Effect of buffered lidocaine in local anaesthesia during subcutaneous implantable venous access devices insertion: a prospective, randomized, double-blind study.

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Introduction:

Subcutaneous implantable venous access devices (*Port-a-Cath*) through the subclavian vein are routinely implanted under local anaesthesia. Lidocaine is the most commonly used local anesthetics (LA). However, patients often complain of pain during the injection of local anaesthesia.

The aim of this study was to evaluate the effectiveness of sodium bicarbonate-buffered lidocaine on reducing pain during subcutaneous implantable venous access devices.

Material and methods:

After approval local ethic’s committee, a prospective controlled, randomized and double-blind study was conducted over a period of 14 months (February 2015 to March 2016). Patients scheduled for *Port-a-Cath* under local anesthesia, at the subclavian vein for chemotherapy treatment, were recruited. Exclusion criteria were a history of allergy to LA, chronic pain, analgesic drug consumption or any contraindications.

- Patients were randomized into two groups of 60 each:
- Group B:** Buffered lidocaine: Lidocaine 2% epinephrine (0.005 µg/ml) **10ml** + 42‰ sodium bicarbonate **5 ml** (pH= 7.33).
 - Group P:** Plane lidocaine: Lidocaine 2% epinephrine (0.005µg/ml) **10 ml** + 9 ‰ saline solution **5 ml** (pH= 3.5).

All insertions were made by the same operator using a standard technique under real-time ultrasound-guided cannulation of the subclavian vein. We assessed pain at LA infiltration using a VAS score (0-100mm). Secondary end points were patient satisfaction, time to anesthesia onset, per procedural pain intensity and adverse events.

The required sample size was calculated hoping a decrease of 30 mm of the VAS score during the injection of the alkalinized LA solution (1-β= 90%, α= 5%). A p value of 0.05 was considered statistically significant.

Results:

A total of 120 patients were enrolled in this study. Patients characteristics were similar in the two groups (**Table1**). There was no difference detected between the two groups on admission and during needle insertion. Pain associated with the infiltration of LA was significantly lower with the buffered lidocaine than the plane lidocaine: VAS scores were 15.70 ± 7.58 mm in group B vs.46.90 ± 12.27 mm in group P (p<0.001) (**figure1**).

The time to onset of anesthesia was shorter with buffered lidocaine 3.25±1.33 minutes than plane lidocaine 5.46±1.28 minutes (p=0.01).

Table 1: Patients characteristics

	Group B	Group P	p
Age (mean ± SD) (ys)	51.5 ± 12.7	50.2 ± 12.6	0.51
Gender			
Male (%)	22 (36.7)	27 (45)	0.35
Female (%)	38 (63.3)	33 (55)	
Cancer localization			
Breast (%)	24 (40)	28 (46.7)	0.53
Ovary (%)	1 (1.6)	4 (6.7)	
Colorectal (%)	19 (31.7)	17 (28.3)	
Gastric (%)	4 (6.7)	3 (5)	
Other (%)	12 (20)	8 (13.3)

Figure1: Mean VAS score (mm ±SD) at different times of the procedure

Overall patient satisfaction was high for implantation of venous access devices under local anaesthesia: VAS scores were 95.75±4.06 mm in group (B) vs 70.25±20.15 mm in group (P).

No adverse events were reported.

Conclusion:

In our study, increasing the pH of lidocaine decreased the pain associated with its infiltration, hastened the onset of anesthesia and increased patient preference for the pH-adjusted lidocaine.