

Research Brief

Impact of the risk-treatment paradox on in-hospital and long-term outcomes in patients with very high-risk non-ST-elevation acute coronary syndrome

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Background and objectives: The risk-treatment paradox (RTP) has not been studied in very high-risk patients with non-ST-elevation acute coronary syndrome (NSTEMI-ACS). We aimed to describe the cohort of very high-risk NSTEMI-ACS patients, analyse the impact of RTP on outcomes, and identify subgroups of patients who derive the greatest benefit from immediate invasive coronary angiography (ICA).

Methods: This retrospective analysis included 340 patients diagnosed with NSTEMI-ACS who met at least one of the established criteria for very high risk at admission. RTP was defined as any management tactic other than emergency (<2 h) ICA. Ongoing myocardial ischaemia (OMI) was defined as a combination of ongoing or recurrent chest pain and/or dyspnoea, along with at least one additional established very high-risk criterion.

Results: RTP was identified in 213 cases (62.6%). There was no adverse effect of RTP on in-hospital mortality [14% vs. 10% in the RTP group, P = 0.34, odds ratio (OR) 0.708; 95% confidence interval (CI) 0.36–1.37] or on the incidence of long-term major adverse coronary events (MACE). An independent predictor of adverse outcomes was evidence of OMI at hospital admission. Signs of OMI were observed in 168 patients (49.4%). In this subgroup, failure to perform emergency invasive coronary angiography was associated with a higher incidence of MACE during the three-year follow up (29% vs. 47.5% in the RTP group, P=0.02, OR 2.2; 95% CI 1.0–4.5).

Interpretations and conclusions: There was no significant effect of risk-treatment paradox on outcomes in very high-risk patients. Patients with signs of ongoing myocardial ischaemia benefit most from undergoing emergency invasive coronary angiography with the intention of performing percutaneous coronary intervention within two hours.

Keywords Acute coronary syndrome; Coronary angiography; Non-ST-elevation myocardial infarction; Ongoing myocardial ischaemia; Percutaneous coronary intervention; Very high-risk non-ST-elevation acute coronary syndrome

The incidence of acute coronary syndrome is progressively increasing, with a growing proportion of patients presenting with non-ST-elevation acute coronary syndrome (NSTEMI-ACS).^{1,2} Registry data show persistently high rates of adverse long-term outcomes in this patient category, with no significant decline in recent years.^{3,4} The highest frequency of adverse events already during the hospital stay is characteristic of very high-risk NSTEMI-ACS patients. The vulnerability of this group is attributed to advanced age, substantial comorbidity burdens,^{5,6} and limited evidence supporting the recommended immediate invasive strategy.⁷

The risk-treatment paradox (RTP), widely discussed in literature and characteristic of all NSTEMI-ACS patients, may help explain the high rate of adverse outcomes.^{8,9} RTP refers to situations in which patients at very high-risk of NSTEMI-ACS are not treated with timely (within 2 h) invasive coronary angiography (ICA) with the intention of performing percutaneous coronary intervention (PCI). Most often, this is due to concerns about the potential risks of invasive intervention. However, prior studies evaluating the timing of invasive strategies have often excluded very high-risk NSTEMI-ACS patients,^{10,11} potentially skewing

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the true risk-benefit ratio of invasive treatment in this subgroup. The influence of RTP on clinical outcomes in very high-risk patients remains unclear. Investigating the impact of RTP on outcomes in this population, using real-world clinical data, may offer insights not apparent in randomised clinical trials and could generate hypotheses for future research.

This study aimed to analyse the impact of RTP on in-hospital and long-term outcomes in real clinical practice, and to identify the subgroup of patients who derive the greatest benefit from an emergency (immediate) invasive strategy.

Methods

This observational study was conducted by the department of Cardiac Emergency, Cardiology Research Institute, Tomsk National Research Medical Center, Tomsk, Russian Federation. Patients were retrospectively recruited for this study during 2023–2024. The study was conducted in compliance with the principles of the Declaration of Helsinki and was approved by the Human Research Ethics Committee of the Institute. The study included 340 patients (aged >18 yr) of both sexes, hospitalized in the emergency cardiology department from January 2019 to June 2021 with a diagnosis of NSTEMI-ACS.

