Short sheath benefit in radial artery injury after PCI – optical coherence tomography serial study

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Background and Aims. Transradial catheterization is the predominant access site for coronary catheterization and percutaneous coronary interventions (PCI). Previous studies have reported a high incidence of radial artery (RA) injury. The aim of this investigation was to evaluate the incidence of RA injury using last generation optical coherence tomography (OCT) intravascular imaging in a serial manner.
Methods. 100 patients with a diagnosis of non-ST-elevation myocardial infarction (nSTEMI) treated by PCI were enrolled. OCT of RA was performed immediately after the index PCI. OCT was repeated 9 months later.
Results. There were 11 patients with RA injuries (11.0%) at baseline, including 3 patients with RA medial dissection and 8 patients with intimal tears. In the follow-up OCT data, the number of RA injuries was 10 (10.0%), including 7 patients with RA medial dissection and 3 patients with intimal tear. All injuries were clinically asymptomatic and there was no finding of vessel perforation. There was no significant difference between the baseline and follow-up procedure in terms of number of injuries.
Conclusion. The study showed no significant difference between baseline and follow-up RA injury incidence. There was a higher risk of radial injury for repeated catheterization in women. The conclusion is that radial catheterization is a very safe procedure in terms of radial artery damage. This is evidenced by considerably fewer injuries compared to published studies. The use of the short radial sheath (7 cm in this study) is protective and reduces the incidence of radial injury.

Key words: optical coherence tomography, radial artery, injury, introducer

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INTRODUCTION

Transradial catheterization (TRC) has become increasingly popular in the interventional cardiology community in the last decade. The first TRC was performed by Campeau in 1989 (ref.[1]) and the first coronary stent was implanted via radial artery by Kiemeneij and Laarman in 1993 (ref.[2]). After more than two decades, the rate of transradial access (TRA) for percutaneous coronary interventions (PCI) is shown to be considerably higher than transfemoral access in many centers. However, the preference for radial artery (RA) as a catheterization access site is more common in Asia and Europe than in USA (ref.[3,4]). Compared to the femoral artery, RA access is followed by lower rates of complications including bleeding[5] and even lower mortality rate[6]. TRA has some disadvantages: due to the anatomical specifications, the RA has a smaller diameter than the femoral artery in the typical patient[3] and is more prone to injury during the procedure.

Previous studies investigated RA after TRC using either intravascular ultrasound (IVUS) (ref.[7]) or time-domain optical coherence tomography (OCT) (ref.[8]). Most authors reported an alarming incidence of radial artery damage, albeit most of the radial injuries were subclinical. We aimed to perform the first prospective serial OCT study of radial artery damage after transradial PCI in consecutive patients who had experienced their first-in-life TRC. A frequency-domain OCT (FD-OCT) was performed at the end of the index PCI procedure and 9 months later. We used serial OCT imaging to capture the injury incidence both in native vessel and then in the RA used for the intervention 9 months previously.

FD-OCT uses near-infrared light spectra for tissue imaging. The spatial resolution is close to 10 microns[9] but the method is limited by light tissue penetration. For RA vessel wall imaging (Fig. 1), OCT is currently the best option for assessing discreet changes in intimal and medial layer injuries. During the FD-OCT recording, the vessel has to be continuously flushed, usually with a 100% contrast fluid to clean the optical environment of blood cells and allow light to pass through. The standard data acquisition speed is 18 mm per second which allows for high resolution data from the vessel in 3 s (for the usual 54 mm record length).

METHODS

100 consecutive patients were included in the project as a part of larger group of patients (140 subjects) enrolled into a study focusing on OCT analysis of the coronary vessels in patients with the diagnosis of myocardial infarction without ST segment elevation (nSTEMI). The inclusion criteria were as follows: patients with a diagnosis of nSTEMI, indication for the first-in-life transradial coronary catheterization and the PCI had to be performed during the index procedure. Exclusion criteria were myocardial infarction with ST segment elevation (STEMI), left main coronary artery lesion, renal insufficiency with a creatinine level above 150 umol/L, acute heart failure symptoms, coronary anatomy compromising the ability to perform the OCT procedure and refusal to sign the informed consent. All patients had to provide written informed consent to the study which was approved by the local Ethics Committee. The protocol conformed to the ethical guidelines of the latest Declaration of Helsinki.

