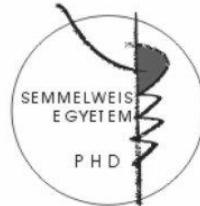


**Treatment of ST-elevation Myocardial
Infarction with Percutaneous Coronary
Intervention:
Analysis of Quality Parameters**

Doctoral Thesis

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Introduction

In Hungary, the majority of people die due to cardiovascular diseases. Within this, most frequently the different types of acute coronary diseases as myocardial infarction, unstable angina pectoris lead to death. Also the young, active, family-supporting population is affected considerably. In the same age, the mortality caused by coronary artery disease for 100 000 people is less than half in Austria and about two third in Czech Republic compare to our country.

The treatment of coronary artery disease, especially the treatment of acute myocardial infarction has been developed a lot in the last four decades. As the reperfusion therapies had been launched in the '70s, the survival improved substantially. After the initial success of thrombolytic therapy - in the '80s-'90s – the primary percutaneous coronary intervention had an increased role. For the years after the turn of the century had been decided that the best survival in ST-elevation myocardial infarction can be realized with primary PCI.

Although many factors influence the procedure's success rate. The *early* trials that compare the thrombolytic therapy to primary PCI did not prove the priority of coronary intervention technique in some cases. These results are explained with technical (less developed interventional tools) and organizational reasons. Several

factors was described that influence the prognosis of the patients essentially: number of patients with infarction treated by the given center, number of PCI's performed by the interventional cardiologist per year, the availability of the PCI center, the continuous medical attendance day in and day out. According to the data based on the literature, the prognosis of patients who arrived during off-hours is much worse in the developed countries as well. The time delay while transporting to intervention also worsen significantly the chance of survival. The organization of the primary PCI service is an important factor. We have a few data about advantages and disadvantages of PCI services that cover a large territory with big population. A well organized, unified PPCI service which is available for all patients in 24 hours is not operating neither in the majority of large Western European cities. In many countries are setting up most recently the standardized, centralized interventional networks.

In our country the first primary PCI was performed by László Szatmári M.D. in 1997. The first organized primary PCI duty was started in Zalaegerszeg in 1999.

The data of this analysis were derived from the interventional infarction treatment network which started in Budapest 1th January 2003 and was enlarged for the whole Central Hungarian Region in 2006. The so called „Budapest-model” is a landmark in the inland infarction treatment. With the help of this system the primary PCI

became available for 3 million people living in this region. Hopefully this fact will help improving the cardiovascular indicators in our country.

On the other hand, it was seen when reviewing the literature that this modern (and expensive) treatment in itself will not improve the morbidity and mortality data of the population. Up to now we do not have an exact, long term data about the effectiveness of this kind of network in Hungary. The success are influenced by the factors mentioned above and it is dependent on the complex healthcare system of the given country. The outcomes of international trials may not adopt for a whole country or region without considering the local results of this kind of treatment.

II. Aims

Our aim was to analyse in detail the data of 1890 consecutive patients with ST-elevation myocardial infarction (STEMI) treated with percutaneous coronary intervention at the Heart Center, Semmelweis University between 1th January 2003 and 31th December 2005 within the confines of „Budapest-model”. We intended to prove the effectiveness of an organized infarction treatment network and to provide data for an occurent whole country system organization, and last but not least to provide data for dissolving false medical doctrines.

Concrete aims:

1. Does the difference disappear in point of prognosis of patients admitted during on-hours compare to off-hours?
2. Does the first medical contact impact on outcome? We analysed the subject of the first medical contact (personnel of Emergency Service versus other medical staff); and the way of getting to the interventional center (direct versus secunder transport).
3. We intended to determine the prognosis of patients in the most severe condition (resuscitated or in cardiogenic shock). Beyond short term mortality data, what is the long term survival of these patients?
4. We analysed separetly the data of the old (> 75 years) and very old (> 80 years) patients due to more frequent comorbidity and worse general condition.
5. Based on the literature, the female gender has a negative predictive value on outcome? Whether is it still exist in an organized PCI sytem?

6. Analysis of subgroups with special „thrombogenicity“:
 - a. Analysis of prognosis after rescue PCI
 - b. Analysis of cardiovascular events
7. We determined the safety of early discharge (on the third day) following successful primary PCI.
8. We examined the the differential diagnostic value of cardiac MRI following negative coronarography in acute chest pain syndrome with ST segment elevation.

III. Methods

We performed a prospective analysis of the data of 1890 consecutive patients admitted with STEMI and treated with PCI within the confines of Central Hungarian Region Primary PCI System between 1th January 2003 and 31th December 2005. We recorded the patients' main demografic and anamnestic data, the main evaluation test reports, medical events, procedures, pharmacological and non pharmacological treatments, complications and the date of admisson and discharge. The data collection and a portion of analysis was performed with the help of Microsoft Windows Excel 97-2003 spreadsheat software.

Following a continuous data collection we had for each patient at least 58 principal and derived parameters; so finally we analysed more than 90 000 data. The follow up was carried out with the help of the National Health Insurance Fund's database and of the Semmelweis University Computer System. Questionable or missing data were recovered by personal or telephone contact. We had data about „hard endpoints” from the National Health Insurance Fund based on Insurance Number. With the help of these three above mentioned techniques we had a 100 per cent follow up rate.

We processed the clinically most relevant, publishable data which do not harm personality rights. During the follow up we could study the data listed below:

- mortality
- reinfarction
- rePCI
- coronary artery bypass surgery
- stroke
- „Major Adverse Cardiac Event” /MACE/
derived from data described above:
mortality+reinfarction+rePCI.

