MODIFIED TREATMENT TOLERABILITY EVALUATION SCORE IN PATIENTS UNDERGOING TEMPORARY ANCHORAGE DEVICES (TAD) UNDER TOPICAL LIGNOCAINE AEROSOL 15% WITH LIGNOCAINE WITH OR WITHOUT ADRENALINE INFILTRATION DURING ORTHODONTIC TREATMENT

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ABSTRACT

Introduction: This study was undertaken primarily to compare the efficacy and safety of topical Lignocaine aerosol 15%, Lignocaine 2% with or without Adrenaline (1:80000) used in Temporary Anchorage Devices (TAD) placement in Orthodontic Treatment. **Method:** The study population included all patients of both gender and aged above 12 years, who were scheduled for placement of Temporary Anchorage Devices (TAD) in orthodontic treatment, and willing to participate in the study were included in the study. Depending on the local anaesthetic used, the patients were divided into Group 1 (Topical Lignocaine Aerosol 15% USP + Lignocaine 2% with Adrenaline), Group 2 (Lignocaine 2%) and Group 3 (Lignocaine 2% with Adrenaline). All the groups were assessed for immediate adverse drug reactions. The severity of adverse effects was graded by using Modified Treatment Tolerability Evaluation Score (MTTES) for the signs and symptoms **Results:** There was no statistically significant difference between age and gender of the three treatment groups. MTTES score was lowest in Group 2 followed by Group 3. It was significantly higher in Group 1. **Conclusion:** Group 1 (topical and infiltration lignocaine) and 3 combinations showed higher MTTES score for the adverse effect profile, whereas Group 2 appeared safer in terms of both the variables. Thus, use of topical and infiltration lignocaine raises concerns regarding safety of this combination.

Keywords: Topical Lignocaine; MTTES; Orthodontic treatment; Temporary Anchorage Devices

INTRODUCTION

Temporary Anchorage Devices (TADs) is a therapeutic alternative to traditional methods of anchorage in orthodontic treatment. The intraoperative pain control by means of local anaesthesia is an intrinsic part of the procedure of TAD placement. Infiltration or topical local anaesthetics can be used in TAD placement [1].

Local anaesthetics abolish sensation (and, in higher concentrations, motor activity) in a limited area of the body by reversibly blocking impulse conduction along nerve axons and other excitable membranes that use sodium channels as the primary means of action potential generation without producing unconsciousness [2,3].

Systemic absorption of injected local anaesthetic from the site of administration is determined by several factors, including dosage, site of injection, drug-tissue binding, local tissue blood flow, use of vasoconstrictors (e.g. adrenaline/epinephrine), and the physicochemical properties of the drug itself [2].

In clinical practice, a vasoconstrictor, usually adrenaline is often added to local anaesthetics [4].

Adverse reactions of Lignocaine are directly proportional to its concentration achieved in the circulation. The systemic manifestations of the combination involve the Central nervous system [3], Cardiovascular system [4], Psychogenic Reactions, allergic reactions [5] and local tissue damage [6].

In view of the use of the above-mentioned modalities with advantages and disadvantages of each of them, it was thought prudent to evaluate safety in terms of Modified Treatment Tolerability Evaluation Score (MTTES) of use Lignocaine with or without adrenaline (1:80000).

MATERIAL AND METHODOLOGY

Study design: The study was a longitudinal study

Ethical approval: The study was commenced after obtaining the institutional ethical committee clearance and obtaining written informed consent from the patient.

Study location & period: Carried out in Department of Orthodontics & Dentofacial Orthopaedics, Rural Dental College, Loni, from 2017 to 2019.

Inclusion criteria: The study population included all patients of both gender and aged above 12 years, who were scheduled for placement of Temporary Anchorage Devices (TAD) and received topical Lignocaine aerosol

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15%, or Injection Lignocaine 2% with or without adrenaline in orthodontic treatment, willing to participate in the study were included in the study. The number of sites and details of TAD placement in terms of side and quadrant was recorded.

Grouping: Depending on the local anaesthetic used the patients were divided into Group 1 (Topical Lignocaine Aerosol 15% USP + Lignocaine 2% with Adrenaline), Group 2 (Lignocaine 2%) and Group 3 (Lignocaine 2% with Adrenaline).

Methodology: All the groups were assessed for immediate adverse drug reactions. The severity of adverse effects was graded by using Modified Treatment Tolerability Evaluation Score (MTTES) for the signs and symptoms listed below [7]:

Score 0: Symptom is not present (Absent)

Score 1: Symptom is present but is not annoying or troublesome (Mild)

Score 2: Symptom is frequently troublesome but would not interfere with normal daily activity or sleep (Moderate)

Score 3: Symptom is sufficiently troublesome to interfere with normal daily activity or sleep (Severe)

RESULTS

In the present study, 60 patients were recruited, of which 22 were males and 38 were females.

