



Topical anaesthesia before transradial approach for supraoartic vessels angiography and stenting in the elderly: a feasible alternative

Gianluca Rigatelli^{1,*}, Marco Zuin^{2,3}, Fabio Dell'Avvocata¹, Dobrin Vassiliev⁴

¹Section of Cardiovascular Diagnosis and Endoluminal Interventions, Rovigo General Hospital, Rovigo, Italy

²Section of Internal and Cardiopulmonary Medicine, Department of Medical Science, University of Ferrara, Ferrara, Italy

³Department of Cardiology, Rovigo General Hospital, Rovigo, Italy

⁴Head Cardiology Department, Alexandroska University Hospital, Sofia, Bulgaria

J Geriatr Cardiol 2017; 14: 644–648. doi:10.11909/j.issn.1671-5411.2017.10.009

Keywords: Carotid artery stenting; Stenosis; Transradial approach

Over the years, the use of transradial approach (TRA) for carotid artery stenting (CAS) with distal embolic protection has been recognized as a valid alternative to the conventional femoral approach, improving the outcomes compared to carotid endoarterectomy.^[1–3] Indeed, despite the femoral artery remains the conventional access site for the endovascular treatment of supraoartic vessels, concomitant anatomical variations and/or peripheral vascular disease could complicate the cannulation of such arteries.^[4] Moreover, the TRA has been related with a lower incidence of bleeding complications and a shorter bed rest after the interventional procedure.^[5]

Generally, before any endovascular procedure, local analgesia, obtained through the cutaneous/subcutaneous injection of local anaesthetic, as lidocaine, is performed to reduce the patient's pain and discomfort.^[6] As known, the radial artery is a mobile and collapsible vessel, often associated with unusual course, which are normal anatomic variations. Moreover, given that the radial artery is prone to spasm during TRA and exchange of catheters, due the presence of α -adrenoreceptors and a thicker muscular layer compared to others peripheral arteries,^[7,8] some physicians prefer to combine the injection of a local anaesthetic with a small amount of nitro-glycerine to promote the dilatation of the radial artery.^[9] Recently, some studies have demonstrated that a topical mixture of lidocaine-prilocaine cream (EMLA[®]; AstraZeneca Group PLC, London, England) was equally effective, in terms of pain, artery cannulation time and spasm when compared to the injectable lidocaine before transradial coronary angiography. Furthermore, similar results were obtained by previous studies, in which patients needed radial artery cannulation in intensive care unit for monitoring purposes.^[10–12]

However, to the best of our knowledge, no previous studies have investigated and compared the use of a topical anaesthetic cream versus injectable lidocaine in patients undergoing supraoartic vessels angiography and stenting via TRA. For these reasons, we analysed and compared the efficacy of topical anaesthesia versus the traditional injection of subcutaneous lidocaine injection in patients underwent supraoartic vessels angiography and stenting through the TRA in a retrospective fashion.

A total of 60 consecutive elderly patients, aged > 65 years old, who have undergone transradial supraoartic vessels angiography and/or stenting in our Institution from May 2015 to May 2017, received topical anaesthesia before the radial artery cannulation. A matched 1: 1 cohort of consecutive patients receiving the same endovascular procedure and treated according the local clinical practice, by means of injectable 1% lidocaine was reviewed and used as control group. Inclusion criteria were: (1) symptomatic internal carotid artery (ICA) stenosis (defined as > 70%) evaluated by magnetic resonance imaging or computed tomography angiography (CTA); (2) critical asymptomatic ICA stenosis (defined as > 80%) evaluated with the same imaging techniques, according to the NASCET criteria;^[13] (3) neurologically symptomatic vertebral stenosis \geq 70%; (4) subclavian steal syndrome; (5) arm functional impotence; and (6) subclavian stenosis with gradient > 40 mmHg in patients scheduled for left internal mammary artery grafting. Conversely, exclusion criteria were: (1) contraindications to the transradial access (negative Allen test and/or non-palpable radial artery); (2) recent history of acute myocardial infarction or stroke (< 2 months); (3) surgery or trauma in the previous 2 months; (4) hemodynamical instability and/or unconsciousness; and (5) hypersensitivity to lidocaine or prilocaine.

*Correspondence to: jackyheart71@yahoo.it

Considering the aim of the study, no additional sedation before the interventional procedure was performed since the concomitant use of this drug, as it would have been a confounding factor in assessing the efficacy of the topical anaesthesia. All patients signed the informed consent before the procedure and the Department Editorial Board approved this study. Circumference of wrist was assessed by using a tape at the site of arterial cannulation and anaesthesia application, between 1 and 1.5 cm from the styloid process. Cardiovascular risk factors and comorbidities were also recorded. Patients were assessed for any local complications at the TRA after the procedure and before the discharge.

