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ORIGINAL ARTICLE

# Validity of the Stent Thrombosis Risk Score in Predicting Early Stent Thrombosis after Primary Percutaneous Coronary Intervention

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**Abstract**

*Background*: **The thrombosis of the stent is one of the most important complications of percutaneous interventions, resulting in complete occlusion of the stented vessel. Aim of this study was to determine the validity of Stent Thrombosis Risk Score (STRS) in predicting early stent thrombosis (ST) after primary Percutaneous Coronary Intervention (PCI).**

*Methods*: **For this study, 569 consecutive patients undergone primary PCI from July 2018 to December 2018 were recruited. Early ST was defined as ST occurred during or within 30 days after the procedure. The STRS was calculated as proposed, developed, and validated in a past study. The receiver operating characteristic curve analysis was performed to determine the optimal cut-off value and area under the curve (AUC).**

*Results*: **A total of 569 patients were included, the median age was 56 [61−50] years. Early ST was observed in 33 (5.8%) patients. The median STRS was 4 [5−3] vs. 3 [4−2]; p = 0.009 for patients with and without Early ST respectively. STRS was found to be an independent predictor of early ST with an adjusted odds ratio of 1.41 (1.02−1.95). AUC was 0.631 and the optimal cut-off value was ≥5. Early ST rate was 3.3% at STRS of 0−2, which raised to 5.0% at STR of 3−4, and 17.2% at STRS of ≥5.**

*Conclusions*: **In conclusion, STRS was found to be an independent predictor of early ST after primary PCI and has significant discriminating power. The rate of early stent thrombosis after primary PCI exponentially increased at STRS cut-off value of ≥5.**

*Keywords:* Percutaneous coronary interventions, Stent thrombosis, Risk score, Validity, Predictive value

## 1. Introduction

Worldwide, the incidence and prevalence of cardiovascular diseases vary depending upon the multiple factors including socioeconomic status, health care systems, etc. but we are lacking precise data so far. Among cardiovascular diseases, acute coronary syndrome (ACS) is one of the major causes of morbidity and mortality [1]. Current guidelines suggest that the patients, who present with ACS, specifically ST-segment elevation myocardial infarction (STEMI), must be gone through primary percutaneous intervention (PCI) emergently to reduce both mortality and morbidity [2]. Like any other intervention procedure, primary PCI has its own complications and thrombosis of the stent is the most important one resulting in complete occlusion of the stented vessel. A large prospective study, Harmonizing Outcomes with Revascularization and Stents in Acute Myocardial Infarction (HORIZONS-AMI), showed the overall rate of

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stent thrombosis at 30 days between 1.9% and 2.5% [3], that was considerably higher than 0.1%–0.6% early stent thrombosis rates in patients with stable coronary artery disease, observed from the randomized controlled trials of DES [4],[5] and also higher than that was observed in high and moderate risk patients with non-STEMI in the Acute Catheterization and Urgent Intervention Triage Strategy (ACUITY) trial, i.e early ST rate of 1.5% [6].

Over the past several years, many researchers have investigated potential predictors of stent thrombosis especially acute and sub-acute categories and identified a number of angiographic, clinical, procedural and post-procedural risk factors of stent thrombosis [7–10]. Dangas et al. [11] formulated a stent thrombosis risk score to stratify the patients at higher risk of stent thrombosis after pPCI. This potentially useful proposed risk assessment tool has never been validated for setting other than development settings. Therefore, aim of our study was to determine the validity of the Stent Thrombosis Risk Score in Predicting Early Stent Thrombosis after pPCI in our setting.

## 2. Materials and methods

The ethical review committee approval and permission were taken to access the institutional ST-segment elevation myocardial infarction (STEMI) database of the National Institute of Cardiovascular Diseases (NICVD), Karachi, Pakistan. Hospital records were obtained for the consecutive patients who went through primary PCI for STEMI from July 2018 to December 2018. As an institutional practice, written informed consent before the procedure was obtained from all the patients regarding the use of data obtained from hospital records for research purposes. And records of the patients who refused to give consent were inaccessible to the researcher. The primary PCI procedures were performed by the consultant cardiologists culprit artery was attempted and staged PCI was planned wherever needed. Conventional stenting technique i.e. stenting followed by post-dilation of stent with NC balloon. No complex procedures were done considering the setting of primary PCI and the need for timely restoration of TIMI flow to avoid ischemic myocardial injury.