The inclusion criterion was the presence of at least one very high-risk feature of NSTEMI-ACS. The very high-risk criteria were assessed retrospectively in each patient according to the updated European Society of Cardiology guidelines (2023)⁷, based on the data from the case records: (i) Hemodynamic instability or cardiogenic shock; (ii) ongoing or recurrent chest pain refractory to pharmacotherapy; (iii) life-threatening arrhythmias or cardiac arrest; (iv) mechanical complications of myocardial infarction; (v) acute heart failure; and (vi) recurrent dynamic ST-segment deviations or T-wave changes.

The assessment was performed by an independent expert. Very high-risk criteria were evaluated at the time of hospital admission, regardless of the invasive strategy chosen during hospitalisation.

RTP was defined as any patient management tactic other than emergency invasive strategy. In the present study, RTP was investigated only from the perspective of invasive strategies. Details of medical treatment were not assessed. Patients received standard treatment for

NSTEMI-ACS according to current clinical guidelines⁷, unless contraindicated.

Ongoing myocardial ischaemia (OMI) was defined as a combination of ongoing/recurrent chest pain and/or dyspnoea with at least one additional established very high-risk criterion. In cases where the patient presented with dyspnoea as the sole clinical symptom against the background of acute heart failure and/or cardiogenic shock (in the absence of chest pain), dynamic ischaemic changes in the ST-T complex on an electrocardiogram were additionally considered to confirm signs of myocardial ischaemia.

Data were stored in a personalized electronic database using Excel 2010 (Certificate of State Registration No. 2023622190 dated 03.07.2023).¹²

Study exclusion criteria: (i) Patients with an initial diagnosis of acute coronary syndrome with persistent ST elevation; (ii) Lack of clinical and diagnostic data necessary to make a meaningful assessment of the condition and to study disease outcomes; or (iii) No consent for the processing of personal data signed by the patient or their legal representative at enrolment.

Endpoints:

Primary endpoint: All-cause mortality during index hospitalisation.

Secondary combined endpoint: long-term major adverse cardiovascular events (MACE) at 1 month, 1 year, and 3 years post-index hospitalisation, including: myocardial infarction; acute cerebrovascular accident; and all-cause mortality.

Statistical analysis: Data analysis was performed using SPSS 23.0 (IBM SPSS Statistics, USA). Quantitative variables are presented as medians and interquartile range (IQR), while qualitative variables are presented as absolute values (n) and relative frequencies (%). Intergroup comparisons of quantitative variables were performed using the Kruskal-Wallis test. Odds ratios (OR) with 95% confidence intervals (CI) were calculated using contingency tables. Comparisons between two independent groups were conducted using the Mann-Whitney U test and Pearson's χ^2 test or Fisher's exact test (for expected observations <5 in a 2×2 table). The Kaplan-Meier method (log-rank test) was used to compare freedom from MACE. Independent predictors of in-hospital mortality and MACE at 1 and 3 years were analyzed using univariate and multivariate logistic regression with predefined covariates. All covariates had <5% missing data. Statistical significance was defined as $P < 0.05$.

Results

The patient cohort (n=340) predominantly consisted of males (185; 54.4%), with a median age of 70 years (62;79). Primary myocardial infarction was diagnosed in 113 patients (33.2%), recurrent myocardial infarction (28 days or more after the previous myocardial infarction) in 116 patients (34.1%), and unstable angina in 111 patients (32.7%).