The average age of the group was 66.4. More men (67.0%) than women were enrolled. The baseline characteristics of the patient population are shown in Table 1.

Coronary angiography and PCI procedure

Cardiac catheterization was performed according to the local medical standards in the 24/7 tertiary PCI center. The center has wide experience with transradial catheterizations and interventions with a 97% rate of transradial procedures in 2014. All the procedures were performed via 6F Radiofocus Introducer II kit (Terumo, Japan) with an intravascular sheath length of 7cm. The RA was punctured with the kit according to local standards. A vasodilating drug (typically 2.5 mg of verapamil) was administered. 6F guide catheters were used for the coronary procedures. Clinical signs of radial artery injury were recorded during and after the procedure.

Table 1. Baseline characteristics.

		n (%)
Gender	Man	67 (67.0)
	Woman	33 (33.0)
Age	(n=100)	66.4 (45.0; 80.2)*
BMI	(n=96)	28.2 (23.1; 37.1)*
Hypertension		68 (68.0)
Dyslipidemia		34 (34.0)
Diabetes mellitus		35 (35.0)
Peripheral vasculopathy		4 (4.0)
Smoking	Smoker	28 (28.6)
	Former smoker	29 (29.6)
	Never smoked	41 (41.8)
Alcohol addiction	≥ 1 drink/week	15 (15.3)
	≥ 1 drink/month	33 (33.7)
	< 1 drink/month	50 (51.0)
Creatinine (μmol/L)	(n=84)	87.5 (52.0; 118.0)*

*(5th – 95th percentile)

OCT procedure protocol

After the index coronary angiography and subsequent PCI, OCT of the RA was performed. The standard coronary wire and OCT catheter were placed in the radial artery through the 6F guiding catheter and the guiding catheter was retrieved from the radial sheath. The sheath itself was shifted 3cm out of the artery (distally), remaining inside the RA with a length of 4 cm. An X-ray contrast ruler was used to navigate the OCT start to a distance 8cm proximal to the actual sheath tip position. From that point, OCT pullback recording was performed, using a 100% contrast fluid to flush the vessel. The length of the pullback was 54 mm. (Fig. 2) We used the Dragonfly Duo catheter and Optis Ilumien OCT system (St.Jude, MN, USA) to perform the OCT procedure. The puncture site was covered with a compress band for two hours to allow hemostasis after the procedure.

The procedure was repeated 9 months after the index catheterization, using the same protocol as described above.

The radial artery OCT was well tolerated by patients despite a general mild discomfort in the forearm during the contrast fluid flush. There were no clinically significant adverse events related to the RA OCT procedure.

OCT analysis

OCT records were analyzed offline manually by two experienced OCT analysts. The vessel injury was divided into 3 groups: intimal tear, medial dissection and vessel perforation. The intimal tear was characterized as a vessel wall disruption, involving only the intimal layer which had a 3D-spatial coherence (cross-sectional picture and longitudinal continuity). The medial dissection involved medial layer of the vessel wall with the same spatial conditions. Vessel perforation was characterized by complete loss of vessel wall continuity with fluid leak into the interstitial tissue space (Fig. 3).

Statistical analysis

Standard descriptive statistics included absolute and relative frequencies for categorical variables and median with 5th-9th percentile range for continuous variables. The statistical significance of differences in the incidence of the radial artery injuries was tested using Fisher's exact test and McNemar's test. We considered $P < 0.05$ as statistically significant. We used the SPSS 22.0.0.1 (IBM Corporation, 2014).

