ISSN: 0975-833X

Available online at http://www.journalcra.com

International Journal of Current Research
Vol. 8, Issue, 05, pp.31841-31845, May, 2016

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

RESEARCH ARTICLE

COMPARATIVE EVALUATION OF EFFICACY OF 15% LIGNOCAINE SPRAY AND 4% LIGNOCAINE GEL IN REDUCING THE PAIN DURING ADMINISTRATION OF INFRAORBITAL INJECTIONS IN ORTHODONTIC EXTRACTIONS

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ARTICLE INFO

Article History:
Received 17th February, 2016
Received in revised form
05th March, 2016
Accepted 14th April, 2016
Published online 31st May, 2016

Key words:

Pain, Local anesthetics,
Topical administration,
Lignocaine gel,
Lignocaine spray.

ABSTRACT

Purpose: Pain control serves as a basis for successful oral and maxillofacial surgical practice. However, the commonest method of intraoperative pain control itself is stimulus for pain induction. In spite of various methods to reduce the pain on injection, topical anesthetic application is still most frequently used. This study compares the efficacy of two forms of topical anesthetics prior to nerve block injections.

Methodology: 40 patients were divided into 2 groups. Group I- Side of the patients receiving 4% lignocaine gel; Group II - Side of the patients receiving 15% lignocaine spray. On one side 4% Lignocaine gel was applied. Following this an infraorbital nerve block and necessary dental extraction was carried out. Each patient was asked to note the pain during the injection on a 10 mm VAS scale. Similar procedure was repeated on the opposite side after 7 days using 15% lignocaine spray. The data was subjected for statistical analysis.

Results: Pain on injection was significant statistically, while others were not significant.

Conclusion: This study reveals that 4% lignocaine gel has better reduction in pain during administration of infraorbital nerve block injection comparatively.

Citation: Vijay Gupta, Santhoshkumar, S. N., Aziz Pahadwala, Kalyani Bhate and Padmasree Patowary, 2016. "Comparative evaluation of efficacy of 15% lignocaine spray and 4% lignocaine gel in reducing the pain during administration of infraorbital injections in orthodontic extractions", *International Journal of Current Research*, 8, (05), 31841-31845.

INTRODUCTION

Pain control serves as a basis for successful oral and maxillofacial surgical practice. Intraoperative pain control was revolutionized with advent of local anesthesia since 1884 (Wildsmith, 2012). However, the pain on injection is the most dreaded part of oral and maxillofacial surgical practice. Fear associated with injection has been reported to be a factor in avoiding dental and / or oral surgical treatment (Milgrom *et al*., 1997; Kudo, 2005; Moore, 1981 and Palmon, 1998). The actual method of administrating the injectable local anesthetic is painful, because of stimulation produced by the needle during insertion and the injection of the acidic local anesthetic solution. The mechanisms by which the injection of the anesthetic solution causes pain have not yet been clearly identified, although various factors affecting it are properties of the injected solution, technique of administration of administration of injection and the tissue sensitivity of the injection site (Rosa, 1999).

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Needle insertion produces mechanical trauma of the tissues and the intensity of pain is related to the area of injection and the design of the needle bevel, which affects its penetration. Needles that have secondary bevels cause the least pain. On the other hand, the needle's diameter, within dental standards, does not interfere in the intensity of the pain caused by needle insertion (Rosa *et al*., 1999). Previous studies have shown that the commonly used needle gauges of 25, 27, or 30 do not differ significantly in patient's perception of pain (Nakanishi *et al*., 1996). Reducing the pain on injection and overcoming fear of needles remain important objectives in the management of such patients, particularly those with increased levels of anxiety. Proper technique in the administration of local anesthetic should minimize patient's pain on injection needle insertion. This includes utilizing chair side manner to gain the patient's confidence, making the tissue taut, and distracting the patient by communicating with them effectively. Unfortunately, this may not be sufficient (Nakanishi *et al*., 1996). Additional means to reduce the pain on injection are utilization of smaller gauge needles, administration of topical anesthesia (Santhosh Kumar, 2015 and Stecker *et al*., 2002), buffering the local anesthetic solution (Bowles *et al*., 1995 and Al–Sultan, 2004),

refrigeration of the target area prior to injection (Crecelius, 1999; Ghaderi *et al*., 2013), local application of vibratory devices (Santhosh Kumar, 2015; Davoudi *et al*., 2016; Salgotra *et al*., 2014 and Yoshikawa *et al*., 2003), use of needleless syringes (Santhosh Kumar, 2015; Davoudi *et al*., 2016; Salgotra *et al*., 2014; Yoshikawa, *et al*., 2003 and Faizal, 2013), utilization of computer-controlled local anesthetic delivery system (Santhosh Kumar, 2015; Davoudi *et al*., 2016; Salgotra *et al*., 2014 and Yoshikawa, *et al*., 2003) and use of sedation with local anesthesia (Crecelius, 1999). Application of topical anesthetics has been used most frequently, to minimize the pain caused by needle insertion. Topical anesthetics are available in various forms such as, gel, aerosol, patch, ointment and solution. However, gels and aerosols are the most frequently used topical anesthetics in dentistry (Malamed, 1997).

