

Stručni rad / Professional article

Registar perkutanih koronarnih intervencija u Kliničkom bolničkom centru *Sestre milosrdnice*

Percutaneous Coronary Intervention Registry in University Hospital Centre Sestre milosrdnice

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SAŽETAK: Unatoč činjenici da je koronarna bolest srca (KBS) prvi uzrok smrtnosti, u Hrvatskoj ne postoji sveobuhvatni registar osoba koje boluju od KBS, a registre za perkutanu koronarnu intervenciju (PCI) imaju samo pojedini laboratoriji za kateterizaciju srca, koji se značajno razlikuju i nisu međusobno kompatibilni. Laboratorij za invazivnu i intervencijsku kardiologiju Kliničkog bolničkog centra Sestre milosrdnice 1. siječnja 2011. godine je oformio vlastiti registar za PCI. Ovaj registar dostupan je u elektroničkom obliku, s visokim stupnjem zaštite pristupa. U registar se upisuje 45 različitih podataka koji su podijeljeni u pet skupina: opći podaci, čimbenici rizika, simptomi i znakovi akutne bolesti, zahvat i utrošeni materijal te dijagnostički i terapijski nalaz. Osnovne razlike ovog registra, u odnosu na postojeće, jest model prema kojem je upis podataka za svakog bolesnika podijeljen između medicinskog tehničara, inžinjera medicinske radiologije i intervencijskog kardiologa, izrazita jednostavnost, kratko vrijeme potrebno za upis te istovremeno ispisivanje nalaza kateterizacije. Tek nakon što su ispunjeni svi traženi podaci intervencijski kardiolog upisuje dijagnozu i nalaz te se podaci zaključavaju. Na taj smo način osigurali da se u bazu podataka upisuju sve varijable vezane uz svaku pojedinačnu učinjenu intervenciju, mogu ispisati u Excel ekstenziji te implementirati u bilo koji registar.

Nakon prve godine uporabe zaključili smo da je Registar značajno olakšao svakodnevni rad te da predstavlja nadopunu novih tehnologija uvedenih u liječenje KBS. Formiranje ovog Registra samo je korak prema zajedničkom cilju, formiranju nacionalnog registra PCI te sudjelovanju Republike Hrvatske u europskom registru bolesnika s akutnim koronarnim sindromom.

KLJUČNE RIJEČI: koronarna bolest srca, perkutana koronarna intervencija, registar.

Registar se definira kao specijalni statističko-epidemiološki alat za poimenično praćenje osoba s određenim oštećenjem zdravlja. U svijetu su, u području kardiologije, osnovani registri koji se dijele u 3 skupine: registar akutnog koronarnog sindroma (ACS), registar za perkutanu

SUMMARY: Despite the fact that coronary heart disease (CHD) is the first cause of mortality, in Croatia there is no comprehensive registry of patients with CHD, while the registries for percutaneous coronary intervention (PCI) are maintained only by specific cardiac catheterization laboratories, which greatly differ from each other and are not mutually compatible. Laboratory of Invasive and Interventional Cardiology of the University Hospital Centre Sestre milosrdnice established its own PCI registry on 1st January 2011. This registry is available in electronic format, with a high access protection level. The registry includes 45 different data which are divided into 5 groups: general data, risk factors, symptoms and signs of acute disease, procedure and materials used, and diagnostic and therapeutic results. The main differences of this registry compared to the existing registries is a model according to which the entry of data for each patient are divided between a medical technician, medical radiology engineer and an interventional cardiologist, its utmost simplicity, short time required for the registration and writing the findings of catheterization at the same time. Only after all the required data have been filled in, an interventional cardiologist will enter a diagnosis and findings and the data are locked. In this way we have ensured that all the variables relating to each individual intervention performed are entered in the database, they can be written in Excel extension and implemented in any registry.

After the first year of use, we have reached a conclusion that the Registry has greatly facilitated the daily work and that it complements the new technologies introduced in the treatment of CHD. The establishment of this Registry is only a step towards a common goal, establishment of the national PCI registry and participation of the Republic of Croatia in the European registry of patients with acute coronary syndrome.

KEYWORDS: coronary heart disease, percutaneous coronary intervention, registry.

