Effect of Intravenous Fentanyl to Prevent Radial Artery Spasm During Trans Radial Intervention

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Abstract

Background: Radial artery spasm (RAS), one of the commonest complications in trans radial cardiac intervention, leads a variety range of adverse events. Different prevention strategies had been introduced and the use of sedation is one of them. Use of Fentanyl is common in cardiac interventions to achieve sedation and analgesia and also offers a potent vasodilatory effect.

Objective: This study aimed to explore the role of fentanyl in the prevention of RAS in trans radial intervention.

Methods: This observational analytic study was conducted in National Institute of Cardiovascular Diseases (NICVD) for a period of 1 year following approval of the protocol in the total of 260 patients who underwent coronary intervention through trans radial approach (Coronary Angiogram and or Percutaneous Coronary Intervention). They were categorized in 2 group- group I patients received intravenous fentanyl and group II patients didn't receive fentanyl. Besides this, each patient received all treatments according to standard protocol of NICVD. RAS was identified by subjective and objective evidence. Patient is discomfort was quantified with a visual analogue scale.

Results: The frequency of RAS was 17.70% in group I versus 30.80% in group II (p = 0.014). Intravenous use of fentanyl significantly reduced radial artery spasm (p < 0.05). Bivariate logistic regression analysis showed use of fentanyl had lower odds to prevent radial artery spasm (odds ratio [OR]: 0.430, 95% confidence interval [CI]: 0.239 to 0.779). The number needed to treat to avoid 1 case of spasm was 8. Multivariate logistic regression analysis also revealed use of fentanyl was the strong predictor of RAS ([OR]: 0.370; 95% [CI]: .195-.703) as well as use of reprocessed sheath, smoking, catheter diameter 6Fr and visual analogue scale (VAS) Score during cannulation became independent predictaor of RAS. Patient discomfort in VAS score was 4.75 \pm 2.70 in Group I versus 5.33 \pm 2.64 in group II (p < 0.05).

Conclusion: In this study, use of fentanyl reduced the frequency of radial artery spasm and the procedure related level of patient discomfort.

Key words: Radial artery spasm (RAS), Fentanyl, Coronary Intervention (CAG and or PCI)

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Introduction:

Cardiovascular disease (CVD) remains the most common cause of death worldwide. CAG is the gold standard method for the diagnosis and for establishing treatment strategies.¹

CAG can be performed via femoral, radial, brachial, ulnar or axillary arteries. Due to drawbacks of TFA, coronary procedure through trans-radial approach (TRA) has been adopted. Through the TRA the first CAG was performed by Lucian Campeau in 1989² and first PCI was performed in 1992 by Ferdinand Kiemeneij.³ The radial artery has become the preferred choice due to easy compressibility and distance from major veins and nerves, accompanying blood flow through the ulnar artery to the palmar arch, improved time to ambulation and shorter hospitalization duration,⁴ additional comfort to patient, lower hospital expenses,⁵ and improve clinical outcomes including survival by reducing potentially life-threatening complications. That's why TRA for coronary procedure is gaining momentum as an alternative. Although TRA in coronary intervention is well established, it has disadvantages too like somewhat challenging, difficult to master, and requires more learning curve.⁶ Trans-radial specific vascular complications are radial artery spasm (RAS), compartment syndrome, radial artery occlusion (RAO). Other complications of TRA include bleeding, hematoma, perforation, laceration, dissection, avulsion of artery, arteriovenous fistula, pseudoaneurysm, digital ischemia.⁷

RAS can be defined as a temporary, sudden, narrowing of the radial artery.⁸ It is usually diagnosed clinically and angiographically during cardiac intervention. The reported incidence of RAS during TRA ranged from 4% to 20%^{.9,10}

The big range in the rate of incidence could be accounted partly by different types of intraarterial vasodilatory cocktails used in different cardiac intervention laboratories. Predictors of spasm includes female gender, smaller wrist circumference, lower body mass index, tobacco abuse, vaso occlusive disorder, ad hoc coronary interventions, >2 catheters during a procedure, >6 French catheters, smaller intra-luminal radial artery diameter, operator inexperience, traumatic puncture, radial artery to sheath ratio <1, increased procedure duration and radial artery anatomic anomalies¹¹ and catheter properties, including coating and length.¹²

Fentanyl, a potent synthetic μ receptor– stimulating opioid, has become one of the most used drugs for both procedural analgesia and sedation in patients undergoing CAG and or PCI. Routine administration of relatively low doses of an opioid and benzodiazepine combination during trans-radial interventional procedures is associated with a substantial reduction in the rate of spasm, the need for access site crossover, and the procedure-related level of patient discomfort. The absence of peri-and post-procedural complications represents the starting point of future research about preventive use of fentanyl not only for sedation purposes but also to prevent arterial spasm. The present study was conducted to find out the efficacy of fentanyl to prevent RAS during trans radial intervention.