RESULTS

In the baseline OCT records, we found overall 11 RA injuries (11.0%), consisting of 3 patients with RA medial dissection and 8 with intimal tears. In the follow-up OCT data, we found 10 RA injuries (10.0%), consisting of 7 patients with RA medial dissection and 3 patients with intimal tear. There was no vessel perforation found in the group. The difference between the baseline and follow-up procedure injuries incidence was not significant (P = 0.999) (Fig. 4, Table 4)

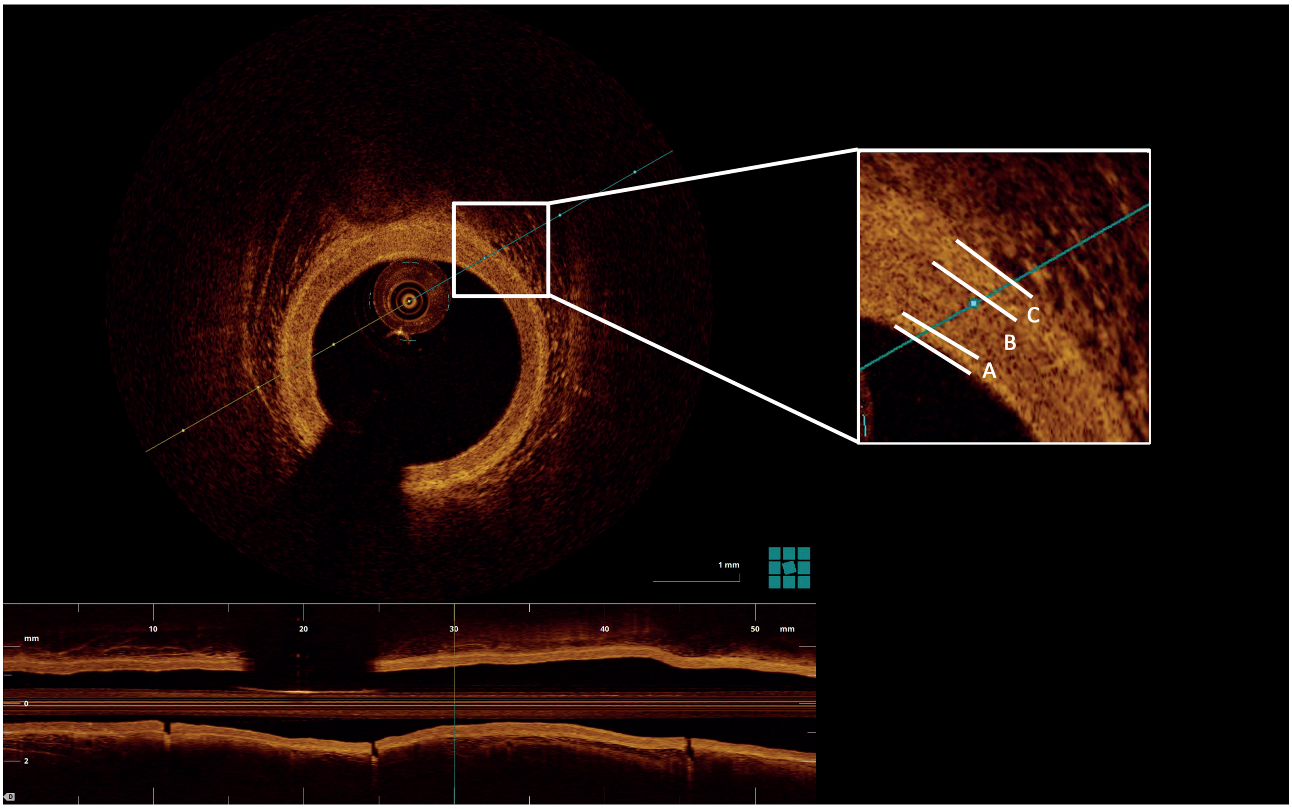

Fig. 1. Representative OCT crossection of normal radial artery. A-intimal layer, B-media, C-adventitia

