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PRACA ORYGINALNA
ORIGINAL PAPER

Assessment of effect of coronary angioplasty within main trunk of left main coronary artery using scoring balloon catheter in comparison with technique using non-compliant balloon catheter – preliminary results

Ocena efektu angioplastyki wieńcowej w obrębie pnia głównego lewej tętnicy wieńcowej z użyciem cewnika balonowego nacinającego w porównaniu z techniką z użyciem cewnika balonowego niepodatnego – wyniki wstępne

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ABSTRACT

INTRODUCTION: The paper discusses the techniques of modifying the atherosclerotic plaque in the left main coronary artery along with the results of the author's own procedures using a scoring catheter (AngioSculpt) and a non-compliant (NC) balloon catheter.
MATERIAL AND METHODS: 23 patients who met the inclusion criteria in the absence of exclusion criteria were enrolled in the study. 13 patients underwent coronary angioplasty using a scoring balloon catheter, and 10 patients underwent coronary angioplasty (percutaneous coronary intervention – PCI) with a NC balloon catheter.
RESULTS: The groups did not differ in terms of demographics or comorbidities. In the study group, a larger diameter of the left main (LM) trunk was obtained, as assessed by the intravascular ultrasound (IVUS) technique. In the control group, the two-stent technique was used more often; however, due to the small number of participants, statistical

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significance was not achieved. In the control group, greater use of contrast was associated with more frequent use of the two-stent technique. Despite one myocardial infarction (MI) related to the procedure in the control group, the 2-year mortality rate between the groups was similar. Logistic regression did not reveal any of the studied variables to be significantly related to 2-year mortality.

CONCLUSIONS: The preliminary results of our study suggest that there is no difference in early 30-day results and 2-year mortality in a randomized group of patients undergoing coronary angioplasty using a scoring balloon catheter and a non-compliant catheter. Selection of the optimal treatment strategy in LM stenosis is still a matter of research and the operator's experience is of fundamental importance.

KEY WORDS

PCI, left main coronary artery disease, plaque modification, scoring balloon catheter, non-compliant balloon

STRESZCZENIE

WSTĘP: W pracy omówiono techniki modyfikacji blaszki miażdżycowej w pniu lewej tętnicy wieńcowej wraz z przedstawieniem wyników własnych zabiegów z użyciem cewnika nacinającego (AngioSculpt) oraz cewnika niepodatnego (*non-compliant balloon* – NC balloon).

MATERIAŁ I METODY: Do badania włączono 23 pacjentów spełniających kryteria włączenia przy braku kryteriów wyłączających z badania. U 13 pacjentów przeprowadzono angioplastykę (*percutaneous coronary intervention* – PCI) z użyciem cewnika nacinającego, u 10 pacjentów z użyciem cewnika balonowego niepodatnego.

WYNIKI: Grupy nie różniły się pod względem danych demograficznych ani chorób współistniejących. W grupie badanej uzyskano większą średnicę pnia lewej tętnicy wieńcowej (*left main* – LM) w ocenie za pomocą ultrasonografii wewnątrznaczyniowej (*intravascular ultrasound* – IVUS). W grupie kontrolnej częściej stosowano technikę dwustentową; jednak ze względu na małą liczbę uczestników nie osiągnięto istotności statystycznej. W grupie kontrolnej użycie większej ilości kontrastu wiązało się z częstszym stosowaniem techniki dwustentowej. Pomimo jednego zawału mięśnia sercowego (*myocardial infarction* – MI), związanego z zabiegiem w grupie kontrolnej, śmiertelność 2-letnia między grupami była podobna. Regresja logistyczna nie wykazała istotnego związku żadnej z badanych zmiennych z 2-letnią śmiertelnością.

WNIOSKI: Wstępne wyniki naszego badania sugerują, że nie ma różnicy we wczesnych wynikach 30-dniowych oraz 2-letniej śmiertelności w randomizowanej grupie pacjentów poddawanych angioplastyce wieńcowej pnia lewej tętnicy wieńcowej z użyciem cewnika balonowego nacinającego i cewnika balonowego niepodatnego. Wybór optymalnej strategii leczenia zwężenia LM jest nadal przedmiotem badań, a doświadczenie operatora ma fundamentalne znaczenie.