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The Registry is defined as a special statistical and epidemiological tool for individual monitoring of persons with certain health impairment. Registers that are divided into 3 groups: the registry of acute coronary syndrome (ACS), the registry for percutaneous coronary intervention

koronarnu intervenciju (PCI) te registar za elektrofiziologiju (EP).¹

Podaci prikupljeni u registru PCI koriste se za utvrđivanje prevalencije i incidencije koronarne (ishemische) bolesti srca (KBS), za određivanje socio-demografskog profila bolesnika, identifikaciju visoko rizičnih skupina kojima je potreban invazivni oblik dijagnostike i liječenja, za određivanje efikasnosti terapijskih metoda i pridržavanja kliničkih smjernica za terapiju KBS te ujedno olakšavaju znanstveno-istraživački rad.^{2,3}

Prema podacima Hrvatskog zavoda za javno zdravstvo KBS je prvi uzrok smrtnosti u 2010. godini u Hrvatskoj sa stopom od 21,6%.⁴ Unatoč ovom alarmantnom podatku, u Hrvatskoj ne postoji nacionalni registar osoba koje boluju od KBS, a koji bi zasigurno pomogao u borbi protiv te masovne bolesti visoke smrtnosti. Jedini registar za akutni infarkt miokarda i to za područje grada Zagreba, uspostavljen je 1979. godine u tadašnjem Centru za bolesti srca i krvnih žila. 2003. god. preimenovan je u Registar akutnog koronarnog sindroma za grad Zagreb, a epidemiološki i klinički podaci se kontinuirano prikupljaju u sektoru epidemiološko-informatičke djelatnosti, Poliklinike za prevenciju kardiovaskularnih bolesti i rehabilitaciju, Zagreb.^{5,6}

Prvi registar PCI uspostavljen je već 1987. god. u Švicarskoj, a uspostavilo ga je Švicarsko kardiološko društvo. U početku se ispunjavao standardizirani upitnik na papiru, a kasnije se prešlo na elektronički oblik i internetsku povezanost sa središnjicom registra. Danas registru podatke dostavlja 25 bolničkih institucija koje obavljaju PCI.⁷ Godine 1992. American College of Cardiology (ACC) osniva nacionalni registar, *National Cardiovascular Data Registry* (NCDR), unutar kojeg funkcioniра *CathPCI Registry* koji prikuplja podatke o: ustanovi, bolesniku i leziji, zahvatu i utrošenom materijalu te usklađenosti terapije s ACC kliničkim smjernicama. Registru podatke dostavlja oko 60% svih PCI odjela u SAD.⁸ Iste godine osnivaju se nacionalni registri u Njemačkoj i Austriji, a 1998. god. u Švedskoj. Mnoge europske zemlje poput Velike Britanije, Španjolske, Francuske, Poljske, Irske, itd. osnovale su slične registre, kao i Europsko kardiološko društvo čiji registar (*European PCI Registry*) obuhvaća 25 zemalja i oko 11 tisuća bolesnika.⁷

Godine 2004. na inicijativu Irskog zavoda za javno zdravstvo i Irskog kardiološkog društva, u suradnji s ESC te pod pokroviteljstvom Europske komisije izrađen je projekt CARDS (*The Cardiology Audit and Registration Data Standards*). Cilj projekta bio je usuglasiti definicije pojmove u kardiologiji, standarde podataka i načine prikupljanja podataka s ciljem uspoređivanja podataka iz registara različitih država. Na temelju usuglašenih zaključaka izdane su smjernice za oblikovanje registara i tipova podataka koji se prikupljaju, a koji su podijeljeni u sljedeće skupine: opći podaci, anamneza, čimbenici rizika, akutni simptomi i znakovi, zahvat, ishod, stanje kod otpusta, kliničko praćenje (nakon 30 dana i 12 mjeseci).³

U ožujku 2011. god. realiziran je stručni simpozij Hrvatskog kardiološkog društva (HKD) na temu sudjelovanja Hrvatske u europskom registru bolesnika s akutnim koronarnim sindromom. Prof. dr. sc. Rafaelle Bugiardinni iz Bolonje i prof. dr. sc. Davor Miličić ispred HKD predstavili su registar bolesnika razvijen za prikupljanje podataka o invazivno liječenim bolesnicima (*The International Survey of Acute Coronary Syndromes in Transitional Countries; ISACS-CT*).⁹

U Hrvatskoj, za sada, ne postoje sveobuhvatni registri kako za akutni koronarni sindrom, tako niti za perkutanu koronarnu intervenciju, a samo pojedini laboratorijski za kateterizaciju

(PCI) and registry for electrophysiology (EP)¹ have been established in the field of cardiology at an international level.

