COMPARISON OF DURATION OF ACTION OF BUFFERED AND NON-BUFFERED LOCAL ANAESTHETICS IN INFERIOR ALVEOLAR NERVE BLOCK: A RANDOMIZED DOUBLE-BLINDED CONTROLLED STUDY

BALA, M.[1]*, TAIWO, A.O.[1], IBIKUNLE, A.A.[1], SULAIMAN, A.O.[3], CHUKWUMA, B.C.[1], BRAIMAH, R.O.[1], ILE OGEDENBE, B.[4], OKORO, N.N.[5], OGBEIDE, M.E.[1] AND JAAFARU, R.[1,2]

[1]Dept. of Oral and Maxillofacial Surgery, [2]Dept. of Restorative Dentistry, Usmanu Danfodiyo University Teaching Hospital, Sokoto, Nigeria, [3]Dept. of Restorative Dentistry, University College Hospital, Ibadan, Nigeria, [4]Dept. of Dental and Maxillofacial Surgery, Federal Medical Centre, Birnin Kebbi, Nigeria, [5]Dept. of Oral and Maxillofacial Surgery, University of Benin Teaching Hospital, Benin City, Nigeria

ABSTRACT

One of the desirable properties of local anaesthetic agents (LA) is the sufficient duration of anaesthesia. This study aimed to compare the duration of action of buffered and non-buffered 2% lignocaine with 1:100,000 adrenaline in inferior alveolar nerve block. This was a randomised double-blinded controlled study conducted over a period of 7 months at the Dental Clinic, Usman Danfodiyo University Teaching Hospital, Sokoto. Ethical approval was obtained from the institution's Research and Ethics committee, and all consenting patients aged 18 years and above screened for routine extraction of permanent mandibular molars and who met the selection criteria were recruited. A simple random sampling technique was employed in allocating study participants into buffered and non-buffered groups as A and B respectively. Participants' demographics were recorded. The duration of action was measured using two different techniques as D1 and D2. D1 was the time (measured in minutes) from the onset of the local anaesthesia to the first feeling of painful sensation after the extraction and D2 was the time from the onset of the local anaesthesia to the total recovery of sensation of the lower lip. Data obtained were analysed using SPSS version 21.0. There were 62(51.7%) males and 58(48.3%) females in the age range of 18 to 74 years with a mean±SD of 38.6±14.1 years. There was no statistically significant difference between the duration of action of sodium bicarbonate buffered and non-buffered 2% lignocaine with adrenaline in both techniquesD1 (p=0.659) D2 (p=0.428). Buffering of LA did not affect the duration of the anaesthesia. However more clinical trials are recommended to draw a more accurate conclusion.

Keywords: buffered, duration of action, local anaesthetic agent, non-buffered.
***Correspondence:** mujtababala@yahoo.com, +2348061267162

INTRODUCTION

Many drugs have been tried and used for achieving local anaesthesia in both medical and dental specialties [1]. The first regional anaesthesia in the oral cavity was performed by Halsted in 1884 when he extracted the third molar using cocaine infiltration but soon became unpopular due to associated high mortality [1, 2]. A new era of local anaesthesia in dental practice was started in 1905 when Einhorn reported the synthesis of procaine which was thereafter followed by other agents like chloroprocaine, tetracaine and propoxycaine, but these agents did not gain the desired support of dentists due to the high incidence of allergic reactions. In the year 1943, Lofgren synthesized lignocaine, which was the first "modern" local anaesthetic drug that had a quick onset of action, good course and safe recovery [2]. Thereafter, many other agents like mepivacaine (1956), procaine (1960), bupivacaine (1963) and, etidocaine (1971), are being used in dental practice but lignocaine remains the preferred choice for most dental practitioners [2, 3].

