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Validation of an NCDR-score-based risk model for cardiac catheterization procedures in a European population

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Background and purpose: Cardiac catheterization procedures carry complication risks dependent on setting and patient comorbidities. The National Cardiovascular Data Registry (NCDR) risk scores for mortality, major bleeding (MB) and acute kidney injury (AKI) have proven to be accurate outcome predictors in North American populations. However, their application in Europeans remains elusive, and we thus aimed to verify their use in our population.

Methods: NCDR-Scores for mortality, MB and AKI and corresponding clinical outcomes were retrospectively assessed in patients undergoing cardiac catheterization for ST-segment elevation myocardial infarction (STEMI), non-ST-segment elevation myocardial infarction (NSTEMI) or for elective cardiac catheterization (ECC) in a tertiary hospital from 2014 to 2017.

Results: Patients were undergoing catheterization for STEMI (565 patients, 43%), NSTEMI (461 patients, 35%) and ECC (285 patients, 22%); 5.8% (11% of STEMI and 3% of NSTEMI patients) were in cardiogenic shock, 4.1% had resuscitated preprocedural cardiac arrest. Radial access was used in 47% of procedures, cross-over was necessary in 4.1%. In-hospital mortality was 7.2% overall (STEMI 13%; NSTEMI 4.1%; ECC 0%) and 41% in cardiogenic shock; major bleeding events occurred in 5% of patients (STEMI 8.3%, NSTEMI 6.3%, ECC 0%); acute kidney injury (AKI, KDIGO) was detected in 19.1% (STEMI 23.7%, NSTEMI 24.9%, ECC 0.7%), amounting to KDIGO stage I/II/III in 11.7%/4.1%/3.3%. The NCDR score prediction model performed very well for mortality (c-statistic 0.88, confidence interval (CI) 0.85–0.91) and moderately well for MB (c-statistic 0.74, CI 0.69–0.78) and AKI (c-statistic 0.74, CI 0.71–0.77), coming close to the original validation performance (c-statistic 0.93, 0.77, 0.71 for mortality, MB and AKI respectively). The NCDR scores predicted mortality and AKI event rates accurately in low- and intermediate-risk patients, however underestimated high-risk patients. MB was overestimated consistently.

Conclusions: NCDR-Score-based periprocedural risk prediction in cardiac coronary catheterization procedures is very accurate for mortality, and moderately accurate for major bleeding and acute kidney injury in a European population.

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The ARDVAARC study: real-world outcomes and the utility of bleeding risk scores in patients who require anticoagulation following percutaneous coronary intervention (PCI)

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Background: Patients with an indication for anticoagulation following PCI pose a common clinical challenge in balancing the benefit of reduced ischaemic events versus an increased risk of adverse bleeding. Recent trials have challenged the traditional standard regimen of "triple" therapy with dual antiplatelets (DAPT) and warfarin (VKA).

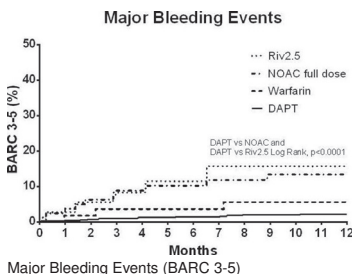
PIONEER-AF provided an appealing suggestion that the use of rivaroxaban at 2.5mg BD (Riv2.5) may provide equivalent thrombotic protection with reduced bleeding compared to VKA when used in addition to DAPT. We present real-world outcomes in our cohort of patients treated with this strategy.

Methods: All patients undergoing PCI in a single centre from 2013 to 2017 were included in the study. DAPT was defined as the use of aspirin and a second antiplatelet agent. Triple therapy was defined as use of DAPT with either VKA, a novel anticoagulant at full dose (NOAC) or Riv2.5.

The primary outcome was major bleeding (defined by Bleeding Academic Research Consortium (BARC) type 3 to 5 bleeding). Secondary outcomes included a composite of myocardial infarction, stroke and all cause death (MACCE).

Results: 781 patients were included in the analysis. 136 patients received triple therapy (VKA 41%, NOAC 34%, Riv2.5 25%). Triple therapy patients were older (73±10yrs) than those treated with DAPT alone (68±12yrs). Median follow up for both groups was 12 months (DAPT IQR 9.1–12; Triple IQR 12–12).

There were 14 (2.2%) major bleeding events in the dual therapy group versus 13 (9.6%) in the triple therapy group (HR 9.6, 95% confidence interval 3.5–26.4; p<0.0001). 14% of patients on Riv2.5 experienced a major bleed (figure 1), with no significant difference in major bleeding compared to full dose NOAC or VKA.