The selection of EMLA or injectable lidocaine was on physician's discretion. Specifically, patients treated with topical anaesthesia, received a layer of 2.5 gr EMLA cream between 1 cm and 1.5 cm above the styloid process of the radius, 30 min before the arterial puncture. This period was chosen considering the pharmacodynamics characteristics of the topical drug. Conversely, patients treated with injectable lidocaine, the local anaesthesia was obtained through the subcutaneous injection of 2 mL 1% lidocaine, using a 24-gauge needle, 1 min before the radial artery puncture, between 1 and 1.5 cm proximal to the styloid process. After the radial artery cannulation, pain assessment was performed using a verbal numerical score (VNS). Specifically, "no pain" was labelled as a VNS = 0 while the "worst pain imaginable" as a VNS = 10. Seldinger technique and micropuncture set (Terumo, Tokyo, Japan) was used for cannulating the radial artery with a 6 French transradial sheath (Radiofocus Introducer II, Terumo Cooperation, Terumo Europe N.V., Leuven, Belgium). Hemodynamic stability was assessed before and after vasodilator injection. Specifically, nitroglycerin 200 µg was administered intra-arterially, and all patients received 50 units/kg of unfractionated heparin intravenously. The occurrence of radial artery spasm (RAS), if any, was evaluated either angiographically or clinically by the operator as any signify any resistance in catheter advancement or prolonged arm pain during catheter manipulation. After the radial catheterization procedure, the introducer sheath was quickly pulled back 4–5 cm and immediately a TR Band™ (Terumo Medical Corporation, Somerset, NJ) was placed around wrist. The sheath was completely removed during inflation of the TR Band™ bladder to 12–15 atmospheres. The band was left in place for 2 h and subsequently the device was removed by slowly deflating with syringe while evaluating access site for bleeding.

Barbeau's test was performed immediately following compression removal to verify radial artery patency. In the event of bleeding the device was re-inflated and re-evaluated

at 45-min increments. Continuous variables were expressed as mean ± SD and compared with Student *t*-test. Categorical variables were presented as percentages and compared using Chi-square and Fisher exact test, as appropriate. Patients were divided into two groups: subjects who received topical anaesthesia and those treated with subcutaneous lidocaine. Pearson's correlation was used to evaluate the correlation between wrist circumference and body mass index (BMI) with the VNS. All statistical analyses were carried out using SPSS statistical software version 19.0 (SPSS Inc, Chicago, IL, USA). A *P* value < 0.05 was considered statistically significant.

Patients baseline characteristics, including demographics, cardiovascular risk factors and comorbidities, neurological status and location of disease and procedural data were comparable between the two groups (Table 1). Procedural success was achieved in all patients. Patients treated with topical anaesthesia showed a similar wrist circumference (WC, 18.2 ± 6.2 vs. 17.1 ± 4.1 cm, *P* = 0.25) when compared to those subjects who received subcutaneous lidocaine. The number of radial artery attempts resulted similar among groups (1.21 ± 0.5 vs. 1.19 ± 0.77, *P* = 0.77). Similarly, more than one radial puncture attempt was performed in 16 (26.6%) and 19 (31.6%) patients treated with EMLA and injectable lidocaine (*P* = 0.61), respectively. At the same manner, the cannulation time not differ among groups (61.1 ± 14.2 vs. 64.2 ± 11.3 s, *P* = 0.18). Patients treated with EMLA and subcutaneous lidocaine not differ in post-procedural complications (5.0% vs. 8.3%, *P* = 0.47). More precisely, all the three patients in the topical anaesthesia group experienced a local hematoma, completely self-resolving, during the recovery. However, all these three subjects performed a periprocedural bridging strategy with low-molecular-weight heparin (LMWH) due treatment with warfarin for chronic atrial fibrillation. Conversely, in the lidocaine group, three patients reported a local hematoma (only one with a periprocedural bridging strategy with LMWH) while two patients experienced a self-resolved pain in the forearm during the days after the procedure. Notably, all the patients with a post-procedural hematoma had a normal International Normalized ratio before the procedure. No significant differences were observed in RAS rate (3.3% vs. 5.0%, *P* = 0.64). Intriguingly, during the radial puncture, pain assessed by the VNS was equally intense both in topical and injectable anaesthesia group (3.6 ± 1.9 vs. 4.0 ± 1.8, *P* = 0.23). No significant differences were observed among the groups in procedural time, X-ray dose, fluoroscopy time, contrast volume and hospitalization days (Table 2).

A significant direct relationship between VNS and WC (*r* = 0.749, *P* < 0.001) and between VNS and BMI (*r* = 0.658,

Table 1. General characteristics of the patients enrolled stratified according the type of local anaesthesia and rocedural characteristics.

