

## RESEARCH ARTICLE

## Topical lidocaine and or/ intravenous midazolam before radial coronary angiography to prevent radial artery spasm

Mohamed Zakariya Elattar, Reda Biomy, Wael Anwar Haseeb, Mohamed Kamal Salama

### Abstract

**Objective:** To investigate the possible advantage of topical lidocaine and intravenous midazolam in preventing spasm and pain related to the radial artery.

**Methods:** The prospective, comparative study was conducted at the catheterization laboratory of the cardiology department Kafrelsheikh University Hospital, Egypt, from January 2021 to January 2022, and comprised adult patients of either gender who were due to undergo coronary angiography and/or percutaneous coronary intervention for different indications. The patients were randomised control group I which was administered a cocktail of nitroglycerine, verapamil and heparin, intervention group II which was administered the control cocktail plus topical lidocaine, group III which was administered the control cocktail plus midazolam intravenously, and group IV which was administered the control cocktail plus topical lidocaine and intravenous midazolam. The groups were compared for frequency of radial artery spasm, access site cross-over and the difference in occurrence as well as procedure events, including the puncture number, time and complications. Data was analysed using SPSS 25.

**Results:** Of the 120 patients, there were 30(25%) in each of the 4 groups. Overall, there were 72(60%) males and 48(40%) females. Gender and mean age were not significantly different among the groups ( $p>0.05$ ). Spasm of the radial artery occurred in 22(18.3%) patients, with higher incidence in the group I 12(40%). The median visual analogue scale score was higher in patients with radial artery spasm patients ( $p<0.001$ ). The groups showed no significant differences in terms of frequency related to ad hoc percutaneous coronary intervention, contrast volume and fluoroscopy time ( $p>0.05$ ), while they showed a significant difference in puncture time ( $p<0.05$ ). Significant differences were noted among the groups in the incidence of radial artery spasm, visual analogue scale scores, requirement of multiple punctures, and the number of indicated punctures ( $p<0.05$ ). Access site cross-over was more in the group I, while age, complication rates, visual analogue scale score, incidence of multiple punctures, and puncture time were significantly higher in patients with radial artery spasm ( $p<0.05$ ).

**Conclusion:** Cutaneous analgesia and procedural sedation before transradial access for coronary interventions were found to be associated with a substantial reduction in radial artery spasm and procedure-related discomfort.

**Keywords:** Coronary intervention, Transradial access, Radial artery spasm, Topical lidocaine, Intravenous midazolam.

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### Introduction

Coronary artery disease (CAD) is a leading cause of morbidity and mortality across the world.<sup>1</sup> Considerable advancement in CAD management has been introduced by the evolution of percutaneous coronary intervention (PCI).<sup>2</sup> Transradial access (TRA) is currently the preferred route for PCI.<sup>3</sup> It reduces bleeding and vascular complications compared to the standard femoral approach<sup>(4)</sup>. This is particularly evident in patients with acute coronary syndrome (ACS).<sup>5</sup> Moreover, TRA has been reportedly connected to a better quality of life (QOL).<sup>5-6</sup>

Radial artery spasm (RAS) is frequently challenging the TRA. It is the transient abrupt radial artery narrowing.<sup>7</sup> The radial artery is characterised by alpha ( $\alpha$ )-adrenoreceptors

abundance in the adventitia. Therefore, it is highly vaso-reactive and undergoes spasm following local injury.<sup>8</sup> RAS usually manifests by resisting the advancement of wire or catheter after which forearm discomfort occurs.<sup>9</sup> This is complicated by the need to change from radial access to femoral one.<sup>10-12</sup>

Various preventive measures are adopted to preclude RAS. Cutaneous analgesia before TRA has been also assumed to reduce the RAS during coronary interventions. Yet, this method cannot be used in acute conditions because it requires a longer time for producing beneficial effects<sup>13</sup>. The current study was planned to assess the possible advantage of topical lidocaine and intravenous (IV) midazolam in preventing spasm and pain related to the radial artery.

### Patients and Methods

The prospective, comparative study was conducted at the catheterization laboratory of the cardiology department

Department of Cardiology, Kafrelsheikh University, Egypt.