Study Methods:

This prospective observational analytic study was conducted in NICVD from January, 2020 to December, 2020 on patients who underwent coronay procedure through TRA with positive modified Allen's test. Objective of the study was evaluation of the efficacy of intravenous fentanyl during trans radial coronary intervention to prevent the radial artery spasm. Patient with history of radial and/or ulnar artery injury and surgery, acute heart failure, congestive cardiac failure, cardiogenic shock, end stage renal disease having arterio-venous fistula or planned for making arterio-venous fistula, known peripheral arterial disease of upper limb, non palpable radial artery/ipsilateral ulnar artery, prior CABG surgery using radial artery, abnormal liver function test and chronic opioid and benzodiazepine use were excluded from the study. RAS was the dependent and use of fentanyl was the independent variable.

Radial artery spasm (RAS)¹³: Clinical RAS

The operator assessed RAS on the basis of a questionnaire addressing the following five sign

- · Persistent forearm pain,
- · Pain response to catheter manipulation,
- Pain response to sheath insertion and withdrawal,
- Difficult catheter manipulation after being "trapped" by radial artery,
- Considerable resistance on withdrawal of the sheath.

Patients who had at least 2 of the 5 signs or by the presence of just 1 when it is necessary to administer a second dose of spasmolytic agent were diagnosed as clinical RAS.

Angiographic RAS

- Angiographic RAS was divided into mild (<30%), moderate (30%–70%) and severe (>70%) spasm by radial artery angiography. Moderate and severe spasm were defined as angiographic RAS.
- The diagnostic criterion was the combination of clinical and or angiographic RAS. RAS was diagnosed by at least two experienced operators.

A total of 260 patients were enrolled in this study according to inclusion and exclusion criteria among 260 patients. 130 patients were included in group I and 130 patients were included in group II. After reviewing the most current vital signs, only the group I patients were given 25 microgram IV fentanyl slowly over 2 minutes at the beginning of the procedure (during preparation of the access site). One additional dose was allowed 60 min after the first one. Selection of patient of this group was done by opertaor's own discretion. Arm rest was provided with the table, so that the patients arm was in abduction. A 500 ml plastic sachet of normal saline was placed on the armrest beneath the wrist to elevate the wrist. The hand was then fixed in hyperextension with adhesive tape, prepared in a sterile fashion and the draped positioned. Pre-procedure ipsilateral radial pulse strength (0-4+) was documented for all (4+ Bounding, 3+ Increased, 2+ Normal, 1+ Weak, 0+ Absent or nonpalpable). Vitals signs were checked every 30 minutes (±10 minutes) after application of the intravenous fentanyl for 60 minutes (± 10 minutes) then every 60 minutes (± 10 minutes) up to the end of the procedure in all patients. The respiration and oxygen saturation of the patient were constantly monitored by a dedicated interventional trained nurse. Angiographic views of radial artery obtained just after sheath insertion