For statistical analysis we used the SPSS 15.0 software.

IV. Results

1890 patients were admitted between 1st January 2003 and 31st December 2005. 37% of the patients were female. Almost 18% of them were in severe condition (heart failure/cardiogenic shock/malignant arrhythmia/resuscitated), it means that almost every fifth patient needed immediate intensive care. A higher portion of patients (64.5%) were admitted in off-hours. After analysing in detail the data we had the undermentioned results:

1. The patients (n=1890) who were treated at the Semmelweis University Heart Center had a similar or even better short and long term survival rate than other countries with more developed healthcare system (30 days mortality: 8.7%, one year mortality: 14.9%). The patients who were admitted in off-hours had a similar mortality and cardiovascular event rate than patients admitted in on-hours (on-hours/off-hours: 30 days mortality: 8,6% vs. 8,8%, one year mortality: 15,3% vs. 14,7%, one year MACE: 11,2% vs. 11,3% p=0,94).
2. The patients who called the ambulance first (656/1890 34,7%) had clearly better prognosis at 30 days and at one year also (7,3% vs. 9,5%

p=0,123 and 12,7% vs. 16,1% p=0,042). The prognosis of patients transferred directly to PCI center (n=838/1890) was significantly better as well (on year mortality: 12,6% vs. 16,7% p=0,028).

3. Early mortality of patients in severe condition as cardiogenic shock (n= 90/1890 - 4,8%) or resuscitated (n= 84/1890 - 4,4%) was high as expected, however prognosis of patients surviving the acute stage is relatively good as a result of adequate intensive care. The additive mortality rate at one year 11% in cardiogenic shock and 8.3% after resuscitation. This is not or minimally higher than mortality of patients without resuscitation and without cardiogenic shock.
4. A significant portion of patients are elderly (patients > 80 years: n= 217/1890 - 11,5%) from the sum population with infarction. Although the mortality rate was higher, the prognosis was relatively good even in the very old patient population: one year survival: 128/217 = 59% thanks to the well organized care.
5. Female patients arrived with a longer time-window (5,8±5,6 hours vs. 5,3±4,7 hours), they arrived more frequently with secondary transport (59,8% vs. 53,3%), and they were more severe condition

on admission (cardiogenic shock: $n=39/692 - 5,6\%$ vs. $n=51/1198 - 4,3\%$). One year mortality: $138/692 - 19,9\%$ vs. $144/1198 - 12,0\%$ - $p=0,24$ - corrected for age. In the following year after myocardial infarction the frequency of rePCI is lower in this population: ($51/692 - 7,4\%$ vs. $138/1198 - 11,5\%$ $p =0,014$). This fact may attract attention for possible deficiencies of patient care.

6. Patients ($n=31$) who had rescue PCI were younger (mean age: $59,5\pm 11,7$ vs. $63,8\pm 13,5$ $p=0,078$), more were haemodynamically unstable (cardiogenic shock: $3/31 - 9,7\%$ vs. $87/1859 - 4,7\%$ - $p=0,19$), but their long term prognosis is not worse compare to non rescue PCI one year mortality: $3/30 - 9,7\%$ vs. $279/1859 - 15\%$ - $p=0,6$.

Patients who had stent thrombosis ($n=47/1890$) had a worse prognosis even on long term compare to patients with „de novo” STEMI one year MACE: $55,3\%$ vs. $31,2\%$ - $p<0.001$).

7. Patients in good general condition, treated with successful PCI without complications can be discharged early and safely. The 30 days additive mortality is very low: $1/568 - 0,2\%$ vs. $14/1242 - 1,1\%$.
8. We analysed 14 patients who were admitted with acute chest pain and ST segment elevation on their

ECG. Following a negative coronarography a cardiac MR was performed in each cases. To establish the correct diagnosis was difficult at these patients as 12 of them – contrary of usual findings in peri-myocarditis – had only local (not involving all 12 ECG leads) ST elevation. The mean age in this population was: $31,2 \pm 13,1$ years. In acute myocardial infarction MR reveal segmental oedema and sub/transmural necrosis while in acute myocarditis diffuse/nodular oedema and necrosis can be seen. Evaluation with MR demonstrated hypokinesia at 8 patients, oedema at 11 patients, late contrast cumulation at 12 patients. According to local or diffuse abnormalities at 10 patients peri-myocarditis, at 2 patients myocardial infarction was diagnosed. At 2 patients we were not able to get the final diagnosis based on this method.

V. Conclusions

The below listed new statements were established in this doctoral thesis:

In a well organized, net-work based interventional center with appropriate intensive care background the difference in prognosis during off hours and on-hours – known from the literature – can be erased.

We proved the magnitude on prognosis of first medical treatment and of the type of transport to PCI center.

In the very old, age above 80 years, patient group a relatively good long term survival rate can be achieved with the help of a successful PCI.

Women at a disadvantage – also known from the literature – can be dissolved with the above mentioned complex care.

Analysing in detail the data can be appointed that patients suffer from a notable selection before sending them for rescue PCI. Elderly patients and patients in the most severe condition do not or rarely get into the PCI center after failed thrombolysis.

Patients who are admitted due to STEMI caused by stent thrombosis (n=47/1890), in spite of longer hospital course, special care and more aggressive antithrombotic treatment have a higher risk for a repeated cardiovascular event in the following year.

STEMI patients without complications after successful PCI can be discharged safely on the third day following the event.

In interventional centers cardiac MRI has an increasing role in clarifying the etiology after negative coronarography. With the help of this method can be differentiate between peri-myocarditis and myocardial infarction. This fact will basically influence these patients further treatment and prognosis.

VI. Publication list

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