

Coronary rotational atherectomy in patients with unsuccessful classical angioplasty – in-hospital and six-month follow-up

Rotablacja tętnic wieńcowych u pacjentów po nieskutecznej klasycznej angioplastyce – obserwacja wewnątrzszpitalna i sześciomiesięczna

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Abstract

Background: The data regarding follow-up of high-risk patients after coronary rotational atherectomy (RA) are poor.

Aim: The aim of this study was to evaluate the in-hospital and 6-month outcome of patients with uncrossable or undilatable lesions who were treated with RA.

Material and methods: The RA was performed in 62 consecutive patients (mean EuroSCORE: 6.8 ±4) and all of them were enrolled. Major adverse cardiac events (MACE) were defined as all-cause death, cardiac death, stroke, myocardial infarction (MI), target lesion revascularization (TLR), and target vessel revascularization (TVR).

Results: The procedural success rate was 94%. The incidence of MACE was 9.7% in hospital (6 MIs, 3 of them with signs of ischemia) and 9.7% at 6-month follow-up (2 deaths, 3 MIs, 1 TLR). Death occurred in 2 patients (3%): due to definite stent thrombosis, and because of acute heart failure in a patient with low ejection fraction (EF).

Conclusions: In this very high risk population RA provides good outcomes with relatively low risk of MACE.

Key words: percutaneous coronary interventions, highly calcified coronary lesions, rotational atherectomy

Streszczenie

Wstęp: Dane dotyczące obserwacji pacjentów z wysokim ryzykiem poddawanych rotacji tętnic wieńcowych są skąpe.

Cel: Ocena bezpośrednia i półroczna pacjentów ze zmianami, na które nie można wprowadzić cewnika balonowego lub nie można go w pełni rozprężyć, leczonych za pomocą rotacji.

Materiał i metody: Rotację wykonano u kolejnych 62 pacjentów (średni EuroScore 6,8 ±4) i wszyscy zostali włączeni do obserwacji. Złożony punkt końcowy zdefiniowano jako wystąpienie każdego zgonu, zgonu sercowego, udaru mózgu, zawału mięśnia serca, konieczności ponownej rewaskularyzacji zmiany oraz rewaskularyzacji tętnicy.

Wyniki: Skuteczność procedury wyniosła 94%. Złożony punkt końcowy wystąpił w 9,7% przypadków w obserwacji wewnątrzszpitalnej (6 zawałów mięśnia serca, 3 z nich z objawami niedokrwienia) i w 9,7% przypadków w obserwacji 6-miesięcznej (2 zgony, 3 zawały mięśnia serca, 1 konieczność ponownej rewaskularyzacji zmiany). Odnotowano 2 zgony (3%) – z powodu pewnej zakrzepicy w stencie oraz ostrej niewydolności serca u pacjenta z obniżoną funkcją skurczową.

Wnioski: W grupie osób z bardzo dużym ryzykiem rotacja zapewnia dobre wyniki przy relatywnie niskim prawdopodobieństwie wystąpienia złożonego punktu końcowego.

Słowa kluczowe: przeszłokrotne interwencje wieńcowe, zwapnienia tętnic wieńcowych, aterektomia rotacyjna

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Introduction

Calcified and fibrotic lesions in the coronary arteries are often a nightmare of interventional cardiologists and one of the most frequent causes of percutaneous coronary intervention (PCI) failure. Often, they do not permit one to introduce the balloon catheter to the site of stenosis or to completely expand it. In these situations guidelines of the European Society of Cardiology (ESC) recommend rotablation of the coronary arteries [1]. This procedure is very rarely performed in our country.

Aim

The aim of this study was to evaluate the efficacy and safety of rotablation during both in-hospital and 6-month follow-up in patients with significantly calcified coronary artery stenosis, in whom classic angioplasty was unsuccessful.