SŁOWA KLUCZOWE

PCI, choroba pnia lewej tętnicy wieńcowej, modyfikacja blaszki miażdżycowej, cewnik balonowy nacinający, cewnik balonowy niepodatny

INTRODUCTION

Left main coronary artery disease (LMCAD) is an important clinical issue, and selection of the optimal intervention method is often a subject of controversy in the consultation of the HeartTeam. For many years, critical left main (LM) stenosis was recommended only for cardiac surgery (coronary artery bypass grafting – CABG). New scientific evidence and the results of large randomized comparative studies made it possible to consider transcatheter treatment in selected patients [1,2,3,4,5,6]. The current 2018 European Society of Cardiology guidelines recommend percutaneous LM trunk angioplasty as an alternative to CABG in the same class I recommendations at evidence level A, but only in patients with a Syntax score of 0 to 22 points on the coronary image. With a higher score, the level of recommendation is lowered, and with a score ≥ 33 points, only cardiac surgery is recommended [7].

In recent years, there has been visible development of technologies related to endovascular intervention within the LM trunk, including techniques for modifying the structure of atherosclerotic plaque, introducing new generations of drug-eluting stents (DES) with an antiproliferative effect on the endothelium, as well as the technique of stent implantation into the LM trunk. Due to the multiplicity and complexity of clinical situations, the optimal strategy for interventions in the LM trunk remains under discussion. In this study, the currently performed techniques to modify the plaque in the LM trunk were reviewed, together with the presentation of the author's own results in the field of LM trunk angioplasty using a scoring balloon catheter (AngioSculpt).

The population of patients undergoing coronary angioplasty has changed significantly over the past 20 years. Increasingly, they are elderly people with numerous comorbidities, often with calcified coronary lesions. In published studies, the occurrence of such calcifications in patients over 70 years of age was seen more often in men than in women (90% vs 67%) [8]. In IVUS imaging, the detection of calcification is particularly high and amounts to 73%, compared to the

classic coronary angiography image, where calcification is found much less frequently, only in 48% of cases [9]. Coronary angioplasty performed in calcified lesions is associated with a higher percentage of failure (target lesion), deaths, infarctions, and revascularization [10,11] compared to procedures performed in non-calcified lesions. There are also greater difficulties in delivering the stent to the implantation site.

During angioplasty of the left main coronary artery, one of the first stages of the procedure before stent implantation is so-called plaque preparation – modification of its structure (plaque modification) before final placement of the stent.

Among the techniques used to prepare the LM trunk, we can distinguish:

1) balloon angioplasty using a scoring balloon (AngioSculpt) [12]
2) balloon angioplasty using a cutting balloon (CB) [13,14]
3) coronary angioplasty using a balloon catheter emitting ultrasound waves (S-IVL intravascular lithotripsy – Shockwave Medical) [15]
4) rotational atherectomy (RA Rotablator – Boston Scientific) [16,17,18,19]
5) orbital atherectomy (OAS orbital atherectomy – CSI Diamondback 360 Orbital Atherectomy System) [20,21]
6) laser atherectomy (excimer laser coronary atherectomy – ELCA, Spectranectics CVX-300) [19,22].

The aim of the study was to compare the early 30-day results and late (2-year mortality) of left main coronary artery angioplasty using a scoring balloon catheter or a non-compliant (NC) balloon catheter as a method of preparing atherosclerotic plaque for stent implantation. The patients were randomly assigned to the treatment group using a scoring balloon catheter or a NC balloon catheter.

MATERIAL AND METHODS

In the period from 2017 in the Department of Interventional Cardiology a comparative study was carried out of the results of early (30 days) LM trunk angioplasty using a scoring balloon catheter (AngioSculpt) in relation to the classical method of balloon angioplasty using a NC balloon catheter using a randomized selection of patients meeting the inclusion criteria, in the absence of exclusion criteria. The studies assessed the number of dissections and the effectiveness of the intervention in a 30-day follow-up. The study was approved by the Bioethics Committee KNW/0022/KB1/84/I/18 and was awarded a grant by the Medical University of Silesia, Katowice, Poland, No. KNW-1-151/N/8/K.

The AngioSculpt scoring balloon catheter (Figure 1) is designed to widen (redistribute) the atherosclerotic plaque along with its controlled incision. AngioSculpt is made of a semi-compliant balloon catheter with three or four (depending on the diameter) helically wound nitinol wires. It comes in four sizes: 2.0 mm, 2.5 mm, 3.0 mm, 3.5 mm. By means of the nitinol wires, helical cuts are made in the atherosclerotic plaque. In addition, by means of the wires, which are square in cross-section, the catheter is anchored in the lesion, which prevents it from slipping (watermelon seed phenomenon) and thus reduces the potential risk of vessel damage following the lesion. In our research, we used a technique of intervention on the LM trunk using a scoring balloon catheter in comparison with a NC balloon catheter.