All patients in our study were preloaded with soluble aspirin (300 mg), Clopidogrel (600 mg), unfractionated Heparin as bolus (body-weight adjusted dose of 70–100units/kg) and glycoprotein IIb/IIIa inhibitor i.e. tirofiban as bolus dose during the procedure. Glycoprotein IIb/IIIa inhibitor (tirofiban) as IV infusion in patients with high thrombus burden and short ischemic time. All these patients were prescribed with dual antiplatelet therapy (DAPT) for a one-month duration and Clopidogrel for 12 months duration and aspirin indefinite period of time.

**Abbreviations**

| | |
|---|---|
| ST | Stent thrombosis |
| STRS | Stent Thrombosis Risk Score |
| PCI | Percutaneous Coronary Intervention |
| ROC | receiver operating characteristic |
| AUC | area under the curve |
| STEMI | ST-segment elevation myocardial infarction |
| ACS | acute coronary syndrome |
| DES | drug eluting stent |
| NICVD | National Institute of Cardiovascular Diseases |
| ARC | Academic Research Consortium |
| TIMI | thrombolysis in myocardial infarction |

Patients' demographic characteristics, cardiac risk profile, angiographic characteristics, and in-hospital outcomes were obtained from the hospital record of the patients. Along with the ongoing institution quality controls intact, information of all the included patients, available in the institutional electronic database were verified by the patient's physical file and angiographic films and discrepancies, when found, were addressed appropriately.

Early stent thrombosis (ST) included ST during the procedure or within 30 days after the procedure. The definition proposed by the Academic Research Consortium was used to classify stent thrombosis [12]. Data regarding ST during the procedure and during the hospital stay after the procedure were obtained from the hospital recorded. And a telephonic follow-up was made to obtain data regarding ST within 30 days after the procedure. Verbal consent was obtained during telephonic follow-up.

The Stent Thrombosis Risk Score was calculated as proposed by Dangas GD et al. [11], it is a practical risk score in predicting the risk of early stent thrombosis (ST) after PCI for ACS. Variables included in this risk score were baseline platelet count, insulin-dependent diabetes mellitus, baseline thrombolysis in myocardial infarction (TIMI) flow grade 0-I, early anticoagulant therapy (pre-PCI), ulcerated or aneurysmal lesion, number of treated vessels, and final TIMI flow grade<III. The scoring schema for the calculation of the Stent Thrombosis Risk Score is presented in Fig. 1. Ulcerated or aneurysmal lesions were classified based on angiographic morphology proposed by Ambrose JA et al. [13]

| Serial | Variable | Levels and scoring schema |
|---|---|---|
| 1 | Baseline platelet count, K/µl | <250 [+0]<br>250 to 400 [+1]<br>>400 [+2] |
| 2 | History of IDDM | Yes [+2]<br>No [+0] |
| 3 | Baseline TIMI flow grade of 0-I | Yes [+2]<br>No [+0] |
| 4 | Early anticoagulant therapy | Yes [+0]<br>No [+1] |
| 5 | Aneurysm or ulceration | Yes [+2]<br>No [+0] |
| 6 | Number of vessels treated | <2 [+0]<br>2 [+1]<br>3 [+2] |
| 7 | Final TIMI flow grade of 0-II | Yes [+2]<br>No [+0] |
| *IDDM = insulin-dependent diabetes mellitus* | | |

*Fig. 1. Scoring schema for the calculation of the Stent Thrombosis Risk Score.*[11]

At a 95% confidence level and 5% margin of error, the sample size for the study was calculated with an expected AUC (area under the curve) of 0.67 for ST risk score in predicting early ST [11]. A minimum sample size of n = 230 was calculated and a design factor of 2.25 was considered in order to address loss to follow-up and other biases, under these considerations a sample size of 518 was calculated to be sufficient for the study.