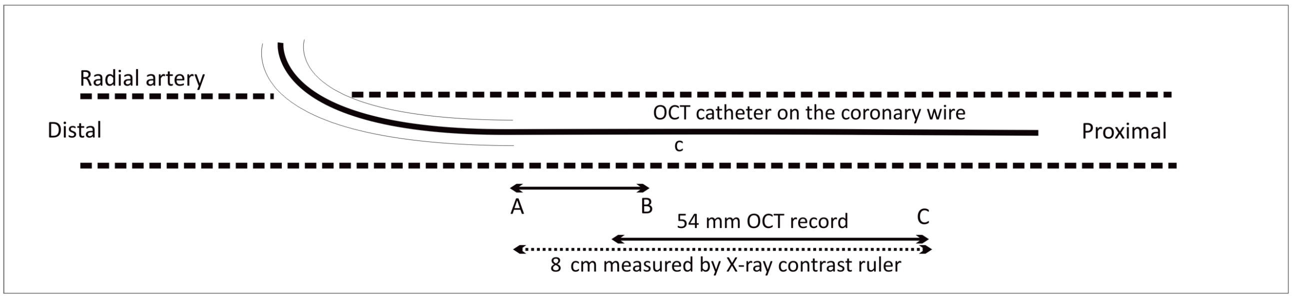

Fig. 2. Optical coherence tomography of RA – procedure scheme.
A-Sheath tip position during the OCT procedure, B-Original sheath tip position during the PCI, C-Start position of the OCT probe

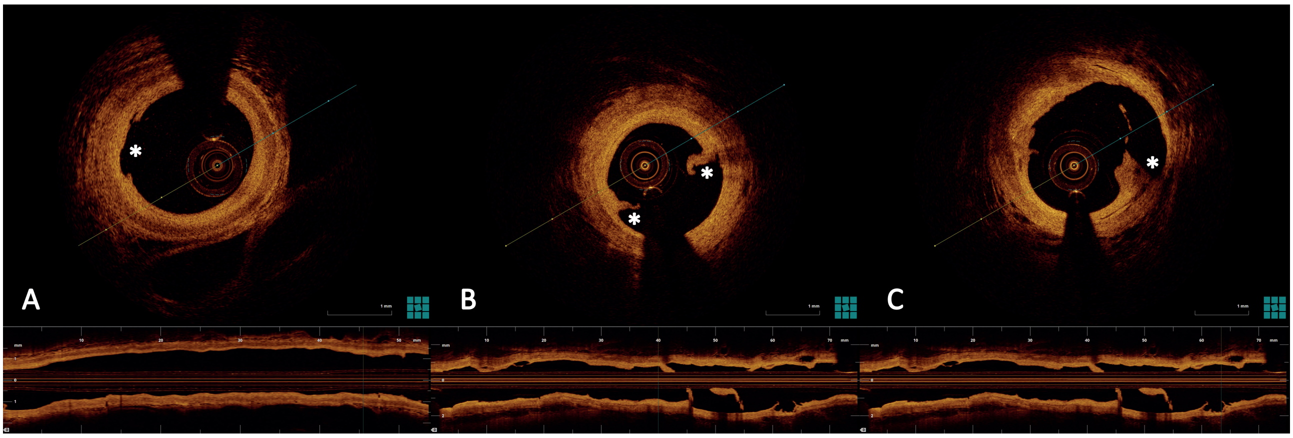

Fig. 3. Representative OCT pictures of radial artery injuries. A-intimal tear, B-medial dissection, C-perforation. Pathology marked by asterisk(s) in every crossection

