

Clinical research

Utility of the SYNTAX Score in the risk stratification of patients undergoing rotational atherectomy

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Abstract

Introduction: The SYNTAX Score (SS) evaluates the angiographic complexity of coronary artery disease to assess the cardiovascular risk after coronary revascularization. The aim of the study was to evaluate whether SS results are associated with in-hospital and 1-year outcomes of patients undergoing percutaneous coronary intervention (PCI) requiring rotational atherectomy (RA).

Material and methods: We analyzed data of 207 consecutive patients who underwent PCI with RA. Patients were divided into two groups: those with high SS (> 33 points) and those with low/intermediate SS (0–33 points).

Results: In 21 (10%) patients SS was high and 186 (90%) patients had low/intermediate SS. Patients with high SS were older (76 vs. 71 years, $p = 0.008$) and more frequently diagnosed with chronic kidney disease (38% vs. 18%, $p = 0.03$) and heart failure (71% vs. 30%, $p = 0.0001$). In patients with high SS the RA procedure was longer ($p = 0.004$), required more contrast ($p = 0.005$) and higher radiation doses ($p = 0.04$), and contrast-induced nephropathy was more frequent (14% vs. 2%, $p = 0.001$).

Conclusions: In our RA patients there was no significant difference between the frequency of in-hospital and 1-year adverse cardiovascular events depending on the SS result. High SS correlates only with parameters describing the extensity and technical complexity of the procedure. However, the unavailability of other risk assessment tools in this population raises the need to create a new more specific risk score for patients requiring RA.

Key words: myocardial revascularization, percutaneous coronary intervention, coronary artery stenosis.

Introduction

Rotational atherectomy (RA) is a well-recognized method of percutaneous coronary intervention (PCI) facilitation, especially in patients with complex lesions with severe calcifications [1, 2]. RA is mainly used in patients with challenging coronary anatomy and many comorbidities [3, 4]. It is technically difficult, has a long learning curve and should be performed by experienced operators [5, 6]. Most recommendations regarding RA in ESC guidelines and recommendations are based only on the expert consensus (class C) due to limited data from clinical trials [7].

The shortage of contemporary research is mainly seen in the area of procedural technique [8]. Nevertheless, the number of RA procedures is increasing mainly due to the increasing need of PCI facilitation in the elderly population with severe calcifications in coronary arteries [5, 9]. Since the RA procedure does not require cardiocirculatory backup, more and more smaller centers have started performing RA [10]. This raises the need for an adequate pre-procedural risk stratification and patient selection in order to minimize the risk of complications in less experienced, low-volume centers. The SYNTAX Score (SS) is a tool widely accepted by interventional cardiologists and validated in patients undergoing PCI in general [11]. SS is designed for comprehensive anatomical assessment of coronary artery lesions which helps to predict the complexity of the PCI procedure [12, 13]. The use of SS was also proved to be effective in predicting mortality after PCI procedures [14–16]. Due to the accessible online calculator (<http://www.syntaxscore.com/>) it is easy to apply in everyday practice. The score is based on evaluation of 12 variables concerning coronary artery lesions.

No studies so far have assessed the usefulness of SS in patients undergoing PCI accompanied by RA. The aim of the study was to assess the periprocedural, in-hospital and 1-year outcomes of patients undergoing PCI with RA, depending on the value of SS.

Material and methods

Study population

In this single center observational retrospective study we included all consecutive patients undergoing PCI with RA performed in the institution from 2008 to 2016. Baseline demographics, clinical characteristics and detailed procedural data were collected, along with lesion characteristics and basic quantitative coronary angiography parameters. Information on all postprocedural complications as well as in- and out-of-hospital adverse cardiovascular events was collected. One-year follow-up data regarding all-cause mortality, recurrent hospitalizations, and adverse events were obtained from the Polish National Health Fund database, so no patient was lost to follow-up. The study protocol was accepted by the local ethics committee and was in accordance with the Declaration of Helsinki.

Coronary angiography assessment

SS calculations and angiographic results were assessed independently by 2 experienced operators. In case of inconsistency a third calculation was done by the supervisor cardiologist. Scores

linked to SS were additionally assessed: residual SS and Syntax Revascularization Index. The clinical risk was assessed according to the logistic EuroSCORE II scale. Patients were divided into two groups: patients with SS 34 points or higher (high SS group) and patients with SS up to 33 points (low SS group).

Procedure and treatment

The RA procedure was performed using the standard Boston Scientific Rotablator system (Boston Scientific, Marlborough, MA, USA). All procedures were performed by experienced interventional cardiologists. The radial or femoral route was used according to the operator's discretion. In-hospital treatment before and after RA was conducted according to current standards, including adequate pharmacotherapy in patients with comorbidities such as heart failure, atrial fibrillation, and diabetes mellitus, which was left to the discretion of physicians in charge of the patients. In patients with multivessel coronary artery disease disqualification from the coronary artery bypass grafting (CABG) procedure and qualification for RA were performed by the local Heart Team.

