

SHORT THESIS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY
(PhD)

**Acute coronary syndrome: challenges and
opportunities for managing and treating patients**

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1. INTRODUCTION

Acute coronary syndrome (ACS) remains a leading cause of cardiovascular morbidity and mortality worldwide. Over the past decades, rapid advances in percutaneous coronary intervention (PCI) techniques have significantly improved the survival and quality of life of patients with ACS, aided by the unified cardiovascular (CV) patient pathway management model that we have developed at the National Ambulance Service (NAS). The use of the digital trans-telephonic ECG (TTECG) and intelligent on-board terminals/tablets at the National Ambulance Service has enabled transparent and authentic data collection in Hungary, which can be analysed using business intelligence and artificial intelligence-based systems. The aim of this is to improve the efficiency of out-of-hospital emergency and in-hospital care for myocardial infarction (STEMI).

Despite this, in-stent restenosis (ISR) following PCI remains a clinical challenge, as it can lead not only to the onset of new symptoms, but also to repeated interventions and more serious outcomes. Advances in stent types, from bare-metal stents (BMS) with metal mesh to drug-eluting stents (DES), have undoubtedly reduced the incidence of ISR, but the problem has not been completely eliminated even with the use of the most modern devices.

ISR is a complex pathophysiological process involving mechanical, inflammatory and cellular factors. In addition, patient-specific characteristics such as gender, comorbidities or medication may also influence the risk of ISR. The aim of our research is to investigate these factors in detail by analysing a retrospective clinical database, which may contribute to the refinement of risk stratification and the development of new prevention and therapeutic strategies. Our work will pay particular attention to the potential protective effect of Trimethazidine (TMZ), the role of technical parameters related to stenting, and the exploration of gender differences.

The aim of this dissertation is to contribute to the reduction of CV mortality and the development of prevention and treatment of ISR by presenting a nationally consistent CV patient pathway model and new scientific findings, thereby improving the efficiency and long-term outcome of care for patients with acute coronary syndrome.

2. OBJECTIVES

The aim of our research is to analyse and demonstrate that, with proper patient pathway organisation, CV patients can be transferred to the appropriate care site with the availability of a haemodynamic laboratory in the shortest possible time, thus avoiding waiting in emergency departments. This also reduces the time it takes to open a blocked vessel and the workload in emergency departments.

Another aim is to improve the prevention and management of ISR after PCI. Despite significant advances in interventional techniques, ISR remains an unresolved problem, a frequent, clinically relevant complication that negatively affects clinical outcome. Our study aims to contribute to the prevention and management of ISR by identifying new patient- and treatment-related factors by analysing the database of the Department of Cardiology, University of Debrecen Clinical Centre, from 01.01.2010 to 31.12.2011.

Our aim is to identify independent predictors that increase or decrease the likelihood of developing ISR after PCI intervention. Using retrospective database analysis, we examined (1) patient demographics, anamnestic data (e.g. comorbidity and risk factors), (2) CV pharmacotherapy, (3) PCI-related parameters (4) and the impact of laboratory findings on the development of ISR.

This will provide a better understanding of the mechanisms and factors influencing the development of ISR. The aim of our study is not only to increase scientific knowledge but also to provide concrete recommendations for clinical practice.

Based on the identified predictors, prophylactic strategies and new intervention protocols can help clinicians reduce the risk of ISR, thus improving patient care and outcomes after PCI. Although our research relies primarily on the database of the Department of Cardiology, University of Debrecen Clinical Center, the wider applicability of our results is expected. The acquired knowledge and recommendations may contribute to the development of international guidelines, the construction of international databases, the development of a uniform patient pathway approach and the global improvement of ISR prevention strategies. As a result of this research, significant progress in the management of patients with acute coronary syndromes, in particular in the prevention and treatment of ISR, can be achieved. The development of newly identified predictors and associated clinical guidelines can improve the quality of life of patients and reduce morbidity and mortality from coronary artery disease, which is of public health importance.

