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Efficacy and Safety of Articaine versus Lignocaine in Minor Oral and Maxillofacial Surgery

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Abstract:*An effective and safe anaesthesia is one of the most important essentials for present day's oral and maxillofacial surgery. Local anesthetic agents (LAAs) play the fundamental role of ensuring pain-free surgeries. A plethora of LAAs are available commercially. The rational use of a particular type will presuppose that the potency, latency, duration of anaesthetic effect, pharmacokinetics, and pharmacodynamics including toxicity of the LAAs are evaluated and considered to make the appropriate choice in every given clinical situation. In making this decision on appropriate LAA for use, the availability and price are also factors for consideration. This study aims to compare the efficacy and safety of articaine and lignocaine (both with 1:100,000 adrenaline) in patients presenting for routine minor oral surgery. The study is designed as a randomized clinical trial in patients requiring simple routine minor oral surgery. The subjects had 1.8mls of 4% articaine (1:100,000 epinephrine) or 1.8mls of 2% lignocaine (1:100,000 epinephrine) for maxillary infiltrations. The principal outcome measures were anaesthetic success/efficacy (latency and onset of surgical anaesthesia) and post-injection adverse events or post-injection pain. There were a total of 93 subjects that participated in this study. This number was made up of 49 females and 44 males. A-100 cohort consists of 47 subjects while L-100 consists of 46 subjects. The mean ± SEM of the age of the subjects was 39.2 ± 1.7 years and 37.2 ± 1.7 years for the A-100 and L-100 cohorts respectively (p=0.403) . The mean latency time ± SEM was 35.0 ± 1.0 seconds and 46.0 ± 1.0 seconds for the A-100 and L-100 cohorts respectively (p=0.000). Time of onset of surgical anaesthesia ± SEM was 2.0 ± 0.8 minutes and 3.5 ± 0.2 minutes for the A-100 and L-100 cohorts respectively (p=0.000). Mean surgery time ± SEM was 16.8 ± 0.7 minutes and 16.4 ± 0.6 minutes for the A-100 and L-100 cohorts respectively (p=0.690). Majority reported no pain for both cohorts (A-100, 46; A-L, 42). Whereas 1 subject reported mild pain in A-100 cohort, 3 reported mild pain in the L-100 cohort, (p=0.104). No adverse reactions were recorded throughout the study period. The latency time for action was significantly lower in the articaine cohort. Also, the time for onset of surgical anaesthesia was significantly lower in the articaine cohort. Both articaine and lignocaine appear relatively safe for use in the study population.*

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I. Introduction

Continuous advancement in pharmacotherapeutics necessitates clinicians to constantly apprise themselves of new drugs[1]. The control of pain through anaesthesia of terminal branches of maxillary nerve is one of the loco-regional anesthetic techniques most widely used in oral and maxillofacial surgery[2]. The commonest procedure in everyday oral and maxillofacial practice is the extraction of teeth. An effective and safe anaesthesia is the most important essentials for this surgery.This affords comfort and safety for both the patient and the surgeon, when used correctly.Local anesthetic agents (LAAs) play the fundamental role of ensuring pain-free surgeries[1,2]. A plethora of LAAs are available commercially, for use in oral and maxillofacial surgeries. The rational use of a particular type of LAAs in a given clinical situation presupposes that the potency, latency and duration of anaesthetic effect are considered. Other considerations are pharmacokinetics, toxicity of the LAAs, availability and the cost price[3].

Local anesthesia is the temporary loss of sensation including pain in one part of the body produced by a topically-applied or injected agent, without depressing the level of consciousness[4,5]. LAAs are the most commonly used drugs in dentistry, and related surgical feilds[6,7]. When given, LAAs prevent transmission of pain sensation during procedures. The protocol for effective and safe management of pain starts at the time of initial interview, before admission for surgery. This protocol involves appropriate comportment of the surgeon, establishment of good rapport and adequate educations on the patients' expectations vis-à-vis the possible outcomes based on information available in the body of knowledge[8,9].