Literature search using pubmed search engine has revealed a number of clinical studies regarding the effectiveness of gel form of topical anesthetics with varying results. However, analysis of these studies has disclosed that these clinical studies presented with some methodological problems such as, the use of low-sensitivity pain scales, the injection of a local anesthetic that could mask the effect of the topical anesthetic, a long period of application, or application of anesthetic on areas with little pain sensitivity. Hence, there is still doubt in the literature about the clinical effectiveness of commonly used gel form of topical anesthetics. The general consensus established in these studies is that gel is not very much effective in all areas of the oral cavity (Nusstein, 2003).

MATERIALS AND METHODS

Source of data

It is an in-vivo, prospective, split-mouth study conducted on 40 patients attending the Department of Oral and Maxillofacial Surgery over a period of 1 year. Institutional ethics committee clearance was obtained prior to commencement of the study.

Inclusion Criteria

- Patients undergoing orthodontic extractions.
- Patient's age between 18-35 years.
- Patients willing to give written informed consent for the study.

Exclusion Criteria

- Patients with history of allergy to lignocaine.
- Patients with recent history of antimicrobial therapy.

Methodology

All the subjects were informed about the anesthetic injections and the procedure in detail before obtaining a valid informed consent.

The topical anaesthetics used were

- 4% lignocaine gel (Fig. no-1).
- 15% lignocaine spray (Fig. no-2).

40 patients fulfilling the above criteria were included in this study. They were divided into 2 groups.

Group I- Side of the patients receiving 4% lignocaine gel.
Group II - Side of the patients receiving 15% lignocaine spray.

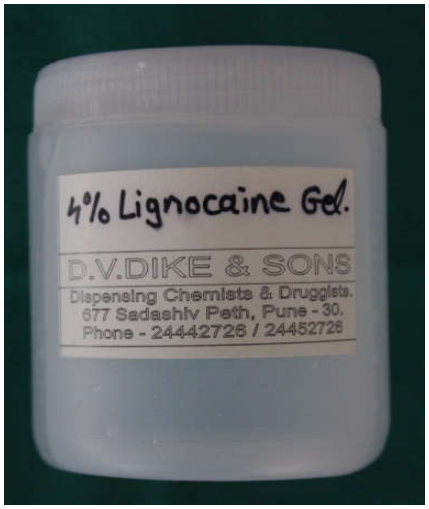

Fig.1. 4% lignocaine gel for topical application

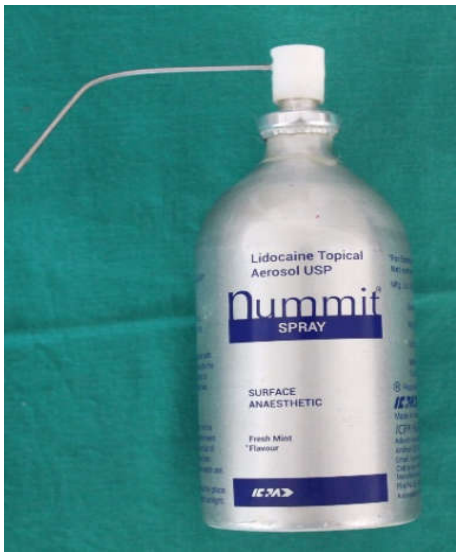

Fig.2. 15% lignocaine topical aerosol spray

The side receiving 4% lignocaine gel was decided by *flip coin* method. Under aseptic conditions 4% lignocaine gel was applied. 2 minutes following its application, infraorbital nerve block injection was administered and necessary dental extraction was carried out. The extraction of the desired premolar was carried out once the subjective symptoms and objective signs of effective nerve block were confirmed. After the dental extraction, each patient was asked to note the pain during the injection by marking an "X" on a 10 mm VAS scale, with 0 denoting no pain, and 10 corresponding to worst possible pain. Similar procedure was repeated on the opposite side after 7 days using 15% lignocaine spray. The data obtained was tabulated and sent for statistical analysis. The methods of statistical analysis employed were Mann-Whitney U Test and Kruskal-Wallis Test.