Table 1: Comparison of Mean Age in three treatment groups

Group	Age (Mean ±SD)	Anova
1	21.15±6.23	0.49
2	19.11±4.02	
3	20±5.2	
Total	20.12±5.24	

There was no statistically significant difference between mean ages of patients in the three groups (P= 0.49, ANOVA). Thus the groups are comparable age wise.

When the distribution of patients in the groups with respect to gender was considered, as shown in Table no. 2, there is no statistically significant difference between the treatment groups (P= 0.653, Chi-square)

Table 2: Gender wise distribution of three treatment groups

Group (N)	Male (%)	Female (%)	Chi square
1 (20)	6 (30)	14 (70)	0.653
2 (10)	9 (44.4)	10 (55.6)	
3 (22)	8 (36.4)	14 (63.6)	
Total (60)	22(36.7)	38 (63.3)	

Table no. 3 shows comparison of Local reactions after administration of anesthetic preparations. Applying Kruskal Waillis Test there was a statistically significant difference (P=0.004) in the number of swelling reported between three groups. There was no significant difference in reporting of other local reactions between the three groups.

Post hoc analysis by Dunn's test shows that Group 1 patients reported significantly higher MTTES scores as compared to group 2 & 3.

Table no. 4 shows a Comparison of CNS symptoms after administration of anesthetic preparations. On applying Kruskal Wallis Test, there was statistically significant difference between Headache (p=0.002), Blurring Vision (p=0.02), numbness of tongue (p=0.006), metallic taste (p<0.001) Dysarthria (p=0.01) & Sedation (p=0.009). There was no significant difference in reporting of other CNS symptoms between the three groups.

Post hoc analysis (Dunn's test) shows that Group 1 patients reported significantly higher MTTES scores for Headache, Dizziness, numbness of tongue, metallic taste, dysarthria, & Sedation as compared to group 2 followed by group 3.

Table no. 5 displays a comparison of CVS symptoms after administration of anesthetic preparations. On Applying Kruskal Waillis Test, there was statistically significant difference (p<0.001) in the number of patients reporting Hypertension between three groups. There was no significant difference in reporting of other CVS symptoms between the three groups.

Table 3: Comparison of Local reactions after administration of anesthetic preparations

Local Reactions	No. of cases											
	Group 1 MTTES scores				Group 2 MTTES scores				Group 3 MTTES scores			
	0	1	2	3	0	1	2	3	0	1	2	3
Pain	14	6	0	0	13	5	0	0	14	8	0	0
Swelling	9	9	2	0	16	2	0	0	20	1	1	0
Necrosis	20	0	0	0	18	0	0	0	21	1	0	0
Delayed wound healing	20	0	0	0	18	0	0	0	22	0	0	0

Table 4: Comparison of CNS symptoms after administration of anesthetic preparations

CNS	No. of cases											
	Group 1 MTTES scores				Group 2 MTTES scores				Group 3 MTTES scores			
	0	1	2	3	0	1	2	3	0	1	2	3
Light-headedness	16	4	0	0	14	3	1	0	21	1	0	0
Headache	5	11	4	0	12	6	0	0	18	2	2	0
Dizziness	9	11	0	0	14	4	0	0	21	1	0	0
Blurring of vision	15	4	1	0	18	0	0	0	22	0	0	0
Tinnitus	20	0	0	0	18	0	0	0	22	0	0	0
Perioral tingling	20	0	0	0	18	0	0	0	22	0	0	0
Numbness of tongue	13	7	0	0	18	0	0	0	22	0	0	0
Metallic taste	3	13	4	0	15	3	0	0	14	8	0	0
Dysarthria	14	6	0	0	18	0	0	0	22	0	0	0
Sedation	12	8	0	0	14	4	0	0	22	0	0	0
Muscular twitching/tremors	20	0	0	0	18	0	0	0	22	0	0	0
Seizures	20	0	0	0	18	0	0	0	22	0	0	0
Coma	20	0	0	0	18	0	0	0	22	0	0	0
Respiratory Arrest	20	0	0	0	18	0	0	0	22	0	0	0

Table 5: Comparison of CVS symptoms after administration of anesthetic preparations

