Pain Relief Durations of Different Concentrations of Lidocaine in Wide Awake Hand Surgery: A Prospective Randomised Clinical Trial

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ABSTRACT

Objective: This study aims to determine the minimal concentration of lidocaine to provide adequate analgesia in wide awake local anaesthesia no tourniquet (WALANT) hand surgeries comparing 3 dilutions of tumescent lidocaine with epinephrine solution.

Study Design: A randomised control trial.

Place and Duration of the Study: The study was held at the Plastic Surgery Department of Mayo Hospital, Lahore, from September 2020 to March 2021.

Methodology: Inclusion criteria were post-traumatic hand contractures and tendon and nerve injuries. The patients were randomised to 3 groups of 30 each: Group A (0.1% lidocaine), Group B (0.2% lidocaine), and Group C (0.3% lidocaine). The dilution of adrenaline also remained constant at 1:200,000. Pain was measured using the Visual Analogue Scale. The three groups were compared for demographics and the total duration of analgesia in minutes.

Results: All groups showed adequate pain relief during surgery with no cases requiring conversion to general anaesthesia. The highest total duration of analgesia was seen in the 0.3% group (805.3±195.2 minutes), followed by the 0.2% group (500.4±87.2 minutes) and 0.1% group (381.3±31.6 minutes) ($p<0.05$). No patient developed any signs of lidocaine toxicity. A low Lidocaine concentration of 0.1% was effective in providing analgesia during surgery though increasing the lidocaine concentration to 0.3% would result in greater post-operative analgesic time without increasing toxicity.

Conclusion: Adequate analgesia was recorded with all 3 lidocaine concentrations. The greatest pain-free duration was however observed in the 0.3% lidocaine group.

Key Words: *Wide awake local anaesthesia no tourniquet (WALANT), Lidocaine concentrations, Hand surgery, Analgesia, Adverse effects.*

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INTRODUCTION

The wide-awake local anesthesia no tourniquet (WALANT) technique utilises local tumescent anaesthesia, precluding the inherent complications, costs, and inconvenience of both general anaesthesia and a tourniquet.[1] Tumescence is achieved by infiltrating a dilute solution of lidocaine with adrenaline until the tissues are firm and pale over the surgical field. Adding adrenaline to the tumescent solution is considered safe in hand surgery for facilitating hemostasis.[2,3]

The safety and efficacy of the tumescent technique is well established and lidocaine concentrations ranging from 0.05% to 2.0% have been reported in literature.[4,5]

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Nevertheless, no studies report the minimum concentration of lidocaine needed to provide sufficient analgesia without inciting adverse events of lidocaine toxicity. Considering the increasing scope of WALANT, the study aimed to determine the minimum concentration of lidocaine that would provide adequate and safe analgesia intra- and postoperatively.

METHODOLOGY

This randomised control trial was conducted at the Plastic Surgery Department of Mayo Hospital Lahore after institutional review board approval was secured. Ninety patients requiring soft tissue hand surgery were selected by consecutive sampling from September 2020 till March 2021. Inclusion criteria included post-traumatic hand contractures and tendon or nerve injuries. Demographics and body weight of all patients were collected. Patients with a history of ischemic heart disease, chronic liver disease, renal disease, bleeding disorders, peripheral vascular disease or allergy to any of the components of the tumescent solution were excluded.

The randomised control trial was planned according to CONSORT requirements (Figure 1). The trial was registered with the U.S. National Library of Medicine on http://Clinical trials.gov under a

National Clinical Trial Number of 04692896. A sample size of 90 cases, 30 for each group, was calculated with a 95% confidence interval and setting the power of the study at 80%. The expected mean duration of analgesia for 0.2% lidocaine tumescent solution was 186.83 +/- 44.02 minutes and for 0.3% lidocaine tumescent solution was 708 +/- 276 minutes.[6,7] Patients were randomised into blocks of 30 each (Groups A, B, and C) by computer-generated random number tables. Both the patients and doctors involved in determining the outcome variables were blinded to the group allocation.

