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Use of Alkalinized Lidocaine in Interventional Radiology for Endovascular Access

Bella Huasen[1], Farda Aazeb[1], Aazeb Khan[1],' Stephen D Souza, Omar Bashir[2*]

[1]Royal Preston Hospital, Lancashire Teaching Hospitals, NHS Foundation Trust, PR2 9HT, UK

[2]King Abdulaziz Medical City, Riyadh, KSA

***Correspondence to:** Omar Bashir, King Abdulaziz Medical City, Riyadh, KSA, E-mail: drobashir@yahoo.co.uk

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Abstract

Purpose: *To demonstrate the effectiveness of alkalinized local anaesthetic (LA) over plain LA in interventional radiology (IR) procedures, in terms of pain experienced by patient, and times of onset of LA action.*

Materials and Methods: *34 patients requiring 2 endovascular access sites, within the same procedure (arterio-venous fistula salvage or bilateral iliac angioplasty/ stenting) were included in the study, 17 patients for each intervention. Alkalinized LA was infiltrated at one site, and plain LA at the other. Pain experienced (on the National Institute of Health numeric pain scale) was compared on LA infiltration and sheath placement for endovascular access, and the time of anesthesia onset was measured.*

Results: *A statistically significant difference was demonstrated in the amount of pain experienced by the patients, with a preference for alkalinized LA, which was also observed to have a quicker onset of action.*

Conclusion: *Use of alkalinized LA in IR procedures is effective, inexpensive and safe.*

Keywords: Lidocaine; local Anaesthetic; Alkalinizing; Buffering; Sodium Bicarbonate; Pain; Interventional Radiology; Endovascular

Introduction

Minimally invasive procedures, involving breach of skin or mucous membrane, require a superficial infiltration of the area with a local anaesthetic (LA). The choice of a LA varies by procedure type, specialty and operator. Endovascular procedures also involve passing of thick needles, sheaths and guidewires through a skin puncture, and thus require LA, which itself can be an uncomfortable start for patients.

LAs are weak bases with higher pKa (acidic strength), poor water solubility and poor dissociation at physiological pH (7.35-7.45) into non-ionized, lipid-soluble active form. LAs are mixed with hydrochloride salts, making them more water soluble with increased shelf-life [1]. Acidifying with an antioxidant (sodium (meta) bisulphite) prevents the oxidative decomposition of this mix, and increases shelf-life further [2]. The vast buffering capacity of the tissues help restore the sodium physiological pH at the injection site, during which time LA is not able to function at full effectiveness, resulting in discomfort for the patient and a slower onset of action.

Alkalinizing (or buffering) the LA with a base (mostly bicarbonate) to almost a physiological pH allows more of the LA to exist in the lipid-soluble form, leading to a quicker onset of action, deepening of the neural blockage, and less injection pain and discomfort[3-5]. However, clinically used LAs cannot be alkalinized beyond a pH of 6.05 to 8, before the LA molecules precipitate from the suspension [6, 7]. Thus, the commercial preparations are not alkalinized, and they need to be prepared just before use due to the short-term stability of the pH of the mixture [8]. Alkalinized LAs have been used since 1990s by several surgical specialties, mostly dental and maxillofacial surgery [9-11]. Overall, patients have preferred alkalinized LA over a plain LA [12].

There is not much literature on the use of an alkalinized LA in interventional radiology (IR) [13, 14]. The purpose of this study is to explore it's benefit over plain LA in gaining percutaneous endovascular access for IR procedures.

Materials and Methods

Study design:

This a prospective, randomised, crossover single centre study, aiming to evaluate the efficacy of alkalinized Lidocaine (with 8.4% sodium bicarbonate) over plain Lidocaine, by comparing the pain experienced on infiltration, and recording the time of onset of anaesthesia.

Eligibility Criteria:

Inclusion criteria were patients requiring two endovascular access points within the same procedure – arterio-venous fistula (AVF) salvage (venous access) or bilateral iliac angioplasty/stenting (arterial access) for this study. Exclusion criteria included age <18 years, hepatic impairment, allergies (to Lidocaine, sodium bisulphite), altered mental status with inability to comprehend the pain scale, altered pain sensorium, scar tissue or infection at the site of intervention.

Procedure

A total of 34 adult patients were enrolled for the study between January 2016 and December 2019 – 17 patients, as they presented to our department who required AVF salvage procedures via double puncture, and 17 who required bilateral iliac angioplasty/stenting, for peripheral vascular disease.