Material and methods

Retrospective analysis included 62 consecutive patients who underwent rotablation between April 2008 and June 2011 in the Department of Cardiology of the Center for Heart Diseases in Wrocław. Calcifications of the coronary arteries were classified on the basis of fluoroscopy according to the division proposed by Mintz as: none or mild, moderate (visible only during cardiac motion before contrast administration), and severe (visible without heart movement before contrast administration) [2]. Morphology of the lesions was also assessed according to the ACC/AHA classification as A, B1, B2 and C [3]. Flow in the coronary arteries was assessed by means of the TIMI criteria [4]. Peripheral atherosclerosis was defined according to current 2011 criteria [5]. Angiographic success was defined as the presence of residual stenosis after implantation < 20% and TIMI flow 3 in the coronary artery. Composite end-point (MACE) was defined as the occurrence of all-cause death, cardiovascular death, myocardial infarction, the need of repeat revascularization and stroke. Myocardial infarction not associated with PCI was defined according to the ESC guidelines as the rise of cardiac biomarkers with at least 1 value above the 99th percentile of the upper reference limit together with the presence of at least one sign of myocardial ischemia (symptoms of ischemia, ECG changes indicative of new ischemia, imaging evidence of new loss of viable myocardium) [6]. Myocardial infarction associated with PCI (type 4a) was defined according to a proposed update of the guidelines presented during the ESC congress in 2011 as a 5-fold increase of cardiac biomarkers above the upper reference limit together with coexisting evidence of myocardial ischemia or a 10-fold increase of cardiac biomarkers without additional symptoms [7]. Target lesion revascularization (TLR) was defined as the need for percutaneous or surgical coronary intervention involving a previously treated lesion or seg-

ments adjoining proximally or distally to the stent. Repeated target vessel revascularization (TVR) was defined as the need of percutaneous or surgical coronary intervention involving any segment of the previously treated vessel. Patients were subjected to 6-month follow-up. Rotablation was performed using the "Rotablator" system (Boston Scientific-Scimed Corporation, Natick, MA, USA) after obtaining informed consent from the patient. The size of a drill was chosen so that the drill/artery size ratio was < 0.7 [8]. Rotational speed of the drill was kept within the limits of 140 000-180 000 rotations per minute. Passage of the drill lasted up to 20 s [8]. During the procedure a continuous flow of unfractionated heparin (5000 U in 500 ml of isotonic saline), verapamil and nitroglycerin was used. "On demand" temporary cardiac pacing was used for procedures on the right coronary artery or a dominant circumflex artery [9]. All patients were on dual antiplatelet therapy. Patients received 300 mg of clopidogrel and 300 mg of aspirin at least 24 h before rotablation. After the procedure it was recommended to use aspirin 75 mg/day for life and clopidogrel 75 mg/day for at least 12 months after drug-eluting stent (DES) implantation and 4 weeks after bare metal stent (BMS) implantation.

Statistical analysis

Statistical analysis was performed with Statistica software (StatSoft, USA). The results of statistical analyses were expressed as mean \pm standard deviation (SD) for continuous variables and as percentage for categorical variables.

Results

The study included 62 consecutive patients qualified for rotablation of *de novo* lesions. Exclusion criteria included contraindications to rotablation: location of the lesion in the saphenous vein graft, presence of dissection or thrombus in the artery undergoing rotablation, tortuous course of the vessel, ST-segment elevation myocardial infarction and the presence of in-stent restenosis (ISR) [9]. Clinical characteristics of the patients are presented in Table 1.

All patients were symptomatic. Mean CCS class on admission to the hospital was 2.7 ± 0.7 including 4 patients (6%) with a diagnosis of an acute coronary syndrome. Angiographic characteristics are presented in Table 2.

Fluoroscopy demonstrated the presence of calcifications of all significant coronary artery lesions. Type B2 or C of the lesions according to ACC/AHA was found in 2/3 of patients. Three-vessel disease was detected in 18 patients (29%) in the studied population. This group was characterized by high risk of peri-procedural complications of surgical treatment (EuroSCORE – 8.9 ± 4 points and logistic EuroSCORE – $19.8 \pm 17.4\%$).