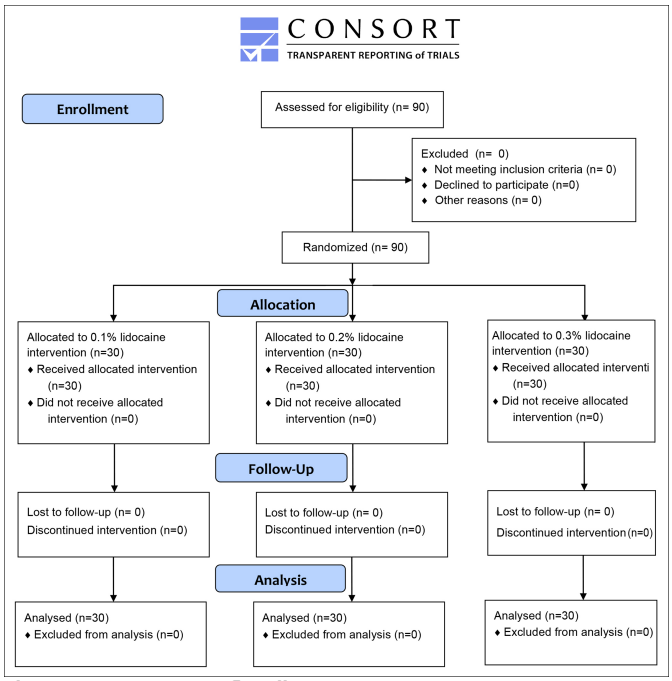

Figure 1: CONSORT 2010 flow diagram.

The groups consisted of receiving either 0.1%, 0.2%, and 0.3% lidocaine prepared in 200 ml infiltrating solution as shown in Table I. Group A received a concentration of 0.1% lidocaine, Group B received 0.2%, and Group C received 0.3%. The total tumescent solution prepared in each group was 200 ml. The dilution of adrenaline also remained constant at 1:200,000 in all 3 solutions.

To decrease interoperator variability, the tumescent solution was prepared and infiltrated by the same person in all cases. A 10 ml syringe with a 27 G needle was used for infiltration. The endpoint of tumescence was determined as pale and firm skin. Surgery was started approximately 25 minutes after infiltration of the tumescent solution.[8] The time at the start of the procedure was noted and documented as the "zero minute". Patients were asked for symptoms and observed for signs of lidocaine toxicity namely perioral numbness, altered taste, ringing of the ears, and blurred vision. Patients were also observed for restlessness, agitation, muscle twitching, and seizures.

Pain after the start of surgery was measured using the Visual Analogue Scale (VAS), range 0-10, where "0" denoted no pain and "10" was the worst possible pain. Additional analgesia was decided to be administered when a patient scored >4 on the VAS scale and was noted as the endpoint. The time-period between the start of the procedure and the point where the patient required more analgesia was recorded.

The three groups were compared for age, gender, diagnosis, duration of surgery, signs and symptoms of lidocaine toxicity, and the total duration of analgesia in minutes. Data were analysed using SPSS version 25. Mean ± S.D was used to present the data with normal distribution and with median ± interquartile range (IQR) for data where distribution was not normal. Cross-tabulation was done for categorical data. The normality of numerical data was checked using Shapiro-Wilk test and a p-value at 5% was considered as significant. For comparison, Kruskal-Wallis H was used to compare the median in the 3 groups. For paired-wise comparison, Mann Whitney U test was used (where Kruskal-Wallis H was significant). Chi-square test was used for the comparison of categorical variables in 3 groups. A p-value ≤0.05 was considered significant.

RESULTS

The mean age of patients in study groups A, B and C was 30.2±9.8, 27.8±6.1, and 23.0±5.3 years, respectively. There were a total of 68 (75.5%) males and 22 (24.4%) females in this study. There were 38 (42.2%) patients who underwent tendon surgery, 31 (34.4%) patients had contracture releases, and 11 (12.2%) patients underwent both tendon and nerve surgeries (Table I). There was no significant difference in the mean volume of injected tumescent solution in the 3 groups (p=0.482), or in the duration of surgery (p=0.108), as shown in Table II. There was a statistically significant difference between lidocaine concentration and the total duration of analgesia with the highest duration of analgesia recorded in Group C (0.3% lidocaine) as displayed in Table II. No patient in any Group complained of pain during surgery or required conversion to general anaesthesia. None of the patients experienced lidocaine toxicity in any group.

DISCUSSION

The provision of adequate analgesia without inciting adverse effects is a logical prerequisite for WALANT surgery. Pain-free surgery was possible in all 3 groups in this study. However, the total duration of analgesia was greatest in Group C (0.3% lidocaine), inferring that lidocaine concentration directly correlates with the duration of analgesia. No statistically significant difference was found among the groups for intraoperative analgesia or duration of surgery.

