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Novel procedural risk factors of myocardial injury following percutaneous coronary interventions with rotational atherectomy

Short title: Indicators of myocardial injury after rotational atherectomy

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INTRODUCTION

Rotational atherectomy (RA) is one of the most widely used methods of plaque modification, especially in the presence of diffuse calcifications[1]. Due to the aggressiveness of the RA procedure and the presence of pulverised microdebris, it is thought to be associated with higher risk of myocardial injury[2]. High-sensitivity cardiac troponin I (hs-TnI) is one of the most sensitive indicators of minor myocardial damage after percutaneous coronary intervention (PCI) [3]. Multiple studies showed high prevalence of elevated hs-TnI after percutaneous procedures, with discordant influence on clinical results [4–6]. It was also shown that the extent of myocardial injury is related to the complexity of the procedure[2]. However, there is no data regarding which procedural aspects of RA are associated with myocardial injury. The aim of this study was to assess the incidence and procedure-specific indicators of myocardial injury.

METHODS

This was a single centre, prospective, observational study. We included patients with clinical indications for RA in accordance with the European expert consensus document [1]. Exclusion criteria were a prior diagnosis of acute coronary syndrome and elevated baseline hs-TnI. The study protocol was accepted by the local ethics committee (ID no. 239/2016) and was in accordance with the declaration of Helsinki. All patients gave written informed consent for their participation in the study.

Treatment was conducted according to local standards and guidelines using the RotaLink system (Boston Scientific, Marlborough, MA, US). All procedural aspects were left to the discretion of the operator. All patients were on dual antiplatelet therapy during the procedure, all patients received acetylsalicylic acid, 38 (90%) received clopidogrel, and 4 (10%) received ticagrelor. All procedures were performed by a single team of experienced operators to ensure consistent results. Operators and physicians providing care to the patients were blinded to hs-TnI results unless a patient presented clinical signs of myocardial ischemia after the index procedure.

Blood samples were collected before the procedure and on the morning after (12–24 hours post procedure). Hs-TnI measurements were performed in a local laboratory using chemiluminescence LOCI^{TM} method. All measurements were performed using Dimension EXL analyzer (Siemens Healthcare Diagnostics, Erlangen, Germany).

Periprocedural myocardial injury and periprocedural myocardial infarction were defined according to the 4th universal definition of myocardial infarction. Myocardial injury was defined as an increase of hs-TnI levels above the 99th percentile of upper reference limit (URL), and substantial myocardial injury was defined as an increase of TnI levels more than five times the 99th percentile URL.

Statistical analysis

Continuous variables with normal distribution are presented as mean and standard deviation. Continuous variables with skewed distribution are presented as median with interquartile range. Categorical variables are presented as numbers and percentages. For continuous variables, intergroup differences were compared using Student's t test or the Mann-Whitney U test, depending on the type of distribution. The χ^2 test (using Yate's correction for continuity where necessary) was used to compare categorical variables. A p-value < 0.05 was considered statistically significant. All statistical analyses were performed using the Statistica 10.0 (StatSoft, Tulsa, OC, US) software.

RESULTS AND DISCUSSION

During the study period (September 2016 to April 2018) 110 patients underwent RA in our institution. 43 (39%) of these patients were hospitalised due to acute coronary syndrome or had elevated hs-TnI levels prior to the procedure, and were therefore excluded from this study. Further, in 25 (22%) of the patients full procedural or laboratory data were not available. As a result, 42 patients with full clinical and procedural data were included in this study.

A Substantial increase (≥5 times upper limit of normal) of hs-TnI was present in 23 (55%) of the patients (referred to below as high TnI group). Median concentration of hs-TnI in this group was 0.28 (0.017–0.04) ng/ml immediately after the procedure and 0.95 (0.44–1.85) ng/ml 12–24 hours later. Non-substantial increase (<5 times upper limit of normal) of hs-TnI was present in 19 (45%) of the patients. Complete demographics, comorbidities, and procedural factors of both groups are presented in Table 1.

