Local infiltration of lidocaine versus lidocaine iontophoresis in pain relief during radial artery cannulation for open heart surgery

H Kamalipour*1, S Ahmadi1

¹Department of Anesthesiology, Shiraz University of Medical Sciences, Shiraz, Iran

Abstract

Background: Traditionally, pain has been thought to be an unfortunate but inevitable part of disease and its treatment. Pain associated with medical procedures was ignored because it was thought to be unavoidable. The question of why physicians should treat pain is as important as the knowledge of preventing it, since it is a right measure to take.

Objective: This study was conducted to compare the effectiveness of lidocaine iontophoresis with that of local infiltration of lidocaine for the prevention and reduction of pain during radial artery cannulation, in patients undergoing open heart surgery.

Methods: The present study comprised 60 adult patients, 36 males and 24 females, aged from 29 to 84 years with a median age of 63.8 (± 10.35 SD) and 65.4 ($10.48\pm SD$) for groups 1 and 2, respectively. The patients underwent elective open-heart surgery in Nemazee Hospital affiliated to Shiraz University of Medical Sciences. Prior to induction of general anesthesia, patients were randomly allocated to one of two groups for analgesia prior to radial artery cannulation on an alternate week basis. Group 1 (n=30) patients received one-week analgesia using lidocaine ion-tophoresis, and analgesia in Group 2 (n=30) was performed using lidocaine infiltration the following week. Both groups were similar in terms of gender distribution.

Results: The VAS scores in group 1 were significantly lower than group 2 with no significant difference in the difficulty of cannulations between the two groups. There was no complaint of pain from patients during iontophoresis, and no report of any significant side effects. Slight skin erythma was noted after removal of the iontophoretic anode patch in 4 patients, which lasted for about 0.5-4 hours.

Conclusion: This study has demonstrated that lidocaine iontophoresis is a useful, non-invasive, rapid, painless alternative to lidocaine infiltration for dermal analgesia for radial artery cannulation.

Keywords: Lidocaine; Lidocaine Iontophoresis; Pain relief; Radial artery cannulation; Open heart surgery

Introduction

The international association for the study of pain has defined pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue

*Correspondence: Hamid Kamalipour, MD, Associate Professor of Anesthesiology, Department of Aneshtesiology, Shiraz University of Medical Sciences, Shiraz, Iran. Tel: +98-917-111-1112; e-mail: kamalih@sums.ac.ir damage, or described in terms of such damage". Pain traditionally has been thought to be an unfortunate but inevitable part of disease and its treatment. Pain associated with medical procedures was ignored because it was thought to be unavoidable. The question of why physicians should treat pain is as crucial as the knowledge of how to eradicate it, the aspects which are first and foremost of prime importance. It is the clinician's obligation to relieve suffering.

Moreover, painful stimuli produce long-term consequences in even the youngest patients. Also, patients are less likely to be fearful of physicians if their visits are not associated with pain. Finally, if pain from injection is alleviated or minimized, perhaps compliance with immunization regimens is facilitated and leads to significant improvements in public health.² Pain control associated with invasive procedures is a major challenge, the magnitude of which has been emphasized in the setting of intensive care medicine.⁴ Radial artery cannulation is a painful procedure frequently performed to facilitate hemodynamic monitoring or for blood sampling.⁵ This procedure is often indicated prior to induction of anesthesia. The standard method of providing analgesia is infiltration of the skin and subcutaneous tissue with lidocaine, using a small gauge needle. However, infiltration per se may be painful and may not provide adequate analgesia.^{6,7} Topical analgesia with EMLA cream has been shown to shorten cannulation time, improve the success rate, and reduce the pain due to radial artery cannulation. Despite these findings, EMLA cream is not widely used, because it is slow acting and takes 2 hours before onset of analgesia. Lidocaine iontophoresis is a transdermal delivery system, which utilizes an electrical current to drive an ionized form of lidocaine into the skin and subcutaneous tissues. It can provide anesthesia to a depth of 10mm within ~10 min² and has been shown to provide significant analgesia for venous cannulation in adults^{6,8} and children.⁸⁻¹³ The present study was a randomized controlled trial which compared the efficacy of lidocaine iontophoresis with that of local infiltration of lidocaine for the prevention and reduction of pain during radial artery cannulation, in patients undergoing open heart surgery.