Relatively lengthy procedures were possible in all 3 lidocaine concentrations (Table II). Prasetyono *et al*. performed flexor tendon repairs with fracture reduction and fixation procedures that ranged between 50 and 240 minutes using 0.2% lidocaine.[6] Huang *et al*. reported adequate analgesia with 1% lidocaine for distal radius fracture surgeries that lasted 85 minutes.[9] Bashir *et al*. reported mean analgesia durations of 107 to 180 minutes during hand surgeries using a concentration of 0.18% lidocaine.[4] Lee *et al*. also successfully performed minor hand surgeries under tumescence with a 0.9% lidocaine concentration.[3,10]

Table I: Comparison of categorical variables in 3 different groups.

		GROUP			Total	Chi-Square	p-value
		0.1	0.2	0.3			
Gender	Female	8(26.7)	6(20%)	8(26.7%)	22(24.4%)	0.481	0.78
	Male	22(73.%)	24(80%)	22(73.3%)	68(75.6%)		
Diagnosis	Contracture	13(43.3%)	11(36.7%)	7(23.3%)	31(34.4%)	13.065	0.22
	Tendon injury	6(20%)	14(46.7%)	18(60%)	38(42.2%)		
	Nerve injury	1(3.3%)	1(3.3%)	0(0%)	2(2.2%)		
	Tendon and nerve injury	6(20%)	2(6.7%)	3(10%)	11(12.2%)		
	Injury to tendon, nerve and artery	3(10%)	1(3.3%)	2(6.7%)	6(6.7%)		
	Dupuytren's contracture	1(3.3%)	1(3.3%)	0(0%)	2(2.2%)		
Contracture	Flame burn	6(46.2%)	9(81.8%)	3(42.9%)	18(58.1%)	8.19	0.22
	Electric burn	3(23.1%)	1(9.1%)	3(42.9%)	7(22.6%)		
	Traumatic	3(23.1%)	0(0%)	0(0%)	3(9.7%)		
	Congenital (camptodactyly)	1(7.7%)	1(9.1%)	1(14.3%)	3(9.7%)		
Tendon injury	Flexor tendon injury	9(60%)	11(64.7%)	18(78.3%)	38(69.1%)	1.63	0.441
	Extensor tendon injury	6(40%)	6(35.3%)	5(21.7%)	17(30.9%)		
Operation	Release and cover	14(46.7%)	11(37.9%)	7(23.3%)	32(36%)	12.42	0.132
	Tendon repair	6(20%)	14(48.3%)	18(60%)	38(42.7%)		
	Nerve repair	1(3.3%)	1(3.4%)	0(0%)	2(2.2%)		
	Tendon and nerve repair	6(20%)	2(6.9%)	3(10%)	11(12.4%)		
	Tendon, nerve and artery repair	3(10%)	1(3.4%)	2(6.7%)	6(6.7%)		

Table II: Descriptive statistics of all variable in both study groups.

Variable	Groups	Median (IQR)	p-value (Kruskal-Wallis H test)	Pairwise comparison (Mann Whitney U test)		
				p-value (0.1 vs. 0.2)	p-value (0.1 vs. 0.3)	p-value (0.2 vs. 0.3)
Age (years)	0.1	28.50 (10.0)	0.001*	0.415	0.001**	0.005*
	0.2	27.50 (6.50)				
	0.3	23.00 (8.25)				
Total tumescent solution infiltrated in ml	0.1	40.00 (50.00)	0.482	--	--	--
	0.2	38.00 (40.50)				
	0.3	40.00 (42.50)				
Lignocaine dose mg	0.1	40.00 (50.00)	<0.001**	0.024	<0.001**	0.011*
	0.2	76.00 (81.00)				
	0.3	1.20 (127.50)				
Mg/kg dose of lidocaine	0.1	0.56 (0.78)	<0.001**	0.026	<0.001**	0.007*
	0.2	1.15 (1.14)				
	0.3	1.76 (1.60)				
Duration of surgery in min	0.1	55.00 (34.25)	0.108	--	--	--
	0.2	80.00 (65.25)				
	0.3	78.00 (55.00)				
Duration of postop anelgesia in min	0.1	3.13 (48.00)	<0.001**	<0.001**	<0.001**	<0.001**
	0.2	3.90 (177.00)				
	0.3	6.90 (315.00)				
Total duration of analgesia	0.1	3.78 (26.75)	<0.001**	<0.001**	<0.001**	<0.001**
	0.2	5.00 (150.00)				
	0.3	7.36 (270.00)				