Mean HAS-BLED and ORBIT scores were 3.2±1.1 and 2.5±1.3 respectively, however these risk scores were not predictive of bleeding events in our population (AUC HAS-BLED 0.56, ORBIT 0.44).

MACCE did not differ significantly between the dual or triple therapy groups. 4 (0.006%) strokes occurred in the dual therapy group versus 1 (0.7%) in the triple therapy group (p=NS).

Conclusion: Triple therapy significantly increases major bleeding risk regardless of anticoagulant, and without effect on MACCE. Guideline recommended clinical scoring systems were not effective at predicting these bleeding events in our population. The optimal pharmacological strategy for management of these patients remains uncertain.

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Utility of SYNTAX score II in revascularization decision-making process in patients with acute coronary syndrome without local heart surgery facilities

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Background: The SYNTAX Score II (SSII) represents a useful decision-making tool providing an individualized approach for the selection of the optimal revascularization strategy: (Coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI)) in patients with multivessel disease (MVD).

However, there is a paucity of data regarding its performance to select the revascularization strategy in patients presenting with acute coronary syndrome (ACS).

Aims: We sought to prospectively investigate the agreement between our team's decision and the recommended strategy by the SSII, then, the number of adverse events that may be prevented by SSII recommendation in a hospital without heart surgery facilities in patients presenting with ACS.

Methods: We enrolled 239 consecutive patients with multivessel disease (MVD) and/or unprotected left main (ULM) disease admitted in the setting of ACS. The SSII was calculated for each patient. Major cardiac and cerebrovascular events (MACCE) were ascertained for both patients undergoing PCI and CABG. One-year clinical follow-up was performed in all patients.

Results: The mean age was 61.9±10.9, and 81.2% were males. The decision of revascularization strategy advocated by our team concluded to: PCI (n=208, 86.7%) and CABG (n=32, 13.3%). The optimal treatment recommendation strategy after applying the SSII were CABG in 59 (24.6%) patients, PCI in 8 (3.3%) patients and CABG or PCI would be the strategy of choice in 173 (72.1%) patients. Only 14 (24%) patients out of 59 in whom SSII recommended CABG were really referred for CABG. Whereas the remaining 45 (76%) patients underwent PCI. Our cardiology team endorsed the SSII recommendation for PCI or CABG in 195 patients (81%). In patients treated by PCI while the SSII recommended CABG, the 1-year MACCE events rate was higher than in those with SSII recommendation in favor of PCI and PCI or CABG (40% vs 23.2% vs 12.5%, P log-rank=0.036). Based on absolute risk reduction between discordantly and concordantly treated PCI patients, it would need to treat 23 patients to avoid the occurrence of MACCE in one patient within 1-year follow up according to SSII recommendation.

Conclusion: The SYNTAX score II showed to be an appropriate tool to select revascularization modality in patients with complex coronary artery referred for ACS.

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Comparison of residual added index with residual SYNTAX score in the risk stratification of patients with incomplete coronary percutaneous revascularization after ST-elevation myocardial infarction

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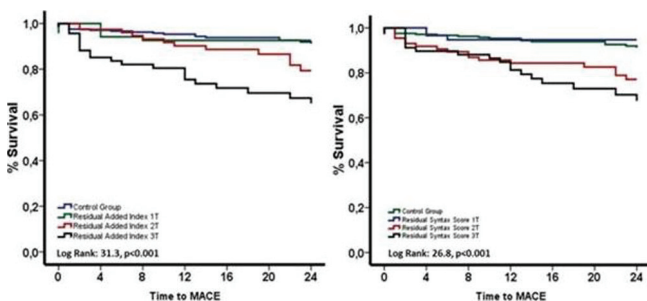
Background: Incomplete coronary revascularization after PCI is common in patients with acute coronary syndromes. The residual syntax score (rSS) has been previously suggested to quantify the degree of residual stenosis after PCI and it has also been showed to predict outcomes at 1 year. However, the rSS reflects stenosis complexity regardless of its related ischemic potential. The Added index, namely the ratio between minimal lumen diameter (MLD) and Duke Jeopardy Score (DJS), showed high accuracy to predict FFR and it might be used to detect functionally significant coronary artery.

Purpose: The aim of the present study was to investigate, in patients presenting with STEMI and undergoing to successful pPCI, the prognostic value of the residual Added Index (rAI) as compared with rSS.

Methods: We included 605 patients presenting with STEMI and in whom pPCI was successful. Patients with previous coronary artery bypass grafts (CABG) or presenting with cardiogenic shock were excluded. Both rAI and rSS were retrospectively calculated. All patients were divided in rAI tertiles (first <1.79 [n=94], second from 1.79 to 3.49 [n=93], and third >3.49 [n=97]) and rSS tertiles (first <3.00 [n=83], second from 3.00 to 6.00 [n=107], and third >6.00 [n=94]), patients without residual coronary artery stenosis served as control (n=321). Primary end points were: 1) major adverse cardiac event (MACE), defined as overall death,

myocardial infarction, repeat revascularizations; 2) non-target vessel oriented adverse cardiac event (VOCE), defined as overall death, non-target vessel related myocardial infarction and non-target vessel related revascularizations.