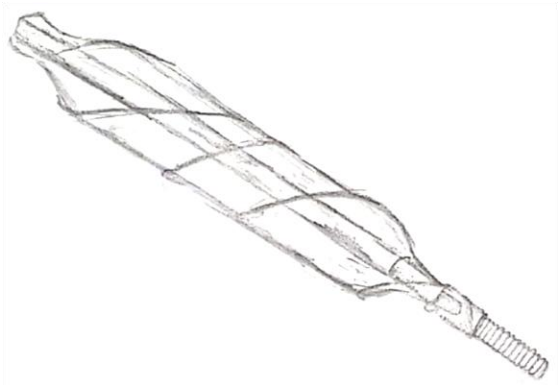

Fig. 1. Diagram of scoring balloon catheter AngioSculpt.
Ryc. 1. Rysunek cewnika balonowego nacinającego AngioSculpt.

Basic criterion for inclusion in the study

Left main stem stenosis > 50% with a low or moderate angiographic index of the complexity of coronary artery disease in patients with indications for coronary angioplasty determined during consultation within the HeartTeam.

Patients with a history of surgical coronary revascularization, chronic coronary syndrome, as well as patients with unstable coronary disease or non-ST-elevation myocardial infarction (NSTEMI) elevation were included in the study.

Criteria for exclusion from the study

1. Lack of consent of the patient to participate in the study
2. Myocardial infarction with ST segment elevation – STEMI
3. Previous left main coronary artery angioplasty
4. Cardiogenic shock
5. Patient expected survival less than 12 months due to serious comorbidity
6. Contraindications to antiplatelet therapy

The patients were randomized [23] to coronary angioplasty using a scoring balloon catheter or a NC balloon catheter.

We compared the procedure-related parameters, including the stenting technique, the total implanted stent length, intravascular ultrasound (IVUS) usage pre/post index percutaneous coronary intervention (PCI) and contrast usage.

The clinical study endpoints included:

- major adverse cardiovascular and cerebrovascular events (MACCE), defined as death, MI, stroke, repeated revascularization within 30 days after index procedure
- mortality in 2-year follow-up.

Statistical analysis was performed by MedCalc v.14.8.1 software (MedCalc Software, Ostend, Belgium). Continuous variables were expressed as the mean ± standard deviation (SD). Qualitative parameters were shown as crude numbers. The type of continuous variable distribution was acquired using the Shapiro--Wilk test. Due to the low n in the samples, and the non--normal type of distribution, two-tailed Mann-Whitney U testing was utilized. The significance of the proportions in the contingency tables was calculated using Fisher's exact test. The variables with $p < 0.1$ in univariate analysis were incorporated into logistic regression analysis to determine independent predictors of 2-year mortality. The p-value level < 0.05 was regarded as statistically significant throughout the analyses.

RESULTS

23 patients were included in the study. Among them 13 patients were randomized to the procedure with a scoring balloon catheter (AngioSculpt). The control group consisted of 10 patients treated with balloon angioplasty using a NC balloon catheter (Table I).

In the study group, in one case, the insertion of the scoring balloon catheter was not successful despite predilation with the NC balloon catheter. In the remaining 12 cases, predilation with the scoring catheter was performed directly. In one patient, the proximal optimization technique (POT) was not performed due to the good result of the procedure in the assessment of IVUS with minimal stent area (MSA) of 15.9 mm^2 in the LM trunk. Pre-PCI IVUS imaging was performed in 7 patients and IVUS imaging was performed at the end of the procedure in 12 patients. Scoring balloon catheters with diameters of 2.5 mm, 3.0 mm and 3.5 mm were used. One patient was scheduled for follow-up coronary angiography after 6 months, which showed a good long-term PCI result. All the PCI procedures were planned in the provisional stenting technique, and in one case the procedure was performed using the double stenting technique – T--stenting. Neither dissection nor perforation were observed during the procedure. In the early 30-day observation, no death, stroke, MI, or repeat revascularization were recorded.