Cocaine was the forerunner among the LAAs in perioperative pain control, but was abandoned because of its low therapeutic index and high potential for addiction[10]. An analogue, procaine came on board in 1904 and remain the sole LAA in dentistry until 1948 with the introduction of lidocaine. Procaine has a long potency period but however elicited so much allergic reactions. Lidocaine was the product of a search for more effective and less toxic LAA and quickly became the gold standard[10-12]. Plain lidocaine supplied in dental cartridges is rarely used as it is relatively ineffective because it has short duration of action. Introduction of adrenaline into the solution produces reliable and profound pulpal anesthesia. This is because of the "tourniquet effect" of adrenaline on the blood vessels. In 1969, articaine was prepared by Rusching as the only amide-linked LAA with an ester side chain in the molecule to date [10,13-15].

Today in dental practice, lidocaine and articaine are the most commonly used and most recently introduced LAAs respectively[16]. Whereas lidocaine is described as the 'gold standard' among the LAAs, articaine is said to be an outstanding LAA for dental procedures[17-18]. However none of these agents has been evaluated among our local population to enable clinician form an evidence-based opinion on these LAAs. Therefore, the objective of this study was to compare the latency, time of onset of surgical anaesthesia, efficacy and safety of articaine and lignocaine in patients presenting for routine minor oral surgery.

II. Material And Methods

This randomizedclinical trial was carried out on patients of Department of Oral and Maxillofacial Surgery, University of Benin Teaching Hospital, Benin-City, Nigeria, between June, 2017 and May, 2018 inclusive. The study population weresubjects requiring simple routine minor oral surgeries using 4% articaine with 1:100,000 epinephrine (A-100 cohort) or 2% lignocaine with 1:100,000 epinephrine(L-100 cohort) for maxillary infiltrations anaesthesia. The principal outcome measures were anaesthetic success: latency, onset of surgical anaesthesia and depth of anaesthesia (post-injection pain). Subjects were also evaluated for post injection adverse events.

Cohorts and selection method: The study population was drawn from consecutive patients who presented for an extraction involving the maxillary molar teeth, between June 1, 2017 and May 31, 2018. The patients were divided into two cohorts A-100 and L-100.A-100 cohort received 1.8mls of 4% articaine with 1:100,000 adrenaline (safco®, Safco Dental Supply Company, Buffalo Groove, IL 60089, Italy) for their extraction, while the L-100 cohort received 1.8mls of 2% lignocaine with 1:100,000 adrenaline(ZEYCO®, LABORATORIOS ZEYCO, S.A. DE C.V. Zapopan, Jalisco, Mexico) for their extraction. All injection solutions were given by 27G, 25mm dental syringe (Unoject®, Estrada do Guerengue 2059, Rio de Janeiro-RJ) using the maxillary infiltration technique. The patient and operator were blinded from the agent used for the procedure (double-blinded design).

Inclusion criteria: Adults over age 18, presenting with an upper maxillary molar requiring extraction.
Exclusion criteria: The existence of acute infection and/or swelling at the time of surgery, systemic disorders, history of complications associated with local anesthetics, and interventions in which anesthetic latency exceeded 5 minutes. Operations lasting more than 30 minutes were also excluded.
Procedure methodology: After informed consent was obtained, subjects were comfortably seated in dental chairs and the maxillary tooth indicated for extraction was anaesthetized via infiltration with 1.8mls of articaine or lignocaine, depending on the allocated cohort. Latency was measured as the interval between injection of the allocated LAA and time patient first report an altered sensation (tingling, itching, crawling or any other term depicting an alteration in sensation). Onset of surgical anaesthesia was measured as the interval between injection of LAA and time patient failed to respond to pain elicited by probing into the gingival crevice of the tooth to be extracted. The depth of surgical anaesthesia was measured by the visual analogue scale (VAS), an eleven point scale minimum 0 (no pain) and maximum 10 (worst imaginable pain).
Statistical analysis: Data was analyzed using SPSS version 20 (SPSS Inc., Chicago, IL). Findings were presented as bar charts and tables, p-values less than 0.05 were considered statistically significant.

Ethical consideration: The study was approved by the research ethics committee of UBTH (Ref: ADM/E 22/A/VOL. II/1486) and all participants gave informed consent before recruitment into the study. The data was analyzed with SPSS statistical software.