After the decision of the team (heart team) and taking into account the preferences of the patients they were eventually qualified for PCI. The same decision was made

Table 1. Clinical characteristics
Tabela 1. Charakterystyka kliniczna

N	62
Age [years]	71 ±9
Women, n (%)	27 (44)
Risk factors	
Hypertension, n (%)	51 (82)
Diabetes mellitus, n (%)	20 (32)
Hyperlipidemia, n (%)	36 (58)
Nicotine smoking, n (%)	25 (40)
Renal failure (GFR < 60 ml/min), n (%)	17 (27)
Peripheral atherosclerosis, n (%)	10 (16)
LVEF [%]	49 ±11
Patients with LVEF < 30%, n (%)	6 (10)
Significant valvular disease, n (%)	8 (13)
Mitral valve regurgitation, n (%)	5 (8)
Aortic stenosis, n (%)	3 (5)
BMI [kg/m ²]	30 ±4
Previous myocardial infarction, n (%)	31 (50)
Previous PCI, n (%)	42 (84)
Previous CABG, n (%)	11 (18)
Mean CCS class on admission	2.7 ±0.7
Acute coronary syndrome on admission, n (%)	4 (6)
Acute coronary syndrome < 4 weeks, n (%)	3 (5)
Hemodynamic instability on admission, n (%)	2 (3)

BMI – body mass index, CABG – coronary artery bypass graft

for a group of 8 patients (13%) with a significant valvular heart disease characterized by a very high risk of peri-procedural complications (EuroSCORE – 11.25 ±2.81 points, logistic EuroSCORE 27.57 ±18.47%) (Table 3).

In 45 patients (73%) a decision to perform rotablation was based on inability to fully expand the balloon catheter with mean pressure of 21 ±3 atm and in 17 patients (27%) because of the inability to position the balloon catheter within the lesion (Figure 1). Characteristics of the rotablation procedure are presented in Table 4.

The most commonly treated vessels were the right coronary artery (42%) and left anterior descending artery (37%) (Figure 2). Two patients (3%) required the use of intra-aortic balloon counter pulsation, because of the initially present hemodynamic instability. The rate of successful procedures was 94%. The procedure failed in 3 patients (5%) because of the inability to cross the lesion with a drill and in 1 patient (2%) because of perforation of the artery during crossing with a drill. In 1 patient the slow-flow phenomenon was observed during the rotablation procedure. The results of in-hospital and 6-month follow-up are presented in Table 5.

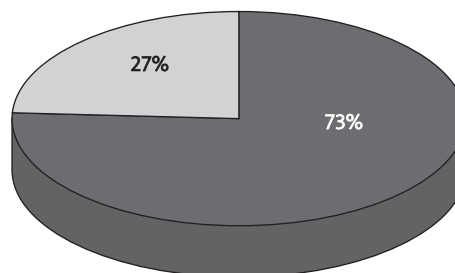
The composite end-point occurred in 6 patients (9.7%) and was in all the cases caused by a peri-procedural

Table 2. Angiographic characteristics
Tabela 2. Charakterystyka angiograficzna

N	62
Calcifications visible on fluoroscopy, n (%)	62 (100)
Calcifications < 10 mm, n (%)	14 (23)
Calcifications ≥ 10 mm, n (%)	48 (77)
Calcifications	
Mild, n (%)	10 (16)
Moderate, n (%)	22 (35)
Severe, n (%)	30 (48)
Mean lesion length [mm]	21 ±8
Mean % of stenosis according to QCA	91 ±7
3-vessel disease, n (%)	18 (29)
Left main stenosis, n (%)	10 (16)
Unprotected left main stenosis, n (%)	3 (5)
Bifurcation, n (%)	17 (27)
Ostial localization, n (%)	10 (16)
Eccentric stenosis, n (%)	8 (13)
Chronic total occlusion, n (%)	5 (8)
Lesion type B2/C according to ACC/AHA, n (%)	52 (84)

Table 3. Estimated perioperative risk
Tabela 3. Szacowane ryzyko okołoperacyjne

Mean EuroSCORE in the whole studied group [points]	6.8 ±4
Predicted peri-procedural mortality in the whole studied group [%]	11.8 ±13
Mean EuroSCORE of patients with indications for surgical treatment, because of the presence of 3-vessel disease [points]	8.9 ±4
Predicted peri-procedural mortality of patients with indications for surgical treatment, because of the presence of 3-vessel disease [%]	19.8 ±17.4
Mean EuroSCORE of patients with indications for surgical treatment because of the presence of significant valvular heart disease [points]	11.25 ±2.81
Predicted peri-procedural mortality of patients with indications for surgical treatment, because of the presence of significant valvular heart disease [%]	27.57 ±18.47