Table 1. Distribution of study participants based on study groups and gender

Group	Gender	N	Mean Rank	Mann-Whitney U value	p value	Inference
I	Male	20	19.27	175.500	0.486	NS
	Female	20	21.73			
	Total	40				
II	Male	20	23.00	150.00	0.183	
	Female	20	18.00			
	Total	40				

Group I- Side of the patients receiving 4% lignocaine gel, Group II - Side of the patients receiving 15% lignocaine spray, N- Sample size, P- value <0.05 significant, NS- Not significant.

Table 2. Distribution of study participants based on study groups and age range

Group	Age	N	Mean Rank	Kruskal Wallis value	p value	Inference
I	18-21	21	20.86	0.126	0.939	NS
	22-25	13	19.62			
	26>	6	21.17			
	Total	40				
II	18-21	21	20.74	0.311	0.856	
	22-25	13	19.31			
	26>	6	22.25			
	Total	40				

Group I- Side of the patients receiving 4% lignocaine gel, Group II - Side of the patients receiving 15% lignocaine spray, N- Sample size, P- value <0.05 significant, NS- Not significant.

Table 3. Distribution of study participants based on study groups

Group	N	Mean Rank	Mann-Whitney U value	p value	Inference
I	40	28.29	311.500	<0.001	S
II	40	52.71			
Total	80				

Group I- Side of the patients receiving 4% lignocaine gel, Group II - Side of the patients receiving 15% lignocaine spray, N- Sample size, P- value <0.05 significant, S- Significant.

RESULTS

The mean age of the study participants was 22.35 ± 3.61 years. The age of the study participants was further divided into 3 groups for analysis. Age ranging from 18-21, 22-25 and 26> respectively. In group I, for the age ranging from 18-21 the mean rank was 20.86. The mean rank was 19.62 for age range of 22-25 and for age at and above 26, it was 21.17. However, it was found to be statistically insignificant (Kruskal Wallis value 0.126, p=0.939). In group II, for the age ranging from 18-21 the mean rank was 20.74. The mean rank was 19.31 for age range of 22-25 and for age at and above 26, it was 22.25. Nevertheless, it was found to be statistically insignificant (Kruskal Wallis value 0.311, p=0.856) Table 1.

Group I comprised of 20 males and females with the mean rank of 19.27 for males and 21.73 for females. However, it was found to be non significant (Mann Whitney U value175.500, p=0.486). Group II comprised of 20 males and females with the mean rank of 23.00 for males and 18.00 for females. Nevertheless, it was found to be non significant (Mann Whitney U value 150.500, p=0.183) (Table 2).

The pain on injection was compared between the groups, based on the analysis of VAS score. Group I had mean rank of 28.29 and group II had mean rank of 52.71. This clearly shows that mean rank of group II was higher than that of group I. This reveals that the pain score in group I was better than group II.

With a p <0.001, it was found to be statistically significant (Mann Whitney U value 311.500, p< 0.05 significant) (Table 3)

DISCUSSION

A split-mouth designed study was used because it allowed for intra-individual comparison and the assessment of pain during administration of infraorbital nerve block also left and right sides could behave differently, and the second injection in the same mouth would be easier and thereby less traumatic. So these possible causes of bias were controlled by randomly assigning the cases to each of the possible combinations (Clauser and Barone, 1994; Paschos *et al*., 2006).

The successful oral and maxillofacial surgical practice not only depends on controlling the pain but also alleviation of the fear and anxiety regarding the treatment. 80% of the patients experienced fear and anxiety concerning dental treatment and its delay (Domoto, 1988). Needle injection of local anesthetic is commonest modality of pain control used today. However it is ironical that the pain control measure itself is a source of fear and anxiety for dental patients. In another study, 88% of the study populations were worried about oral injections, ranging from a little to almost constantly (Wienstein *et al*., 1992). Various studies have demonstrated a variety of tools to reduce the pain of injection, ranging from topical application of anesthetic solutions to computer-controlled local anesthetic

delivery systems (CCLAD). In this study, a total of 40 patients were included. Among these 40 patients, 85% were between the age group of 18-25. The mean average was 22.35 ± 3.61 yrs. The average age of the patients in this study was lesser than that of the (Svensson *et al*., 1994). They studied the efficacy of topical anesthetic in pain and unpleasantness during scaling of gingival pockets. However, Nayak R and Sudha P (Nayak, 2006), (Walimbe, 2014), (Stecker *et al*., 2002), (Primosch, 2002) conducted studies to evaluate the efficacy of topical anesthetics in children. This variation of age distribution may be attributed to the target group of the study population. The present study targeted those undergoing orthodontic extractions. There was an equal distribution of male and female patients in the study population. This was unlike many of the studies such as, (Rosivack, 1990), (Valieri, 2014), Svensson P and Petersen JK (Svensson, 1992) (Primosch, 2000), which showed female predominance amongst the study group. However, a study by (Stecker, 2002) showed male predominance in the study population.