Statistical analysis

Continuous variables with normal distribution are presented as mean \pm 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 was used to compare categorical variables. A *p*-value < 0.05 was considered statistically significant. Cox proportional hazard models were used to determine the predicting factors of death and major adverse cardiac events. All statistical analyses were performed using the Statistica 13.1 (StatSoft, USA) software.

Results

Demographic and laboratory characteristics of study groups

The study group comprised 207 consecutive patients undergoing the RA procedure and 21 patients were included in the high SS group. These patients were older (76 ± 9 vs. 71 ± 9 years, $p = 0.008$), more often diagnosed with heart failure (71% vs. 30%, $p < 0.001$), thyroid disease (29% vs. 12%, $p = 0.033$) and chronic kidney disease (38% vs. 18%, $p = 0.032$). Patients with low SS had more often undergone PCI in the past (78% vs. 33%, $p < 0.001$). There were no differences in the results of basic laboratory tests. Complete demographic and

laboratory characteristics are presented in Table I. Complete data regarding risk scales are presented in Table II.

Procedural and lesion characteristics

Complete data regarding procedural characteristics are presented in Table III. Procedural success was high in both groups (100% and 92%, $p = 0.177$). It should be pointed out that the majority of patients with high SS were disqualified from CABG (67%) by the local Heart Team despite the SS indicated benefit of this method of treatment.

It was caused mainly by numerous comorbidities not accounted for in the SS or other risk stratification tools. RA was performed mainly (60%) with radial access; however, the preferred access site changed during the study period from femoral

at the beginning to radial later on. There were significant differences between the two groups in the extent and duration of the procedure. Amount of contrast used (323 ml vs. 250 ml, $p = 0.004$), radiation exposure (3725 mGy vs. 2559 mGy, $p = 0.035$), fluoroscopy time (30 min. vs. 20 min, $p = 0.001$) and total PCI time (114 min vs. 85 min, $p = 0.003$) were all higher in the high SS group. After the procedure, patients were prescribed standard dual antiplatelet therapy. The majority of patients received acetylsalicylic acid (97%) along with an P2Y12 inhibitor (98%).

Periprocedural, in-hospital and 1-year follow-up complications

The study groups did not differ in terms of incidence of periprocedural complications and

Table I. Clinical and laboratory characteristics

Parameter	All patients	Patients with high SYNTAX Score	Patients with low SYNTAX Score	P-value
Number	207	21 (10%)	186 (90%)	
Age [years]	71 ±9	76 ±9	71 ±9	0.008
Male	137 (66%)	11 (52%)	126 (68%)	0.16
Hypertension	170 (82%)	19 (90%)	151 (81%)	0.29
Diabetes mellitus	88 (43%)	10 (48%)	78 (42%)	0.62
Hypercholesterolemia	96 (46%)	9 (43%)	87 (47%)	0.73
Heart failure	70 (34%)	15 (71%)	55 (30%)	< 0.001
Atrial fibrillation	44 (21%)	7 (33%)	37 (20%)	0.15
Previous MI	130 (63%)	13 (62%)	117 (63%)	0.93
Current smoker	15 (7%)	1 (5%)	14 (8%)	0.64
Previous stroke/TIA	26 (13%)	3 (14%)	23 (12%)	0.80
Thyroid disease	28 (14%)	6 (29%)	22 (12%)	0.03
Asthma/COPD	14 (7%)	4 (19%)	10 (5%)	0.02
Cancer	25 (12%)	3 (14%)	22 (12%)	0.74
CKD	42 (20%)	8 (38%)	34 (18%)	0.03
Previous PCI	152 (73%)	7 (33%)	145 (78%)	< 0.001
Previous CABG	31 (15%)	3 (14%)	28 (15%)	0.93
WBC [$10^3/\mu\text{l}$]	8 ±2	8.2 ±1.8	7.7 ±2.1	0.24
RBC [$10^6/\mu\text{l}$]	5 (4–5)	4.4 ±0.5	4.5 (4.2–4.8)	0.45
HGB [g/dl]	14 ±1.4	13.3 ±1.6	13.6 ±1.3	0.29
PLT [$10^3/\mu\text{l}$]	205 (176–249)	229.3 ±99.3	205 (177–249)	0.79
Glucose [mg/dl]	109 (96–134)	136 ±52.7	108.5 (96–132)	0.16
eGFR ml/min/1.73 m ²	78 (±25)	65 (±23)	79 ±24	0.01

Data are presented as numbers and percentages for categorical variables, mean ± standard deviation for continuous variables with normal distribution, and median with interquartile range for continuous variables with skewed distribution. MI – myocardial infarction, TIA – transient ischemic attack, COPD – chronic obstructive pulmonary disease, CKD – chronic kidney disease.