Invasive coronary angiography (ICA) was performed during the index hospitalization for 277 patients (81.5%); less than half (117; 42%) underwent PCI. The primary reasons for completing ICA as a diagnostic procedure included non-obstructive coronary atherosclerosis (74; 46%), multivessel disease (49; 31%), absence of coronary atherosclerosis (31; 19%), and technical difficulties with PCI (6; 4%), which were related to coronary artery tortuosity and/or severe coronary artery calcification. Subsequently, 21 patients with identified multivessel disease underwent coronary artery bypass grafting (CABG) (42.8%), all later than 24 h after admission, due to the need for preliminary stabilisation and preparation for surgery. CABG was not recommended for 10 patients (20.4%) due to severe comorbid conditions and a high risk of perioperative complications.

ICA within the recommended timeframe (< 2 h) was performed in 127 patients (37.4%). For the remaining cases, ICA was performed later than 2 h after admission (120 cases (35.3%) of early ICA within 2-24 h and 30 cases (8.8%) of delayed ICA within 24-72 h) or not performed (63 cases of conservative treatment; 18.5%), corresponding to RTP situations. Thus, a total of 213 RTP cases (62.6%) were identified.

The main established causes of RTP were chronic kidney disease (stages C3b–C5) (57; 26.7%); medically relieved anginal status in the presence of other signs of very high-risk (40; 18.8%); pulmonary oedema requiring preliminary stabilisation of the condition (28; 13.1%); moderate to severe anaemia (20; 9.4%); and previously known coronary anatomy without data on the presence of an obstructive lesion (18; 8.4%). In 12 patients (5.6%), the cause of RTP was various other clinical conditions, including delirium, nutritional status, infectious conditions, gastrointestinal bleeding, as well as the patient's refusal to undergo ICA. Furthermore, 32 patients (15%) had combined factors of RTP, while in 6 patients (3%), the cause of RTP could not be determined. The main reasons for the complete refusal of invasive strategy (63 cases; 18.5%)

were severe chronic kidney disease and moderate to severe anaemia.

Comparative characteristics of patients according to the presence of RTP are shown in the **Table I**. Disease outcomes were compared based on RTP presence among all patients (n=340). No significant impact on in-hospital mortality was found (14% vs. 10% in the non-RTP vs. RTP groups, $P=0.34$; OR 0.71; 95% CI: 0.36–1.37). Evaluation of MACE showed similar achievement rates for secondary endpoints in both groups at 1 month (3.9% vs. 5.2%, $P=0.78$; OR 1.1; 95% CI: 0.4–3.5) and 1 year (21.2% vs. 18.8%, $P=0.56$; OR 0.9; 95% CI: 0.5–1.6) (**Table II**).

Since ICA did not result in immediate myocardial revascularization in all patients, the outcomes within the PCI subgroups were further analyzed based on the timing of the procedure (within 2 h and >2 h). No statistically significant differences were observed in the frequency of in-hospital mortality or secondary endpoints during long-term follow up (**Table II**).

Given the heterogeneity of the studied cohort, multivariable regression analysis was performed to identify independent predictors of adverse outcomes. Ongoing myocardial ischaemia at admission emerged as an independent predictor of in-hospital mortality (OR 2.3; 95% CI: 1.9–2.7, $P=0.001$) and 1-year secondary endpoints occurrence (OR 4.2; 95% CI: 1.14–15.8, $P=0.03$). RTP did not demonstrate a significant effect on outcomes in the multivariate model. An additional factor associated with the development of 1-year secondary endpoints was ICA performed more than 24 h after admission (24–72 h) (OR 7.5; 95% CI: 1.45–38.3, $P=0.016$). Early ICA (2–24 h) was a protective factor against the development of 1-year MACE (OR 0.4; 95% CI: 0.16–0.99, $P=0.048$) in the overall group of very high-risk patients.

In the subgroup of patients with signs of OMI (168; 49.4%), RTP was detected in 94 patients (56%). Significant differences in 3-year secondary endpoints rates were observed, with a higher incidence in the RTP group (29% vs. 47.5%, $P=0.02$; OR 2.2; 95% CI: 1.1–4.5). Of the 142 patients who underwent ICA in this group, 72 (42.8%) underwent PCI, of which 44 (61.1%) within 2 h and the remaining 28 (38.9%) between 2 and 24 h, corresponding to RTP (**Fig. 1**).