3. METHODOLOGIES (MATERIAL AND METHOD)

3.1. Patient material and methods

In our study in 2018 (Jánosi, 2018), we analysed the components of prehospital delay by analysing the databases of the National Heart Attack Register (NHAR/NMIR) and the National Ambulance Service (NAS), based on data from 10 045 patients treated between 1 January 2014 and 31 March 2016. For the analysis, 7 146 cases where patients were admitted to hospital by ambulance were selected.

Our previous studies (Jánosi, 2018 and 2019) have shown that the significance of the total ischaemic time (TIT) between the onset of the complaint and the opening of the vessel is critical. If this time exceeds 400 minutes, the prognosis of the patient deteriorates significantly.

In a comprehensive analysis of STEMI care in Hungary (Jánosi, 2021), we highlighted regional differences in West, Central and East Hungary, with a total of 18 435 cases. The analysis showed that there are significant regional differences in STEMI prevalence and access to PCI care.

For the other retrospective study in this dissertation, we selected a 2-year interval for the hospital care side, using the database of the University of Debrecen, Clinical Centre for Cardiology. Accordingly, we collected data between 01.01.2010 and 31.12.2011 (n=653). During this period, the proportion of BMS implantations was still significant. Thus, we had the opportunity to selectively investigate ISR following BMS and DES implantations.

Patients underwent primary or elective PCI for ACS (n=341) or severe CCS (n=312). Interventional intervention and drug therapy were performed according to current recommendations.

After index PCI, all patients underwent follow-up angiography within 600 days (198 ± 150 days). The common indications for control coronary angiography were: new-onset ACS, progression of previous CCS or planned PCI of other coronary branches. The index PCI was considered the first stent implantation procedure. All stent implantations were performed in vessels ≥ 2.25 mm in diameter (quantitative measurement). Based on the results of control angiography, patients were divided into 2 groups: 1) in-stent restenosis (221 patients with significant $>50\%$ ISR) and control group (432 patients without ISR). Clinically relevant ISR was defined as a stenosis equal to or greater than 50% diameter in the previously stented vessel or 2 mm proximal or distal to the implanted stent on angiography. The diagnosis of ACS was based on: 1) clinical symptoms 2) myocardial markers and 3) ECG changes (ST-elevation myocardial infarction [STEMI] or non-ST-elevation myocardial infarction [NSTEMI] or Unstable Angina [UA/IA]). For NSTEMI and UA patients usually presented with ST-segment depression and/or T-wave morphological changes (Collet, 2020). For ACS, a trans-physiological ECG was usually obtained during prehospital care and patients were then directly transported to the Cardiology Clinic for

catheterisation. Various second generation DES (sirolimus derivatives 96.4% and paclitaxel 3.6%) and BMS were used for implantation.

Trimethazidine was used as adjunctive therapy in 54.21% of cases (mainly in patients who had been previously treated for angina pectoris). The study was conducted in accordance with the Declaration of Helsinki. Study data were collected with written informed consent from patients. The data handling and collection was approved by the Institute of Cardiology and the Regional and Institutional Research Ethics Committee of the University of Debrecen Clinical Centre (protocol ID: DE RKEB/IKEB: 5903-2021).

3.2. Parameters assessed in the ISR study

All available parameters were examined during data collection and analysis, including demographic parameters (e.g. age and sex), clinical characteristics including risk factors (smoking habits, alcohol consumption), comorbidities (hypertension, diabetes and renal impairment), relevant CV events (previous ACS, PCI in another coronary artery, coronary artery bypass graft surgery [CABG], heart failure). We also compared the results of physical examination (body mass index, resting heart rate) and laboratory and echocardiographic tests. Laboratory parameters were also assessed during the index intervention and subsequent control angiography.

Transthoracic echocardiography was performed only at the time of the first intervention (left ventricular ejection fraction [LVEF] and left ventricular wall motion abnormalities were assessed). Coronary analysis started with anatomical data from the medical records, including coronary circulation dominance (left, right, intermediate and super-right types) and the coronary branch and segment involved. Among the characteristics of the lesion, the degree of stenosis, the presence of dissection and the complexity of the lesion (bifurcation) stood out. In terms of the circumstances of the PCI procedure, balloon dilatation before or after stent implantation, type, length and diameter of the implanted stent were also recorded. All data related to the evaluation of coronary angiography were performed independently by two independent experienced invasive cardiologists.