Data analysis was executed using IBM SPSS Statistics for Windows, Version 21.0. (IBM Corp., Armonk, NY, US). The Kolmogorov–Smirnov test was applied to evaluate the normality of distribution of continuous variables such age (years), length of lesion (mm), length of stent (mm), and diameter of stent. And appropriate t-test or Mann–Whitney *U* test was applied for the between-group comparison in univariate analysis and the Chi-square or Fisher exact test was applied for the categorical response variables. Multivariate logistic regression analysis was performed for early ST with significant variables from univariate analysis and clinically significant variables as explanatory variables. Odds ratio [95% confidence interval] were reported for the logistic regression analysis. To find out the area under the curve (AUC) and optimal cut-off value, Receiver operating characteristic (ROC) curve analysis was performed. The optimal cut-off value of stent thrombosis risk score was computed with the help of the Youden Index. Patients were stratified based on the optimal cut-off value and sensitivity, specificity, and accuracy were calculated. Criteria for statistical significance was P-value of $\leq$0.05.

## 3. Results

A total of 569 patients undergone primary PCI were included, the median age of the patient was 56 [61–50] years. Early stent thrombosis (within 30 days of the procedure) was observed in 33 (5.8%) of the patients. The hypothesis of normality of distribution of age (years), lesion length (mm), stent length (mm), and stent diameter were rejected with Kolmogorov–Smirnov test p-value of <0.001. On univariate analysis diabetes, hypertension, and Killip class III-IV at presentation were found to be related to the development of early ST after primary PCI. Baseline clinical and demographic characteristics and univariate analysis for stent thrombosis are presented in Table 1.

The computed Stent Thrombosis Risk Score was considerably higher among the patients with early ST as compared to the patients without early ST, the median score was 4 [5–3] vs. 3 [4–2]; p = 0.009 respectively. Individual parameters of stent thrombosis risk score (STRS) by early ST are presented in Table 2.

The multivariate binary logistic regression analysis for early stent thrombosis is presented in Table 3. Among the clinically significant factors, Killip Class III-IV at presentation and Stent Thrombosis Risk Score were found to be independent predictors of early stent thrombosis with adjusted odds ratio [95% CI] of 4.24 [1.39–12.92] and 1.41 [1.02–1.95] respectively.

The distribution of Stent Thrombosis Risk Score, ROC curve, and subsequent rate of early stent

*Table 1. Baseline clinical and demographic characteristics and univariate analysis for stent thrombosis.*

| Characteristics | Total | Early Stent Thrombosis | | P-value |
|---|---|---|---|---|
| | | No | Yes | |
| N | 569 | 536 | 33 | – |
| Male | 458 (80.5%) | 431 (80.4%) | 27 (81.8%) | 0.843 |
| Age (years) | 56 [61–50] | 56 [61–49] | 56 [66–50] | 0.256 |
| Diabetes mellitus | 152 (26.7%) | 138 (25.7%) | 14 (42.4%) | 0.036* |
| Hypertension | 232 (40.8%) | 212 (39.6%) | 20 (60.6%) | 0.017* |
| Smoking | 134 (23.6%) | 128 (23.9%) | 6 (18.2%) | 0.454 |
| Obesity | 77 (13.5%) | 73 (13.6%) | 4 (12.1%) | 0.807 |
| Positive family history | 21 (3.7%) | 18 (3.4%) | 3 (9.1%) | 0.09 |
| Killip Class (III-IV) | 24 (4.2%) | 18 (3.4%) | 6 (18.2%) | <0.001* |
| Left dominance | 51 (9%) | 48 (9%) | 3 (9.1%) | 0.979 |
| Multivessel disease (MVD) | 339 (59.6%) | 319 (59.5%) | 20 (60.6%) | 0.901 |
| Lesion length (mm) | 16 (24–13) | 16 (24–13) | 20 (25–14) | 0.281 |
| Bare-metal stent (BMS) | 301 (52.9%) | 285 (53.2%) | 16 (48.5%) | 0.601 |
| Stent length (mm) | 15 (18–12) | 15 (18–12) | 15 (22–15) | 0.293 |
| Stent diameter (mm) | 3.5 (3.5–3) | 3.5 (3.5–3) | 3 (3.5–2.75) | 0.1 |
| Stent Thrombosis Risk Score | 3 (4–2) | 3 (4–2) | 4 (5–3) | 0.009* |