Performing emergency PCI compared to early PCI (2–24 h) in the group of patients with OMI reduced the incidence of in-hospital mortality (13.9% vs. 17.8%, $P=0.05$; OR 1.1; 95% CI: 0.32–4.1) as well as the

Table I. Comparative characteristics of patients according to the presence of RTP

Characteristics, n (%) / Median (IQR)	Group of patients without RTP, n=127 (37.4%)	Group of patients with RTP, n=213 (62.6%)	P
Age, yr	66 (60; 79)	71 (63; 79)	0.019
Charlson comorbidity index, scores	6 (4; 8)	6 (5; 9)	0.02
GRACE, %	3 (1; 10)	3 (1; 9)	0.29
CRUSADE, %	8.6 (5.5; 18.5)	10.1 (7.9-18.6)	0.017
History of coronary heart disease, n (%)	69 (54.3)	154 (72.3)	<0.001
History of PCI, n (%)	26 (20.5)	68 (31.9)	0.02
History of CABG, n (%)	9 (7.1)	19 (8.9)	0.55
Diabetes mellitus type 2, n (%)	35 (27.5)	57 (26.7)	0.87
History of ACCD, n (%)	6 (4.7)	27 (12.7)	0.016
Heart rate, bpm	79 (65; 94)	80 (69; 100)	0.19
Systolic blood pressure, mmHg	131 (110; 147)	136 (114; 154)	0.06
Haemoglobin, g/L	132 (119; 148)	133 (113; 144)	0.24
Glomerular filtration rate, mL/min/1.73 m ²	60 (40; 82)	55 (40; 74.8)	0.05
Left ventricular ejection fraction, %	59 (44; 63)	56 (44; 63)	0.73
Comparative characteristics of the results of invasive strategy			
Invasive coronary angiography total, n (%)	127 (100)	150* (70.4)	<0.001
PCI total, n (%)	59 (46.5)	58 (38.7)	0.19
Acute coronary occlusion, n (%)	18 (14.2)	14 (9.3)	0.2
Non-obstructive coronary atherosclerosis, n (%)	31 (24.4)	43 (28.7)	0.42
Diagnostic ICA due to multivessel disease, n (%)	21 (16.5)	28 (18.7)	0.64
Absence of coronary atherosclerosis, n (%)	14 (11)	17 (11.3)	0.93
Technical difficulties with PCI, n (%)	2 (1.6)	4 (2.6)	0.81
CABG total [†] , n (%)	9 (7.1)	12 (8)	0.77

*63 patients with conservative treatment only were not included. [†]All CABG were performed more than 24 h after admission. Quantitative values are presented according to the law of normal distribution of values: median, interquartile range (IQR), qualitative values are presented with absolute values (n) and relative frequencies (%). ACCD, acute cerebral circulation disorder; CABG, coronary artery bypass grafting; CRUSADE, Can Rapid risk stratification of Unstable angina patients Suppress Adverse outcomes with Early implementation of the ACC/AHA guidelines; GRACE, Global Registry of Acute Coronary Events; PCI, percutaneous coronary intervention; RTP, risk-treatment paradox

number of cases achieving the secondary endpoints by the third year of follow-up (10.8% vs. 39.1%, $P=0.009$; OR 5.3; 95% CI: 1.4–20.1). Kaplan-Meier analysis further confirmed the differences in the incidence of MACE between these two groups (**Fig. 2**).

In patients without signs of OMI, there was no difference in the incidence of development of secondary endpoints in 3 years between the emergency and early ICA groups (10.3% vs. 14.2%, respectively, $P=0.11$). In the emergency PCI group, more cases of in-hospital mortality were observed compared to the early PCI group (26.6% vs. 8.7%), but the difference was not statistically significant ($P=0.09$; OR 0.3; 95% CI: 0.05–2.0).