3.3. Statistical analysis

Statistical analyses were performed using software (GB-Stat v8.0, Dynamic Microsystems Inc.). Comparisons between groups were performed using Student's t-test (5% α level) for normally distributed continuous variables, and Wilcoxon's test (5% α level) for values not following a normal distribution. In the one-tailed logistic analysis, parameters with a value of $p < 0.4$ were examined for comparisons between groups. In our analyses, we calculated odds ratios (OR) and 95% confidence intervals (CI).

Multivariate adjusted logistic analysis was performed to assess the independent predictors. For this analysis, we examined factors that took a value of $p < 0.05$ in the one-tailed analysis. We also calculated adjusted ORs and CIs for the independent predictors. A significant difference was considered to be $p < 0.05$. Heat maps were generated using software for relationship analysis. Its aim was to demonstrate the effect of trimetazidine on ISR formation under different conditions (DES or BMS implantation, stent length and diameter).

4. RESULTS

4.1. Patient organisation model

Looking at the data from 2014-2016 in the National Heart Attack Register, we found that in Hungary, the average time from the start of a complaint to notification/first emergency call of the ambulance service is about two hours (114-121 minutes). There was no significant difference between the time of arrival of ambulance units and the duration of on-site care, but the TIT of patients who were directly transported to the centres was much shorter (260 minutes) than those who were not directly transported to the appropriate care site (356 minutes). This had a significant impact on both 30-day and 1-year survival of patients, demonstrating the importance of rapid revascularisation and the importance of uniform patient pathway planning.

In a comprehensive analysis of STEMI care in Hungary (Jánosi, 2021), we highlighted regional differences in West, Central and East Hungary, with a total of 18 435 cases. The analysis showed that there are significant regional differences in STEMI prevalence and access to PCI care. Eastern Hungary had the highest incidence of myocardial infarction and the longest prehospital (patient) delay (111 minutes on average), compared to the Western (91 minutes) and Central (97

minutes) regions. For this reason, Eastern Hungary also had the worst 30-day and one-year mortality rates, compared to Western Hungary, which had 12% lower mortality.

4.2. Study of ISR

A total of 653 patients who underwent PCI were included in the ISR study between 01.01.2010 and 31.12.2011. The average/mean age of the total patient population was 61.93 ± 10.37 years. A total of 910 stents were implanted during index PCI, with an average stent/patient ratio of 1.38 ± 0.69 . The ISR rate was 33.84% in the total study population. Control coronary angiography was performed 198 ± 150 days after index PCI. Based on the presence of clinically significant ISR after repeat coronary angiography, the study participants were divided into 2 groups (221 patients in the ISR group and 432 patients in the control group [without ISR]).

The results showed that the two groups did not differ significantly from each other, except for gender distribution and alcohol consumption. There were significantly more women in the ISR group than in the control. Interestingly, ISR was also significantly more common among regular alcohol drinkers. While narrower and more tortuous blood vessels may have been responsible for the increased risk of ISR in women, we found no clear explanation for alcohol consumption, suggesting that alcohol-induced inflammatory

mechanisms may underlie this. In addition, the ISR group also had a higher number of people with diabetes compared to the control, but this difference was not found to be significant compared to the control. For other parameters, the two groups (ISR group and control) were relatively balanced.

4.2.1. Drug treatment

Several classes of drugs were tested in the medication. No significant differences were observed between the ISR and control groups in CV pharmacotherapy parameters, except for the use of TMZ. All patients received dual antiplatelet therapy (clopidogrel and acetylsalicylic acid). Most patients received statins, beta-blockers and angiotensin converting enzyme inhibitors (ACEi) and/or angiotensin II receptor blockers (ARBs) according to current guidelines. The only significant difference between the two groups (ISR and control) in terms of medication was the use of TMZ. The control group used TMZ in significantly ($p=0.039$) more patients than the ISR group.