Except for a trend towards older age (mean, 73.4 vs. 68.8; $P = 0.09$) and higher prevalence of diabetes in the high TnI group (74% vs. 47%; $P = 0.07$) there were no differences in common cardiovascular risk factors. Patients with substantial increase in hs-TnI after RA underwent PCI less often in the past (70% vs. 95%, p=0.03) and trended towards higher SYNTAX Score (mean, 21.7 vs. 15.8; $P = 0.051$).

There were no differences in the treated vessels between the groups.

We showed that in the high TnI group total burr use time (median, 194 seconds vs. 82 seconds; $P <0.001$) and total number of burr runs (median, 7 vs. 4; $P = 0.01$) were significantly higher. There was also a trend towards a larger number of stents implanted (mean, 1.56 vs. 1.16; $P = 0.058$) in that group. Procedural success was high in both groups, however significantly higher in the high TnI group (100% vs. 84%; $P = 0.048$).

Rate of complications was low and did not differ between the two groups. Despite significant TnI release, after correlation with clinical data, only one patient in the high TnI group fulfilled the criteria for myocardial infarction type 4a diagnosis.

Our study is, to our knowledge, the first to investigate both incidence and procedural indicators of myocardial injury after RA.

We showed that despite a very high occurrence of any (79%) or significant (55%) TnI elevation after RA, the rate of in-hospital complications was very low with only one type 4a myocardial infarction, and no significant arrhythmias were observed during the procedures.

Previous studies showed that the occurrence of myocardial injury and periprocedural MI related to RA is higher than after traditional PCI [2, 7]. This observation was foreseeable, but until now it could not be connected to specific procedural aspects. Thus far the degree of

myocardial injury was correlated mainly with the atherosclerotic burden and the extent of calcification, which provoked the use of more aggressive techniques [8]. Previous publications demonstrated clinical and anatomical (sequential lesions, acute lesion angulation) predictors of MI after RA. However, none of these studies focused on the procedural aspects of the intervention [9, 10]. Other studies showed that during RA procedures radial access and female sex are risk factors of coronary artery perforation and periprocedural complications (including mortality) respectively [11, 12]. In our study there were no differences between the studied groups in this regard, therefore there is no evidence this factors could impact myocardial injury after RA.

For the first time, we showed that the total time of burr use and number of burr runs are correlated with significant elevation of TnI levels after the procedure. It's worth noting that in most cases time of burr use and the number of burrs used are indeed directly associated with the extent of the calcified plaque, which enforces more aggressive treatment. We also observed higher syntax scores in the "high TnI" group. These observations suggest a larger impact of overall atherosclerotic burden rather than selected procedural aspects on TnI release after RA.

CONCLUSIONS

Myocardial injury after RA, defined as substantial increase in hs-TnI levels, is not uncommon. Clinical significance of this finding requires further studies.

Hs-TnI release occurs even when the procedure is performed without any complications. Frequent significant hs-TnI release after RA seems to be clinically silent. Further studies with clinical endpoints are required to create any new recommendations for RA operators.

Article information

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Table 1. Population clinical and procedural characteristics

	All patients	**No significant (< 5 × ULN) hs-TnI release**	**Significant (≥5 × ULN) hs-TnI release**	***P*-value**
N (%)	42 (100)	19 (45)	23 (55)	
Age, years, mean (SD)	71.3 (8.9)	68.8 (9.6)	73.4 (7.8)	0.09
Male, n (%)	31 (74)	16 (84)	15 (65)	0.16
Hypertension, n (%)	39 (93)	17 (89)	22 (96)	0.43
Diabetes mellitus, n (%)	26 (62)	9 (47)	17 (74)	0.07
Hyperlipidemia, n (%)	18 (43)	8 (42)	10 (43)	0.92
Peripheral artery disease, n (%)	9 (21)	4 (21)	5 (22)	0.96
Left ventricular ejection fraction, %, mean (SD)	48.8 (11.3)	46.2 (12.4)	50.9 (10.0)	0.18
Impaired renal function with eGFR	9 (21)	3 (16)	6 (26)	0.41

