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## Coronary heart disease from a psychosocial perspective

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# Design of the study

The research project 'Social class and its impact on a patient's functional status and recovery process after cardiological or cardiosurgical intervention' is an interdisciplinary study carried out in a cooperation between the University of Groningen, PJ Safarik University in Kosice, and the East Slovakian Institute of Cardiac and Vascular Disease in Kosice. The aim of the project is to explore the impact of socioeconomic status and ethnicity on various psychosocial and medical aspects of the quality of life and the recovery process among patients with coronary heart disease in Slovakia. Previous studies have indicated that both socioeconomic status (1,2,3) and ethnicity (4,5) have significant impact on coronary heart disease. However, such research has been performed rarely in the countries of the Central and Eastern Europe. This chapter provides a general outcome of the design of this study.

## 2.1. Data collection

### 2.1.1. Participants and data collection

Data for this study were collected in the East Slovakian Institute of Cardiac and Vascular Disease in Kosice starting in November 2004 and still continuing to the present. The East Slovakian Institute for Cardiac and Vascular Diseases is a highly specialized medical center, where all patients with diagnosed or suspected cardiovascular problems from the entire East Slovakian region (about 1.5 million inhabitants) are referred for diagnosis and treatment.

Inclusion and exclusion criteria for baseline examination were defined as follows:

*Inclusion criteria:*

1. coronary heart disease in the medical history
2. both males and females
3. age less than 75
4. willing to participate (signed informed consent)

*Exclusion criteria:*

1. cardiovascular problems other than coronary heart disease (e.g. valve disease)
2. severe cognitive impairments
3. serious comorbidity

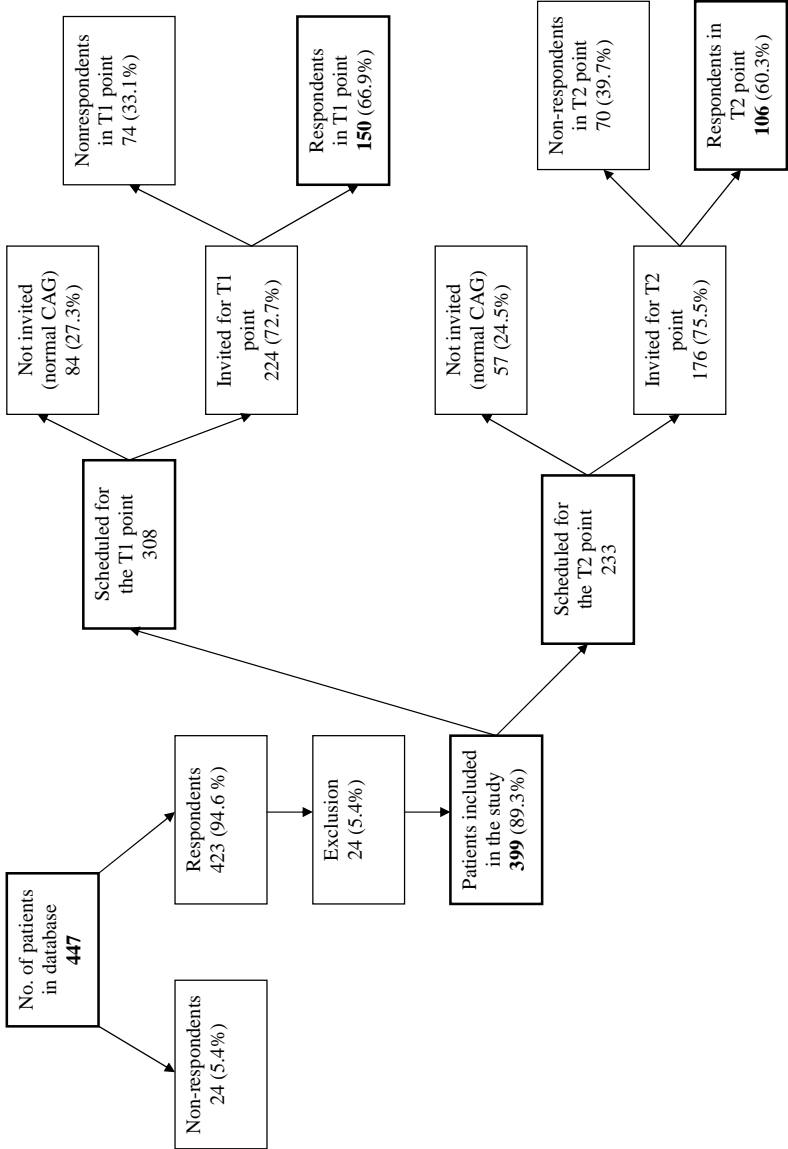
Patients referred for coronary angiography (CAG) by their cardiologist were enrolled in the study. A personal interview was conducted with each participant by a psychologist, and medical data were retrieved from their medical records. Data collection consisted of three waves: cross sectional data collection (T0 time point) and longitudinal data collection (T1 time point and T2 time point). A baseline examination was performed before CAG. The type of therapeutic intervention following the CAG (percutaneous coronary intervention, coronary artery bypass grafting or pharmacology treatment) was determined by a cardiologist based on the results of CAG, independently from participation in this study.