and just before sheath withdrawal or any time during difficulties in wire and catheter manipulation for patients of both groups. After sterile preparation, 0.5 - 1.0 ml of subcutaneous lidocaine was administered and radial artery was cannulated using modified seldinger technique with help of vasofix and intraarterial line was established by 6Fr vascular access sheath. Parenteral radial cocktail (Intra arterial 200 microgram GTN + intra arterial 2.5mg verapamil) was given with exact combination and dose at direction of operator based on patient's hemodynamic status. Repeat use of parenteral radial cocktail was made when there was difficulty in moving catheters, when patients complained of persistent forearm pain, and when operators found resistance during catheter and vascular access sheath introduction as well as withdrawal. Along with that 5,000 unit of unfractionated heparin for CAG and 10,000 unit of unfractionated heparin for PCI were administered during the procedure in the contralateral hand. During PCI activated clotting time (ACT) values were kept between 250-300 sec with additional heparin if needed. Over the 0.032inch exchange wire, the diagnostic catheter (most commonly Tiger catheter) was advanced to the ascending aorta using fluoroscopic guidance to do CAG. Judgkin Right (JR)/Judgkin Left (JL)/ Extra Back Up (EBU) guide catheter were used in cases of PCI. The choice of guidewires and catheters was made by the operator. Parameters were documented. When difficulty was encountered in advancing the wire from the subclavian artery to the ascending aorta, the patient was asked to take a deep breath. The radial artery sheath was removed immediately after completion of procedure, and haemostasis was achieved by conventional hemostatic method with rolled gauge and leucoband. Conventional haemostatic compression was removed when adequate hemostasis was achieved usually after two hours. Patient's perceived peri-procedure forearm discomfort documented in the morning after the procedure with a visual analogue scale (VAS) whereby patient graded the discomfort on a scale of 0 to 10 (0 corresponding to "no discomfort" and 10 to "extreme pain and discomfort"). Post-procedure strength of ipsilateral radial pulse (0-4+) after radial band removal and presence and size of hematoma at access site at time of radial band removal were documented. All data were collected through a structured questionnaire.

Statistical Methods:

The Statistical Package for Social Sciences (SPSS) version 21 software was used for data analysis. Categorical variables were expressed as absolute number and percentages and continuous variables as mean and standard deviation. Categorical variables were compared through chi-square test. Continuous variables were compared through unpaired student t test. Univariate logistic regression analysis as well as multivariate regression analysis was done to identify the predictors of RAS. A pvalue < 0.05 was considered statistically significant.

Results:

Majority of the respondents were in age group 41-50 years old (33.8% in group I and 38.5% in group II) with a mean age of 56.21 ± 7.17 and 55.55 ± 7.32 (SD). No statistical difference was observed between two groups (p=0.457). Majority of the patients were male (63.10% in group I and 73.10% in group II). No statistical difference was observed between both group (p=0.08). In group I, 51.50% underwent Percutaneous Coronary Intervention (PCI) and 49.50% underwent Coronary Angiography (CAG). In group II, 50.80% patients underwent PCI and 49.20% patients underwent CAG.

No statistical difference was observed between group I and group II considering procedure performed (p=0.901). Presenting risk factors among study population were in descending order hypertension (91.9%), dyslipidemia (49.3%), diabetes mellitus (37.7%), active smoking (21.9%), renal dysfunction (15%), peripheral artery disease (14.6%) and family history of CAD (12.30%). Two group did not have any significant statistical difference (p > 0.05) considering coronary artery disease risk factors. No statistical difference was observed between two groups (p > 0.05) in relation with BMI, height and weight. Mean BMI in Group I was 25.86±2.87 and Group II was 25.82±2.66. In 91.9% of patients, right radial artery access was used and left radial artery access was used in 8.1% of patients with no statistical difference. Mean VAS score during cannulation was 4.75±2.70 and 5.33±2.64 among group I and group II accordingly. Pain score was significantly less (p=.046) in group I patients. Self-reported patient discomfort was significantly lower in group I. Spasm was, expectedly, strongly associated with higher patient discomfort. About 10.76% of patients had anatomical anomaly, and 9.61% had subclavian tortuosity with similar distribution in both groups. No. of catheter was ≤ 2 in 71.2% of patients and catheter diameter was 5 France in 51.53% of patients and no significant difference was observed between two groups. New sheath was used in 45.76% and re processed sheath was used in 54.23% of patients with similar distribution in both groups. Post dilatation mean arterial pressure was similar in both groups.