<60 ml/min/1.73 m^2, n (%)				
Prior acute coronary syndrome, n (%)	22 (52)	11 (58)	11 (48)	0.51
Prior PCI, n (%)	34 (81)	18 (95)	16 (70)	0.03
Prior CABG, n (%)	5 (10)	1 (5)	4 (17)	0.23
EuroSCORE, median (IQR)	2.03 (1.2–4.0)	1.65 (1.08–2.83)	2.34 (1.21–5.77)	0.26
Syntax Score, mean (SD)	19.0 (9.8)	15.8 (9.7)	21.7 (9.2)	0.051
Radial access, n (%)	41 (98)	19 (100)	22 (96)	0.36
GP IIb/IIIa inhibitors used, n (%)	0 (0)	0 (0)	0 (0)	1.0
Target vessel				
RCA, n (%)	15 (36)	8 (42)	7 (30)	0.43
LM, n (%)	5 (12)	3 (16)	2 (9)	0.48
LAD, n (%)	17 (40)	6 (32)	11 (48)	0.29
Cx, n (%)	2 (5)	1 (5)	1 (4)	0.89
OM, n (%)	2 (5)	1 (5)	1 (4)	0.89
Dg, n (%)	1 (2)	0 (0)	0 (0)	0.34
Procedural data				
Total time of burr use, second, median (IQR)	114 (79–222)	82 (60–143)	194 (83–327)	0.007
Total number of burr runs, median (IQR)	5 (3–8)	4 (2–6)	7 (3–12)	0.01
Mean burr speed, RPM × 1000, mean (SD)	145.9 (4.9)	146.2 (4.3)	145.7 (5.5)	0.76
Number of burrs used, mean (SD)	1.21 (0.4)	1.21 (0.4)	1.22 (0.4)	0.95
Burr to artery ratio, mean (SD)	0.46 (0.08)	0.46 (0.07)	0.46 (0.08)	0.91

Maximum burr diameter, mean (SD)	1.44 (0.2)	1.45 (0.2)	1.42 (0.18)	0.69
Number of stents implanted, mean (SD)	1.38 (0.7)	1.16 (0.2)	1.56 (0.7)	0.058
Total length of implanted stents, mm, mean (SD)	27.6 (16.2)	25.2 (16.3)	29.4 (16.2)	0.42
Contrast volume, ml, mean (SD)	218 (51)	205 (34)	229 (62)	0.22
Procedural success, n (%)	39 (93)	16 (84)	23 (100)	0.048
Periprocedural complications				
Slow/no-flow, n (%)	0 (0)	0 (0)	0 (0)	1.0
Side branch occlusion, n (%)	0 (0)	0 (0)	0 (0)	1.0
Dissection, n (%)	2 (5)	0 (0)	2 (9)	0.11
Perforation, n (%)	1 (2)	0 (0)	1 (4)	0.36
Emergency CABG, n (%)	0 (0)	0 (0)	0 (0)	1.0
In-hospital outcomes				
Death, n (%)	0 (0)	0 (0)	0 (0)	1.0
Peri-procedural MI, n (%)	1 (2)	0 (0)	1 (4)	0.36
Stroke/TIA, n (%)	0 (0)	0 (0)	0 (0)	1.0
Contrast induced nephropathy, n (%)	0 (0)	0 (0)	0 (0)	1.0
HsTnI immediately post procedure, ng/ml, median (IQR)	0.022 (0.017–0.039)	0.017 (0.017–0.039)	0.28 (0.017–0.04)	0.06
HsTnI 12–24 hours post procedure, ng/ml, median (IQR)	0.371 (0.086–1.181)	0.084 (0.035–0.176)	0.95 (0.44–1.85)	<0.001

Any hsTnI elevation, n (%)	33 (79)	10 (53)	23 (100)	<0.001

Abbreviations: CABG, coronary artery bypass grafting; Cx, circumflex artery; Dg, diagonal artery; eGFR, estimated glomerular filtration rate; hsTnI, high-sensitive troponin I; LAD, left anterior descending; LM, left main; MI, myocardial infarction; OM, obtuse marginal artery; PCI, percutaneous coronary intervention; RCA, right coronary artery; RPM, revolutions per minute; TIA, transient ischemic attack; ULN, upper limit of normal;