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Original article

Acute coronary syndrome – Still a valid contraindication to perform rotational atherectomy? Early and one-year outcomes

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ABSTRACT

Background: Rotational atherectomy (RA) is an acknowledged method of percutaneous treatment of highly calcified or fibrotic coronary lesions. However, using the rotablator system in patients presenting with acute coronary syndromes (ACS) remains controversial and is considered as a relative contraindication. The aim of our study was to assess in-hospital and 1-year outcomes in patients undergoing RA presenting with ACS, in comparison to elective RA procedures.

Methods: This single-center observational study included all consecutive patients who underwent RA and PCI in our institution from April 2008 to October 2015. All patients were subsequently divided into two groups based on clinical presentation: stable angina group (SA) and ACS group. Primary endpoints were in-hospital and 1-year all-cause mortality and 1-year major adverse cardiac events (MACE). Secondary endpoints were procedural success and in-hospital complications.

Results: The study included 207 patients, 164 (79%) in SA group and 43 (21%) in ACS group. In-hospital mortality was higher in patients with ACS (4.7% vs. 0%, $p = 0.01$). Procedural success was similar in both groups, 93% in ACS groups vs. 92.7% in SA group, $p = 0.94$. There were no significant differences in the rate of periprocedural complications (4.7% vs. 10.4%, $p = 0.25$), however postprocedural complications were more frequent in ACS group. At 1-year follow-up MACE rate and mortality were numerically higher, however statistically not significant (25.6% vs. 16.5%, $p = 0.17$ and 16.3% vs. 7.9%, $p = 0.10$; respectively).

Conclusions: Despite higher mortality and complication rate in ACS group observed in postprocedural period, we found no significant difference in 1-year outcomes in comparison to elective patients. Procedural success of RA in ACS patients is similar to elective patients with SA and this procedure should be considered in case of urgent indications, if no other options of treatment exist.

Introduction

Rotational atherectomy (RA) is an acknowledged method of percutaneous treatment of highly calcified or fibrotic lesions that cannot be treated with traditional percutaneous coronary intervention (PCI) [1,2]. However, using the rotablator system in patients presenting with acute coronary syndromes (ACS) remains controversial and is considered as a relative contraindication, due to the presence of unstable plaques and potential complications associated with platelet activation and the risk of thrombotic events [3,4]. Notwithstanding, ACS is the most common cardiac hospitalization reason and its incidence is still slightly increasing in the western world [5]. Recent studies showed the 17–32% prevalence of moderate to severe coronary calcifications in this population [6,7]. The outcomes in this group are unfavorable, that is related to unsuccessful lesion preparation, stent delivery and expansion with subsequent procedure failure, target vessel failure, risk of restenosis, and stent thrombosis [8–10].

On the other hand, high-risk patients, in whom early invasive strategy is advocated and PCI should not be postponed, constitute about one half of ACS [5]. Consequently, early RA is required in an increasing subset of ACS patients and the safety and efficacy of such treatment is yet to be determined. To our knowledge, only one full study and congress reports concerning the utilization of RA in ACS patients have been published while the results are equivocal [11–13].

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Therefore, the aim of our study was to assess in-hospital and 1-year outcomes in patients undergoing RA presenting with ACS, in comparison to elective RA procedures.

Methods

Study population

This single-center observational study included all consecutive patients, who underwent RA and PCI in our institution from April 2008 to October 2015. There were no exclusion criteria. Baseline demographic, clinical characteristics, and detailed procedural data were collected, including indication for procedure, urgency, and lesion characteristics with basic quantitative coronary angiography (QCA) parameters. All patients were subsequently divided into two groups based on clinical presentation: stable angina group (SA) and ACS group according to the European Society of Cardiology guidelines [5].

Preprocedural disqualification from coronary artery bypass grafting (CABG), if necessary, was undertaken by the local heart team. Information on all complications after each intervention, in-hospital and outcome major adverse cardiovascular events (MACE) was collected as well. All patients gave informed consent for the procedure. Follow-up data regarding all-cause mortality and recurrent hospitalizations and MACE were obtained from the Polish National Health Fund database, therefore no patient was lost to follow up. The study protocol was accepted by local ethics committee and was in accordance with the declaration of Helsinki.