Materials and Methods

This study was a prospective, single-blind, randomized controlled trial performed on 60 adult patients (aged 29-84) undergoing elective open heart surgery in Nemazee Hospital affiliated to Shiraz University of Medical Sciences. Radial artery cannulation of the patients was indicated prior to induction of anesthesia for monitoring intra-arterial pressure. Patients were excluded from the study if they had abnormal Allen's test, were receiving concomitant sedative or analgesic medication, suffered from chronic pain syndrome, had cardiac pace-makers or other electrically sensitive

implants, had a known sensitivity to local anesthetics, had a skin lesion or any sort of damage or recent scar tissue at the site of electrode placement, or were suffering from any neurologic disease.

On arrival at the anesthetic room and prior to induction of general anesthesia, patients were randomly allocated to one of two groups for analgesia prior to radial artery cannulation on an alternate week basis. One-week analgesia was obtained using lidocaine iontophoresis, the next week analgesia was performed using lidocaine infiltration. The Group 1 included 30 patients and received lidocaine iontophoresis using a device provided by life-Tech/Inc (IontophorTM PM, model 6111 PM, operating manual).

This apparatus consisted of two 12 K Ohm changeable resistors, a 12 K Ohm fixed resistor, an ammeter and three 9 Volt dry batteries. The maximum electric current delivered by this apparatus was 1.2 mA. The anode plate was set in the bottom of a silicon-rubber box frame with the dimensions of 20 by 15 by 7 mm.

A metal clip that was normally used for electrocardiographic examination was also used as a substitute for the negative pole plate. The skin of ventral aspect of the wrist and forearm over the proposed area of radial artery cannulation was cleaned and degreased with an alcohol wipe. The rectangular anode electrode absorbent pad was placed over the cannulation area prepared earlier. The round-shaped cathode electrode was placed on the ventral aspect of forearm, 15 cm from the anode. The electrodes were placed flat against the skin and around the perimeter of the electrodes were pressed in order to fix the tape to the skin. The red snap of the drug delivery electrode lead wire was connected to the electrode snap, and the black snap of the return electrode lead wire was connected to the electrode snap of the iontophor Subsequently, 4 ml of 4% lidocaine was injected into the holes on anode electrode, and with gently rubbing the top of the electrode, lidocaine was distributed throughout the absorbent pad. Similarly, 2 cc of the meditrode Return Electrode Solution (Life-Tech, part NO.6575) was added into each of the four holes (8 ml in total) and with gently rubbing the top of the electrode, the solution was distributed throughout the absorbent pad. The red and black pin on the electrode lead wires were inserted respectively into the red Drug jack and black Return jack on the applicator cable (Fig. 1). Direct current was applied which was slowly increased to a maximum current of 4 mA, according to subject's comfort. The current was stopped

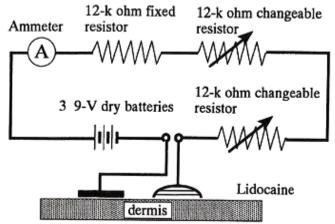


Fig 1: Apparatus of Iontophoresis

This apparatus consists of two 12 k-ohm changeable resistors, a 12 k-ohm fixed resistor, an ammeter and three 9-volt dry batteries. The maximum electric current delivered with this apparatus is 1.2mA. The anode plate was set in the bottom of a silicon-rubber box frame with the dimensions of 20 by 15 by 7mm. A metal clip that is normally used for electrocardiographic examination was also used as a substitute for the negative pole plate.