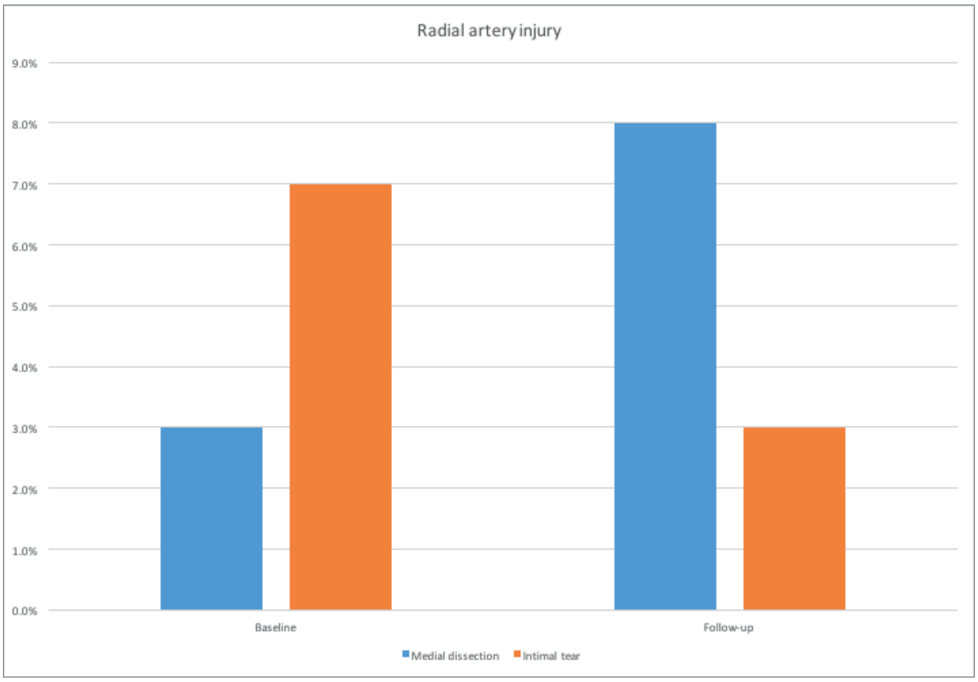

Fig. 4. Injury distribution.

Table 2. Radial artery injuries in baseline and follow-up examination.

		Follow-up injury			
		No (%)	Yes (%)	Total (%)	*P*
Baseline injury	No	81 (81.0)	8 (8.0)	89 (89.0)	0.302
	Yes	9 (9.0)	2 (2.0)	11 (11.0)	
	Total	90 (90.0)	10 (10.0)	100 (100.0)	

For the patients who experienced RA dissection in the baseline procedure, there was no higher probability of RA being injured in the follow-up, either (Table 3).

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Analysis of multiple factor effects on baseline RA injury incidence was performed (gender, age, body-mass index, risk factors and creatinine level). In the follow-up procedures, women and patients with low BMI had significantly more RA injuries. (Table 4). No other significant risk factor associated with intimal injury was identified.

No patients developed any clinical symptoms of radial artery injury, either in baseline, or in follow-up procedures.

DISCUSSION

This is the largest group of patients ever investigated by serial OCT for radial injuries after TRC to the best of our knowledge. Previous studies in this field never used serial imaging in the same patients. In 2008, Burris et al. first used OCT to analyze cadaverous radial artery after endoscopic and open harvesting to evaluate graft quality[10]. Brazio et al. used OCT in the same year to quantify endothelial injury and vasospasm of the radial graft as a promising intraoperative quality assurance tool during the surgery[11]. The first and largest to date study investigating RA injury in vivo was conducted by Yonetsu et al. in 2010 (ref.[8]), on 69 patients, divided into first and repeat -TRC group according to the history of previous catheterization.

Table 3. Radial artery dissection in baseline and follow-up examination.

		Follow-up dissection			
		No (%)	Yes (%)	Total (%)	*P*
Baseline dissection	No	90 (90.0)	7 (7.0)	97 (97.0)	0.999
	Yes	3 (3.0)	0 (0.0)	3 (3.0)	
	Total	93 (93.0)	7 (7.0)	100 (100.0)	

Table 4. Radial artery injuries.