- Full inflation of the balloon catheter within the lesion not possible – 45 patients
- Placement of the balloon catheter within the lesion not possible – 17 patients

Fig. 1. Indications for rotational atherectomy
Ryc. 1. Kwalifikacja do rotablacji tętnic wieńcowych

Table 4. Procedure characteristics
Tabela 4. Charakterystyka procedury

N	62
Mean size of a drill	1.5 ±0.1
Number of drills per lesion	1 ±0.2
The use of > 1 drill per lesion, n (%)	3 (5)
Stent length per lesion [mm]	24 ±10
Stent length per patient [mm]	33 ±22
Post-dilation with NC balloon, n (%)	32 (55)
Maximal inflation pressure during stent implantation [atm]	17 ±3
Maximal inflation pressure in the NC balloon during post-dilation [atm]	20 ±2
Number of procedures requiring > 1 stent, n (%)	21 (34)
DES implantation, n (%)	52 (90)
1 st generation DES, n (%)	5 (8)
Sirolimus, n (%)	3 (5)
Paclitaxel, n (%)	2 (3)
2 nd generation, n (%)	47 (81)
Everolimus, n (%)	45 (73)
zotarolimus, n (%)	2 (3)
Implantation of 1 DES, n (%)	34 (55)
Implantation of > 1 DES, n (%)	6 (10)
Implantation of DES + BMS, n (%)	12 (19)
Implantation of only BMS, n (%)	6 (10)
PCI of > 1 artery, n (%)	5 (8)
PCI ad hoc, n (%)	6 (10)
Successful procedure, n (%)	58 (94)
Slow-flow/no-reflow, n (%)	1 (1.6)
Mean amount of contrast [ml]	262 ±122
IABP, n [%]	3 (5)

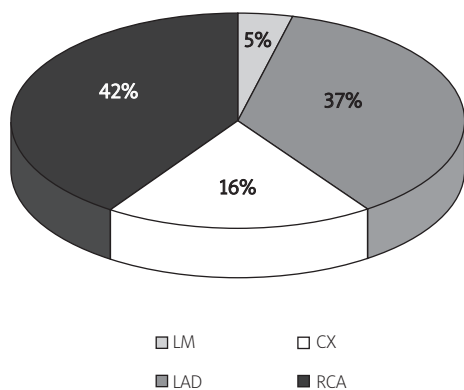


Fig. 2. Artery treated with rotational atherectomy
Ryc. 2. Tętnica poddawana aterektomii rotacyjnej

myocardial infarction type 4a according to the ESC [6, 7]. In half of the cases increased troponin concentration was accompanied by symptoms of ischemia and in other cases myocardial infarction was based solely on an asymptomatic rise of troponin concentration exceeding 10-fold the upper reference limit. During 6-month follow-up the composite end-point occurred in 6 patients (9.7%).

There were 2 deaths (3%): the first one after 15 days of follow-up (in-stent thrombosis in a patient not taking clopidogrel) and the second one after 134 days of follow-up (patient with LVEF = 30% waiting for an ICD implantation in the primary prevention of sudden cardiac death). Non-ST segment elevation myocardial infarction occurred in 3 patients (4.8%) and was caused by *de novo* lesions in 2 of them. The need for target lesion revascularization (TLR) occurred in 1 patient after 175 days of follow-up and was caused by significant restenosis in the previously implanted BMS.

Discussion

Massive calcifications of the coronary arteries constitute a major obstacle to the success of coronary angioplasty [10, 11]. They can prevent the introduction of a balloon catheter and/or its expansion, can cause an injury to the polymer and/or drug layer of the coated stents and may prevent the delivery and full expansion of the stent. Calcified tissues are known to absorb less antimitotic drugs.