The patients served as their own controls. Pre-procedure analgesia taken was recorded. Each of them received one test agent (alkalinized Lidocaine) at Site, and one control agent (plain Lidocaine) at Site 2, both prepared by the scrub nurse just before the planned intervention and kept at room temperature. The 10ml test agent was prepared using 9ml of 1% Lidocaine + 1ml of 8.4% (wt/vol) sodium bicarbonate, without precipitation, (The same is used by anaesthetic, dermatology and plastic surgical teams at the same institute). The control agent was 10ml of 1% Lidocaine. LA vials used within a procedure had the similar date of expiry. Site 1 for the AVF salvage procedure was the proximal venous puncture, and right groin for the iliac procedure; site 2 for the former was the distal venous puncture (about 7cm from the proximal), and the left groin for the later.

Using similar preparation and infiltration equipment, the agents were delivered intradermal/subcutaneously using a 25-gauge spinal needle, under ultrasound guidance. A consistent standardized infiltration technique was used, with similar infiltration volume administered over 15-25 seconds. The depth of LA infiltration (from skin down to the target vessel to be punctured) in millimetres, and the need for repeated injections during the procedure were also recorded. An 8Fr sheath was used for all the AVF salvage procedures, while a 7Fr sheath was used for all the bilateral iliac interventions.

Each patient was asked to assess the level of his/her perceived discomfort/pain (on the National Institute of Health (NIH) numeric, pain-rating scale of 0 to 10 – 0 meaning nothing felt and 10 meaning worst imaginable pain) on LA infiltration, separate from that associated with the needle insertion, and then on site puncture and sheath placement for vascular access. The pain scores were then compared for both sites. The time of analgesia onset was measured using a stopwatch and demonstrated using the tip of the spinal needle.

Post-procedure manual compression was used for all the venous puncture closure for the AVF cases, while a 6Fr angioseal was used for closure of all the arterial punctures in the iliac cases.

Study outcomes:

Primary outcome was pain experienced during injection of the alkalinized Lidocaine. Secondary outcomes were pre- and post-operative pain, use of analgesics, patient satisfaction, return to function, and complications.

Statistical analysis:

The baseline data was analyzed and summarized using standard descriptive statistics. Paired, two-tailed Student's t-test was used for all the statistical analyses. A probability value (p) of <0.05 was taken to be statistically significant.

Results

Table 1 displays patient characteristics. The mean patient age was 70.15 years, while the male to female ratio was noted to be 1:1.3.

Variable	AVF Salvage procedure, N (%)	Bilateral iliac angioplasty/ stenting, N (%)	Total
Number of patients	17 (50)	17 (50)	34 (100%)
Gender			
Male	8 (47)	7 (41)	15 (44%)
Female	9 (53)	10 (59)	19 (56%)
Age (mean ± SD)	69.88 ± 11.67	70.41 ± 10.30	70.15 ± 10.84

Table 1: Sample Description

There was a significant difference in the amount of pain experienced between the two access sites, participant patients reporting lower pain scores at site 1 (**Figure 1**, **Table 2**).The mean pain score for infiltration at site 1 (alkalinized LA) was 0.12 versus 4.09 for site 2 (plain LA), while the mean pain score for puncture at site 1 was 0.06 versus 0.76 at site 2. The time to onset of LA action was also found to be statistically significant (**Table 3**), although it differed between the two groups, likely due to the difference in the sensitivity of different sites of intervention.