Results: Follow-up was obtained in 77% of patients at a median of 24 months (14–36 months). At multivariate analysis, MACE rate was significantly higher in the third tertile of both rAI (30% for the Third Tertile vs. 15% for the Second Tertile vs. 7% for the First Tertile vs. 7% for control patients, adjusted HR: 2.19 [1.53–3.15], $p < 0.001$) and rSS (26% for the Third Tertile vs. 19% for the Second Tertile vs. 5% for the First Tertile vs. 7% for control patients, adjusted HR: 1.92 [1.35–2.75], $p < 0.001$). The rate of VOCE was equally significantly higher in the third tertile of both rAI (24% for the Third Tertile vs. 14% for the Second Tertile vs. 6% for the First Tertile vs. 4% for control patients, adjusted HR: 3.07 [1.91–4.95], $p < 0.001$) and rSS (20% for the Third Tertile vs. 18% for the Second Tertile vs. 3% for the First Tertile vs. 4% for control patients, adjusted HR: 2.77 [1.71–4.49], $p < 0.001$). The predictive accuracy for both rAI and rSS was moderate (respectively, c-statistics for MACE: 0.70 and 0.70, $p < 0.001$).



Conclusions: The residual ADDED index represents a simple tool in the prognostication of patients with residual coronary artery stenosis after primary PCI, allowing prediction of 2-years MACE and VOCE with a moderate accuracy as well as the residual Syntax Score.

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Usefulness of SYNTAX score II in patients with acute coronary syndrome and multivessel disease: a comparison with SYNTAX score I and GRACE score

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Background: The SYNTAX (Synergy between percutaneous coronary intervention with Taxus and cardiac surgery) score II (SS-II) was developed by integrating anatomical SYNTAX score I (SS-I) with clinical characteristics to perform an individualized prediction of long-term mortality. However, there is a lack of data regarding the usefulness of SSII in patients with multivessel disease (MVD) or unprotected left main (ULM) stenosis referred for acute coronary syndrome (ACS).

Aims: We sought to evaluate the added prognostic value of the SS-II in ACS patients with MVD or/and ULM stenosis undergoing percutaneous coronary intervention (PCI), in comparison with SS-I and GRACE score.

Methods: From January 2016 to December 2016, consecutive patients with ACS and MVD or/and ULM stenosis undergoing PCI were enrolled. The SS-II, SS-I and GRACE score were calculated. One-year clinical follow up was performed. Major cardiac and cerebrovascular events (MACCE) were defined as a composite of: cardiovascular death, myocardial infarction (MI), repeat revascularization and stroke. The predictive value of SS-II for MACCE occurrence at 1 year was then compared with that of SS-I and GRACE score.

Results: A total of 208 patients were enrolled. The mean age was 61.8 ± 10.9 years. Eighty-two percent were male. The median SS-II was 27.5 [range 10,8 - 64,7]. Complete revascularization was achieved in 75% of cases. MACCE occurred in 54 (26%) patients: 24 (11.5%) experienced repeat revascularization, 11 (5.3%) MI and death was observed in 10 patients (4.8%). The 1-year MACCE-free survival rate was significantly lower in patients with SS-II ≥ 27.5 , compared with patients with SS-II < 27.5 (52% vs 93.4%, $p < 0.001$).

In multivariate Cox regression analysis, the independent predictors of MACCE at 1 year clinical were SS-II ≥ 27.5 [hazard ratio (HR): 3.15, 95% confidence interval (CI): 1.29–8.22; $p = 0.013$] and complete revascularization [HR: 0.013, 95% CI: 0.01–0.05; $p < 0.001$].

Compared with GRACE score and SS-I, the SS-II showed the best prognostic accuracy (C-statistic index SS-II: 0.74, 95% CI: 0.67–0.8, C-index GRACE: 0.63, 95% CI: 0.54–0.72 and C-index SS-I: 0.62, 95% CI: 0.53–0.7, all $p < 0.001$) and the best calibration (Hosmer-Lemeshow goodness-of-fit test $p: 0.69$). Moreover, the net reclassification improvement index was 0.12 ($p: 0.001$).

Conclusion: By combining both angiographic and clinical variables, SSII proved his superiority compared with the angiographic SS-I and the clinical GRACE score as a useful tool to predict MACCE in patients with ACS and complex coronary lesions undergoing PCI.

