve blocks[1,4,5,12,13]. The mechanism of prolonged action has been described on the basis of multi-modal anti-inflammatory effects of dexamethasone thereby leading to minimal release of inflammatory mediators like leukotrienes and prostaglandins[15].

Similarly, the number of post-operative analgesics consumed in 3 days by the subjects in Group 1 mean (2.75) was less than group 2 (5.40) (Table 1) thereby, the variation obtained was statistically significant (p=0.000). Similar inference was drawn by Chong et al[13] in the systematic review and meta-analysis stating the superiority of perineural administration in comparison with iv administration for post-operative pain control.

The intra-operative VAS score showed statistically no significant difference (mean 2.15 for grp 1, 2.23for grp 2), amount of solution used and number of injections between the 2groups; suggesting that 4mg/ml of dexamethasone might be equally effective as an additive to lignocaine as 12.5 μgm/ml of Adr in terms of depth of anesthesia with similar quantities of solution being used in 2 groups.

The amount of blood loss as assessed indirectly by 2 methods, showed statistically no significant difference, affirming the vasoconstrictive effect of Dexamethasone. M.E. Ullian reviewed the function of steroids in the management of vascular tone and concluded that "corticosteroids enhance the actions of vasoconstrictor hormones thereby augmenting the vascular tone and have direct effect on vascular smooth muscle cells that are unconventional of vasoconstrictor hormones"[16]. Thus, vasoconstrictive effects of dexamethasone are comparable to Adr.

There was statistically no significant difference in SBP, DBP, MABP and HR amongst the 2groups at all intervals (Table 2). There is evidence of sodium and water retention on prolonged usage of glucocorticoids, there by leading to hypertension. However, a single dose of 4mg does not lead to hemodynamic changes.[17]

None of the study subjects reported with any drug related local and/or systemic adverse effects.

Thus, it can be concluded that dexamethasone as an additive may be safely administered with lignocaine for maxillofacial nerve blocks because it alkalinizes the solution, leads to early onset, prolongs analgesia thereby reducing consumption of systemic post-op analgesics.
Administration is easy in a single prick with LA, so no separate injections/ oral administration is required. Due

to its anti-inflammatory properties and added local effect, post-operative Quality of life is better.

Limitations and Future Scope:

Based on the approval from IEC, this study had to be restricted to the subjects from ASA-I category. However, more studies may be designed including medically compromised patients in whom adrenaline is contraindicated or only limited amounts are permissible. Effectiveness of Dexamethasone may be studied with other anaesthetics. The effect of this combination may also be studied with other nerve blocks.

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Conflicts of Interest: None

List of Abbreviations:

- LA: Local anesthesia
- Inj.: Injection
- ASA: American Society of Anesthesiologists
- SBP: Systolic blood pressure
- DBP: Diastolic blood pressure
- MABP: Mean Arterial blood pressure
- HR: Heart rate
- IEC: Institutional Ethics Committee

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Tables :

* = shows a statistically significant difference ($p<0.05$)
** = shows a statistically highly significant difference ($p<0.01$)
# = shows a non significant difference ($p>0.05$)

	Groups	Mean	Std. Deviation	Median	Mann-Whitney U value	Z value	p value of Mann-Whitney U test
Amount of solution injected	Test	3.038	.2372	3	758.500	-1.058	0.290#
	Control	3.225	.8002	3			
number of injections used	Test	1.03	.158	1	760.000	-1.020	0.308#
	Control	1.08	.267	1			
Onset in sec	Test	196.50	13.121	193.5	12.000	-7.585	0.000**
	Control	283.88	43.931	289			
Duration/Rescue analgesic taken after (min)	Test	183.75	18.861	192	38.000	-7.365	0.000**
	Control	109.95	31.233	96			
Depth/VAS score	Test	2.15	.802	2	753.000	-0.480	0.631#
	Control	2.23	.862	2			
Weight of gauze pre-op(gm)	Test	10.45	.749	10	698.500	-1.098	0.272#
	Control	10.68	1.163	10			
Weight of gauze post -op(gm)	Test	12.40	.982	12	672.500	-1.308	0.191#
	Control	12.55	1.061	13			
Difference in the weight of the gauze pre-op and post op(gm)	Test	1.95	.639	2	799.000	-0.011	0.991#
	Control	1.95	.597	2			
Total volume(ml) in the jar at the completion of the procedure (a)	Test	340.25	49.536	330	727.500	-0.707	0.479#
	Control	352.25	60.953	340			
Quantity (ml) of the normal saline used for irrigation (b)	Test	274.50	50.279	280	751.000	-0.485	0.628#
	Control	283.50	60.279	290			
Volume (ml)of blood loss (c)	Test	66.25	23.390	60	705.500	-0.937	0.349#
	Control	70.25	23.478	60			
Post-op pain control/No. of analgesics in 3days	Test	2.75	1.532	2	178.500	-6.053	0.000**
	Control	5.40	1.499	5			