Evaluation of efficacy of topical anesthetics directly relates to the pain perceived during local anesthetic injection. As pain perception is very subjective in nature, various pain assessment tools have been described in literature. In this study, 10mm visual analogue scale was used as this method is simple and easily understandable to the patients. In this study, mean rank of pain was 28.29 in group I, while it was 52.71 in group II. This demonstrates that the pain on injection during administration of infraorbital nerve block was less in group I. This may be attributed to unfavorable bioadhesion, analgesic potential and taste characteristics of lignocaine spray. Also, it is not always possible to confine the expelled amount of solution to the preferred site in spray form. The lignocaine gel penetrates through mucosa, exerting its anesthetic effect and providing intimate contact between gel and absorbing tissue which may result in high drug concentration in local area and high drug flux through the absorbing tissue. This is similar to the studies conducted by (Grover, 2012), (Tulga, 1999), (Grover *et al*., 2012) assessed three topical anesthetic agents namely Eutectic mixture of Local anesthetic (EMLA) 5% cream, Produit Dentaire (20% benzocaine) and Lignocaine 15% spray in pediatric patients during various dental procedures requiring local anesthesia administration. This study was carried out on 210 patients aged between 6-14 years and they were randomly divided into three groups and were subjected to the test agents. They concluded that EMLA agent 5% had the highest onset of action and superior pain reduction followed by benzocaine gel and Lignocaine Spray 15%.

Tulga and Mutlu (1999) studied the pain reducing efficacy of various agents upon local anaesthetic injection was measured by VAS. There were 120 subjects between the ages of 10-15 years old. In group I, Vision Gel was reported to have lower pain score than EMLA by 4mm ($p \leq 0.05$; 28.45±18.07, 24.45±17.48). In group II, EMLA had lower pain score than anesthetic tabs by 20mm ($p \leq 0.01$; 37.00±11.29, 17.50±11.98). In group III, EMLA had lower pain score than xylocaine spray by 10mm ($p \leq 0.05$, 34.70±19.68, 24.70±17.24). In group IV, Vision Gel had lower pain score than xylocaine spray by 8mm ($p \leq 0.05$, 34.75±14.91, 26.95±14.70). In group V, Vision Gel had lower pain score than anesthetic tabs by 25mm ($p \leq 0.01$, 35.75±13.01, 11.00±10.21). In group VI, anesthetic tabs had lower pain score than xylocaine spray by 11mm ($p \leq 0.05$, 36.50±11.82, 25.75±12.06). Xylocaine spray had higher pain scores in all its groups. Vision Gel had the lower pain scores in all its groups.

However, the results of this study were contradictory to (Paschos, 2006). (Paschos, 2006) focused on the effectiveness of intraoral topical anaesthetics; 1.16% tetracaine (Gingicain spray), 20% benzocaine (Gingicaine topical anaesthetic), a solution of 11% benzocaine, 2% tetracaine and 50% dimethysulfoxide (Legecain-solution), and EMLA. The data was analyzed using Wilcoxon Test. In a pre study examination, Gingicain spray scored Facial Pain Scale (FPS) score mean of 1.62 and standard deviation (SD) of 0.87 while Heart Rate Changes (HRC) had a mean of 5.69 and SD of 3.35. The placebo had FPS mean of 2.54 and SD of 1.26 while HRC had mean of 9.46 and SD of 5.27. The authors designated FPS and HRC as primary outcome variables, which resulted in no statistically significant difference between the placebo and any of the four topical anaesthetics. They also found that second injections to be more painful. This difference may be attributed to the fact that (Paschos, 2006) study was a placebo-controlled study, where in each topical anesthetic group was compared with placebo and in turn they were compared against each other. Nevertheless, this study did not perform a blinded approach. Neither did it compare the right and left side, nor first and second injections. Further studies incorporating these flaws in the study design is necessary.

Conclusion

This study reveals that lignocaine gel has better reduction in pain during administration of infraorbital nerve block injection comparatively. This is irrespective of age and gender of the study population. In spite of using higher concentration of lignocaine in spray form, it resulted in higher pain rank during administration of infraorbital nerve block injection. Also, due to its bitter taste, lignocaine spray should be used only in the remote areas of oral cavity, where the gel application is impossible. As the numbers of studies on this subject are sparse, further multicentric studies with larger sample size and various modifications in the study design are required.

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