after 10 min. The maximum total delivery current for each subject was 40 mA min. Immediately following the iontophoresis treatment, the drug and dispersive electrodes were removed and patient was asked to report any pain experienced during iontophoresis. Any side effects such as redness, petechia, small vesicle, itching, dry skin, etc. in site of iontophoresis as well as duration of probable side effect was also reported. In Group 2 (n=30) patients, local infiltration of the skin and subcutaneous tissue of the allocated area of cannulation was performed by a single injection of 1ml of 2% lidocaine concentration using a 25gauge needle. The investigator responsible for administering local anesthesia took no further part in the study. The subject's arm was abducted at an angle of 70° and the wrist was hyperextended over a gauze roll. An expert anesthesiologist who was unaware of method of analgesia, carried out radial artery cannulation using a 20-gauge needle. The procedure was carried out 1min after the removal of iontophoresis electrode or after local infiltration. The anesthesiologist investigator recorded the pain score immediately after the first attempt for cannulation, using 10-cm visual analogue score (VAS) scale as shown in Fig. 2 (0=no pain, 10=severe pain, extreme pain). The blinded investigator also rated the degree of difficulty of the cannulation in the proposed sites (1=easy, successful at first attempt, 2=some difficulty, successful with second attempt, 3=unsuccessful attempt. Data were tested for normality using the Student's T-test, Chi-Square and Mann-Whitney tests. A p value of less than 0.05 was considered significant.

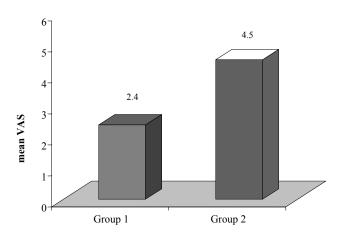


Fig 2: Comparison of mean VAS in Group 1 and Group2

Group 1: Lidocaine iontophoresis group Group 2: Lidocaine infiltration group

Results

Age distribution in both groups was also similar (P=0.5), as the median age of Group 1 and Group 2 were 63.8 (SD=10.35) and 65.4 (SD=10.48) respectively. The median pain score on the VAS in iontophoresis group was 2.4 (1.4±SD) compared with infiltration group that was 4.5 (1.7±SD). The VAS scores in iontophoresis group were significantly lower than infiltration group according to Mann-Whitney test (P<0.001)).

The number of successful radial artery cannulations on the first attempt in iontophoresis group and infiltration group were 24 and 17 respectively. The number of cannulaitons with more than one attempt (2 and 3) in iontophoresis group and infiltration group were 6 and 13 respectively (Table 1).

There was no significant difference in the difficulty of cannulations between the two groups (Fig. 3). There was no correlation between the difficulties of the procedure and the VAS scores in relation to the gender between the two groups. There was no complaint made about pain from the subjects during iontophoresis. The only side effect was slight skin erythema noted in 4 patients after removal of the iontophoretic anode patch, which continued for about 0.5-4 hours. Moreover, no attempt was abandoned in patients under any circumstances.

Table 1: Comparison of difficulty of cannulations in group 1 and 2

		Group		- Total	
		1	2	- i Otai	
1 *	Count	24	17	41	
	% within group	80%	56.7%	68.3%	
	% of total	40%	28.3%	68.3%	
2 & 3 **	Count	6	13	19	
	% within group	20%	43.3%	31.7%	
	% of total	10%	21.7%	31.7%	
Total	Count	30	30	60	
	% within group	100%	100%	100%	
	% of total	50%	50%	100%	

*1: Successful cannulation at the first attempt, **2 and 3: unsuccessful cannulations at the first attempt. (*2: Successful cannulations in the allocated area at the second attempt *3: Failed cannulations in allocated area), Group 1: Lidocaine iontophoresis group, Group 2: Lidocaine infiltration group.

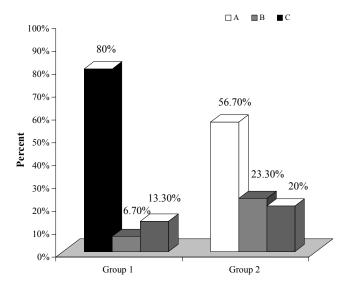


Fig 3: Comparison of difficulty of cannulation in Group1 and 2.