Table II. Risk scales

Parameter	All patients	Patients with high SYNTAX Score	Patients with low SYNTAX Score	P-value
Syntax Score	19 ±10	41 ±6	17 ±8	< 0.001
Residual Syntax Score	8 (0–14)	25 ±10	7 (0–1)	< 0.001
Syntax Revascularization Index, %	59 (42–100)	40 ±17	63 (43–100)	< 0.001
EuroSCORE 2	2.4 (1.4–4.9)	5.1 (3.7–9.5)	2.2 (1.3–4.2)	< 0.001

Data are presented as mean ± standard deviation for continuous variables with normal distribution, and median with interquartile range for continuous variables with skewed distribution.

Table III. Procedural and lesion characteristics

Parameter	All patients	Patients with high SYNTAX Score	Patients with low SYNTAX Score	P-value
Stable patient	165 (80%)	14 (67%)	151 (81%)	0.12
Radial access	125 (60%)	11 (52%)	114 (61%)	0.43
Procedural success	192 (93%)	21 (100%)	171 (92%)	0.18
CABG disqualification	75 (35%)	14 (67%)	61 (33%)	0.002
Stenosis (%)	95 (90–99)	99 (95–100)	95 (90–99)	0.005
Lesion length [mm]	24 (15–35)	37 (±18)	23 (15–35)	0.013
Lesion B2/C	186 (90%)	21 (100%)	165 (89%)	0.10
Ostial lesion	27 (13%)	7 (33%)	20 (11%)	0.004
Bifurcation	81 (39%)	11 (52%)	70 (38%)	0.19
Chronic total occlusion	23 (11%)	7 (33%)	16 (9%)	< 0.001
Severe calcifications	186 (90%)	21 (100%)	165 (89%)	0.10
Amount of contrast [ml]	250 (200–300)	323 (±111)	250 (200–300)	0.005
Radiation [mGy]	2623 (1686–4171)	3725 (±1650)	2559 (1649–4042)	0.04
Fluoroscopy time [min]	20 (15–29)	30 (±10)	20 (15–28)	0.001
PCI time [min]	85 (70–110)	114 (±36)	85 (70–105)	0.004

Data are presented as numbers and percentages for categorical variables, mean ± standard deviation for continuous variables with normal distribution, and median with interquartile range for continuous variables with skewed distribution. CABG – coronary artery bypass grafting, PCI – percutaneous coronary intervention.

cardiovascular adverse events during in-hospital and 1-year follow-up. High SS was also not predictive in Cox regression analysis, regarding both all-cause death (HR = 1.32, 95% CI: 0.39–4.51, $p = 0.66$) and overall adverse cardiac events (HR = 1.03, 95% CI: 0.60–1.50, $p = 0.12$). The only complication occurring more frequently in the high SS group was contrast-induced nephropathy (CIN) (14% vs. 2%, $p = 0.001$). Complete data regarding complications and procedural outcomes are presented in Table IV.

Discussion

The SS values in our study, despite complex description of lesion anatomy, do not correlate with RA results and do not predict either procedural complications or long-term outcomes. A high

score (over 33 points) predicts a higher major adverse cardiovascular event rate and poor outcome after PCI in comparison to CABG [17]. Notwithstanding, the SS seems not to be a suitable tool for risk stratification after RA.

Currently, the SS and clinical SS (including patients' clinical characteristics) are the most useful methods in PCI risk stratification. Although the SS seems to be adequate in predicting outcome after PCI in general, there is a need for more dedicated and accurate tools for assessing risk and outcome of such complex procedures as RA. For another complex PCI subgroup, chronic total occlusions (CTO), adequate dedicated scores (EuroCTO, J-CTO) were created to answer this need [18, 19] and SS also proved its predictive usefulness [20]. Thus far, no such scale has been designed