**Correspondence:** Mohamed Zakariya Elattar

email: mohamed\_pg018@med.kfs.edu.eg

Kafrelsheikh University Hospital, Egypt, from January 2021 to January 2022, and comprised adult patients of either gender who were due to undergo coronary angiography and/or PCI for different indications. The sample size was calculated using G\*Power version 3.1.9.4<sup>14</sup> based on 95% confidence level, Z-score 1.96 and +/- 5% margin of error. After approval from the institutional research ethics committee, a convenient sample of 120 patients was raised from among adult patients of either gender scheduled for coronary angiography and/or PCI for different indications. The inclusion criteria were patients with stable coronary artery disease resistant to medical treatment, patients with high-risk coronary artery disease documented with multi slice computed tomography or coronary angiography, patients with preoperative coronary angiography assessment for valve replacement. Patients with ACS, decompensated heart failure (HF), haemodialysis with vascular access, hypersensitivity to the used drugs, peripheral artery disease (PAD), or previous TRA coronary angiography and/or PCI were excluded.

After taking informed written consent from all the subjects, they were randomised into four groups using the research randomiser<sup>15</sup>. Patients in group I, which was designated as the control group, were administered a cocktail of 100µg nitroglycerine (NTG), 100µg verapamil and 5000IU heparin. Those in group II were administered the cocktail plus topical lidocaine 5% over the anterior aspects of the wrists bilaterally 30 minutes prior to the procedure. Those in group III were administered the cocktail plus 5mg intravenous (IV) midazolam 3 minutes prior to procedure. Those in group IV were administered the cocktail plus topical lidocaine and IV midazolam.

Detailed history of each patient was taken, and they were subjected to routine clinical and laboratory examinations. Allen test was used to evaluate the palmar arch circulation.<sup>16</sup> The right radial artery was the default for cannulation. The left one was cannulated in patients having

previous coronary artery bypass grafting (CABG).

After application of the described medications, the radial artery was punctured using a 21-gauge open needle about 2.5cm above the styloid process. A straight 0.018-inch guide wire was inserted, followed by a 6 French hydrophilic sheath (Prelude Ease, Merit Medical South Jordan UT). After radial sheath flushing, the operator began the TRA procedure after which the radial sheath was removed immediately.

The primary outcomes were RAS frequency, access site cross-over, and the difference in incidence among the groups. The secondary outcomes were the procedure events, including the number of punctures, time, and complications.

Data was analysed using SPSS 25. Numerical data normality was tested using the Shapiro-Wilk test, and, accordingly, data was expressed as means and standard deviations or medians and interquartile ranges (IQRs). Qualitative data was presented as frequencies and percentages. One-way analysis of variance (ANOVA), Kruskal Wallis test, chi-square test and Fisher's exact test were used for inter-group comparisons, as appropriate. Stepwise multivariate logistic regression analysis was performed to assess RAS predictors. The odds ratio (OR) and 95% confidence interval (CI) were calculated.  $P < 0.05$  was considered statistically significant.

## Results

Of the 120 patients, there were 30(25%) in each of the 4 groups. Overall, there were 72(60%) males and 48(40%) females. Gender and mean age were not significantly different among the groups ( $p > 0.05$ ) (Table 1). RAS happened in 22(18.3%) patients, with higher incidence in the group I 12(40%). The median visual analogue scale (VAS) score was higher in RAS patients ( $p < 0.001$ ).

The groups showed no significant differences in terms of ad hoc PCI, contrast volume and fluoroscopy time ( $p > 0.05$ ), while they showed a significant difference in puncture time

**Table-1:** General characteristics of the studied groups.

		(Group I) (n = 30)	(Group II) (n = 30)	(Group III) (n = 30)	Group IV (n = 30)	p-value
<b>Age (years)</b>	Mean ±SD	57 ±8	53 ±9	55 ±8	53 ±9	0.11
<b>Gender</b>	Males n (%)	22 (73.3)	19 (63.3)	17 (56.7)	14 (46.7)	0.193
	Females n (%)	8 (26.7)	11 (36.7)	13 (43.3)	16 (53.3)	
<b>Diabetes mellitus</b>	n (%)	13 (43.3)	11 (36.7)	18 (60.0)	13 (43.3)	0.309
<b>Hypertension</b>	n (%)	17 (56.7)	21 (70.0)	16 (53.3)	13 (43.3)	0.219
<b>Smoking</b>	n (%)	16 (53.3)	10 (33.3)	14 (46.7)	11 (36.7)	0.376
<b>BMI</b>	Mean ±SD	23 ±3	22 ±2	22 ±2	23 ±2	0.278
<b>Dyslipidaemia</b>	n (%)	18 (60.0)	18 (60.0)	17 (56.7)	15 (50.0)	0.846
<b>Known CAD</b>	n (%)	12 (40.0)	8 (26.7)	14 (46.7)	7 (23.3)	0.183