Data collected in the PCI registry are used to determine the prevalence and incidence of coronary (ischemic) heart disease (CHD), to determine the socio-demographic profile of patients, identification of high risk groups that require an invasive form of diagnostics and treatment, to determine the efficacy of therapeutic methods and compliance with clinical guidelines for the treatment of CHD and also facilitate scientific research.^{2,3}

According to the Croatian Institute for Public Health, CHD was the first cause of mortality in 2010 in Croatia with a rate of 21.6%.⁴ Despite this alarming information, in Croatia there is no national registry of patients with CHD, and that would certainly help combat this widespread disease causing high mortality. The only registry for acute myocardial infarction in that region of the city of Zagreb was established in 1979 in the center previously known as Cardiovascular Disease Center. In 2003 it was renamed into the Registry of acute coronary syndrome for the city of Zagreb, while epidemiologic and clinical data are continuously collected in the field of epidemiology and informatics activities of the Institute for Cardiovascular Disease Prevention and Rehabilitation, Zagreb.^{5,6}

The first PCI Registry was established in 1987 in Switzerland and it was established by the Swiss Society of Cardiology. In the beginning, a standardized questionnaire on paper was filled in and later they started using electronic format and Internet connection with the registry main office. Today, 25 hospital institutions that perform PCI submit data to the registry.⁷ In 1992 American College of Cardiology (ACC) established the *National Cardiovascular Data Registry* (NCDR), with *CathPCI Registry* established as a part of the NCDR collecting data on: institution, a patient and lesion, intervention and used materials as well as compliance of a therapy with ACC clinical guidelines. Some 60% of all PCI departments in the USA submit data to the Registry.⁸ During the same year, national registries in Germany and Austria were established, and in 1998 national registry was established in Sweden. Many European countries such as Great Britain, Spain, France, Poland, Ireland, etc. established similar registries as the European Society of Cardiology (ESC) whose registry (*European PCI Registry*) includes 25 countries and around 11 thousand of patients.⁷

The CARDS project (*The Cardiology Audit and Registration Data Standards*) was designed in 2004, upon the initiative by the Irish Institute of Public Health and Irish Society of Cardiology, in cooperation with ESC under the auspices of the European Commission. The goal of the project was to agree upon definitions of terms in cardiology, data standards and the manner of collecting data in order to compare the data from the registries in different countries. On the basis of conclusions agreed upon, they issued the guidelines for the design of registries and types of data that are collected which are divided into the following groups: general information, anamnesis, risk factors, acute symptoms and signs, intervention, outcome, condition at discharge, clinical follow-up (after 30 days and 12 months).³

In March 2011 the Symposium of the Croatian Cardiac Society (CCS) topic the participation in the European registry of patients with acute coronary syndrome took place. Prof. Rafaelle Bugiardinni, PhD from Bologna and Prof. Miličić, PhD representing the CCS presented the registry of patients developed for gathering data on invasively treated patients

srca imaju registre, koji se na žalost značajno razlikuju i nisu međusobno kompatibilni.

Laboratorij za invazivnu i intervencijsku kardiologiju Kliničkog bolničkog centra *Sestre milosrdnice* 1. siječnja 2011. god. u svakodnevni rad uveo vlastiti Registar PCI, institucijski registar koji uključuje sve bolesnike koji se podvrgavaju perkutanoj koronarnoj intervenciji (hitno ili elektivno) te registar za elektrofiziološko ispitivanje srca. Oba registra, u suradnji s intervencijskim kardiologima, osmislio je Ivica Benko bacc. med. techn. Registar PCI dostupan je u elektroničkom obliku, s visokim stupnjem zaštite pristupa. U Registar se upisuje 45 različitih podataka koji su podijeljeni u 5 skupina: 1. opći podaci (ime, prezime, spol, datum rođenja, prebivalište, uputna ustanova), 2. čimbenici rizika (arterijska hipertenzija, dijabetes, pušenje, dyslipidemija, obiteljska anamneza), 3. simptomi i znakovi akutne bolesti (početak bolova, EKG, zahvaćena stijenka, zatajivanje srca, kardiofreni šok, aritmije, reanimacija...), 4. zahvat i utrošeni materijal (lezija, segment, stent- broj, promjer, duljina, vrsta, TIMI protok, myocardial blush grade- MBG, tromboaspiracija te podaci o količini upotrijebljenog kontrasta i vremenu zračenja) te 5. dijagnostički i terapijski nalaz, kojeg upisuje isključivo intervencijski kardiolog (**Slike 1-5**).

(*The International Survey of Acute Coronary Syndromes in Transitional Countries; ISACS-CT*).⁹

There are no comprehensive registries for acute coronary syndrome and percutaneous coronary intervention in Croatia at the moment, while only specific cardiac catheterization laboratories maintain registries which greatly differ from each other and are not mutually compatible.