	Topical anaesthesia (n = 60)	Subcutaneous anaesthesia (n = 60)	P
Age, yrs	68.5 ± 8.8	69.2 ± 7.5	0.64
Males	41 (68.3%)	47 (78.3%)	0.21
Body mass index, kg/m ²	26.7 ± 5.7	27.8 ± 6.4	0.32
Obesity	21 (35.0%)	25 (41.6%)	0.45
Smoking habits			
Current	18 (30.0%)	14 (23.3%)	0.40
Previous	34 (56.6%)	31 (51.6%)	0.58
Arterial hypertension	48 (80.0%)	41 (68.3%)	0.14
Diabetes	34 (56.6%)	39 (65.0%)	0.34
Dyslipidaemia	24 (40.0%)	29 (48.3%)	0.36
HF	14 (23.3%)	19 (31.6%)	0.31
CAD	18 (30.0%)	21 (35.0%)	0.56
PAD	16 (26.6%)	19 (31.6%)	0.56
Previous CEA	6 (10%)	8 (8.3%)	0.74
Indications to angiography and/or Interventions			
Neurologically asymptomatic	30 (50.0%)	35 (58.3%)	0.36
Neurologically symptomatic	18 (30.0%)	13 (21.6%)	0.29
Subclavian steel syndrome	9 (15.0%)	10 (16.6%)	0.81
Significant subclavian stenosis	3 (5.0%)	2 (3.3%)	0.64
Angiographic results			
SAS ≥ 70%	15 (25.0%)	13 (21.6%)	0.66
VAS ≥ 70%	10 (16.6%)	9 (15.0%)	0.81
RICA disease	17 (28.3%)	18 (30.0%)	0.83
LICA disease	12 (20.0%)	13 (21.6%)	0.82
Bovine-LICA	6 (10.0%)	7 (11.6%)	0.77
Controlateral vessel occlusion	20 (33.3%)	23 (38.3%)	0.56
Bilateral vessel disease	15 (25.0%)	11 (18.3%)	0.37
Angiography only	20 (33.3%)	21 (35.0%)	0.84
Angiography + stenting	40 (66.6%)	39 (65.0%)	0.85
SAS	11 (18.3%)	10 (16.6%)	0.80
VAS	6 (10.0%)	8 (13.3%)	0.57
CAS	23 (38.3%)	21 (35.0%)	0.70
Neuroprotection	29 (48.3%)	29 (48.3%)	1.00
Switch to femoral access	2 (3.2%)	1 (1.6%)	0.56

Data are presented as mean ± SD or n (%). CAD: coronary artery disease; CAS: carotid artery disease arterectomy; CEA: carotid endia; HF: heart failure; LICA: left internal carotid artery; PAD: peripheral artery disease; RICA: right internal carotid artery; SAS: subclavian artery disease; VAS: vertebral artery disease.

Table 2. Anthropometrics, interventional and post-interventional data.

	Topical anaesthesia (n = 60)	Subcutaneous anaesthesia (n = 60)	P
Wrist circumference, cm	18.2 ± 6.2	17.1 ± 4.1	0.25
Number of attempts for radial artery cannulation	1.21 ± 0.5	1.19 ± 0.2	0.77
> 1 puncture attempts	16 (26.6%)	19 (31.6%)	0.61
Cannulation time, s	61.1 ± 14.2	64.2 ± 11.3	0.18
Post-procedural complications	3 (5.0%)	5 (8.3%)	0.47
RAS	2 (3.3%)	3 (5.0%)	0.64
VNS during radial puncture (0–10%)	3.6 ± 1.9	4.0 ± 1.8	0.23
Procedure time, min	46.2 ± 16.2	47.1 ± 14.3	0.74
DAPT	60 (100.0%)	60 (100.0%)	1.00
Contrast volume, mL	116.4 ± 16.3	119.5 ± 18.2	0.32
Fluoroscopy time, s	555.6 ± 19.2	560.1 ± 5.5	0.08
Hospitalization days	2.02 ± 1.2	2.1 ± 0.8	0.66

Data are presented as mean ± SD or n (%). DAPT: dual antiplatelet therapy; RAS: radial artery spasm; VNS: verbal numerical scale for assessment of pain.