thrombosis by risk score are presented in Fig. 2. The area under the curve (AUC) of Stent Thrombosis Risk score to predict the early stent thrombosis is 0.631 (0.524–0.738), based on Youden's index the optimal cut-off value was ≥5 with an accuracy of 88%, specificity of 91%, and sensitivity of 30%. Early stent thrombosis was found to be linearly associated with the risk score, early ST rate was 3.3% for the patients with the risk score of 0–2, which raised to 5.0% with the risk score of 3–4, and 17.2% of the risk score of ≥5.

*Table 2. Individual parameters of stent thrombosis risk score (STRS) by early ST.*

| Characteristics | Total | Early Stent Thrombosis | | P-value |
|---|---|---|---|---|
| | | No | Yes | |
| N | 569 | 536 | 33 | - |
| **Baseline platelet count, K/µl** | | | | |
| <250 | 218 (38.3%) | 206 (38.4%) | 12 (36.4%) | 0.027 |
| 250 to 400 | 302 (53.1%) | 288 (53.7%) | 14 (42.4%) | |
| >400 | 49 (8.6%) | 42 (7.8%) | 7 (21.2%) | |
| **History of insulin-dependent diabetes mellitus (IDDM)** | | | | |
| Yes | 14 (2.5%) | 11 (2.1%) | 3 (9.1%) | 0.011 |
| No | 555 (97.5%) | 525 (97.9%) | 30 (90.9%) | |
| **Baseline TIMI flow grade of 0-I** | | | | |
| Yes | 393 (69.1%) | 366 (68.3%) | 27 (81.8%) | 0.103 |
| No | 176 (30.9%) | 170 (31.7%) | 6 (18.2%) | |
| **Early anticoagulant therapy** | | | | |
| Yes | 569 (100%) | 536 (100%) | 33 (100%) | – |
| No | 0 (0%) | 0 (0%) | 0 (0%) | |
| **Aneurysm or ulceration** | | | | |
| Yes | 0 (0%) | 0 (0%) | 0 (0%) | – |
| No | 569 (100%) | 536 (100%) | 33 (100%) | |
| **Number of vessels treated** | | | | |
| <2 | 569 (100%) | 536 (100%) | 33 (100%) | – |
| 2 | 0 (0%) | 0 (0%) | 0 (0%) | |
| 3 | 0 (0%) | 0 (0%) | 0 (0%) | |
| **Final TIMI flow grade of 0-II** | | | | |
| Yes | 22 (3.9%) | 20 (3.7%) | 2 (6.1%) | 0.501 |
| No | 547 (96.1%) | 516 (96.3%) | 31 (93.9%) | |

## 4. Discussion

The principal findings from this study of 569 patients with STEMI are, a higher Stent Thrombosis Risk Score index was associated with the higher risk of early stent thrombosis which was 3.3% for the patients with risk score of 0–2, which raised to 5.0% with the risk score of 3–4, and 17.2% of the risk score of ≥5.

Overall rate of ST (5.8%) in our study was relatively higher than some of the past studies [3–6], [14–16], a recently published data by Tariq S et al.

*Table 3. Multivariate binary logistic regression analysis for early stent thrombosis.*

| Characteristics | Odds Ratio (OR) | 95% confidence interval | p-value |
|---|---|---|---|
| Male | 1.87 | 0.67–5.24 | 0.234 |
| Age (years) | 1.02 | 0.99–1.06 | 0.177 |
| Diabetes mellitus | 1.76 | 0.79–3.94 | 0.168 |
| Hypertension | 1.88 | 0.84–4.2 | 0.122 |
| Smoking | 0.72 | 0.27–1.91 | 0.515 |
| Obesity | 0.78 | 0.25–2.46 | 0.675 |
| Positive family history | 1.9 | 0.44–8.17 | 0.389 |
| Killip Class (III-IV) | 4.24 | 1.39–12.92 | 0.011* |
| Left dominance | 0.73 | 0.18–2.89 | 0.652 |
| Multivessel disease (MVD) | 0.73 | 0.33–1.63 | 0.446 |
| Lesion length (mm) | 1 | 0.94–1.05 | 0.865 |
| Bare-metal stent (BMS) | 1.01 | 0.45–2.27 | 0.988 |
| Stent length (mm) | 1.02 | 0.96–1.08 | 0.464 |
| Stent diameter (mm) | 0.73 | 0.4–1.35 | 0.319 |
| Stent Thrombosis Risk Score | 1.41 | 1.02–1.95 | 0.037* |

