

Making Local Anesthesia Injection Pain Free

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ABSTRACT

Objective: To compare mean pain score on injection between xylocaine with adrenaline and buffered xylocaine with adrenaline with addition of bicarbonate for patients undergoing facial laceration repair in Accident and Emergency Department after trauma.

Study Design: Double Blinded Randomized Control Trial

Place of study: This study was conducted at the Accident and Emergency Department, Liaquat National Hospital, Karachi from March 1st, 2016 to February 28th, 2017.

Materials and Methods: Patients were selected from Accident and Emergency in Liaquat National Hospital. After informed consent, the patients were divided into two groups; with Group A comprising of patients injected with xylocaine with adrenaline; and Group B consisting of patient injected with buffered xylocaine with adrenaline with the addition of bicarbonate. Patient was assigned a group randomly by using lottery method. Buffered or unbuffered local anesthetic solution was prepared by principle investigator. Solution was injected by a second investigator, who was kept unaware about the nature of solution Patient was asked to define his pain as 0 being no pain and 10 being worst pain possible.

Results: The mean age of the patients in group A was 30.9 ± 6.4 and in group B was 32 ± 5.9 . When outcome variables i.e. mean pain of group A was 5.7 ± 0.7 and group B was 1.3 ± 0.4 with p value of <0.0001 , was compared also, mean pain score in specific age groups, mean pain score in different gender, site, mechanism and age were compared, significant differences were observed.

Conclusion: In our study, it is found that buffered xylocaine is less painful to inject as compared to non-buffered xylocaine.

Key Words: Xylocaine with adrenaline, buffered xylocaine with adrenaline adding bicarbonate and traumatic lacerated wounds, pain.

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INTRODUCTION

The administration of local anesthetics often causes significant discomfort. This is commonly perceived as a 'burning pain' sensation,¹ the severity of which depends on the type of local anesthetic used² and the pain threshold of the patients. Few other factors influence pain on injection, including the angle of introduction of needle³, smaller diameter of needle⁴, the rate of injection, temperature of solution⁵, site to be injected, a pause after initial injection⁶, keep anesthesia solution ahead of needle⁷ and the pressure from the fluid distension of the tissue.

Safety of xylocaine with adrenaline is well established even in hand and finger tips. There are still no well-documented cases of finger infarction with lidocaine

and epinephrine in the finger⁸, even with 1:1000 accidental finger epinephrine injection⁹. There is level I evidence that 1 mg of phentolamine in 1 ml of saline reliably reverses epinephrine vasoconstriction in the finger, should this be required as a rescue agent¹⁰. However, this is almost never required in clinical practice^{11,12}.

Xylocaine is the most widely used local anesthetic agent in plastic surgery because of its rapid onset of action and its long duration of sensory blockade¹³. Commercially available solutions of xylocaine with adrenaline have a pH 4.7. The low pH increases the stability and shelf life of the agent,¹⁴ increases the rate of penetration of the anesthetic into the nerve cells, which substantially decreases the burning sensation of infiltration and speeds up the onset of anesthesia¹⁵. Many studies showed that alkalinizing xylocaine with epinephrine significantly reduce injection pain of infiltration^{16,17}. The amount of sodium bicarbonate necessary to neutralize commercially available xylocaine-epinephrine (pH 4.7) to physiologically neutral pH^{7.4} was established in a study. The analysis showed that neutral pH could be accomplished by adding 1.0 ml sodium bicarbonate (8.4 g/l) to 10 ml xylocaine-epinephrine (1%, 5 microgram/ml). Chemical analysis also established that the neutralized xylocaine

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epinephrine was stable for 24 hours after adding sodium bicarbonate¹⁸. In a study, total of 22 patients were analyzed. Pain scores for infiltration pain with the unbuffered preparation were significantly higher than the score when buffered preparation was used ($P = 3.74 \times 10^{-7}$) and the mean pain scores were $5.1(\pm 0.4)$ and $1.8(\pm 0.4)$, respectively.¹⁵

The use of commercial xylocaine buffered with sodium bicarbonate is a common practice in the US.¹⁶ However, very few surgeons in our institute use pH-adjusted local anesthetic. This must be due to unavailability of local literature on the effect of buffered local anesthetic on infiltration and procedure pain. As our study is largest double blinded, randomized so far conducted, we hope that this study will convince surgeons in our institute and across Pakistan to use a buffered xylocaine solution for local anesthetic surgery, as it is a simple, effective, practical and inexpensive way of reducing pain during infiltration.