	Group I	Group II	Total	p value
Access				
Right radial artery*	122 (83.8)	118 (90)	239 (91.9)	.255!
Left radial artery*	8 (6.2)	13 (10)	21 (8.1)	
VAS score of pain	4.75±2.70	5.33±2.64	5.10±2.56	.046!!
during cannulation**				
Anatomical anomaly*	15 (11.53)	12 (9.23)	28 (10.76)	.472!
Subclavian tortuosity*	16 (12.30)	9 (6.92)	25 (9.61)	.323!
No. of catheter*				
≤2	99 (76.2)	86 (66.2)	185 (71.2)	.075!
>2	31 (23.8)	44 (33.8)	75 (28.8)	
Catheter diameter*				
5	68 (52.30)	66 (50.76)	134 (51.53)	.451
6	62 (47.70)	64 (49.24)	126 (48.47)	
Baseline MAP** (mmHg)	95.39±3.83	95.59±3.78	95.48±3.80	.421!!
Used sheath*				
New sheath	58(44.61)	61(46.92)	119 (45.76)	
Re-processed sheath	72(55.38)	69(53.07)	141(54.23)	.643!
Postdialation MAP** (mmHg)	86±3.42	85.56±3.07	85.82	.231!!
Length of procedure* (Min)				
≤30 minute	39 (30)	25 (19.2)	64 (24.6)	.044!
>30 minute	91 (70)	105 (80.8)	196 (75.4)	
Mean±SD	46.42±13.13	50.31±12.90	52.30±8.45	.017!!
Arterial prick before arterial access				
Single	60 (46.2)	56 (43.1)	116 (44.6)	
Multiple	70 (53.8)	74 (56.9)	144 (55.4)	.618!

 Table-I

 Features of procedure underwent among study population:

The procedure was statistically significantly lengthy in group II patients (p=.017). Single arterial prick in group I and group II were 46.2%% and 43.1% respectively. There was no significant statistical difference observed regarding single or multiple arterial prick in between two group (p = 0.618). In group I & II, 23 &40 patients had RAS respectively. The frequency of radial artery spasm was significantly higher (30.80%) in group II versus group I (17.70%) (p=0.014). Absolute Risk of RAS in Group I and II was 0.177 and 0.308 respectively. Aboslute Risk Reduction or Risk Difference of RAS = 0.308-0.177 =0.131. So, addition of fentanyl will reduce 13% more RAS than standard protocol. NNT (Number of patients needed to treat): 1/0.131 = 7.63 = 8. So, number needed to treat to avoid 1 case of RAS was 8. Staistically significant difference was observed regarding severity of RAS in between 2 group (p = .016). Group II patients had more severe radial artery spasm. Group II patients needed more frequent usage of spasmolytic cocktail than group I. In group I, 12.30% required repeat use of spasmolytic cocktail. In group II, 22.30% required repeat spasmolytic cocktail. Group II required statistically more repeat use of spasmolytic cocktail (p =.003). Odds ratio of risk factors for occurrence of radial artery spasm (RAS) in the study population by bivariate logistic regression showed not using of fentanyl [OR .430,95% CI (.239-.779), p<.05], PCI as procedure [OR 2.614, 95% CI (1.448-5.714), p<.05], female gender [OR 2.654, 95% CI (1.470-4.791), p<.05], diabetes mellitus [OR 16.724, 95% CI (7.866-35.560), p<.05], dyslipidemia [OR 4.680,95% CI (2.454-8.927)], use of reprocessed sheath [OR 2.780, 95% CI (1.262-5.038), p<.05], VAS score during cannulation [OR 11.077, 95% CI (4.031-21.1950), p<.05], catheter number >2 [OR 9.133, 95% CI (3.990-9.829), p<.05], catheter diameter (6Fr) [OR 2.073, 95% CI (1.016-3.855), p < 0.05], multiple arterial prick [OR 2.516, 95% CI (1.403-2.532), p<.05], decreasing height of patient [OR .857, 95% CI (.773-.953), p<0.05] and increasing duration of procedure [OR 6.657, 95% CI (1.584-9.740), p<.05] had significantly higher odds for occurring radial artery spasm.

Risk Factors	OR	95% CI	p value*
	Lower limit-Upper limit		
Use of IV Fentanyl	.370	.195703	.002
Type of procedure (PCI)	.838	.498-1.412	.508
Female gender	1.204	.706-2.054	.495
Diabetes Mellitus	1.029	.548-1.932	.929
Smoking	2.230	1.073-4.633	.032
Dyslipidemia	1.204	.706-2.054	.495
Catheter number >2	1.338	.515-3.476	.549
Catheter diameter 6Fr	1.938	1.118-1.99	.048
Increasing VAS score during cannulation	1.988	1.825-2.183	.018
Duration of procedure	1.008	.981-1.035	.566
Use of reprocessed sheath	1.181	1.349-4.121	.024
Height	.691	.552-1.231	.072
Multiple arterial prick	4.430	.756-25.922	.099

 Table-II

 Predictor of RAS in study population

Not using of fentanyl [OR .370, 95% CI (.195-.703), p<0.05], catheter diameter 6Fr [OR 1.938, 95% CI (1.118-1.99), p<.05], use of reprocessed sheath [OR 1.181, 95% CI (1.349-4.121), p<.05], smoking [OR 2.230, 95% CI (1.073-4.633), p=.032] and VAS score during cannulation [OR 1.988, 95% CI (1.825-2.183), p<0.05] were independent predictors of radial artery spasm by multivariate logistic regression analysis.