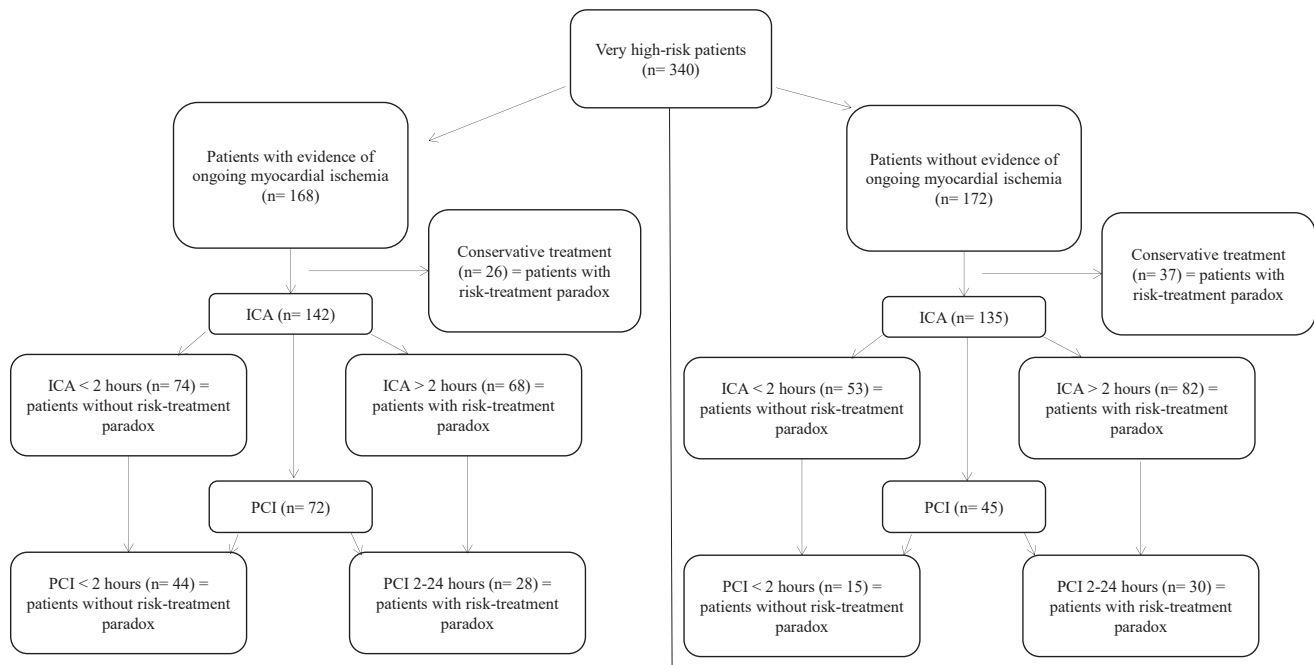
Discussion

We found that failure to perform emergency ICA within less than 2 h (*i.e.*, the risk-treatment paradox) does not have a negative impact on disease outcomes in the overall group of patients with very high-risk NSTEMI-ACS in real clinical practice. In the multivariate logistic regression model, early ICA (2–24 h), but not emergency ICA (<2 h), was a protective factor against the development of one-year MACE. Patients with signs of ongoing myocardial ischaemia, determined based on the proposed combination of criteria, received the greatest benefit from emergency ICA aimed at immediate myocardial revascularization, making the

Table II. Impact of RTP and timing of PCI on in-hospital mortality, repeat invasive treatment (during 3 yr of follow up) and the frequency of achieving the secondary combined endpoints in the overall very high-risk patient group