On 1 January 2011, the Laboratory of Invasive and Interventional Cardiology of the University Hospital Centre Sestre milosrdnice Zagreb, Croatia introduced its own PCI Registry in its daily work. This is the institutional registry which includes all patients undergoing percutaneous coronary intervention (urgently or electively) and registry for the electrophysiological heart test. Ivica Benko, Bachelor of Med. Techn. designed the both registries in cooperation with interventional cardiologists. PCI Registry is available in electronic format with a high access protection level. There are 45 different data which are entered in the Registry and which are divided in 5 groups: 1. general details (first name, surname, gender, date of birth, residence, referral institution), 2. risk factors (hypertension, diabetes, smoking, dyslipidemia, family history), 3. symptoms and signs of acute disease (onset of pain, ECG, affected wall, heart failure, cardiogenic shock,

Figure 1. Demographic.

Osnovne razlike ovog Registra, u odnosu na postojeće su model prema kojem je upis podataka za svakog bolesnika podijeljen između med. tehničara, ing. radiologije i intervencijskog kardiologa te izrazita jednostavnost, jer se većina podataka unosi klikom u već postojeći izbornik podataka. Ukupno vrijeme potrebno za ispunjavanje obrasca po bolesniku iznosi najviše 5 minuta, što predstavlja uštedu vremena, kako u odnosu na prijašnju evidenciju koja se vodila u papirnatom obliku, a bila je oskudnija podacima, tako

arrhythmias, resuscitation ...), 4. procedure and the materials used (lesion segment, stent-number, diameter, length, type, TIMI flow, myocardial blush grade-MBG, thromboaspiration and data on the amount of used contrast material and time of radiation) and 5. diagnostic and therapeutic result, which is entered only by an interventional cardiologist (**Figure 1-5**).

Anamneza i klinički podaci		Značajke infarkta		Terapija		Potrošni materijal		Intervencija		Komentari		NALAZ	
CULPRIT LEZIJA													
LEZIJA	SEGMENT	STENOZA %	NAZIV STENTA	PROMJER STENTA	DULJINA STENTA	VRSTA STENTA	TIKI PRIJE	TIKI NAKON	MBG PRIJE	MBG NAKON			
LAD	Distalni	99	CROCO	2.50	14	BMS	0	3	0	3			
			CROCO	2.50	10								
OSTALE LEZIJE													
LEZIJA	SEGMENT	STENOZA %	NAZIV STENTA	PROMJER STENTA	DULJINA STENTA	VRSTA STENTA	TIKI PRIJE	TIKI NAKON					
1													
2													
3													
4													
5													
Tromboaspiracija	Da		Kissing	Ne									
Predilatacija balonom	Ne		Ukupno stentova	2									
Postdilatacija balonom	Ne		GP IIb/IIIa	Da									
Napomena													
Podatke upisan				hvaljic	19.12.2011 8:49:58	Podatke promjenjen				hvaljic	19.12.2011 8:53:39		

Figure 2. Procedure and used material.

Anamneza i klinički podaci		Značajke infarkta		Terapija		Potrošni materijal		Intervencija		Komentari		NALAZ	
Deblo													
LAD													
ACx													
RCA													
Intervencija Zadnjucak													
Aortografija, desna kateterizacija, ventrikulografija													
Napomena													
Podatke upisan				hvaljic	19.12.2011 8:49:58	Podatke promjenjen				hvaljic	19.12.2011 8:53:39		

Figure 3. Diagnostical and interventional findings.

i prema drugim do sada predstavljenim modelima elektroničkih registara. Tek nakon što su ispunjeni svi traženi podaci intervensijski kardiolog upisuje dijagnozu i nalaz te se podaci zaključavaju, ispisuju kao nalaz kateterizacije i ostalo trajno sačuvani u elektroničkom obliku. Upravo taj model upisa osigurao je da su od uvodenja Registra, u bazu podataka upisani sve varijable vezane uz svaku pojedinačnu učinjenu intervenciju. Podatke iz postojećeg Registra moguće je ispisati u Excel ekstenziji, na taj način statistički obraditi, kao i implementirati u bilo koji postojeći registar.