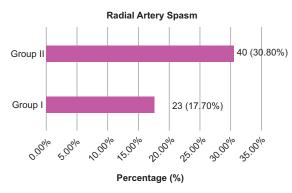


Fig.-2: Frequency of radial artery spasm

Discussion:

The principle finding of this prospective observational analytic study is the reduction in the frequency of radial artery spasm by administration of opioid analgesia during trans radial coronary intervention. This resulted in significant decrease in patient discomfort as well as access site crossover rate. Mean age of the study population was of 55.88±7.22 (SD) years with a majority in age group 51-60 years old. Clear male predominance was observed in both groups. No statistical difference was observed between two groups regarding age and gender distribution (p > 0.05). Shimu¹⁴ observed similar age and gender distribution. Mean BMI was 25.86±2.87 kg/m2 in group I and 25.82±2.66 kg/m 2 in group II patients which correlate with the findings of the study. Mean height was 162.33±4.62cm in group I and 162.82±4.50cm in group II. p valve was not significant between two groups considering BMI and height (p>0.05). In this study, 51.5% of group I and 50.80% of group II patients underwent PCI. No significant statistical difference noted between two groups (p > 0.05). In both groups, majority patients' access was right radial artery (91.9%). Anatomical anomaly and subclavian tortuosity were found in 11.53% and 12.30% of group I patients and 10% and 7.5% of group II patients. Average anatomical anomaly was 10.76% which was similar to the study by Hassan¹⁵ where rate was 12.6%. More than 2 catheters were used in 23.8% of group I patients and 33.8% of group II patients. No significant difference was observed between two groups regarding the use of number of catheters. New sheath was used in 45.76% and reprocessed sheath was used in 54.23% of patients with similar distribution in both groups. Length of procedure was 46.42±13.13 min in group I patients and 50.31±12.90 minutes in group II patients. The procedure was statistically significantly lengthy in group II patient (p 0.017). VAS scale pain score was 4.75 ± 2.70 in group I and 5.33 ± 2.64 in group II which was significantly less in group I patients (p 0.046). Self-reported patient discomfort was significantly lower in Group I. Spasm was, expectedly, strongly associated with higher patient discomfort. In group I, 12.30% required repeat use of spasmolytic cocktail. In group II, 22.30% required spasmolytic cocktail. Group II patients needed more frequent usage of spasmolytic cocktail than group I (p 0.003). Multiple arterial prick was 53.8% in group I and 56.9% in group II with no significant difference (p 0.618). There was no significant statistical difference between the number of 5Fr and 6Fr catheter (p = .128) use.

The frequency of radial artery spasm was 30.80% in group II patients and 17.70% in group I patients. Negative association was found between radial artery spasm and use of fentanyl (p 0.014). Patients' discomfort and pain was also significantly less among patients who received IV fentanyl. The number needed to treat (NNT) to avoid 1 case of spasm was 8. Addition of fentanyl will reduce RAS 13% than standard treatment protocol. Deftereos¹⁶ found that NNT to avoid 1 spasm was 18 which was higher. They found spasm occurred in 2.6% patients of the treatment group versus 8.3% in the control group and RAS was labelled only by subjective measures. In this study, both subjective and or objective evidence were used to define RAS. So, the incidence of RAS was higher in both groups than the study done by Deftereos.¹⁶

Deftereos¹⁶ observed combined use of fentanyl and midazolam reduced radial artery spasm during coronary procedure through trans radial access. Minghui¹⁷ also observed significantly reduced radial artery spasm in coronary procedure through trans radial access. There is a hypothesis that spasm can be triggered by stress and pain, pre-medication with sedatives is being used but the effect of routine administration of sedation and analgesia on the incidence of radial artery spasm has not been systematically evaluated.⁸ Radial artery spasm complicates and prolongs the procedure, frustrates the interventionalist, increases the possibility of subsequent radial artery closure, aggravates patient discomfort & pain and nullifies the advantages of the trans radial approach. In this study use of fentanyl showed significant reduction of radial artery spasm.