Dependent variable: Early stent thrombosis Hosmer and Lemeshow Test (chi-square = 15.747, df = 8, p = 0.046).

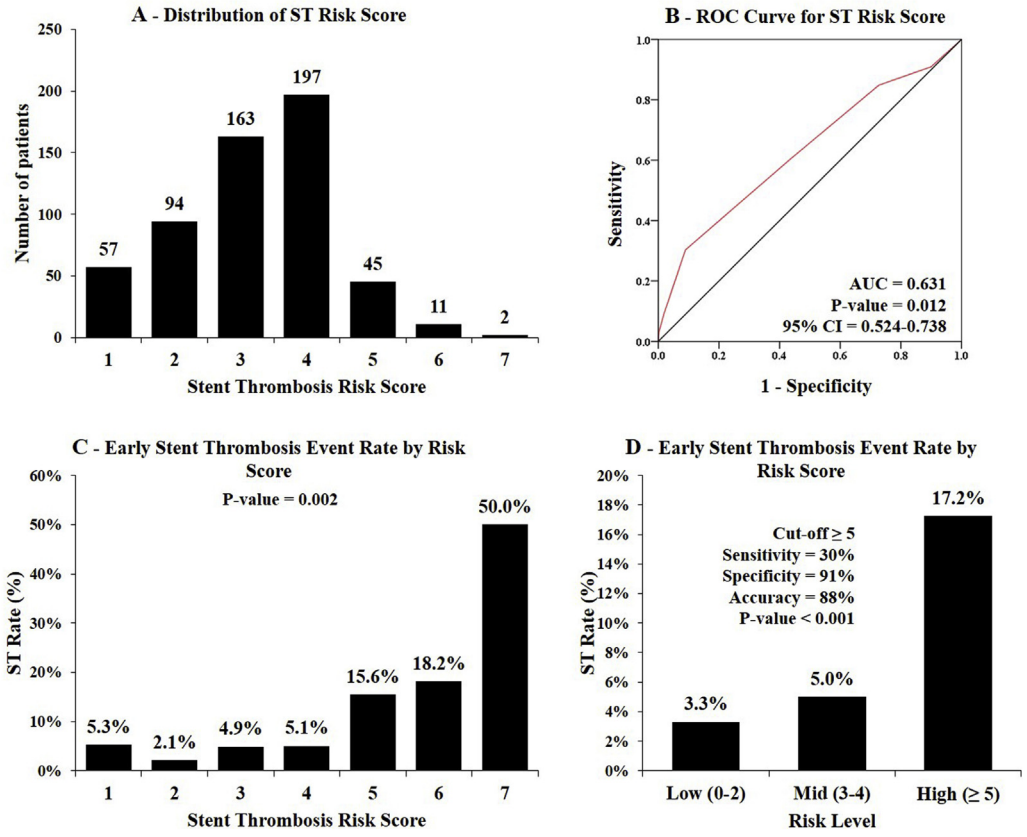


*Fig. 2. Distribution of Stent Thrombosis Risk Score (A), ROC curve (B), subsequent rate of early stent thrombosis by risk score (C and D).*

[17] for the same population reported that prescribing DAPT (Clopidogrel and Aspirin) on discharge is strongly and inversely associated with rate of early ST. The importance of DAPT is well established and non-compliance to the DAPT therapy due to lack of awareness could be one of the cause of high rates of ST in our population. However, premature discontinuation or non-compliance to the DAPT was out of the score of this research and future studies are warranted in this regards.