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STS, EuroSCORE II or SYNTAX II: which is the best score to assess mortality risk for complex coronary artery disease after CABG?

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Introduction: Complex coronary artery disease (CAD) still represents a challenge in clinical management. Coronary Artery Bypass Graft Surgery (CABG) has been established as the standard for the treatment of complex CAD. Prognostic models have been adopted in medical guidelines and are now widely used to assess risk and guide therapy. However, a direct comparison among STS, EuroSCORE II (ESII) and SYNTAX Score II (SSII) have never been performed.

Purpose: The aim of this study was to compare the predictive performance of STS, ESII and SSII for short- and long-term all-cause mortality in patients undergoing isolated CABG for complex CAD.

Methods: All patients with 3-vessel and/or left main CAD of the Multicenter São Paulo's Cardiovascular Surgery Registry (REPLICCAR-I) that underwent isolated CABG were included. Ten participating hospitals enrolled patients between 2013–2016. STS, ESII and SSII were calculated; and their performance to predict short- (30 days) and long-term (4 years) mortality was assessed.

Results: A total of 2961 patients undergoing isolated CABG were included. The median age was 63.34 years (IQR: 56.3–69.3 years); 72.6% were men; 46.8% had previous myocardial infarction; the median left ventricular ejection fraction was 60% (IQR: 50–64%) and 16.9% were on insulin therapy for diabetes. The median STS was 0.6% (IQR: 0.41 to 1.29%); the median ESII was 1.4% (IQR 0.85 to 2.09%) and the median SS II was 25.15% (IQR: 18.6 to 32.3%).

The all-cause mortality at 30 days was 3.4%. As shown in Figure 1A, all scores demonstrated good performance for short-term mortality. However, both STS and ESII had better accuracy for this time point ($p < 0.05$).

The mortality at 4-year follow-up was 5.3%. The SSII had the best discriminative ability to separate low-, medium, and high-risk groups (SSII: 54%, 27% and 17% vs STS 99.3%, 0.7% and 0% vs ESII 93%, 4.5% and 1.5%). Additionally, the SS II was the most precise in predicting long-term mortality [Calibration-in-the-large (CL) = 0.01; Figure 1B].

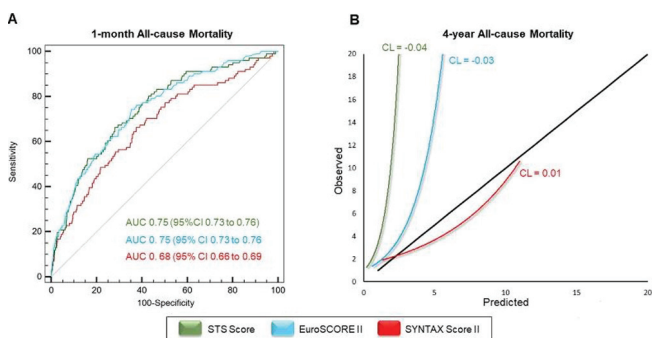


Figure 1. (A) Receiver operating characteristic (ROC) curves of STS, EuroSCORE II (ESII) and SYNTAX score II (SSII). (B) Calibration plots of STS, ESII and SSII for 4-year all-cause mortality. The black diagonal line represents the reference for a perfect model. CL=calibration in the large.

Conclusions: All scores were validated for short-term mortality, with better performance for STS and ESII. However, the SSII was the only score able to stratify patients more precisely in the long-term horizon.

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SYNTAX score and outcomes after coronary artery bypass grafting: a long-term follow-up analysis

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Background: Evaluation of coronary artery disease (CAD) complexity by the SYNTAX score is known to impact on outcomes after percutaneous coronary intervention, but its usefulness to predict adverse events after coronary artery bypass grafting (CABG) is controversial.

Purpose: Our aim was to evaluate the influence of the SYNTAX score on outcomes in a long-term follow-up of patients after elective CABG.

Methods: This was a single center, registry-based study that enrolled patients from the MASS Group Database. Baseline SYNTAX scores were calculated from patients undergoing CABG by cardiologists blinded to clinical characteristics and outcomes. Scores results were categorized in three groups: low (<23), intermediate (23–32) or high (>32). The primary outcome was a composite of death, myocardial infarction, repeat revascularization, or stroke (MACCE).

Results: Data from 324 surgical patients were included in this analysis. Median follow-up was 8.9 years (IQR: 4.9–9.8). The median SYNTAX score was 22 (IQR: 25–75), with a median of 17 (IQR: 13–19), 27 (IQR: 25–29.5) and 36 (IQR: 33.5–38) among patients in low (n:173), intermediate (n:109) and high (n:42) group respectively. During follow-up 67 events were documented. MACCE-free survival was 80.3%, 81.7% and 69% among patients in low, intermediate and high