For the follow-up assessment, patients were individually invited via mail. The first follow-up (T1 time point) was performed 3 to 6 month after the CAG and/or subsequent treatment. A second follow-up (T2 time point) was performed 12 to 24 month after the CAG and/or subsequent treatment. For the follow-up examinations only patients who were indicated for the percutaneous transluminal coronary angioplasty (PTCA), coronary-artery bypass grafting (CABG) or for pharmaceutical treatment were invited. This means that participants with a normal coronary angiogram at the baseline were not enrolled in the follow-up. Details on respondents and non-respondents at all three time points (T0, T1, T2) can be found in Table 1.

**Table 1.** Description of the samples used in this study.

<b>Sample</b>	<b>First sample: cross-sectional</b>	<b>Second sample: Roma/non-Roma</b>	<b>Third sample: longitudinal</b>
Chapter	<b>4, 5</b>	<b>6</b>	<b>7</b>
Data collection	Personal interview with <b>362 patients</b> invited for CAG	<b>114 patients =</b> 38 Roma + 38 non-Roma with low SES + 38 non-Roma with high SES (selected from 399 interviewed)	<b>106 patients</b> interviewed in baseline and follow-up (12-24 month after baseline)
Time period	November 2004 - March 2007	November 2004- June 2007	November 2004 (start T0)- November 2005 (start T2)- December 2007
Response rate	94.1 %	94.6%	60.3%- at follow-up
Age - mean	55.9	53.4	57.4
SD	7.3	6.9	6.7
Range	27-75	27-72	34-73
Gender - males	245 (67.7%)	93 (81.6%)	90 (84.9%)
females	117 (32.3%)	21 (18.4%)	16 (15.1%)

**Figure 1.** Data collection - details on respondents and non-respondents.



All participants were provided with information about the study and signed an informed consent letter before their inclusion in the study. Ethical approval for this study was obtained from the Ethics Committee of the East Slovakian Institute for Cardiac and Vascular Diseases in Kosice.

### **2.1.2. Samples used in this study**

This thesis is intended to give an overview of the research work done on the project 'Social class and its impact on a patient's functional status and recovery process after cardiological or cardiosurgical intervention' during the period 2004-2008. The data collection for this research project was carried out continuously during that time and continues still. As the five articles (Chapter 3- Chapter 7) used in this thesis were written at different times during data collection, three different samples are used within this thesis:

#### *First sample (cross-sectional)*

- 362 participants
- cross-sectional data collection between November 2004 and March 2007
- sample used in Chapters 4 and 5

#### *Second sample - Roma/non-Roma (cross-sectional)*

- 114 patients (selected from 399 participants)
- 38 Roma matched with 38 low SES non-Roma, and 38 high SES non-Roma
- matching criteria: age, gender, education and type of intervention after CAG
- cross-sectional data collection between November 2004 and June 2007
- sample used in Chapter 6

#### *Third sample (longitudinal)*

- 106 participants interviewed at two time points
- first wave of data collection between November 2004 and December 2006
- second wave of data collection between November 2005 and December 2007
- follow-up 12 to 24 month after the CAG and/or subsequent treatment
- exclusion criteria for the follow-up: normal coronary angiogram at the baseline
- sample used in Chapter 7

A brief description of the samples and information about their use in separate chapters is provided in Table 2. [you previously inserted table 1]