4.2.2 Invasive treatment parameters

Parameters associated with invasive treatment were also examined. A total of 910 stents were implanted during the index PCI, with an average stent/patient ratio of 1.38 ± 0.69 . Among the intervention parameters, the number of stents implanted, stent type (BMS or DES), stent length and stent diameter had a significant role in the

development of restenosis. Significant differences between groups were seen for BMS and DES implantation. DES use was higher in the control group, while BMS implantation was more frequent in the ISR group. Significant differences in stent/patient ratio, total length and diameter of stents implanted between groups were also examined. The ISR group had a significantly smaller stent diameter and longer implanted stent length. The proportion of patients undergoing balloon dilatation before stent implantation was also significantly higher in the ISR group compared to the control, but the differences were not statistically significant ($p=0.382$).

No significant difference was observed between the two groups in other parameters such as coronary anatomy (branch and segment of the coronary artery under investigation), lesion characteristics, index PCI or indication for subsequent coronary angiography.

All stent-related parameters were also examined by sex (men and women). Significantly lower ($p<0.001$) stent diameters were found in female patients (2.76 ± 0.39 mm) than in male patients (2.95 ± 0.44 mm). No significant differences were found between the two sexes in other stent-related parameters (stent/patient ratio and total stent length).

4.2.3. Laboratory test results

We have also analysed laboratory parameters in our clinical research. Blood chemistry and blood counts were examined in all patients both at baseline and after control coronary angiography. No significant differences were found between the two groups in most parameters such as urea, GFR or triglyceride levels. As expected, fasting glucose levels were significantly higher in the ISR group compared to the control group (corresponding to a higher proportion of diabetes in the ISR group), but the difference did not prove to be statistically significant.

At the start of the study, patients with restenosis had significantly lower haemoglobin and red blood cell counts.

The differences found at baseline did not change significantly during the follow-up period. With regard to blood count, besides differences in haemoglobin and red blood cell count, significant differences were observed in neutrophil and lymphocyte count and the resulting neutrophil-lymphocyte ratio (NLR). The latter, as an indirect inflammatory parameter, showed significantly higher values in the ISR group compared to the control, indicating the predominance of inflammatory processes during the PCI period of the index.

In light of this, we were curious to see how the inflammatory status of patients evolves after stent implantation. During follow-up, in the majority of cases, both in the ISR (2.71 ± 1.09) and control (2.89 ± 1.92)

groups, there was a significant ($p < 0.001$) decrease in the NLR, a parameter that characterises inflammation. This correlation was pushed down by TMZ treatment. The difference between the two equations (TMZ and no-TMZ) was significant in terms of reduction in the risk of ISR. Our analysis illustrates the ISR and inflammation reducing effects of TMZ therapy. It was also shown that the reduction in NLR (i.e., reduction in inflammation) after stent implantation clearly increased the restenosis-inhibitory efficacy of TMZ.

In summary, our analysis clearly indicates that 1) the greater the NLR reduction during follow-up, the lower the probability of developing ISR and 2) TMZ significantly reduced the chance of developing ISR at each NLR value.

4.2.4. Relationship between Trimethazidine and stent parameters

Since TMZ treatment has been shown to be an independent positive predictor of ISR development, we decided to investigate the effect of different stent parameters (stent type, stent diameter and length) and trimetazidine therapy on the likelihood of restenosis development using heat maps. The map clearly shows that in both DES and BMS implanted patients, an increase in the risk of ISR is caused by 1) low stent diameter and 2) increased stent length.

Based on our further analysis, we found that the protective effect of TMZ against ISR was mainly present in 1) narrow coronary arteries (stent diameter <3 mm, OR 0.52, CI 0.32-0.82; p=0.005 and stent diameter >3 mm, OR 0.84, CI 0.52-1.35; p=0.468) and 2) BMS implanted patients (OR 0.64, CI 0.36-0.95; p=0.022).