**BMI:** Body mass index, **CAD:** Coronary artery disease, **SD:** Standard deviation.

**Table-2:** Procedural characteristics of the studied groups.

		<b>Group I (n = 30)</b>	<b>Group II (n = 30)</b>	<b>Group III (n = 30)</b>	<b>Group IV (n = 30)</b>	<b>p-value</b>
<b>Ad hoc PCI</b>	n (%)	13 (43.3)	9 (30.0)	14 (46.7)	15 (50.0)	0.419
<b>Radial artery spasm</b>	n (%)	12 (40.0)	1 (3.3)	4 (13.3)	5 (16.7)	0.002
<b>VAS score</b>	Median (range)	1 (0 - 10)	0 (0 - 8)	0 (0 - 10)	0 (0 - 9)	0.027
<b>Access site cross over</b>	n (%)	7 (23.3)	1 (3.3)	3 (10.0)	3 (10.0)	0.125
<b>Vagotonia</b>	n (%)	0 (0.0)	0 (0.0)	1 (3.3)	1 (3.3)	1.0
<b>Vascular perforation</b>	n (%)	1 (3.3)	0 (0.0)	0 (0.0)	0 (0.0)	1.0
<b>Multiple punctures</b>	n (%)	11 (36.7)	1 (3.3)	2 (6.7)	3 (10.0)	0.001
<b>Number of punctures</b>	One n (%)	19 (63.3)	29 (96.7)	28 (93.3)	27 (90.0)	0.007
	Two n (%)	6 (20.0)	1 (3.3)	1 (3.3)	1 (3.3)	
	Three n (%)	5 (16.7)	0 (0.0)	1 (3.3)	2 (6.7)	
<b>Other Complications</b>	n (%)	8 (26.7)	0 (0.0)	3 (10.0)	2 (6.7)	0.009
<b>Puncture time (minutes)</b>	Median (range)	2.5 (1 - 6)	2 (1 - 4)	2 (1 - 6)	3 (3 - 5)	<0.001
<b>Contrast volume (ml)</b>	Median (range)	150 (50 - 450)	70 (50 - 700)	150 (40 - 500)	125 (50 - 300)	0.245
<b>Fluoroscopy time (min)</b>	Median (range)	15 (5 - 60)	10 (4 - 55)	10 (5 - 60)	13 (5 - 30)	0.084

PCI: Percutaneous coronary intervention, VAS: Visual analogue scale.

Kruskal Wallis test was used for quantitative data. Chi-Square or Fisher's exact test was used for categorical data

**Table-3:** General characteristics according to radial artery spasm (RAS).

		<b>Radial artery spasm</b>		<b>p-value</b>
		<b>Yes (n = 22)</b>	<b>No (n = 98)</b>	
<b>Age (years)</b>	Mean ±SD	60 ±9	53 ±9	0.002
<b>Gender</b>	Males n (%)	14 (63.6)	58 (59.2)	0.7
	Females n (%)	8 (36.4)	40 (40.8)	
<b>Diabetes mellitus</b>	n (%)	10 (45.5)	45 (45.9)	0.969
<b>Hypertension</b>	n (%)	15 (68.2)	52 (53.1)	0.197
<b>Smoking</b>	n (%)	8 (36.4)	43 (43.9)	0.519
<b>BMI</b>	Mean ±SD	22 ±2	23 ±2	0.458
<b>Dyslipidaemia</b>	n (%)	13 (59.1)	55 (56.1)	0.8
<b>known CAD</b>	n (%)	9 (40.9)	32 (32.7)	0.461

PCI: Percutaneous coronary intervention, VAS: Visual analogue scale.