Table IV. Periprocedural complications and in-hospital and 1-year adverse events

Parameter	All patients	Patients with high SYNTAX Score	Patients with low SYNTAX Score	P-value
No/slow flow	3 (1%)	0 (0%)	3 (2%)	0.56
Side branch occlusion	5 (2%)	1 (5%)	4 (2%)	0.46
Dissection	8 (4%)	2 (10%)	6 (3%)	0.16
Perforation	3 (1%)	0 (0%)	3 (2%)	0.56
Emergency CABG	0 (0%)	0 (0%)	0 (0%)	–
AVB with PM	0 (0%)	0 (0%)	0 (0%)	–
Overall complications	19 (9%)	3 (14%)	16 (9%)	0.39
In-hospital stroke/TIA	1 (0%)	0 (0%)	1 (0.5%)	0.74
In-hospital MI	28 (14%)	5 (24%)	23 (12%)	0.15
In-hospital death	2 (1%)	1 (5%)	1 (0.5%)	0.06
In-hospital major bleeding	14 (7%)	3 (14%)	11 (6%)	0.15
Access site complications	3 (1%)	0 (0%)	3 (2%)	0.56
TVR	1 (0%)	0 (0%)	1 (1%)	0.74
CIN	6 (3%)	3 (14%)	3 (2%)	0.001
Overall in-hospital events	30 (14%)	5 (24%)	25 (13%)	0.20
Death in 1-year follow-up	20 (10%)	3 (14%)	17 (9%)	0.45
MI in 1-year follow-up	20 (10%)	2 (10%)	18 (10%)	0.99
Stroke in 1-year follow-up	2 (1%)	1 (5%)	1 (0.5%)	0.06

Data are presented as numbers and percentages. CABG – coronary artery bypass grafting, AVB – atrioventricular block, PM – pacemaker, TIA – transient ischemic attack, MI – myocardial infarction, TVR – target vessel revascularization, CIN – contrast-induced nephropathy.

for RA procedures. The widely used EuroSCORE II scale is very helpful to assess the risk of cardiac surgery but takes into consideration only clinical data without the complexity of coronary artery disease and is inadequate to assess an RA procedure. However, a rising interest in RA has been observed recently. A lot of low volume centers engaged in RA procedures have appeared as a result of an increase in the number of patients with highly calcified coronary lesions. So far, many observational studies have confirmed safety and efficacy of RA [21–25]. However, due to the technical complexity of RA and the importance of operator experience, an accurate pre-procedural risk stratification becomes a crucial point in a patient's qualification for the procedure. Low risk procedures could be performed relatively safely even by less experienced operators in low volume centers. On the other hand, to maintain high procedural success and low complication rates, patients with a calculated higher pre-procedural risk should be referred to a tertiary center.

We decided to analyze whether a well-known anatomical SS could assess the risk and predict complications of RA procedures. To our knowledge, no study has regarded the target use of the

SS for risk stratification after RA. The SS includes many variables significant for RA procedures such as the degree of calcifications, and length and tortuosity of the lesion. Presumably, it might be useful for assessing results in this population. However, our research showed that there were no differences in the incidence of perioperative complications between patients with high and low/intermediate SS. Differences were found only in variables associated with the extent of procedure complexity. Procedures performed in patients with a high SS lasted longer, more contrast was used and the radiation exposure was higher. As expected, CIN was observed more often in this group (14% vs. 2%) [26]. Also during 1-year follow-up no significant differences in the incidence of adverse events, including death, myocardial infarction and stroke, were observed. These observations support the conclusion that SS assessed prior to the procedure does not correlate with the frequency of procedural complications and 1-year outcomes after RA and therefore the SS seems not to be a useful tool for risk stratification in patients undergoing RA procedures. It may be partially associated with some differences in clinical characteristics of studied populations and our results are to

be confirmed in larger population. In the SYNTAX study, the studied population was younger (65 vs. 71 years) and had a lower incidence of prior myocardial infarction (32% vs. 63%), stroke (8% vs. 13%), diabetes (28% vs. 43%) and heart failure (4% vs. 34%) compared to our study group.

RA is the only remaining revascularization option for many patients. Interventional cardiologists should be encouraged to perform this procedure, but have to take into account a long learning curve [5]. Therefore proper risk stratification and patient qualification are of paramount importance. A new specific score would be useful in clinical practice, correlating with the results of RA and giving a better risk stratification of procedural success. Such a scale, due to the additional differences of RA from conventional PCI, should contain RA specific parameters – not included in the SS. This would make it possible to distinguish technically easier RA and enable some of the procedures to be performed in smaller, less experienced centers.

This was a single-center retrospective observational study conducted on a relatively small population. Underestimation of outcomes is possible, so the results should be considered mainly hypothesis-generating. Only all-cause mortality was reported during follow-up without differentiating the group of cardiac death patients.

In conclusion, the SS despite comprehensive description of lesion anatomy does not correlate with RA results and does not predict either procedural complications or long-term outcomes. Our results are to be confirmed in a larger population. However, the SS seems not to be a suitable tool for pre-procedural risk stratification. Taking into account the need for accurate patient qualification to maintain a high procedural success and low complication rate both in low and high volume centers, a new risk assessment tool dedicated for RA procedures would be useful in clinical practice.

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Conflict of interest

The authors declare no conflict of interest.

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