***Highly significant, *Significant.*

Lidocaine is known to have a duration of action of at least 120 minutes, which can be increased to 180 minutes if adrenaline is added.[11] However, in this study, the mean duration of analgesia recorded was 311 minutes for the 0.1% group, 416 minutes for the 0.2% group, and 719 minutes for the 0.3% lidocaine group. Ramon *et al.* achieved pain-free intervals of 708±276 minutes with 0.3% lidocaine during facelifts.[12] Prasetyono *et al*. found that the addition of adrenaline enhanced the duration of lidocaine action even at low concentrations. They narrated a total analgesia time of 186.83 minutes with a 0.2% lidocaine and adrenaline solution compared with a mere 99.67 minutes if 2% plain lidocaine was used.[6] The vasoconstrictive effect of adrenaline and the increased tissue hydrostatic pressure consequent to tumescence could possibly be the plausible mechanism for delaying lidocaine absorption and subsequential prolonged pain relief.[11,13]

Though Lidocaine has a faster onset of action compared to ropivacaine or bupivacaine,[7] the latter two have a longer duration of action (300-360 minutes).[14] Therefore, many surgeons add ropivacaine or bupivacaine to lidocaine and adrenaline mixtures in the initial tumescent solution or at the end of the procedure for enhancing the longevity of analgesia.[15] The extended longevity of epinephrine fortified lignocaine and the benefits of tumescence should ratify the omission of these longer acting analgesics to the infiltration solution. Additionally, there are studies reporting lesser doses of lidocaine than bupivacaine required in establishing nerve blocks.[16] In another study, the VAS values for pain during injection were lower for lidocaine than for bupivacaine groups and also decreased postoperative pain recorded for lidocaine.[17]

The Food and Drug Administration (FDA) recommends a maximum lidocaine dose of 7mg/kg in conjunction with epinephrine,[18] whereas the American Society of Dermatological Surgery suggests an upper limit of 55mg/kg for skin-related surgeries. Both advisories cite no tangible data to support their recommendation.[19] Klein *et al.* using tolerance interval analysis propounded 45mg/kg to be a safe dose for lidocaine (with epinephrine) in liposuction and 28 mg/kg (with epinephrine) for other procedures done under tumescence.[16]

The highest dose of lidocaine infiltrated in this study was 7.74 mg/kg in Group C (0.3% lidocaine) with no side effects. Large volumes of solution are not required to achieve tumescence in a relatively small area such as the hand, but if 28mg/kg is to be considered safe,[19] it should potentially be possible to infuse significant quantities of a tumescent solution without inciting toxic reactions. Therefore, it can be deduced that higher concentrations of lidocaine in conjunction with adrenaline are safe for tumescence with the concomitant advantage of increased duration of analgesia.

Pain threshold differences among patients may have introduced some bias in the results, even though the total duration of analgesia recorded was consistently longer for patients in Group C. This was a single-centre study which decreases its external validity. Not all types of hand surgery were included. Furthermore, serum plasma levels of lidocaine were not analysed and the study observations relied only on the presence or absence of side effects. Future research would be targeted to redress these shortcomings. Nevertheless, the strengths of the study include the prospective randomized study design, an adequately powered sample size, and a practical clinical study question.

CONCLUSION

Hand surgery with WALANT using lidocaine can be readily performed with concentrations as low as 0.1%. There was no difference in pain experienced by patients with lidocaine concentrations of 0.1%, 0.2% or 0.3%. However, increasing the concentration to 0.3% increased the total duration of analgesia time without inciting lidocaine toxicity.

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ETHICAL APPROVAL:
Ethical approval for this study was obtained from the Ethical Approval Committee of King Edward Medical University, Lahore prior to commencing the study.

PATIENTS' CONSENT:
Patients' consent for inclusion in this study and using their data in publishing the study was obtained prior to commencing this study.

COMPETING INTEREST:
No competing interest has been declared for this study.

AUTHORS' CONTRIBUTION:
HA: Literature search, study design, and facilitating conduction of study.
HBS: Study design, statistical assistance, and conduction of the study.
SNJ: Study design, drafting, revisions, and editing.
ZT: Study conduction and design.
MMB: Study design, conduction, statistical assistance, and manuscript editing.
All the authors have approved the final version of the manuscript to be published.

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