Several studies have identified different predictors of early stent thrombosis. Mosca et al. identified some factors related to the higher risk of developing stent thrombosis including presentation as a STEMI and anteroseptal infarction on ECG, female gender and patients already on clopidogrel prior to primary PCI [18]. Iakovou et al. identified premature discontinuation of DAPT, bifurcation lesions, renal failure, low ejection fraction, diabetes and, for sub-acute thrombosis, stent length as predictors of stent thrombosis [19]. The EXAMINATION trial identified a lower ejection fraction and worse Killip class at discharge, older age, lack of ST-segment resolution of at least 70%, BMS implantation at the index procedure as predictors of stent thrombosis [20].

Dangas et al. [12] formulated and validated a risk score for ST which can be used in routine and it was all grounded on a pooled analysis of patients undergoing PCI with stent implantation in the two large trials, HORIZAN-AMI and ACUITY. They found that with increasing risk score index values, there is a significant rise in ST rates, which is also statistically significant in both the development as well as the validation datasets. In this study area under the curve (AUC) of ST risk score in predicting early ST was reported to be 0.76 and 0.67 in development and validation cohort respectively. Our aim was to determine the validity of the Stent Thrombosis Risk Score in our population. These findings were consistent with our study, in our study, AUC of Stent Thrombosis Risk score for the prediction of early stent thrombosis was found to be 0.631. Based on ROC analysis the optimal cut-off value for early stent thrombosis was $\geq$5 with an accuracy of 88%, specificity of 91%, and sensitivity of 30%. The score was found to be linearly associated with the risk score, early ST rate was 3.3% for the patients with

the risk score of 0–2, which raised to 5.0% with the risk score of 3–4, and 17.2% of the risk score of ≥5.

Stent Thrombosis Risk Score was established as an independent predictor of early stent thrombosis with an adjusted odds ratio (95% CI) of 1.41 (1.02–1.95) along with Killip Class III-IV at presentation 4.24 (1.39–12.92). Hence, Stent Thrombosis Risk score is a practical approach, with statistically significant predictive strength, for the early stent thrombosis risk stratification after primary PCI. It comprises of seven readily available and simple variables and it can be easily adopted in clinical practice and investigation in the setting of acute ST-Segment Elevation Myocardial Infarction (STEMI).

To the best of our knowledge, this is the first study to assess the validity of stent thrombosis risk score other than development setting. However, our study has few limitations, first patients for this study were recruited retrospectively from hospital records, and secondly, we only considered patients who underwent primary PCI, early invasive or non-emergent PCI were not included, thirdly, small sample size, and finally, the data regarding study outcome were obtained on telephonic follow-up. Implanted stent type and subtypes were reported to be associated with varying ranges of rate of ST in various studies, therefore, further studies are warranted to address the validity of Stent Thrombosis Risk Score for various types and subtypes of stents.

## 5. Conclusion

In conclusion, our study has demonstrated that the Stent Thrombosis Risk Score (STRS) was found to be an independent predictor of early stent thrombosis (ST) after primary PCI and has statistically significant discriminating power. Early ST rate after primary PCI exponentially increased at STRS cut-off value of 5 or higher. Therefore, STRS can be used for the risk stratification of early ST after primary PCI.

## Author contribution statement

**RK**: Conception, Design, Fundings, Materials, Data collection and/or processing, Analysis and/or interpretation, Literature review, Writer. **ST**: Conception, Design, Materials, Data collection and/or processing, Analysis and/or interpretation, Literature review, Writer. **TS**: Conception, Supervision, Fundings, Materials, Critical review. **SNHR**: Conception, Supervision, Materials, Critical review. **MK**: Design, Data collection and/or processing, Analysis and/or interpretation, Literature review, Writer. **JAS**: Design, Supervision, Fundings, Materials, Critical review. **MF**: Data collection and/or processing, Analysis and/or interpretation, Literature review, Writer. **MKB**: Data collection and/or processing, Analysis and/or interpretation, Literature review, Writer.

## Disclaimer

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## Conflict of interest

The authors have no conflicts of interest relevant to this article.

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