Table I. Clinical characteristics of patients undergoing procedures with scoring balloon catheter (AngioSculpt) and non-compliant balloon catheter (NC balloon)
Tabela I. Charakterystyka kliniczna pacjentów poddawanych angioplastyce wieńcowej z użyciem cewnika balonowego nacinającego (AngioSculpt) i cewnika balonowego niepodatnego (NC balloon)

Parameter	Scoring catheter n = 13	Non--compliant catheter n = 10	P value
Average age in years	70.1	73.5	NS
Men/Women	8/5	6/4	NS
Hypertension	13/13	10/10	NS
Hyperlipidemia	13/13	9/10	NS
Diabetes	7/13	4/10	NS
CHF LVEF < 35%	2/13	4/10	NS
Nicotinism	2/13	2/10	NS
COPD	2/13	2/10	NS
PAD	4/13	2/10	NS
History of stroke	4/13	1/10	NS
CKD GFR < 60 ml/min/1.73 m^2	4/13	2/10	NS
Average GFR ml/min/1.73 m^2	67.1	70	NS
ACS – NSTEMI	5/13	6/10	NS
Unstable angina	2/13	2/10	NS
Chronic coronary syndrome	6/13	2/10	NS
Prior-CABG	5/13	3/10	NS

Fisher's exact test was applied to compare all qualitative parameters shown above; NS – non-significant, CHF LVEF – chronic heart failure left ventricular ejection fraction, COPD – chronic obstructive pulmonary disease, PAD – peripheral arterial disease, CKD – chronic kidney disease, GFR – glomerular filtration rate, ACS – acute coronary syndrome, NSTEMI – non-ST-elevation myocardial infarction, CABG – coronary artery bypass graft

Table II. Angiographic characteristics of left main (LM) stenosis according to Medina angiographic classification. Group of patients who underwent angioplasty using scoring balloon catheter (AngioSculpt) and non-compliant balloon catheter (NC balloon)
Tabela II. Angiograficzna charakterystyka zwężenia pnia lewej tętnicy wieńcowej (LM) wg klasyfikacji Medina. Grupy pacjentów poddawanych angioplastyce wieńcowej z użyciem cewnika balonowego nacinającego (AngioSculpt) i cewnika balonowego niepodatnego (NC balloon)

Medina angiographic classification	Scoring catheter n = 13	Non-compliant catheter n = 10
Medina 1,0,0	4/13	2/10
Medina 1,1,0	6/13	4/10
Medina 1,1,1	3/13	3/10
Medina 0,1,1	0/13	0/10
Medina 0,0,1	0/13	1/10
Medina 0,1,0	0/13	0/10

Table III. Characteristics of percutaneous coronary intervention using scoring balloon catheter (AngioSculpt) and non-compliant catheter (NC balloon)
Tabela III. Charakterystyka zabiegu angioplastyki wieńcowej z użyciem cewnika balonowego nacinającego (AngioSculpt) i cewnika balonowego niepodatnego (NC balloon)

Procedure characteristics	Scoring catheter n = 13	Non--compliant catheter n = 10	P value
NC balloon predilation	1/13	10/10	–
AngioSculpt predilation	12/13	0/10	–
AngioSculpt 2.5 mm	2/13	0/10	–
AngioSculpt 3.0 mm	5/13	0/10	–
AngioSculpt 3.5 mm	5/13	0/10	–
POT postdilation	12/13	9/10	1.0*
Final Kissing Balloon	1/13	3/10	0.28*
Provisional stenting	13/13	10/10	1.0*
T-stenting / TAP	1/13	3/10	0.28*
DK Crush	0/13	0/13	1.0*
Cullote stenting	0/13	0/13	1.0*
Average length of stent (AVG ± SD)	19.1 ± 5.6 mm	22.9 ± 6.3 mm	0.17#
IVUS pre PCI	7/13	1/10	–
IVUS post PCI	12/13	7/10	–
IVUS MSA LM mm^2 (AVG ± SD)	15.0 ± 2.6	12.0 ± 2.9	0.23#
Use of contrast agent ml (AVG ± SD)	173 ± 71	219 ± 49	0.11#
30-day MACCE	0 (0%)	1 (10%)	0.43*
2-year mortality	4 (31%)	3 (30%)	1.0*