Calcifications within the atherosclerotic plaques are present in 50% of those aged 40-49 years and in 80% of those aged 60-69 years [12]. The factors favoring their occurrence include male sex, age, obesity, nicotine smoking, hypertension, type 2 diabetes, hyperlipidemia and impaired glomerular filtration rate [12]. Little is known about calcified lesions and optimal methods of management in these situations not only because they were a rare subject of scientific analysis, but also because they generally created a contraindication in the qualification process for many important randomized trials [13-15]. In the era of drug-eluting stents there has not been a single randomized study focusing on rotablation, except for one presentation at the recent TCT congress [16]. The only data we have come from randomized trials performed before the era of drug-eluting stents and from observational studies. The most important result of our retrospective observation is the demonstration that the use of rotablation in a population of patients in whom classic angioplasty is ineffective is associated with a relatively high efficacy and a low rate of complications, both in-hospital and at 6-month follow-up. In case of unsuccessful angioplasty, if rotablation is not used, two management options come into consideration: cardiac surgery or conservative treatment. The latter option is not good for patients with medium severity of angina despite optimal pharmacotherapy (2.7 according to CCS), because of the significant deterio-

Table 5. Results
Tabela 5. Wyniki

End-point	In-hospital follow-up	6-month follow-up	Total during follow-up
All-cause death, <i>n</i> (%)	0	2 (3.22)	2 (3.22)
Cardiovascular death, <i>n</i> (%)	0	2 (3.22)	2 (3.22)
Myocardial infarction, <i>n</i> (%)	6 (9.67)	3 (4.83)	9 (14.51)
TVR, <i>n</i> (%)	0	1 (1.61)	1 (1.61)
TLR, <i>n</i> (%)	0	1 (1.61)	1 (1.61)
Stroke, <i>n</i> (%)	0	0	0
Composite end-point (MACE)	6 (9.67)	6 (9.67)	12 (19.35)

ration in quality of life, but also a worse prognosis in patients with more advanced coronary artery disease. Cardiac surgery on the other hand is a much more invasive option in comparison to rotablation especially in patients with single-vessel disease located in the right coronary artery or circumflex artery or in patients with two-vessel disease and the same location (RCA and Cx). Although the ESC practice guidelines for revascularization allow surgical treatment in exceptional cases, it is doubtful whether this strategy is rational if rotablation is available. Surgery is surely and indisputably an excellent option in case of two-vessel disease involving the proximal segment of the left anterior descending artery or three-vessel disease or left main stenosis except the situations where operational risk is increased. Three-vessel disease or left main stenosis was present in approximately half of the patients in the studied group. Calculation of an expected operational risk on the basis of the EuroSCORE scale for this group of patients clearly indicates that the incidence of complications observed with rotablation is much smaller. It should not be forgotten however that, according to many experts, the EuroSCORE scale overestimates mortality. Similar considerations apply to patients with coexisting valvular heart disease, mainly in the form of aortic stenosis. It is worth noting that we had also performed revascularization with the use of rotablation in some patients who underwent percutaneous aortic valve implantation.

Another important argument for the widespread use of rotablation is the fact that many patients are disqualified from cardiac surgery due to age, general clinical condition or comorbidities. There is no doubt that the proportion of these patients will undergo a further increase. The results of our study demonstrate that rotablation may be a rational therapeutic option also for these patients. There were no deaths or strokes during the in-hospital course, but 6 patients experienced a myocardial infarction. It is worth noting that in 3 patients this was a myocardial infarction diagnosed on the basis of biomarkers, recognized only on the basis of more than 10-fold increase of the troponin T concentration. Only 3 patients experienced clinically symptomatic myocardial infarction. Some

of the adverse events which occurred after discharge certainly could have been avoided (two deaths), some of them resulted from disease progression, but it is difficult to associate them with the use of rotablation.

Many of the foreign reports draw attention to the fact that rotablation constitutes 2-4% of all PCI procedures performed in these centers. Data from the Database of the Section of Cardiovascular Interventions of the Polish Cardiac Society (PTK) show that there were 190 rotablation procedures performed in Poland in 2009-2010, which is about 0.2% of all PCI procedures. To our knowledge, the presented observation is the first Polish original report on rotablation and provides a reference point in the evaluation of potential complications, especially for inoperable patients and for patients with markedly increased operational risk. In our opinion rotablation requires further dissemination.

Conclusions

Rotablation of the coronary arteries is an effective and relatively safe form of treatment of massively calcified coronary artery lesions.

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