Parameter	Patients without RTP (n=127)	Patients with RTP (n=213)	OR	95% CI	P
In-hospital mortality, n (%)	18 (14)	22 (10)	0.708	0.36-1.37	0.34
Frequency of repeat ICA, n (%)	25 (19.5)	49 (23.1)	1.3	0.7-2.1	0.44
Frequency of repeat PCI, n (%)	18 (14)	35 (16.5)	1.2	0.6-2.2	0.57
Follow up					
Secondary endpoints at 1 month, n (%)	5 (3.9)	11 (5.2)	1.1	0.4-3.5	0.78
Secondary endpoints at 1 yr, n (%)	27 (21.2)	40 (18.8)	0.9	0.5-1.6	0.56
Secondary endpoints at 3 yr, n (%)	40 (31.5)	81 (38)	1.0	0.6-1.6	0.38
Patients who underwent PCI					
Parameter	PCI within 2 h (n=59)	PCI >2 h (n=58)	OR	95% CI	P
In-hospital mortality, n (%)	11 (18.6)	7 (12.1)	0.59	0.2-1.7	0.32
Follow up					
Secondary endpoints at 1 yr, n (%)	7 (11.9)	5 (8.6)	0.7	0.2-2.3	0.56
Secondary endpoints at 3 yr, n (%)	10 (17)	17 (29.3)	2.03	0.8-4.9	0.11

CI, confidence intervals; ICA, invasive coronary angiography; OR, odds ratios

**Fig. 1.** Flowchart for assigning patients to analysing groups. ICA, invasive coronary angiography; PCI, percutaneous coronary intervention.

implementation of an emergency invasive strategy most justified in this subgroup (**Supplementary Figure**).

Previous efforts have primarily aimed to determine the most optimal timing for invasive strategies in the general NSTEMI-ACS population.¹³ Research specifically focused on identifying the benefits of emergency intervention in the very high-risk group remains limited. Our results are consistent with the findings reported by Lupu *et al*.⁶ The authors observed

insufficient adherence to clinical guidelines: only 6.4% of 156 very high-risk patients underwent emergency intervention as recommended by current guidelines. However, despite the limited power of this study, the low frequency of emergency PCI did not result in worse outcomes.

In this study, we defined RTP as the refusal to perform emergency ICA. This approach aligns with previous studies investigating the effectiveness of invasive

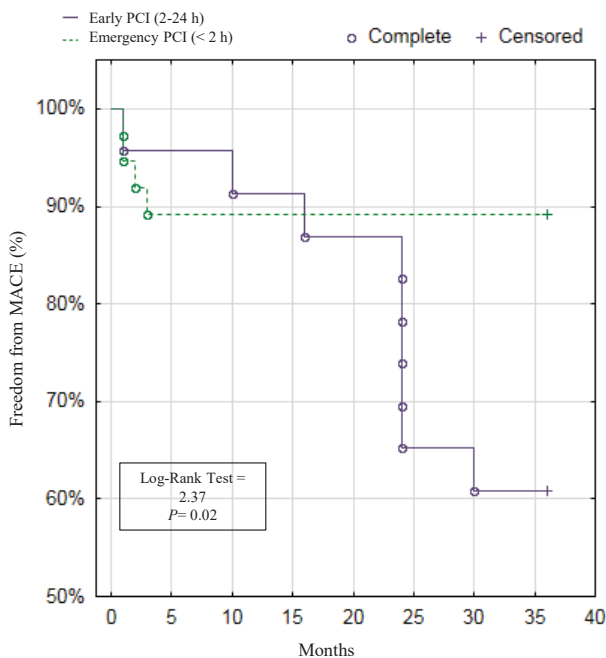


Fig. 2. Freedom from MACE during three-year follow up in the group of patients with evidence of ongoing myocardial ischaemia according to time of percutaneous coronary intervention (Kaplan-Meier curves, log-rank statistic). MACE, major adverse cardiovascular events.

strategies in patients with NSTEMI-ACS, with a specific focus on the timing of ICA, generally regardless of the characteristics of coronary lesions.¹³ Our additional analysis showed no significant difference in outcomes between patients with PCI within 2 h and those with PCI after 2 h in the overall very high-risk cohort, similar to the RTP findings.