$P < 0.001$) were found only in patients treated with topical anaesthesia ($r = 0.121$, $P = 0.28$ and $r = 0.081$, $P = 0.47$ in patients treated with lidocaine, respectively). Indeed, dividing the patients treated with cutaneous anaesthesia and lidocaine among WC and BMI tertiles, significant lower pain was observed in subjects with small wrist (3.0 ± 1.1 vs. 3.8 ± 0.9 , $P = 0.006$) and (Table 3) and low BMI (3.1 ± 1.3 vs. 3.9 ± 1.1 , $P = 0.02$). No adverse drug reactions, systemic or local, as skin reactions, were recorded among patients treated with EMLA. Our small study demonstrates that the use of a topical anaesthesia with a mixture of lidocaine-prilocaine cream is a feasible and effective alternative to the injection of subcutaneous lidocaine before radial artery cannulation for supraortic vessels angiography and/or stenting, in elderly subjects with low BMI and small wrist. During the last years, a growing attention has been posed in innervational strategies able to minimize the patient's pain during transradial endovascular procedures. Previous studies and trials evaluating the TRA for CAS have always used injectable lidocaine before the arterial cannulation. Conversely, previous investigations have tried to assess the use of a topical mixture of lidocaine-prilocaine, as local anaesthetic before the endovascular procedure, especially during the radial artery cannulation for hemodynamic monitoring in intensive care units. In accordance with our results were the findings of Russel, *et al.*,^[14] which randomized 60 patients who received EMLA (60 or 90 minutes before the arterial cannulation) versus patients treated with 2% local lidocaine infiltration. They reported that patients treated with EMLA 90 min before the procedure, experienced significantly less pain ($P < 0.001$) than either treated with EMLA 60 min before or with lidocaine.^[14] Similarly, Smith, *et al.*^[15] randomly randomized 40 un-premedicated patients into four groups to receive EMLA cream alone, EMLA and 0.9% saline infiltration, EMLA and 1% lidocaine infiltration or placebo cream and 1% lidocaine infiltration. Using a

visual analogue score, a significant lower pain scores were observed in all subjects treated with EMLA compared with those received the placebo cream and lidocaine infiltration ($P < 0.001$) and no significant differences between the three EMLA groups were observed.^[15] Kim, *et al.*^[16] observed a reduced wrist pain during TRA for coronary procedures, without any significant drug-related complications when the application time was between 1 to 3 h before the procedure. Recently, Latsios, *et al.*^[17] have demonstrated that EMLA was equally effective in terms of pain, artery spasm or artery cannulation time, when compared to the traditional injectable lidocaine. Our study has also demonstrated that the VNS after topical anaesthesia application significantly correlates with BMI and wrist circumferences. From a pharmacological point of view, it is well known that the skin penetration of a topical anaesthetic is both time-dependent and related to the depth of dermal layer. Moreover, pKa (ionization constant) differences between the anaesthetic route of administration could be a further explanation for the correlation between BMI and wrist circumferences in respect to the use of a topical anaesthetic. Conversely, the injection of a local anaesthetic allows a deeper bio-distribution in the area.^[18] These aspects suggest that patients with a higher BMI and wrist circumference, could not be the ideal candidates for topical anaesthesia in TRA supraortic vessels angiography and/or stenting. Conversely, patients with a smaller wrist and normal BMI could be ideal candidates for this anaesthetic approach. Regarding the incidence of RAS, no significant differences were observed in our studies. This aspect could be due to the relative low number of patients enrolled and to the vasodilator cocktail administered before the procedure. Our study suffers from different limitations as the non-randomized, retrospective design, and the limited number of patients enrolled. However, the use of topical anaesthesia based on a mix of lidocaine-prilocaine cream seems to be a valid alternative in the pre-operative

Table 3. Evaluation of pain through the verbal number scale during radial artery puncture among the WC and BMI tertiles.

	1 st tertile 10.3 ± 2.4 cm	2 nd tertile 17.5 ± 3.4 cm	3 rd tertile 22.2 ± 4.4 cm	P for trend
Topical anaesthesia VNS	3.0 ± 1.1	3.6 ± 1.3	3.6 ± 1.7	< 0.001
Subcutaneous anaesthesia VNS	3.8 ± 0.9	4.0 ± 1.4	4.1 ± 1.8	< 0.001
P between topical anaesthesia VNS and subcutaneous anaesthesia VNS	0.006	0.29	0.30	-
BMI	1 st tertile 23.2 ± 2.6	2 nd tertile 26.5 ± 4.2	3 rd tertile 29.3 ± 3.2	P for trend
Topical anaesthesia VNS	3.1 ± 1.3	3.5 ± 1.5	3.7 ± 1.3	< 0.001
Subcutaneous anaesthesia VNS	3.9 ± 1.1	4.1 ± 1.2	4.2 ± 1.5	< 0.001
P between topical anaesthesia VNS and subcutaneous anaesthesia VNS	0.02	0.11	0.20	-

Data are presented as mean ± SD unless other indicated. BMI: body mass index; VNS: verbal numerical score; WC: wrist circumference.

analgesia in elderly patients undergoing supraaortic vessels angiography and/or stenting through TRA especially in presence of small wrist and normal or low BMI.

Acknowledgments

The authors report no financial relationships or conflicts of interest regarding the content herein.

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