In bivariate logistic regression analysis, not using of fentanyl was observed having 4.3 times higher odds for occurring radial artery spasm in this study. PCI as procedure [OR 2.614, 95% CI (1.448-5.714), p<0.05],

female gender [OR 2.654, 95% CI (1.470-4.791), p<0.05], diabetes mellitus [16.724, 95% CI (7.866-35.560), p<0.05], dyslipidemia [OR 4.680,95% CI (2.454-8.927)], use of reprocessed sheath [OR 2.780, 95% CI (1.262-5.038), p<0.05], VAS score during cannulation [OR 11.077, 95% CI (4.031-21.1950), p<0.05], catheter number >2 [OR 9.133, 95% (3.990-9.829), p<0.05], catheter diameter (6Fr) [OR 2.073, 95% CI (1.016-3.855), p < 0.05], multiple arterial prick [OR 2.516, 95% CI (1.403-2.532), p<0.05], decreasing height of patient [OR .857, 95% CI (.773-.953), p<0.05] and increasing duration of procedure [OR 6.657, 95% CI (1.584-9.740), p<0.05] had significantly higher odds for occurring radial artery spasm. Deftereos, et al., (2013) also did a univariate analysis and patients with shorter stature and lower body mass index were more prone to spasm along with female sex and smoking as also predisposing factors. They also found that spasm was more frequent in patients undergoing combined coronary angiography and PCI procedures and multiple number of catheter used/procedure. Increased duration of the procedure had higher odds for radial artery spasm. These findings corroborate with present study observation.

In multivariate logistic regression analysis, Not using of fentanyl [OR .370,95% CI (.195-.703), p<0.05], catheter diameter 6Fr [OR 1.938, 95% CI (1.118-1.99), p<0.05], use of reprocessed sheath [OR 1.181, 95% CI (1.349-4.121), p<0.05], smoking [OR 2.230, 95% CI 1.073-4.633, p=.032] and VAS score during cannulation [OR .988, 95% CI (.825-1.183), p<0.05] were significant predictors of radial artery spasm. In the multivariate analysis, where the occurrence of spasm was entered as the dependent variable, the independent association of treatment with the incidence of spasm was tested after accounting for sex, height, diabetes mellitus, smoking, multiple arterial prick, number of catheter used/ procedure, procedure type (CAG and or PCI), use of reprocessed sheath and procedure duration. Deftereos¹⁶ also did multivariate analysis and found that patients with active smoking, short stature and low body mass index were more prone to spasm along with female gender. They also observed spasm was more frequent when number of catheter used was multiple and combined coronary angiogram and PCI was done. They denoted that the administration of sedation and analgesia was independently associated with a marked reduction in the incidence of spasm (multivariate hazard ratio: 0.140, 95% CI: 0.073-0.271; p<0.001). These findings also corroborate with present study observation.

Present study indicates that use of fentanyl reduces radial artery spasm among patients undergoing coronary intervention. Pre-medication with oral benzodiazepines has been introduced aiming to reduce spasm during arterial catheterization, but the effect of routine administration of analgesia on the incidence of radial artery spasm is still under-evaluated. So, the routine administration of analgesia in patients undergoing elective coronary intervention may led to a significant reduction in spasm occurrence.

Limitations:

All samples were collected from a single center (NICVD). Sample size was not representative to generalize the findings. Spasm cannot be always defined with objectivity. Definition used in study was quite restrictive because it required angiographic confirmation. Some patient subgroups were excluded. Findings might not apply to other sedative medications. The respondents who underwent CAG followed by PCI were generally considered as PCI procedure. Selection of the patients were operator's choice. Preprocedural duplex USG of radial artery was not done.

Conclusion:

In this study, use of fentanyl reduced the frequency of radial artery spasm and the procedure related level of patient discomfort.

Recommendation:

Radial artery spasm (RAS) is one of the obstacles of successful trans radial intervention. Some preventive measures could reduce the incidence of RAS including preoperative intravenous fentanyl. Strategies to prevent RAS and preserving radial artery should start from the patient selection with considering predictors of RAS. More similar studies are needed for strengthening the finding of our study. However, the result of this study needs further confirmation in a randomized large scale multi centre prospective cohort study.

Conflict of Interest:

None.

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