Two main reasons can be identified to explain why RTP did not have a negative impact on disease outcomes in the study group. First, very high-risk criteria in isolation are highly nonspecific and often mimic signs of acute coronary insufficiency. This is reflected by the high prevalence of non-obstructive coronary artery atherosclerosis in this cohort: 35.4% of patients who underwent emergency ICA had no indications for myocardial revascularization. Second, the expected positive effects of emergency PCI are not fully realized, likely because of the significant influence of comorbid conditions on the patients' current clinical state. These factors diminish the potential benefits of the recommended emergency ICA.

Data from the Czech CZECH-3 registry¹⁴ have demonstrated that OMI may be an additional predictor of emergency ICA. However, this study included both NSTEMI-ACS and ST-elevation myocardial infarction

patients, which may have confounded the real benefit of immediate intervention. According to our study, patients with signs of OMI at admission who underwent emergency PCI experienced better hospital and three-year outcomes compared to the early invasive treatment group (2–24 h). The obtained data may be explained by greater specificity of signs united under the concept of OMI in verifying myocardial ischaemia compared to using isolated very high-risk criteria. This reflects the need for emergency ICA, aimed at performing PCI in patients with very high-risk NSTEMI-ACS and OMI signs at hospital admission.

In the group of patients who underwent PCI within the proper timeframe (<2 h) but lacked OMI signs, the rate of in-hospital deaths was unexpectedly higher. These results may have been influenced by concerns regarding the risks associated with ICA and PCI.^{15,16} Given these results, it is suggested that, in this very high-risk patient subgroup, a later intervention (up to 24 h) might be feasible, allowing additional time for differential diagnosis and stabilization. However, this conclusion requires further confirmation through larger studies.

This study has several limitations. First, the study is observational, and the retrospective data analysis does not exclude subjectivity during the assessment of very high-risk criteria and unintentional distortion of the patient's real clinical condition. Second, the study is single centre in nature, resulting in the potential influence of established diagnostic and treatment practices at this institution on patient management decisions.

To conclude, our study did not find a negative impact of the risk-treatment paradox on disease outcomes in the overall group of patients with very high-risk NSTEMI-ACS. The group of patients with signs of ongoing myocardial ischaemia requires increased attention from clinicians, as such patients benefit most from undergoing ICA with the intention of performing PCI within 2 h.

Author contributions: AN: Study concept and design, recruitment of patients, formation of the database, statistical processing of data, manuscript writing; DV: Recruitment of patients, formation of the database, statistical processing of data, manuscript writing; VR: Conceptualisation and design of the study, manuscript writing. All authors have read and approve the final printed version of the manuscript.

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शोध-संदेश

इस अध्ययन में बहुत अधिक जोखिम वाले नॉन-एसटी-एलिवेशन एक््यूट कोरोनरी सिंड्रोम (NSTEMI-ACS) के रोगियों में “जोखिम-उपचार विरोधाभास” (Risk-Treatment Paradox) का मूल्यांकन किया गया। अध्ययन का उद्देश्य ऐसे रोगियों के समूह का वर्णन करना, इस विरोधाभास का उपचार परिणामों पर प्रभाव समझना, तथा यह पहचानना था कि किन रोगियों को तुरंत कोरोनरी इंजियोग्राफी (ICA) से सबसे अधिक लाभ मिलता है। अध्ययन के निष्कर्षों से यह पाया गया कि अत्यधिक उच्च-जोखिम रोगियों में RTP का कुल रोग परिणामों पर कोई महत्वपूर्ण प्रभाव नहीं था, जबकि जिन रोगियों में मायोकार्डियल इश्चिमिया के संकेत और लगातार छाती में दर्द तथा सांस लेने में कष्ट बना रहता है, उन्हें आपातकालीन इंजियोग्राफी कराकर दो घंटे के भीतर परक्यूटेनियस कोरोनरी इंटरवेंशन करने से सबसे अधिक लाभ प्राप्त हुआ।

Conflicts of Interest: None.

Use of Artificial Intelligence (AI)-Assisted Technology for manuscript preparation: The authors confirm that there was no use of AI-assisted technology for assisting in the writing of the manuscript and no images were manipulated using AI.

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