5. DISCUSSION

Early treatment with PCI and secondary prevention with drugs (RAAS inhibitors, beta-blockers) significantly improve survival.

There are 20 invasive centres in Hungary, providing unified, nationally coordinated care for STEMI patients. The National Ambulance Service (NAS) plays a prominent role in the organisation of patient journeys. The use of TTECG enables rapid recognition of acute myocardial infarction, direct communication with PCI centres and rapid, efficient patient pathway planning.

The prevalence of ISR varies widely across studies and databases. The incidence of ISR has been estimated to be 30-40% after BMS implantation (Agostoni, 2006; Stettler, 2007) and 5-15% after DES implantation (Farooq, 2011). In our own patient population, the ISR rate was in a similar range (BMS 38.99% and DES 15.00%). Several different pathomechanisms are hypothesized to underlie the development of ISR. These are 1) artery elastic collapse (recoil), 2) vascular remodelling and 3) neointimal hyperplasia.

ISR is a nonspecific inflammatory response to endothelial injury resulting from internal mechanical vascular injury during stenting and PCI.

Chronic wall stress stimulates inflammatory processes and smooth muscle cell migration and proliferation from the tunica media and tunica adventitia to the tunica intima, resulting in neointimal hyperplasia. The introduction of DES has drastically reduced neointima proliferation, thus inhibiting one of the main causes of ISR development. This led to a significant reduction in ISR formation (Stefanini, 2013).

Newer generation DESs are considered safer and more effective than first generation DESs (Park, 2013). Consistent with these observations, in our own study DES was also found to be a strong independent predictor (OR 0.17, CI 0.09-0.30; $p < 0.001$) of the prevention of ISR development. However, the cost of modern DES is currently too high for many developing countries, so BMS stents still remain a viable option.

We came to a similar conclusion to the literature based on our own data: both stent diameter and total stent length were found to be independent predictors of ISR development. In our study, we demonstrated a mild but significant beneficial effect of TMZ treatment on the development of ISR. TMZ was particularly effective in patients with narrow coronary arteries implanted with BMS.

In our database, the ISR rate was higher for women than for men. The role of gender in the development of ISR and response to TMZ treatment is not yet fully understood.

Contradictory observations in the international literature point to the fact that the development of ISR is complex and still not fully understood in terms of gender differences.

Most clinical trials have not separately examined differences in response to TMZ therapies between the two sexes. In our own patient population, we found that the diameter of stents used in women was significantly smaller than in men. Our results suggest that the therapeutic effect of Trimethazidine is primarily associated with the female sex, where it significantly reduced the incidence of ISR even with a lower stent diameter and increased inflammatory response. Our study thus suggests that the gender-differential efficacy of TMZ may require a new approach in the design of future personalized cardiovascular prevention strategies.

6. CONCLUSIONS

Our studies emphasise that although patient decision time/delay is the most significant factor in late coronary reopening, patient education and telemedicine could bring further improvements. National Ambulance Service digital improvements, the use of TTECG and telemedicine, and continuous analysis of regional variations will help to further improve ACS care, thus reducing mortality from myocardial infarction in Hungary (Follow-up of our NHAR/NMIR analysis, 5 years on, is currently under publication.)

Our study is a retrospective, clinical database analysis study that explored the risk factors for the development of ISR and their clinical correlates in patients undergoing PCI for ACS or CCS. The results of the study revealed several new scientific findings and practical implications.

1) We aimed to identify new independent predictors of the incidence of ISR.

Multivariate adjusted logistic regression showed that three parameters – the use of TMZ therapy, the implantation of DES, and larger stent diameter – act as independent significant protective factors for the development of ISR.

In contrast, longer implanted stent length was an independent negative predictor. These findings provide further evidence to support clinical decision support, particularly in centres using BMS or in countries with lower technology coverage.

2) The use of Trimethazidine reduces the risk of ISR, especially in women and with smaller stent diameters.