III. Results

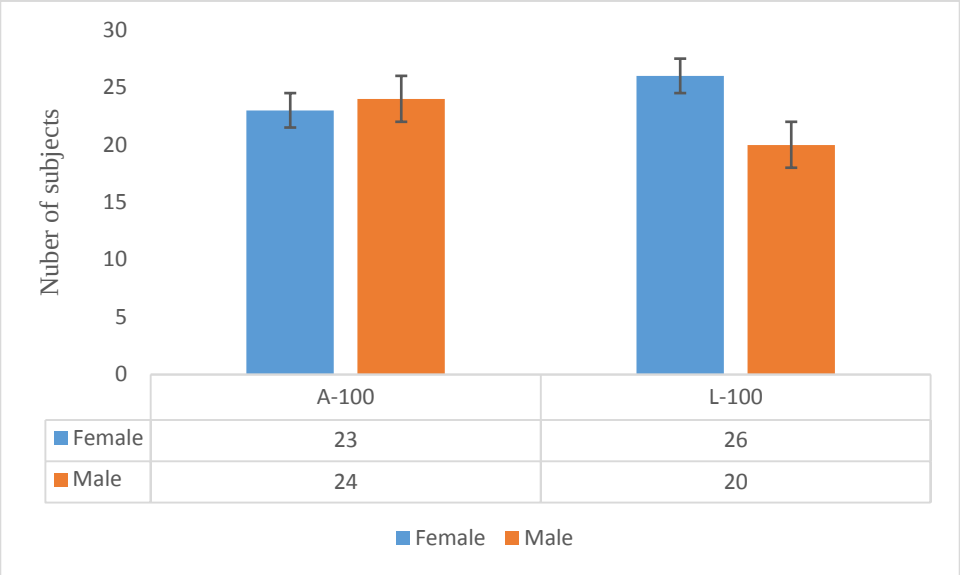

Figure 1: Gender distribution of study participants.There were a total of 93 subjects that participated in this study. This number was made up of 49 females and 44 males. A-100 cohort consists of 47 subjects (23 females and 24 males). L-100 consists of 46 subjects made up of 26 females and 20 males (t= 0.08; P = 0.936).

Table 1: Comparison of the mean ± standard error of mean (SEM)age, latency time and time of onset of surgical anaesthesia between the cohorts.

	COHORTS		
CHARACTERISTICS	**A-100 Mean ±SEM**	**L-100 Mean± SEM**	***p*-value**
Age (years)	39.2±1.7	37.2±1.7	0.403
Latency time (Seconds)	34.6±1.1	45.6±1.2	0.000*
Onset of surgical anaesthesia (Minutes)	1.9±0.1	3.5±0.2	0.000*

*Significant p-values. Whereas the ages within the cohorts were statistically similar, there are significant differences between the latency and onset of surgical anaesthesia in both cohorts.

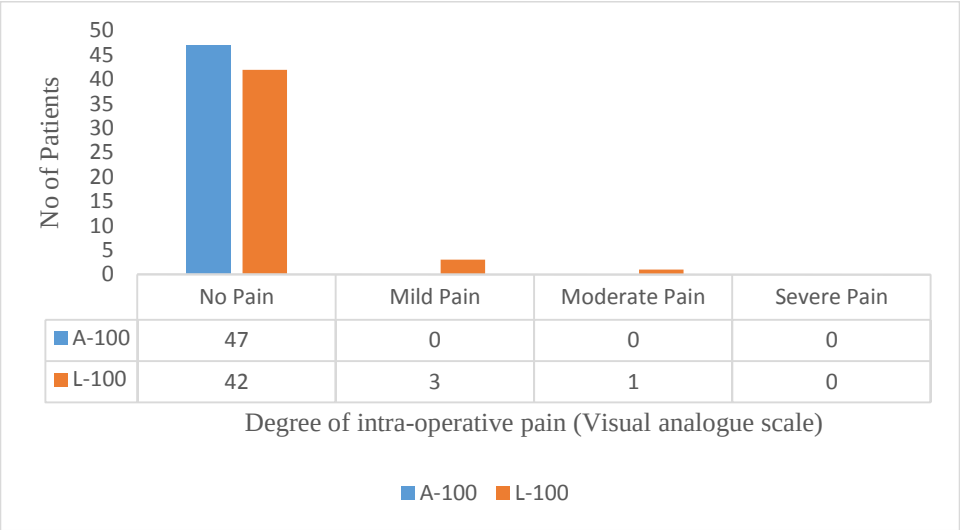

Figure 2: Quality of Anaesthesia between the cohorts. All patients in A-100 cohort reported excellent quality of anaesthesia. Three patients in L-100 reported mild pain and 1 reported moderate pain. None of the cohorts reported pain beyond the moderate level (t = 2.804; p = 0.007).