There are many properties required for an ideal local anaesthetic drug. These include faster onset of action, sufficient duration of action, reversibility, non-irritant to the tissues, no or minimal allergy or systemic toxicity, quick metabolism in the body and stability at room temperature [4]. To achieve or strengthen some of these properties, several agents/adjuvants including; clonidine, dexmedetomidine, opioids (such as fentanyl, morphine), Vasoconstrictors (such adrenaline), steroids (such as dexamethasone), sodium bicarbonate, magnesium sulphate, methyl paraben have previously been tried along with lignocaine hydrochloride [4, 5]. Adrenaline has remained the commonest and most effective vasoconstrictor agent used as a constituent of local anaesthetic for over a century [4] One of the main roles of adrenaline as an adjuvant is to prolong the duration of action of local anaesthetics and this is very necessary for dental anaesthesia especially, in those procedures carried out with infiltration anaesthesia. In some cases, repeated injection is necessary before the completion of the dental procedure [6]. The prolonged duration of local anaesthesia is also desirable in the management of some chronic pains such as cancer pain and neuropathic pain.

Several studies have reported an improvement in the quality and success of local anaesthesia with buffered local anaesthetics particularly in having faster

onset of action, and lesser pain on injection [7 - 10]. When a buffer (commonly 8.4% sodium bicarbonate) is added to local anaesthetic agent, it raises the pH of the solution to nearly a physiologic pH, that favours the predominance of the uncharged base form of the local anaesthetic molecules required for instance nerve penetration [11]. An extensive literature search revealed a paucity of data regards the status of the duration of action of buffered lignocaine with adrenaline hence, the need to explore more in this subject.

The aim of this present study was to compare the duration of action of buffered 2% lignocaine with 1:100, 000 adrenaline and non-buffered 2% lignocaine with 1:100,000 adrenaline.

MATERIALS AND METHODS

This was a randomised double-blinded controlled study conducted over a period of 7 months (23rd June 2020 to 22nd January 2021). Ethical approval (UDUTH/HREC/2019/NO.800) was obtained from the institution's Research and Ethics committee. A written informed consent was obtained from the participants after the aims and objectives of the study was explained to them and safety of the drugs and confidentiality assured. Participants included in the study were healthy patients aged 18 years and above who presented for routine extraction of lower permanent mandibular molars at the Dental and Maxillofacial Surgery clinics, Usmanu Danfodiyo University Teaching Hospital, Sokoto were recruited. Excluded were patients with any known co-morbidity that may adversely affect their haemodynamic stability, pain perception, or healing. These co-morbidities include but are not limited to hypertension, diabetes, thyroid disorders, psychiatric illness, and epilepsy. Patients who had a history of allergy or hypersensitivity to any of the agents/constituents to be administered. Pregnant and lactating mothers were also excluded. The minimum sample size of 108 (54 per group) was calculated using equation for randomized control clinical trial $N = 2SD^2(Z\alpha+Z\beta)^2/d^2$ with SD derived from previous similar study by Thimmaiaha *et al.,* [12].

A simple random sampling technique was used in allocating participants into buffered and non-buffered groups A and B respectively. On each day of the research, participants who fulfilled the selection criteria were randomly allocated into two groups (A and B) using a computer-generated table of random numbers. A computer-generated randomization list that was used in allocating the participants into the two groups was printed and participants to receive either of the drug solutions were assigned according to this list by a well-trained research assistant who also prepared the drug solution. The drug solutions administered were given to the researcher by the same research assistant. The researcher and the participants were not aware of the group of the drug solution administered. In this way, both the researcher and the participants were blinded. The second trained research assistant did the data recording.

Participants in group A were injected with 2mls of sodium bicarbonate buffered 2% lignocaine containing 1:100,000 adrenaline while participants in group B were injected with 2mls of non-buffered 2% lignocaine containing 1:100,000 IU adrenaline. The participants' demographic variables were recorded and the duration of action of the local anaesthetic agents was measured using two different techniques as D1 and D2. D1 is the time measured in minutes from the onset of the anaesthesia to the participants 'first perception of pain after the extraction procedure and D2 is the time from the onset of the local anaesthesia to the complete recovery of sensation of the lower lip after the extraction and, the participants were asked to stay until the duration of action has been measured. Data obtained from this study were analysed using IBM SPSS version 21.0.

RESULTS

A total of one hundred and twenty 120 participants including 62(51.7%) males and 58(48.3%) females in the age of ranged of 18 to 74 years were recruited. The age mean ±SD for groups A and B were 37.4±15.2 years and 39.9±13.0 years respectively. There was no statistically significant difference in age categories between the groups when tested using chi-square ($\chi2=4.079$, $p=0.130$), (Table 1). The gender distribution also showed no significant difference ($\chi2=1.201$, $p=0.273$) (Table 1).