CVS	No. of cases											
	Group 1 MTTES scores				Group 2 MTTES scores				Group 3 MTTES scores			
	0	1	2	3	0	1	2	3	0	1	2	3
Bradycardia	20	0	0	0	18	0	0	0	22	0	0	0
Hypotension	20	0	0	0	16	2	0	0	22	0	0	0
Hypertension	9	6	5	0	18	0	0	0	16	6	0	0
Cyanosis	20	0	0	0	18	0	0	0	22	0	0	0
Chest pain	20	0	0	0	18	0	0	0	22	0	0	0
Cardiac arrhythmia	20	0	0	0	18	0	0	0	22	0	0	0

Post hoc analysis (Dunn's test) shows that Group 1 patients reported significantly higher MTTES scores for hypertension as compared to group 3 followed by group 2. (table 5)

Table no. 6 shows a Comparison of mean Total MTTES Score between three anesthetic preparations. There was statistically significant difference between the mean MTTES score among the groups ($p<0.001$, ANOVA). It was lowest in Group 2 (2.06, 1.55) followed by Group 3 (2.45, 2.19). It was significantly higher in Group 1 (6.75, 1.94)

Table 6: Comparison of mean Total MTTES Score between three anesthetic preparations

Group	Mean	ANOVA
1	6.75±1.94	p<0.001
2	2.06±1.55	
3	2.45±2.19	
Total	3.77±2.86	

DISCUSSION

Dental practitioners use local anesthetic injections with various concentrations of adrenaline. In this study, the use of local anesthetic alone or along with adrenaline was found for the TAD placement.

In Patients of Group 1 (n=20), Topical Lignocaine Aerosol 15% USP was followed by infiltration of Lignocaine 2% with Adrenaline (1:80000). The use of topical anesthetic is very common before infiltrative anesthesia to decrease the discomfort in the application of the latter [8].

Regarding the infiltrative anesthetic, used in patients of Group 3 (n=22), lidocaine hydrochloride + adrenaline (epinephrine) 1:80,000 in Group 3 was used because it is mostly employed in Dentistry with low toxicity rates and enough anesthetic effect. Additionally, this combination is injected in the area of the mucosa where the mini implant would be placed by infiltration in such a way that satisfactory anesthesia is achieved without making the surrounding structures from being anesthetized, as suggested by the literature [9].

As seen from Table no.1 and 2, there was not-statistically significant difference between the age and gender of the three groups, indicating that the groups were comparable with respect to age and gender.

Post hoc analysis shows that Group 1 patients reported significantly higher MTTES scores as compared to group 2 & 3 for the symptom of pain. Pain at the site of implant and swelling were as the most common local symptoms (Table 3).

Topical anesthetics used in Group 1 is indicated to minimize the sensation of needle insertion or for very brief relief from painful mucosal lesions. Their effectiveness in preventing pain due to injection is equivocal, but they may be of value for many patients [3].

Localized toxicity occurs following the injection of local anaesthetic directly into a structure or when a structure is exposed to a high concentration for a prolonged period. Direct injection into a muscle provokes an intense inflammatory reaction resulting in areas of muscle necrosis, which is worsened by added vasoconstrictors [10].

There was statistically significant difference between Headache ($p=0.002$), Blurring Vision ($p=0.02$), numbness of tongue ($p=0.006$), metallic taste ($p<0.001$) Dysarthria ($p=0.01$) & Sedation ($p=0.009$). There was no significant difference in the reporting of other CNS symptoms between the three groups. Post hoc analysis shows that Group 1 patients reported significantly higher MTTES scores for Headache, Dizziness, numbness of tongue, metallic taste, dysarthria, & Sedation as compared to group 2 followed by group 3. (Table 4).

In our study there was statistically significant difference ($p<0.001$) in the number of patients reporting Hypertension between three groups. There was no significant difference in reporting of other CVS symptoms between the three groups. Post hoc analysis shows that Group 1 patients reported significantly higher MTTES scores for hypertension as compared to group 3 followed by group 2. (Table 5).

The cardiovascular system (CVS) response to local anesthetic toxicity also is biphasic. Initially, the CVS is subject to stimulation; heart rate and blood pressure may increase This may be further precipitated in the local anaesthetic with vasoconstrictor Epinephrine. The above results in group 1 and 3 may be due to the biphasic response and addition of epinephrine further accentuating the effect [11].

Tukey's test used for post hoc analysis showed that the mean MTTES scores were significantly higher in Group 1 ($p<0.001$) as compared to Group 2 & 3. MTTES score is lowest in Group 2 followed by Group 3. It is significantly higher in Group 1 (Table 6).

CONCLUSION

Group 1 (topical and infiltration lignocaine) and 3 combinations showed higher MTTES score for the adverse effect profile, whereas Group 2 appeared safer in terms of both the variables. Thus, use of topical and infiltration lignocaine raises concerns regarding safety of this combination.

Conflict of interest : Nil

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