IV. Discussion

This randomized clinical trial involved 93 subjects made of 49 females and 44 males. A-100 cohort consists of 47 subjects (23 females and 24 males). L-100 consists of 46 subjects made up of 26 females and 20 males (t= 0.08; P = 0.936). This number was uniformly distributed into the two cohorts (figure 1). The mean ± SEM age was39.2±1.7years for A-100 cohort and 37.2±1.7years for the L-100 cohort (p=0.403). This pattern of distribution ensured that uniform subjects have been studied within the cohorts. The uniform distribution and double-blind design of the study were the importance factors in the validation of this study findings.

Themean latency time ± SEM for A-100 cohort was 34.6±1.1 seconds and 45.6±1.2 seconds for the L-100 cohort (p=0.000). Silvia *et al.,*[19]in a study to evaluate similar agents found a mean latency time ± SEMof 54.3±5.98 seconds for 4% articaine with 1:100,000 epinephrine and 62.05±9.98 seconds 2% lignocaine with 1:100,000 epinephrine. The findings of Silvia *et al.,* differ from this present study in two aspects. First the latency period was lower in this present study than that of Silva *et al.* Secondly the difference in the latency period between the two agents was statistically significant in this study but not so in the finding of Silvia *et al.* This basis for shorter latency time in this study may be environmental and/or genetic differences between the study populations. Another possible explanation for the shorter latency time seen in this study could be that, whereas it was infiltration that was used in this study, Silvia *et al.* used a block technique for the inferior alveolar nerve. A similarity however exists between this present study and that of Silvia *et al.,* in that the latency time was higher for 2% lignocaine with 1:100,000 epinephrine. Thispresent study also showed lower latency time than that of Jain and John in 2016, who found a mean latency time ± SEMof56.57 ± 9.82 seconds versus 88.26 ± 12.87 seconds for 4% articaine with 1:100,000 epinephrine and 2% lignocaine with 1:100,000 epinephrinerespectively[20]. However both studies are similar in finding statistically significant differences between the latency times for both preparations. The latency of a pharmacologic agent is directly influenced by the corresponding pKa value (smaller pKa values being associated to shorter latency). Accordingly, 4% articaine (pKa = 7.8) would at least in theory present a shorter latency than 2% lidocaine (pKa = 7.9)[3,21]. Our results coincide with this assumption, since the latency was shorter for articainetreated cohort than the lignocaine treated cohort.

The mean time of onset of surgical anaesthesia wastofound be statistically different between articaine and lignocaine (p=0.000). This finding is similar to the findings of Kaur and Kataria[22] in 2017. The absolute values were however higher in this present study. Kaur and Kataria, in a study in India found a mean onset time for surgical anaesthesia of 58.7 seconds for articaine and 86.5 seconds for lignocaine[22] though they used a blocking technique while this study used an infiltration technique, the difference in values may have an explanation in the genetic and environmental differences.

Articaine provided a statistically superior anaesthesia compare to lignocaine in this present study (t=2.804, p=0.007). This finding in the present study is similar to the study in an Indian population, by Jain and John[20] in 2016 as well as that byKaur and Kataria[22], in 2017. The scientific explanation of this may be due to the chemical structure of articaine. The substitution of the aromatic ring with a thiophenic ring increases the liposolubility of the drug as well as its potency[3]. The increased liposolubility permits articaine to diffuse to the teeth in addition to the main action of blocking nerve action potential thereby providing profound anaesthesia. It is worthy to note that no adverse reaction were recorded throughout the study period.

V. Conclusion

This study concludes that the latency time for action was significantly lower for articaine than for lignocaine. Also, the time for onset of surgical anaesthesia was significantly lower for articaine than for lignocaine. Though articaine and lignocaine are efficacious for anaesthesia in minor oral surgery, they are not equipotent. Both agents appear relatively safe for use in the study population.

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