The mean ±SD duration of the local anaesthesia from the first method D1 for groups A and B were 185±45.3 minutes and 181±51.2minutes respectively and no statistically significant difference was found between the two groups ($t=-0.442$, $p=0.659$). The mean±SD duration of the local anaesthesia from the second method D2 for groups A and B were 193±44.9 minutes and 186±50.8 minutes respectively and when compared no significant difference was found between the two groups ($t=0.796$, $p=0.428$).

Table 1: Analysis of demographic characteristics of the study population

Variable	Frequency		Test statistics	Level of significance
	Group A n (%)	Group B n (%)		
Age				
≤ 30 years	26(43)	17(28)		
31-60years	27(45)	38(63)	$\chi 2$=4.079	p=0.130
>60years	7(12)	5(9)		
	Total 120(100)			
Gender				
Male	34(57)	28(47)	$\chi 2$=1.202	p=0.273
Female	26(43)	32(53)		
	Total 120(100)			

$\chi 2$= Chi-square

Table 2: Comparison of duration of local anaesthesia between the study groups A and B using two different methods.

Variable	Group A Mean (±SD)	Group B Mean (±SD)	Test statistics	Level of Significance
Duration of local anaesthesia(minutes) by method (D1)	185 (±45.3)	181(±51.2)	t=0.442	P=0.659
Duration of local anaesthesia(minutes) by method (D2)	193(±44.91)	186(±50.8)	t=0.796	p=0.428

DISCUSSION

The duration of the action of lignocaine is between 3 to 4 hours [11]. Longer duration of action is a desirable property of local anaesthetic agents [4]. A relatively longer duration of action of local anaesthesia is an advantage especially for longer medical or dental procedures that may require repeated injections. Adrenaline has so far been established as a vasoconstrictor agent that can prolongs the duration of action of lignocaine [13]. This present study compared the duration of action of sodium bicarbonate buffered lignocaine with adrenaline and compared it with non-buffered lignocaine with adrenaline in inferior alveolar nerve block during routine extraction of mandibular molars.

The gender and age distribution of participants in the two groups were not statistically significant which implies that the two groups are comparable. There were a little more male than females in the present study, which is consistent with findings in some previous research. [14, 15]. This could be because male participants when compared with females are more likely to consider tooth extraction rather than conservative treatment as previously observed by some authors [16, 17]. The exclusion of pregnant and lactating mothers could also explain the slight male predilection.

This study revealed that there was no statistically significant difference in duration of action between the sodium bicarbonate buffered 2% lignocaine and non-buffered 2% lignocaine with adrenaline using two different subjective assessment methods. This finding is in concordance with that of Lingraj *et al.*, [18] in India, and, Jumpitaz *et al.*, [19] in Spain and Christopher *et al.*, [14] who concluded that buffering of the local anaesthetic agents did not affect the duration of action of lignocaine or mepivacaine. Warren *et al.*, [20] used a more objective assessment methods (electric pulp testing as well as cold testing) to compare the duration of pulpal anaesthesia between the buffered and non-

buffered lignocaine with adrenaline during inferior alveolar nerve block. They also reported no statistically significant difference between the two solutions using the two different objective assessment tools. Shyamala *et al.,* [5] also reported that the anaesthetic duration remains unchanged when the local anaesthetic agents was buffered during surgical removal of impacted third molars and also stated that the methods of assessment (subjective or objective) do not influence the results of this comparison. Warren *et al.,* [20] opined that buffering does not affect the mechanisms explaining the duration of action of local anaesthetics such as protein binding capacity and vasoconstrictive or vasodilatation capabilities.

Contrarily, Oluwatola *et al.,* [21] in their study, examined the effect of buffering on the duration of action of lignocaine with adrenaline using the infiltration technique on the face by subjective assessment. They reported a significantly longer duration of action in the buffered LA in 80.9 percent of the participants (p-value =0.004). The difference in the technique used in administering the LA (block versus infiltration) may explain the difference in findings.

CONCLUSION

This study revealed that sodium bicarbonate buffering of 2% lignocaine with adrenaline did not affect the duration of action of the 2% lignocaine with 1:100,000 adrenaline by subjective assessment. However more clinical trials are recommended to draw a more accurate conclusion.

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