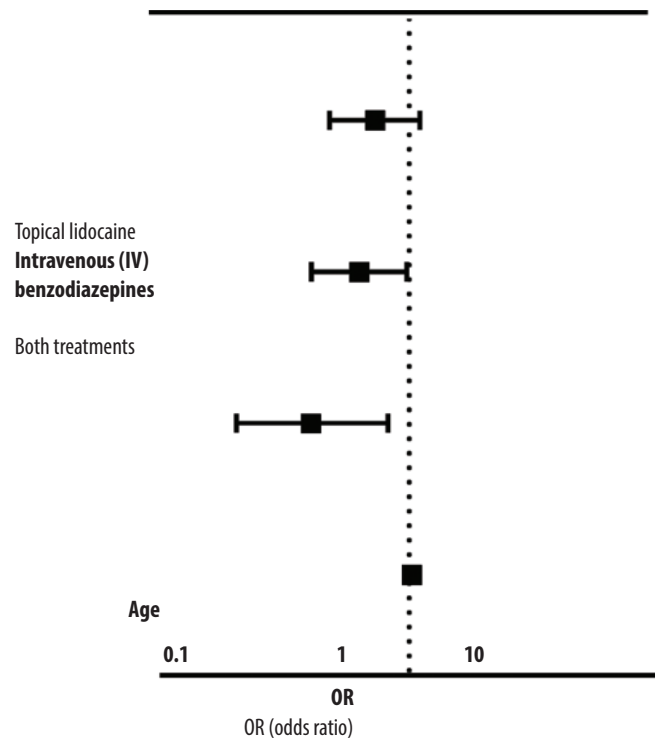
Kruskal Wallis test was used for quantitative data. Chi-Square or Fisher's exact test was used for categorical data

**Table-4:** Procedural characteristics according to radial artery spasm (RAS).

		<b>Radial artery spasm</b>		<b>p-value</b>
		<b>Yes (n = 22)</b>	<b>No (n = 98)</b>	
<b>VAS score</b>	Median (range)	8 (2 - 10)	0 (0 - 5)	<0.001
<b>Access site cross over</b>	n (%)	12 (54.5)	2 (2.0)	<0.001
<b>Vagotonia</b>	n (%)	1 (4.5)	1 (1.0)	0.334
<b>Multiple punctures</b>	n (%)	15 (68.2)	2 (2.0)	<0.001
<b>Puncture time (minutes)</b>	Median (range)	3.5 (2 - 6)	2.5 (1 - 4)	<0.001
<b>Other Complication</b>	n (%)	13 (59.1)	0 (0.0)	< 0.001
<b>Contrast volume (ml)</b>	Median (range)	150 (50 - 500)	75 (40 - 700)	0.266
<b>Fluoroscope time (min)</b>	Median (range)	18 (5 - 60)	10 (4 - 60)	0.064

VAS: Visual analogue scale.

Mann Whitney U test was used for quantitative data. Chi-square or Fisher's exact test was used for categorical data



**Figure:** Forest plot for predictors of radial artery spasm (RAS).

( $p < 0.05$ ). Significant differences were noted among the groups in RAS incidence, VAS scores, requirement of multiple punctures, and the number of indicated punctures ( $p < 0.05$ ). Access site cross-over was more in the group I, but the difference was not significant ( $p > 0.04$ ). The highest complication rate was in group I 8 (26.7) and comprised hematoma, vagotonia, vascular perforation and catheter entrapment (Table 2).

Age, complication rates, VAS score, incidence of multiple punctures, and puncture time were significantly higher in RAS patients (Tables 3-4).

Multivariate stepwise logistic regression illustrated that age was a predictor for developing RAS (OR: 1.082; 95% CI: 1.016-1.153;  $p=0.014$ ), while topical lidocaine (OR: 0.064; 95% CI: 0.008-0.551;  $p=0.012$ ) and IV benzodiazepines (OR: 0.246; 95% CI: 0.065-0.933;  $p=0.039$ ) were significantly associated with reduction of RAS risk (Figure).

## Discussion

RAS prevention is of great interest. Several prophylactic approaches have been mentioned in literature, like NTG and verapamil have demonstrated effective vasodilator effects, and have been pointed out to be the most effective RAS preventive measure.<sup>17</sup> TRA is greatly limited by radial artery occlusion (RAO), which is mainly a thrombotic process, hence, use of anticoagulation is considered to eliminate such complications. Considering this, verapamil, NTG, and heparin were administered to all patients in the current study as the standard cocktail.