MATERIALS AND METHODS

This study was conducted at the Accident and Emergency Department, Liaquat National Hospital, Karachi from March 1st, 2016 to February 28th, 2017.

Inclusion criteria:

1. Age between 20-55 years
2. Traumatic lacerated wounds
3. Wound within 6 hours of injury.
4. Wound size 2-10 cms
5. Wound site (face)

Exclusion criteria:

1. Major psychiatric illness, chronic renal and/or respiratory insufficiency (Assessed from history or documented medical record).
2. Diabetic or neuropathic wounds, was assessed clinically or medical record.
3. Chronic wounds were assessed clinically.
4. Malignancy was assessed from documented medical record.
5. Pregnant or lactating women were assessed from history.
6. Medications interfering with effect of xylocaine and clotting (any pain medications)

First 300 patients came to Accident and Emergency in Liaquat National Hospital with linear lacerated wound on their face meeting the inclusion and exclusion criteria during the study period were included in this study. Informed consent was taken from the patients by principal investigator. The patients were divided into two groups; with Group A comprising of patients injected with xylocaine with adrenaline; and Group B consisting of patients injected with buffered xylocaine with adrenaline adding bicarbonate. Patient was assigned a group randomly by using lottery method. Patient demographics and history including age, sex,

educational status, wound size, site and mechanism of injury was noted by principle investigator. After all aseptic measures, principle investigator prepared a local anesthetic solution. 2% Xylocaine with adrenaline 10cc ampule was used and for buffering 1 cc of bicarbonate 8.4% was added in same syringe of 10 cc making it 11 cc solution. Expire date of all drugs were checked. Solution is injected subdermally using a 27 G needle holding perpendicular to the skin by a second investigator, who didn't know about the solutions preparation to make this study a double blinded. Patient was asked to define his pain according to visual analog score as 0 being no pain and 10 being worst pain imagine. All the data was collected on a pre-designed proforma by the principle investigator. Biasness and confounding variables were controlled by strictly following the inclusion and exclusion criteria.

Data analysis: Data was analyzed by using Statistical Package for Social Sciences SPSS (19). Descriptive statistics was calculated for qualitative and quantitative variables. Frequency distribution and percentages were calculated for qualitative variables i.e. gender, mechanism and site of laceration. Mean $\pm$ SD was calculated for quantitative variables i.e. age, baseline pain score, size of laceration, duration of laceration and pain score. Difference in pain scores between two groups on injection was analyzed with independent T-test taking $P \leq 0.05$ as significant. Stratification was done on the effect modifiers i.e. age, gender, baseline pain score, site, mechanism, duration and size of laceration to see effect of these on the outcome with t test and $P \leq 0.05$ was considered as significant.

RESULTS

Total of 300 patients of lacerated traumatic wound were included in this study. 150 were given xylocaine adrenaline and 150 were given buffered xylocaine with adrenaline adding bicarbonate on injection.

Table No.1: Mean pain score

Groups	Pain score		P-value
	Mean	SD	
Group A (n=150)	5.7	0.7	<0.0001
Group B (n=150)	1.3	0.4	

The age of the patients ranged from 20-55 years. The average age of the patients in group A was 39 ± 8.5 and in group B was 40.1 ± 7.9 , baseline pain score in group A was 6.7 ± 0.4 and in group B was 6.9 ± 0.4 , size of laceration in cm in group A was 3 ± 1.4 and in group B was 3.2 ± 1.7 and average duration of lacerated wound in hours in group A was 3.7 ± 0.7 and in group B was 4.0 ± 0.9 . 86(57.3%) of the patients were male in group A and in group B, 90(60%) were male and 64(42.6%) were female in group A and 60(40%) were female in

group B. In group A, 65(43.3%) were injured from knife and 85(56.6%) got injured from glass and in group B, 69(46%) were injured from knife and 81(54%) were injured from glass.