A: Successful cannulation at the first attempt

B: Successful cannulation in allocated area at second attempt

C: Failed cannulation in allocated area

Group 1: Lidocaine iontophoresis group

Group 2: Lidocaine infiltration group

Discussion

Most patients receive injectable lidocaine as local anesthetic before surgery, which can be painful. In addition, a significant portion of adults have "needle phobia", 14 the ideal topical anesthetic should be painless, effective and rapid-acting and should be of adequate duration, eliminate needle phobia, and have minimal side effects. 15 Lidocaine is delivered iontophoretically by placing it in a positively charged electrode and repelling it into the skin when the current is turned on. 16 Currently available systems are easy to use and have been well tolerated in adult and pediatric trials.¹⁷ This study has demonstrated lower pain scores during radial artery cannulation in patients receiving lidocaine iontophoresis as analgesic than those receiving lidocaine infiltration. Moreover, the quality of analgesia in the iontophoresis group was much better than infiltration group. In a similar study reported by Sherwin et al, 30 patients, of whom 15 were subjected to iontophoresis and 15 to infiltration, underwent vascular surgery. The results showed that during radial artery cannulation, the quality of analgesia produced by lidocaine iontophoresis was similar to that produced by local infiltration of the skin by lidocaine. 18 Both studies were performed on 30 patients, and the cannulation was done using 20 G cannula by an investigator who was blinded to the method of analgesia. Another study investigating 100 patients undergoing elective cardiac surgery found that treatment with 4% topical amethocaine gel was as effective as local infiltration with 2% lidocaine.⁶ Amethocaine gel was applied at least 60 min before attempting radial artery cannulation and all patients were premedicated with 1-3mg Lorazpam. However, our study performed on 60 patients, demonstrated good analgesia after only 10 min of iontophoresis with no premedication. A study conducted by Joly and colleagues on 538 patients showed that patients treated with EMLA, 2 hour prior to cannulation had superior analgesia and a higher success rate as compared to patients subjected to lidocaine infiltration.¹⁹ Relatively high pain scores (VAS=7) was reported in the local infiltration group, which may reflect the use of an 18G cannula rather than the 20G canula used in our study. Furthermore; the volume of local anesthetic, 1ml, infiltrated in our study was larger than that used in Joly's study (0.5-0.7 ml). It therefore seemed likely that better pain control can be achieved with a larger volume of lidocaine. The radial pulse was superficial, with little subcutaneous tissue. Local swelling produced in the site of lidocaine injection made it difficult to percept radial artery pulse, so that cannulation was more difficult and success rate decreased in the infiltration group. Furthermore; reduction of pain by iontophoresis might have favorably limited hand movements and radial artery spasm. Anesthesia by lidocaine iontophoresis was faster than that of EMLA, a major advantage in busy ambulatory surgery centers^{13,20} which could be preferable for deeper procedures, as EMLA cream anesthetized to a depth of 5mm in an hour, whereas lidocaine iontophoresis provided anesthesia of greater than 8mm in 10 min. 17,21,22 Studies on radial artery cannulation using EMLA as analgesic, have clearly shown that 60 min application was insufficient to produce effective anesthesia. ^{23,24} In a comparative trial of EMLA and lidocaine iontophoresis, lidocaine iontophoresis was shown to be significantly more effective in reducing the pain associated with venous cannulation in children. 9,13 However, in another comparative study, it was shown that analgesia produced by EMLA was superior to that of lidocaine iontophoresis.²⁰ EMLA could be considered for procedures covering a larger surface area or simultaneous multiple procedures,²⁰ while area anesthetized by the iontophoretic system was limited, and was only applicable to one site at a

time.¹³ Iontophoresis can cause itching, tingling, or burning sensations. Transient erythma, urticaria and petechia could also occur after electrode removal. 16 The incidence of burns resulting from iontophoresis was reported as 1 in 10,000 to 1 in 20, 000 treatments. In our study, only a transient erythma was seen in 4 patients that resolved within 0.5-4 hours. Our study showed not only reduced pain during radial artery cannulation, but also an improved success rate when iontophoresis was used for analgesia. The increasing cost of iontophoresis must be weighed against the improved success rate of cannulation, which avoided the use of a second set for arterial cannulation. Our study was not double-blind, because the injection of normal saline around the radial artery was unethical. We adopted a single-blind design, whereby the investigator performing cannulation was not present during infiltration or iontophoresis. However, the blinding of the operator may have been affected in a few patients by the slight erythma present on removing the iontophoretic anode patch. In conclusion, this study has demonstrated that lidocaine iontophoresis was a useful, non-invasive, rapid, painless alternative to lidocaine infiltration to provide dermal analgesia for radial artery cannulation.

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