The study showed a RAS incidence of 18.3%. Most of the patients underwent successful access site cross-over. The reported frequency of RAS in trans-radial procedures ranges 4-20, and it was reported to be 15% in a systematic review comprising 7,197 patients from 19 different studies.<sup>18</sup>

In the current study, most RAS cases were in the control group. Significantly fewer RAS cases were found in the other groups, where midazolam and/or topical lidocaine were administered, with the least number of cases being from the topical lidocaine group.

The benzodiazepines-related reducing effect on the RAS occurrence is attributed to its well-known sedative and analgesic effect. They improve the haemodynamic status and prevention of arterial spasm.

In the current study, an evaluation of the adding value of topical lidocaine application prior to the procedure was done. The group treated with topical lidocaine in addition to the standard cocktail showed excellent outcome in terms of the least RAS and access site cross-over incidence, and the least pain VAS scores. The findings are consistent with the study of Tali et al, that demonstrated topical lidocaine's significant reducing effect on RAS incidence<sup>19</sup> Cutaneous lidocaine decreased the incidence of spasm and pain related to the radial artery.

In the current study, <sup>17</sup>(14.2%) patients required more than one attempt for radial artery cannulation. Multiple trials of puncturing the radial artery predispose to spasm and

haematoma. Patients who developed RAS showed significantly higher age, VAS scores, the incidence of multiple puncture requirements, and puncture time. Also, age was found to be a predictor for RAS in the the current study.

Regarding pain scores, several studies have addressed the importance of sedation for reducing procedure-associated pain. Woodhead et al. reported that periprocedural pain was significantly less likely in patients premedicated with diazepam.<sup>20</sup> Similarly, Beddoes et al.<sup>21</sup> and Ashraf et al.<sup>22</sup> observed superior patient comfort after oral diazepam. Deftereos et al.<sup>23</sup> observed that VAS scores were significantly lower in patients medicated with midazolam. Contradictory findings were reported by Alamri et al. who noted no difference in pain or anxiety in patients who were medicated with oral diazepam.<sup>24</sup>

Sedation agents, however, have their drawbacks, including paradoxical agitation, disorientation, cardiac and respiratory depression, and prolonged recovery time. The Society for Cardiovascular Angiography and Interventions (SCAI) Expert Consensus Statement on Best Practices in the Cardiac Catheterisation Laboratory (CCL) stated that sedation use should be avoided as far as possible in high-risk patients.<sup>25</sup>

A few studies evaluated the result of cutaneous lidocaine application on the incidence of RAS. Youn et al. demonstrated that the cutaneous lidocaine and prilocaine before TRA coronary angiography decreased pain, but did not reveal a statistically significant reduced RAS incidence.<sup>26</sup> However, the study did not use spasmolytic agents during the procedure. Cutaneous lidocaine decreased pain and spasm of the radial artery.

In the current study, cross-over was indicated in one case that had RA perforation caused by marked vessel tortuosity, and it was managed by elastic compression. Another case had marked right subclavian artery tortuosity during the manipulation of diagnostic catheter.

The failure rate in the current study was 8%. This is comparable to the 7.2% rate reported by Agostoni et al.<sup>27</sup> We think that this rate could decrease as the learning curve increases. In this context, Louvard et al. reported an initial rate of 10% that decreased to 3-4% after 500 patients, and then it stabilised at <1% after 1,000 patients.<sup>28</sup>

Our findings are congruent with earlier reports that the procedure time and the number of punctures are risk factors for developing RAS.<sup>29-30</sup> The results are also consistent with Gorgulu et al. who found that patients with RAS had higher mean age.<sup>31</sup> However, some other studies showed an inverse relationship between age and RAS<sup>32-38</sup>.



This difference is understandable in view of the wide variation of the RAS definition, the prophylactic protocol, and the procedure technique.

The present study showed other procedure-related complications, such as forearm haematoma managed by elastic compression and catheter trapping relieved by repeated IV NTG, verapamil and sedation.

To the best of our knowledge, the current study is the first to investigate the compare the use of topical lidocaine versus systemic midazolam in addition to the standard spasmolytic. In view of the potential adverse effects of IV midazolam, the use of topical lidocaine in addition to the standard spasmolytics is recommended to obtain a better outcome in TRA procedures. However, in view of the 30 minutes of time needed after topical lidocaine application, IV sedation is recommended in acute settings.

## Conclusion

Coronary interventions through TRA could be safe and feasible after proper medications to control RAS.

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**Conflict of Interest:** None.

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