Table No.2: Mean pain score, age group 20-40 years

Groups	Pain score		P-value
	Mean	SD	
Group A (n=112)	5.4	0.5	<0.0001
Group B (n=123)	1.7	0.4	
Mean pain score, age group 40-55 years			
Group A (n=38)	5.8	0.8	<0.0001
Group B (n=27)	1.7	0.4	

Table No.3: Mean pain score, male patients

Groups	Pain score		P-value
	Mean	SD	
Group A (n=86)	5.4	0.5	<0.0001
Group B (n=90)	1.3	0.4	
Mean pain score, female patients			
Group A (n=64)	5.7	0.7	<0.0001
Group B (n=60)	1.4	0.5	

Table No.4: Mean pain score, knife cut

Groups	Pain score		P-value
	Mean	SD	
Group A (n=65)	5.6	0.7	<0.0001
Group B (n=69)	1.4	0.5	
Mean pain score, glass cut			
Group A (n=85)	5.7	0.8	<0.0001
Group B (n=81)	1.3	0.4	

Table No.5: Mean pain score, baseline pain score <5

Groups	Pain score		P-value
	Mean	SD	
Group A (n=27)	5.7	0.3	<0.0001
Group B (n=38)	1.7	0.4	
Mean pain score, baseline pin score >5			
Group A (n=123)	5.3	0.4	<0.0001
Group B (n=112)	1.8	0.4	

Table No.6: Mean pain score, injury right side of face

Groups	Pain score		P-value
	Mean	SD	
Group A (n=84)	5.7	0.7	<0.0001
Group B (n=78)	1.4	0.5	
Mean pain score, injury left side of face			
Group A (n=66)	5.6	0.8	<0.0001
Group B (n=72)	1.2	0.4	

In group-A, 84(56%) had lacerated wound on right side of face and in group-B, 78(52%) had lacerated wound on the right side of the face. When outcome variables i.e. mean pain score was compared between two

groups, significant difference was observed. (Table no: 1) When outcome variables were stratified with respect to age group (Table no: 2), gender (Table no: 3), mechanism of injury (Table no: 4), baseline pain score (Table no: 5) and side of laceration (Table no: 6), significant difference was observed.

DISCUSSION

Xylocaine is known to be painful to inject.¹ Adjustment of pH through the use of bicarbonate or other buffering solutions has been shown to improve the pain of injection of anesthetics with or without epinephrine in intact skin of volunteer.^{13,16} Buffered xylocaine has been studied in laceration repair. The exact mechanism of improving the pain of injection is uncertain¹⁵ but alkalization might reduce the acidity of xylocaine to some extent is a possible mechanism. The findings of this study clearly indicate that buffered xylocaine solution causes the patient to experience less pain. There was also no variation between genders, age groups, site and mechanism of wound in the results. The solution should be clear without any cloudy precipitate. Do not inject any solution that appears cloudy because this may indicate that the anesthetic has precipitated out of solution because of time elapsed or higher-than-required concentration of sodium bicarbonate. Third, the mixture be made the same day as surgery, because the sodium bicarbonate has a shelf life of 1 day after the bottle is opened, and potentially a few days longer if the mixture is refrigerated.¹⁹ The sterility of the mixed solution is no less than unbuffered xylocaine based on previous study results that reported no increase in infections for buffered solution.¹⁷ Although no studies have examined the infection rate of buffered xylocaine as the primary outcome measure, there are studies detailing the infection rate of botulinum toxin type A, which also must be mixed at time of use. These studies found no increased incidence of infection caused by performing mixing and even long-term storage and reuse.²⁰ The cost and time required to buffer xylocaine injections are minimal, as are the potential risks, and should be considered to improve patient comfort. Because this study controls many of the confounding variables present in previous studies, we believe it definitively establishes that buffered xylocaine reduces initial injection pain in periocular subcutaneous anesthesia without adjunctive topical, oral, or intravenous anesthesia or sedation. When used appropriately, buffered xylocaine minimizes the pain associated with injection and offers a safety profile equal to that of unbuffered xylocaine.

CONCLUSION

In our study, it is found that buffered xylocaine is less painful to inject as compare to non-buffered xylocaine. Ultimately, surgeons should not underestimate the

effect of pain reduction, in any amount, on a patient's satisfaction with their care.

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Author's Contribution:

Concept & Design of Study: Obaid ur Rahman

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Conflict of Interest: The study has no conflict of interest to declare by any author.

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