**Table 2.** Brief summary of the variables and measurements used in this study.

<b>Construct</b>	<b>Measure</b>	<b>Type of variable (Chapters)</b>	<b>Short description</b>
Psychological well-being	General Health Questionnaire (Goldberg & Hilier, 1979), Self-reported questionnaire	Dependent (ch. 4, 6) Independent (ch. 7)	Measuring psychological well-being (symptoms of depression and anxiety)
Health-related quality of life	SF-36 (Ware, Kosinski & Keller, 1994) Self-reported questionnaire	Dependent (ch. 4, 6) Independent (ch. 7)	Measurement of health-related quality of life comprised of the components: physical and mental
Vital exhaustion	Maastricht Interview for Vital Exhaustion (Meesters & Appels, 1996) Structured interview by psychologist	Dependent (ch. 5, 6) Independent (ch. 7)	Interview assessing the feeling of excessive fatigue, troubles with sleeping, tiredness, demoralization, etc.
Type-D personality	DS 14 (Denollet 2005) Self-reported questionnaire	Dependent (ch. 6) Independent (ch. 7)	Measuring of the tendency to experience negative emotions and not to express emotions in social interactions
Hostility	Cook-Medley hostility scale (Barefoot et al., 1989) Self-reported questionnaire	Dependent (ch. 6)	Indicator of hostility comprising of subscales: cynicism, aggressive responding and hostile affect
Socioeconomic status	Educational level, Income level Structured interview by psychologist	Independent (ch. 4, 5, 6, 7)	Education - basic (elementary), middle, high (university) Income - based on minimum wage income used within social system in Slovakia
Ethnicity	Roma / non-Roma Structured interview by psychologist	Independent (ch. 6)	Based on self-identification and objective assessment
<b>Construct</b>	<b>Measure</b>	<b>Type of variable (Chapters)</b>	<b>Short description</b>
Functional status	Combination of NYHA (Criteria committee of the New York Heart Association, 1994) and CCS (Campeau, 1976), assessed by a cardiologist	Independent /covariate (ch. 4, 5, 6, 7)	NYHA- dyspnea symptoms (problems with breathing) CCS - severity of chest pain

Construct	Measure	Type of variable (Chapters)	Short description
Type of the intervention	Based on the results of the coronary angiography, assessed by cardiologist	Independent/covariate (ch. 5, 7)	Invasive treatment: CABG (Coronary-artery Bypass Grafting) PTCA (percutaneous transluminal coronary angioplasty) Non-invasive treatment: Pharmaceutically (no invasive treatment)
Ejection fraction	Indicated by the results of echocardiography (McGowan & Cleland, 2003), assessed by a cardiologist	Independent/covariate (ch. 6)	Measure of the systolic function of the left ventricle- indicating the disease severity

## 2.2. Measures

In this section an overview of the variables and measures used in this study is given.

We used the following psychological, sociodemographic and medical variables: psychological well-being, health-related quality of life, vital exhaustion, type-D personality, hostility, socioeconomic status, ethnicity, functional status, type of the intervention and ejection fraction.

The central dependent variables were the indicators of psychological well-being, vital exhaustion and the health related quality of life. Psychological well-being is an individual mood often operationalized by the level of symptoms of anxiety and depression and within the study is assessed by the General Health Questionnaire-GHQ 28 (6). The structured Maastricht Interview for Vital Exhaustion (7) measures feelings of excessive fatigue; questions focus on the symptoms of tiredness, lack of energy, irritability, disrupted sleep, etc. The SF-36 questionnaire was used as measure of quality of life. This questionnaire intends to capture the subjective (self-perceived) health status of a patient as a reflection of his/her disease. The outcome parameter of the SF-36 is usually defined as health-related quality of life (HRQL). This variable can be used to evaluate the broad impact of a chronic disease on all dimensions of patient's life and the effectiveness of intervention strategies (8).

The main independent variable used in all the chapters was socioeconomic status indicated by the level of education and income. In Chapter 6, ethnicity was employed as an independent variable as well. Medical characteristics (functional status, type of the intervention and ejection fraction) were put in the regression models as possible

covariates. The origin of the measurements, a short description of them and information about in which chapter the variables were used, are presented in the Table 2.

### 2.3. Statistical analysis

Several statistical methods were used across this study to analyze data. All analyses were performed using the statistical software package SPSS, versions 10.1., 12.0. and 14.0. More details on the analyses can be found in the 'statistical analysis' sections following each chapter. Descriptive statistics were used for analyzing the basic demographic, medical and psychological characteristics of participants. T-tests for repeated measures were used in Chapter 7 to assess the statistical significance of the change in the outcome variable between the baseline and the follow-up. Analysis of variance (ANOVA) and Scheffe post hoc tests were employed in Chapter 6 in order to explore the differences in dependent variables between ethnic groups. Logistic regression models for exploring the relative effects of different levels of socioeconomic status on outcome variables were used in Chapters 4 and 5. Use of linear regression models in Chapter 6 (the enter method) enabled the examination of the effect of ethnicity, and in Chapter 7 the identification of predictors of change in the health related quality of life. In this chapter we also assessed the clinical relevance of the change in the quality of life using a distribution-based model: effect sizes and SEM-based criterion (SEM- standard error of measurement).

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