*Fisher's exact test; #two-tailed Mann-Whitney U test; POT – proximal optimization technique, TAP – T and protrusion, DK Crush – double kissing crush, AVG – average, SD – standard deviation, IVUS – intravascular ultrasound, PCI – percutaneous coronary intervention, MSA – minimal stent area, LM – left main, MACCE – major adverse cardiovascular and cerebrovascular events

In the control group, all the patients were predilated using the NC balloon. In one patient, POT was not performed due to the good result of the procedure in the assessment of IVUS with an MSA of 9.4 mm^2 in the LM trunk. One patient underwent IVUS imaging before PCI and seven patients underwent IVUS imaging at the end of the procedure. All the PCI procedures were planned in the provisional stenting technique, and finally, in three cases, the procedure was performed using the double stenting technique – T-stenting.
In the early 30-day follow-up, no death, stroke, or repeat revascularization were found, but one MI associated with the type of procedure (type 4a) was diagnosed.

DISCUSSION

Left main trunk coronary angioplasty remains a challenge for the invasive cardiologist. Personalized medicine is becoming ever more important [24], which is of particular importance in the case of LM procedures [25,26]. The dangerous phenomenon of uncontrolled dissection with subsequent thrombosis can lead to catastrophic consequences. Due to the continuity of the middle aorta and the proximal part of the LM trunk, there is an additional risk of aortic dissection. Avoiding vessel dissection during the procedure reduces the risk of death or MI. In addition, reducing the risk of uncontrolled slippage of the device from the lesion may lead to a reduction in the frequency of subsequent stent implantation. Reducing the risk of stent thrombosis can be achieved by obtaining a larger diameter of the vessel lumen after angioplasty. In turn, carrying out high--pressure post-dilatations may damage the struts of the stent and the polymer. Proper preparation of the plaque can reduce this risk. By modifying the atherosclerotic plaque, the systolic-diastolic mobility of the left coronary trunk division may be improved. Balloon catheter techniques (scoring catheter, cutting catheter, ultrasonic wave catheter) are technically simpler to perform. The difference between the scoring and cutting balloon is the depth of incision in the plaque. The cutting balloon is made of a balloon catheter with three or four atherectomes (microsurgical blades) anchored along the long axis of the catheter. Thanks to this structure, it is possible to cut the atherosclerotic plaque in a controlled manner and potentially reduce the pressure trauma of the vessel. In the event of spontaneous dissection of the coronary arteries (SCAD), the use of a cutting balloon may enable fenestration of the intramural hematoma (IMH) and thus prevent the hematoma from propagating [13]. The use of a cutting balloon may be useful in the situation of restenosis due to the greater increase in the lumen of the vessel compared to the use of a conventional balloon catheter, which was confirmed in the IVUS study [14]. In the case of restenosis in the LM trunk, the use of a cutting balloon catheter followed by the use of a drug-eluting balloon (DEB) may avoid the introduction of another DES.
In the case of ablation-based techniques (rotational atherectomy, orbital atherectomy, laser atherectomy), material is released from the atherosclerotic plaque. A registry of LM trunk coronary angioplasty using AngioSculpt [12] demonstrated the safety of procedures using this technology. Our preliminary experience also confirms this observation.

The study group and the control group did not differ in terms of demographic data or comorbidities. In the study group, a larger diameter of the LM trunk was obtained, as assessed by the IVUS technique. In the control group, the two-stent technique was used more often; however, due to the small number of participants, statistical significance was not achieved. In the control group, greater use of contrast was associated with more frequent use of the two-stent technique. Despite one MI related to the procedure in the control group, the 2-year mortality rate between the groups was similar. Logistic regression did not reveal any of the studied variables to be significantly related to 2-year mortality.

Limitation

The main limitation of the study is the small number (n = 23) of participants.

CONCLUSIONS

The preliminary results of our study suggest that there is no difference in the early 30-day results and 2-year mortality in a randomized group of patients undergoing coronary angioplasty using a scoring balloon catheter and a non-compliant catheter. Selection of the optimal treatment strategy in LM stenosis is still a matter of research, and the operator's experience is of fundamental importance.

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Author's contribution

Study design – P. Żurek, Z. Gąsior, A. Ochała
Data collection – P. Żurek
Data interpretation – P. Żurek, Z. Gąsior, A. Kułach, A. Ochała
Statistical analysis – P. Żurek, A. Kułach
Manuscript preparation – P. Żurek, Z. Gąsior, A. Kułach
Literature research – P. Żurek, Z. Gąsior, A. Kułach, A. Ochała

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