Table 1: shows Inter group comparison of amount of solution injected, number of injections, Onset, duration, depth, vasoconstrictive effects and post-op pain control.

	Group	Mean	Std. Deviation	Median	Mann-Whitney U value	Z value	p value of Mann-Whitney U test
SBP pre-op	Test	127.25	3.986	128.00	788.000	-0.116	0.907#
	Control	127.13	3.763	128.00			
SBP 5min	Test	139.45	4.591	140.00	685.000	-1.113	0.266#
	Control	140.73	3.234	140.00			
SBP 10 min	Test	140.13	8.010	142.50	616.000	-1.781	0.075#
	Control	144.03	2.796	143.00			
SBP 15 min	Test	141.63	9.919	144.50	630.000	-1.642	0.101#
	Control	145.33	3.983	145.00			
SBP 30 min	Test	137.08	7.426	139.00	635.000	-1.603	0.109#
	Control	139.38	3.801	140.00			

SBP 45 min	Test	130.85	5.366	132.00	661.000	-1.347	0.178#
	Control	132.93	2.379	133.00			
DBP pre-op	Test	80.98	5.659	80.00	685.500	-1.112	0.266#
	Control	82.78	4.359	80.50			
DBP 5 min	Test	93.00	4.163	93.50	739.000	-0.593	0.553#
	Control	93.08	4.287	94.00			
DBP 10 min	Test	97.25	6.376	98.00	791.500	-0.082	0.934#
	Control	97.30	6.035	97.50			
DBP 15 min	Test	100.83	5.861	102.00	677.000	-1.190	0.234#
	Control	102.43	5.068	102.00			
DBP 30 min	Test	96.43	6.197	96.50	779.500	-0.198	0.843#
	Control	96.70	5.566	97.50			
DBP 45 min	Test	88.05	4.663	89.50	717.000	-0.806	0.421#
	Control	89.03	3.025	90.00			
MABP pre-op	Test	96.400000	4.6078095	95.666667	713.000	-0.839	0.401#
	Control	97.558333	3.9269596	96.500			
MABP 5 min	Test	108.483333	3.0428563	109.333333	701.000	-0.955	0.340#
	Control	108.958333	2.8933439	109.500			
MABP 10 min	Test	111.541667	4.9841272	112.333333	657.500	-1.374	0.170#
	Control	112.875000	4.5458647	112.833			
MABP 15 min	Test	114.425000	6.1542321	116.333333	646.500	-1.480	0.139#
	Control	116.725000	4.2579823	117.166			
MABP 30 min	Test	109.975000	5.2256149	111.333333	721.500	-0.756	0.449#
	Control	110.925000	4.0067518	112.000			
MABP 45 min	Test	102.316667	4.1109610	103.000000	679.500	-1.164	0.244#
	Control	103.658333	2.0063823	103.667			
HR pre-op	Test	79.83	6.812	77.50	788.500	-0.112	0.911#
	Control	79.63	6.003	78.00			
HR 5min	Test	87.33	8.198	85.00	684.500	-1.124	0.261#
	Control	88.93	6.518	86.00			
HR 10 min	Test	93.35	7.685	92.00	751.000	-0.474	0.635#
	Control	93.43	7.386	90.00			
HR 15 min	Test	99.20	5.249	100.00	791.500	-0.082	0.934#
	Control	99.55	4.181	99.50			
HR 30 min	Test	90.00	10.392	91.00	637.000	-1.573	0.116#
	Control	93.25	8.221	92.00			
HR 45 min	Test	82.15	8.226	80.00	673.000	-1.225	0.221#
	Control	84.05	7.002	83.00			

Table 2: Shows Inter group comparison of hemodynamic variables