Our results showed that trimetazidine therapy had an independent, significant ISR-preventive effect. The positive effect of TMZ was particularly marked in female patients with stents implanted in narrow (<3 mm) coronary arteries and in the population receiving BMS. With this observation, we are, to our knowledge, among the first to identify that the efficacy of TMZ is sex-differentiated, which may offer a new approach to non-specific drug prevention strategies.

3) The predictive value of NLR as an inflammatory biomarker in the development of ISR.

In our study, the elevated NLR rate in the ISR group was significant at the time of the index intervention. Furthermore, we showed that the extent of NLR reduction after PCI was inversely proportional to the occurrence of ISR, i.e., the more significant the NLR reduction, the lower the risk of ISR. Our results showed that TMZ treatment further strengthened this association, for which we also used heatmap

visualization. Exploring the interaction between NLR and TMZ at this level is considered a novelty in the literature.

4) New approach to gender differences in ISR risk and drug response.

Significant differences were observed between men and women in terms of stent diameter and the incidence of ISR. Women not only had smaller diameter stents but also had a higher incidence of ISR. At the same time, the response to TMZ therapy also differed by gender, with a significant reduction in ISR in female patients, whereas this was not statistically significant in male patients. With these results, our study may contribute to the development of gender-specific personalised drug therapy in cardiac catheterisation.

5) Using heatmap data visualisation to support clinical decision making.

The heatmap relationship analysis used in our study represents a methodological innovation in the study of ISR prevention. The method allowed us to visually demonstrate that the use of TMZ in BMS patients with narrow diameter and long stenting significantly reduced the incidence of ISR. This approach can be interpreted as a new tool for clinical predictive modelling.

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Last but not least, I would like to thank all my colleagues (bothers-in-arms) of the National Ambulance Service for their work: their high quality of activity and analysis of patient care data contribute to the fact that Hungary has one of the best organised and highest quality ambulance services in the world.

APPENDIX 8



Registry number:

DEENK/27/2025.PL

Subject:

PhD Publication List

Candidate: Gábor Csató

Doctoral School: Kálmán Laki Doctoral School

List of publications related to the dissertation

1. **Csató, G.**, Erdei, N., Ványai, B., Balla, T., Czuriga, D., Csanádi, Z., Kőszegi, Z., Édes, I., Szabó, G. T.: Predictors of restenosis following percutaneous coronary stent implantation: the role of trimetazidine therapy.
Front. Cardiovasc. Med. 9, 1-9, 2022.
DOI: <http://dx.doi.org/10.3389/fcvm.2022.873899>
IF: 3.6
2. Jánosi, A., Pach, P. F., Erdős, G., **Csató, G.**, Pápai, G., Andréka, P.: Incidence, pre-hospital delay and prognosis of acute myocardial infarction in big regions of Hungary: population data from the Hungarian myocardial infarction registry.
Int. J. Clin. Pract. 75 (11), 1-11, 2021.
DOI: <http://dx.doi.org/10.1111/ijcp.14831>
IF: 3.149

List of other publications

3. Bíró, K., Deák, M. S., Pápai, G., Nagy, A. C., Dombrádi, V., Szabó, G. T., Boruzs, K., Bányai, G., **Csató, G.**: The Emergency Performance of the Hungarian Ambulance Service during the COVID-19 Pandemic.
Healthcare. 10 (11), 1-10, 2022.
DOI: <https://doi.org/10.3390/healthcare10112331>
IF: 2.8
4. Jánosi, A., Pach, P. F., Erdős, G., **Csató, G.**, Pápai, G., Vajer, P., Andréka, P.: Az ST-elevációval járó szívinfarktusos betegek ellátásának vizsgálata Magyarország nagy régióiban.
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megnyitásáig.
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is an independent predictor of decreased hospital mortality in patients with ST-segment
elevation myocardial infarction treated with primary percutaneous coronary intervention.
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DOI: <https://doi.org/10.1177/1357633X18814335>
IF: 6.184

Total IF of journals (all publications): 24,734

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The Candidate's publication data submitted to the iDEa Tudóstér have been validated by DEENK on
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