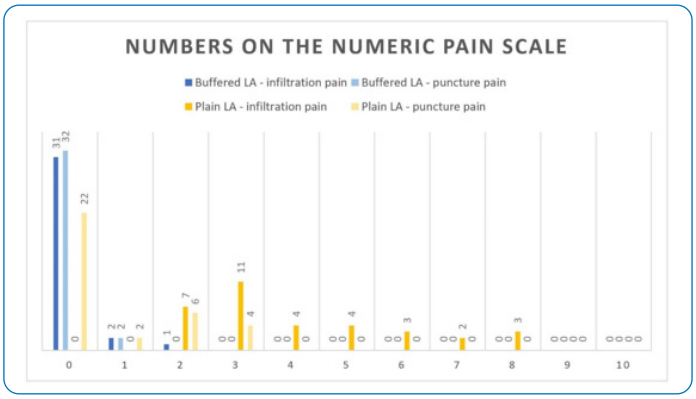

Figure 1: Number of patients on pain scale

		AVF Salvage (Venous puncture)		Bilateral iliac angioplasty/stenting (Arterial puncture)	
		Site 1 (proximal)	Site 2 (distal)	Site 1 (right groin)	Site 2 (left groin)
Buffered LA	Amount infiltrated (ml)	2		10	
	Depth of infiltration (mm)	<3		Between 3-9 (mean 6.71)	
	LA infiltration pain score*	0.06 ± 0.24		0.18 ± 0.53	
	Puncture pain score*	0.00 ± 0.00		0.12 ± 0.33	
	Time of onset of analgesia (sec)*	45.00 ± 3.67		75.71 ± 4.74	
Plain LA	Amount infiltrated		3		10
	Depth of infiltration (mm)		<3		Between 3-8 (mean 6.53)
	LA infiltration pain score*		4.41 ± 1.91		3.76 ± 1.92
	Puncture pain score*		0.65 ± 1.11		0.88 ± 0.17
	Time of onset of analgesia (sec)*		52.35 ± 4.68		87.76 ± 4.48

Table 2: Results

*on NIH pain scale, shown as mean ± SD

	AVF Salvage Procedure	Bilateral iliac angioplasty/stenting
Pain on LA infiltration	3.36E-07	3.06E-07
Pain on puncture	0.0289	0.0047
Time of analgesia onset	5.6E-07	5E-09

Table 3: p-values

No adverse events (intra- or immediately post-operative) or LA-related toxicity were reported. All the patients were discharged the same day, all of them expressing satisfaction with alkalinized LA. None of the patients had the need for repeated LA injections, or post-operative analgesia.

Discussion

Infiltration of LA can be painful. Alkalinizing it as a measure to reduce this pain has not been explored in IR, where all the percutaneous procedures use LA skin infiltration prior to placement of sheath for endovascular access. As most of them are day case procedures, making them less painful significantly impacts patient satisfaction and their early discharge.

The numeric pain-rating scale was used due to its simplicity and practicality in assessing pain quickly. Without changing any other aspects of the operator's practice, compared to plain LA, analysis of our data confirms patients reporting significantly

reduced pain with the alkalinized Lidocaine, both during its infiltration and vessel puncture. Furthermore, a reduced time of onset of analgesia was observed as well.

Compared to other studies involving pooled data from different operators with different LA infiltration and procedure techniques, our study had only one operator performing all the procedures using the same standard technique. To avoid bias, a fixed amount of LA was used in the 2 groups of patients, as we believed using a varying dose of LA would affect the perception of pain. Other studies used a variable amount of LA between patients. The depth of LA infiltration varied for the iliac interventional cases due to varying thickness of subcutaneous tissue between skin and target vessel.

Limitations of this study include a small sample size, which lowers the power of the study. Factors such as frequent questioning about pain levels, operator's conversation and rapport with the patient, and other distractions may also have had an effect on the perceived and reported pain. Unlike some studies, pH of the alkalinized LA solutions was not checked before injection, which may have an impact on both the pain perception and onset time of analgesia. The ratio of buffering was not explored either, as a less painful mixture with more sodium bicarbonate, could have been tried, without precipitating the solution. Such solutions are stable in the short-term, but preparing them just before the procedure is recommended [15-17].

We believe that alkalinizing Lidocaine with 8.4% sodium bicarbonate is a simple, inexpensive, and effective method of reducing the pain levels and enhancing onset of analgesia. It adds no extra time to the planned procedure time, and hence does not delay the flow of patients through the theatre list. The implications of this study are wider than just in the context of endovascular access in IR, and it may be useful for other IR procedures as well, which would require further studies. In addition, other such pain-reducing measures with the use of LA in IR, quoted in the literature, can be studied as well, for instance, prior application of topical LA, warming the LA solution, pre-cooling the area with ice packs, starting with entering the skin perpendicularly, using a small bore needle initially, pausing before deeper infiltration, and slow injection.

Conclusion

Our results confirm the efficacy of alkalinized Lidocaine in reducing pain on infiltration, and quicker onset of anaesthesia. Its use for IR procedures is effective, safe and simple, reducing peri- and early post-operative pain, and its widespread use should be encouraged.

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