			Radial artery injury		
		n	Baseline	Follow-up	*P*
Total		100	11 (11.0%)	10 (10.0%)	0.999
Gender	Man	67	8 (11.9%)	3 (4.5%)	0.227
	Woman	33	3 (9.1%)	7 (21.2%)	0.219
Age	< 60	32	3 (9.4%)	2 (6.3%)	0.999
	60-69	38	2 (5.3%)	3 (7.9%)	0.999
	≥ 70	30	6 (20.0%)	5 (16.7%)	0.999
BMI	< 25	13	0 (0.0%)	4 (30.8%)	0.125
	25-29	50	7 (14.0%)	5 (10.0%)	0.727
	≥ 30	33	4 (12.1%)	0 (0.0%)	0.125
Hypertension	Yes	68	7 (10.3%)	7 (10.3%)	0.999
	No	32	4 (12.5%)	3 (9.4%)	0.999
Dyslipidemia	Yes	34	3 (8.8%)	4 (11.8%)	0.999
	No	66	8 (12.1%)	6 (9.1%)	0.774
Diabetes mellitus	Yes	35	4 (11.4%)	4 (11.4%)	0.999
	No	65	7 (10.8%)	6 (9.2%)	0.999
Peripheral vasculopathy	Yes	4	1 (25.0%)	0 (0.0%)	0.999
	No	96	10 (10.4%)	10 (10.4%)	0.999
Smoking	Smoker	28	4 (14.3%)	3 (10.7%)	0.999
	Former smoker	29	5 (17.2%)	1 (3.4%)	0.219
	Never smoked	41	2 (4.9%)	6 (14.6%)	0.125
Alcohol addiction	≥ 1 drink/week	15	2 (13.3%)	1 (6.7%)	0.999
	≥ 1 drink/month	33	3 (9.1%)	3 (9.1%)	0.999
	< 1 drink/month	50	6 (12.0%)	6 (12.0%)	0.999
Creatinine	< 100 µmol/L	65	8 (12.3%)	6 (9.2%)	0.754
	≥ 100 µmol/L	19	1 (5.3%)	3 (15.8%)	0.625

Intimal tears were observed in 49 RAs (67.1%) and medial dissections were found in 26 RAs (35.6%). The frequency of acute injury was significantly higher in repeat-TRI RAs ($P < 0.001$). In the Yonetsu's study, 16 cm radial sheath and older Time domain-OCT technology was used. The last available study was performed by deVito et al. in 2014 (ref.[12]). Intimal tears were detected in 37% of patients, medial dissections were described in 9.8%. The study included 51 patients, divided into first and repeat -TRC group as well. They used even longer (25 cm) sheaths and FD-OCT technology.

As Yonetsu et al. found most of the injury in the proximal part of the RA in the forearm, we focused on this region. Our study showed very few radial injuries and a much lower rate than the published data. We believe that the short sheath is one of the factors that favor vessel safety. However, without a randomized trial, we cannot confirm our results. However, overall we showed that transradial catheterization and PCI is an extremely safe procedure, especially using vasodilatation and a short sheath.

Limitations

The study is limited by lack of a control group: This was unavoidable: The investigation was based on patients after PCI for acute coronary lesion and no control group with no PCI was possible under these circumstances. Multiple OCT pullbacks and evaluation of longer RA segments could have been used. To maintain amount of contrast fluid administration and procedure time at a reasonable level, only one pullback was carried out. Despite these limitations, to the best of our knowledge, this is the first serial and largest OCT trial investigating radial artery damage after PCI so far carried out.

CONCLUSION

We investigated one hundred patients with the diagnosis of nSTEMI treated by transradial PCI. Overall 200 OCT records of the radial artery was analyzed in the serial manner, both during the baseline coronary event and after 9 months.

We haven't found any significant difference between the baseline and follow-up RA injury incidence. The vessel injury incidence at the baseline procedure, even simplified to a medial dissection, does not result in higher risk of injury in the follow-up catheterization. For women, we found a higher risk of radial injury during a repeated catheterization. Generally, and in the light of the results, we have to consider radial catheterization to be extremely safe (in terms of the radial artery damage). We describe considerably lower number of injuries comparing to published studies. Therefore, we believe, that usage of the short radial sheath (7 cm in our study) is protective and decrease the incidence of radial injury. To prove that, randomized trial comparing different sheaths would be necessary.

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