Study and endpoints definitions

Procedural success was defined as angiographic success [residual stenosis of <30% after stent implantation with thrombolysis in myocardial infarction (TIMI) flow grade III] without periprocedural complications. Baseline and follow-up myocardial infarction (MI) was defined according to the universal definition of myocardial infarction [14]. Contrast-induced nephropathy (CIN) was defined as a relative increase in serum creatinine concentration of >25% or as an absolute increase in serum creatinine concentration >0.5 mg/dl from baseline within 72 h after PCI. Relevant access site bleedings were defined as at least type 3a according to Bleeding Academic Research Consortium [15]. Undilatable lesion indicated the lesion that cannot be adequately dilated by a balloon during inflation while uncrossable lesion indicated the lesion that can be crossed by a wire, however cannot be crossed with even smallest balloons. Direct use of RA indicated the third, primary reason to perform RA, in case of severe massive calcifications of coronary vessels visible in angiography and unclear PCI failure indicated that the reason was not clearly described, that concerned patients transferred from other catheterization laboratories. The clinical risk was assessed according to logistic Euroscore II and baseline Syntax Score (SS) along with residual SS.

Primary endpoints were in-hospital and 1-year all-cause mortality and 1-year MACE defined as the composite endpoint of all-cause mortality, follow-up MI, and stroke. Secondary endpoints were procedural success and in-hospital complications.

Procedure

RA procedure was performed using standard Boston Scientific Rotablator system (Boston Scientific, Marlborough, MA, USA). Radial or femoral route was performed according to operator discretion. Burr speeds were between 140,000 and 180,000 rpm with a run duration of about 20–30 s. In all procedures an intracoronary continuous infusion of heparin, verapamil, and isosorbite dinitrate via the burr sheath was used. Heparin was given to maintain an activated clotting time >250 s. All patients were pretreated with aspirin and clopidogrel, except 3 patients treated with ticagrelor and 1 treated with prasugrel. In-hospital treatment in both groups was conducted according to current standards for ACS and SA and was left to the discretion of physicians in charge of the patients.

Statistical analysis

Continuous variables with normal distribution are presented as mean ± standard deviation, continuous variables with skewed distribution as median with interquartile range, and categorical variables 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 was used to compare categorical variables. Univariate and multivariate Cox proportional hazard models were used to determine the predicting factors of all-cause death and composite endpoint (MACE). The multivariate model included all variables with $p < 0.05$ in the univariate model. Survival and event-free survival curves were created using the Kaplan–Meier method. Differences in survival and event-free survival rates were compared using the log-rank test. A p-value < 0.05 was considered statistically significant. All statistical analyses were performed using the Statistica 10.0 (StatSoft/Tibco, Palo Alto, CA, USA) software.

Results

Patient characteristics

Our study included 207 patients, 164 (79%) in SA group and 43 (21%) in ACS group, including 21 (49%) patients with unstable angina, 21 (49%) with non-ST-segment elevation MI, and 1 (2%) with ST-segment elevation MI.

Baseline demographics, comorbidities, and laboratory results in both groups are presented in Table 1. Patients in ACS group were older (75 ± 10 years vs. 70 ± 9 years, $p < 0.001$), had lower left ventricle ejection fraction (LVEF) (47 ± 13% vs. 51 ± 11%, $p = 0.02$), and less often history of prior PCI (58% vs. 77%, $p = 0.01$). They had significantly higher systolic blood pressure (145 ± 25 mmHg vs. 133 ± 20 mmHg, $p < 0.01$), heart rate on admission (79 ± 19 bpm vs. 69 ± 10 bpm, $p < 0.001$), white blood cell count [8.1 (7–10.1) × 10^3/μl vs. 7.4 (6.1–8.8) × 10^3/μl, $p = 0.02$], and glucose level [127 (103–145) mg/dl vs. 107 (96–130) mg/dl, $p = 0.001$]. Euroscore II was also higher in patients with ACS [5.3 (2.6–9.3) vs. 2.1 (1.3–3.8), $p < 0.001$]. The prevalence of other traditional cardiovascular risk factors, as well as comorbidities and medications at discharge were similar in both groups.

Procedure characteristics

Coronary anatomy in patients with ACS was reflected by higher SS [21 (15–29) vs. 17 (11–24), $p = 0.02$] with concomitant higher residual SS [10 (1–18) vs. 7 (0–12), $p = 0.04$]. Patients in ACS group were also more frequently disqualified from CABG (54% vs. 32%, $p = 0.01$), because of high operative risk. Culprit stenoses were angiographically tighter (95 ± 5% vs. 92 ± 7%, $p < 0.01$) and hospital stay after RA was longer in ACS group [3 (2–6) days vs. 2 (1–3) days, $p < 0.001$]. All other procedural aspects were comparable between groups and are shown in Table 2.

In-hospital and 1-year outcome

In-hospital and 1-year outcomes are presented in Table 3 and Fig. 1. In-hospital mortality was higher in patients with ACS (4.7%