Nakon godinu dana upotrebe svi djelatnici uključeni u rad Registra slažu se da je on značajno olakšao svakodnevni rad (skraćeno je vrijeme potrebno za unos podataka, veća je preglednost podataka, lakše je pretraživati podatke, svi podaci su u elektroničkom obliku) te se stvara baza podataka koja će olakšati praćenje rada laboratorija za invazivnu i intervensijsku kardiologiju, svakog intervensijskog kardiologa zasebno i postati temelj za budući znanstveno-istraživački rad. Nadalje, provodi se i nadogradnja Registra podacima o farmakoterapiji prije i nakon zahvata. U nadolazećim mjesecima nastojat ćemo što više uskladiti Registar sa standardima CARDS projekta, uvesti kliničko praćenje i ishod lije-

The main differences of this Registry compared to the existing registries is a model according to which the entry of data for each patient is divided between a medical technician, a medical radiology engineer and an interventional cardiologist, its utmost simplicity, because the most of the data are entered by clicking in the already existing data menu. Total time required for filling in a form for a patient takes no more than 5 minutes, resulting thus in time saving, not only compared to the previous records maintained in paper format and which contained less information, but also compared to the other electronic registries which have been presented so far. Only after all the required data have been filled in, an interventional cardiologist will enter a diagnosis and results and such data are locked, printed as the results of catheterization and remain permanently preserved in electronic format. It is the model of entry owing to which all the variables relating to each individual intervention performed have been entered in a database since the introduction of the Registry. Data from the existing Registry can be printed in Excel extension, statistically processed and implemented into any existing registry.

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 ZAVOD ZA KARDIOVASKULARNE BOLESTI
LABORATORIJ ZA INVAZIVNU I INTERVENCIJSKU KARDIOLOGIJU
NALAZ KATETERIZACIJE SRCA

Prezime i ime bolesnika: **HRVOJE**
 Godište: **1961**
 Odjel: **Koronarna jedinica**
 Datum pretrage: **19.12.2011**
 Broj pretrage: **1234/11**
 Dijagnoza:

KORONAROGRAFIJA
DEBLO:
LAD:
ACx:
RCA:

AORTOGRAFIJA

DESNA KATETERIZACIJA

VENTRIKULOGRAFIJA

INTERVENCIJA [ZAKLJUČAK]:
 Napomena:

Kateterizirao: **Doc.dr.sc. Pintarić Hrvoje**
Dr. Babić Zdravko

   

Figure 4. Finding print.

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PROTOKOL PRAĆENJA KATETERIZACIJE SRCA

Prezime i ime bolesnika: **HRVOJE** ID 1234/11
 Godište: **1961**
 Odjel: **Koronarna jedinica**
 Datum pretrage: **19.12.2011**
 Dijagnoza:

Učinjene intervencije:	KORONAROGRAFIJA	Uputna ustanova: Sisak - mreža
	PCI	Prijem: Hitni STBMI
	ASPIRACIJA TROMBA	

   

Krvotilni pristup: TR
 Culprit lezija: LAD
 Predilatacija balonom: Ne, Postdilatacija balonom: Ne
 Količina utrošenog kontrasta: 234 mL
 Dijaskopija: 7 min., 5678 cGycm²
 Početak procedure: 19.12.2011 8:49:58, Kraj procedure: 19.12.2011 8:58:42

Dijagnostički kateteri:	Guiding kateteri:
Koronarna žica:	PTCA baloni:

STENT:
 CROCO 2.50 14
 CROCO 2.50 10

Ukupno STENTova: 2

Primjenjena terapija za vrijeme kateterizacije:
 8:50 Heparin 5000 i.j. i.a.
 8:50 Isoptin amp. 1 amp. i.a.
 8:51 Fiziološka otopina 500 mL i.v.

Figure 5. Protocol print.

čenja bolesnika, kako bolnički tako i nakon 30 dana i 12 mjeseci.

Na temelju stečenog iskustva smatramo da je Registar PCI, u stvari, nadopuna novih tehnologija uvedenih u liječenje KBS. Sustavno i kontinuirano prikupljanje podataka o bolesnicima, zahvatima i ishodima, farmakoterapiji te kliničko praćenje, omogućuje statističku i epidemiološku obradu i evaluaciju podataka kojima se donose zaključci o pridržavanju kliničkih smjernica, kvaliteti tih smjernica, kvaliteti rada u Laboratoriju i Zavodu za kardiovaskularne bolesti te novim mogućnostima liječenja. Iz svega navedenog proizlaze potencijalni pozitivni pomaci u kvaliteti kliničke skrbi o bolesnicima i bolji ishod liječenja, kao i bolja iskoristivost raspoloživih materijalnih sredstava u liječenju KBS.

Cinjenica je, međutim, da je formiranje Registra samo korak prema zajedničkom cilju, formiranju nacionalnog registra PCI te sudjelovanju Republike Hrvatske u europskom registru bolesnika s akutnim koronarnim sindromom.

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After a year of use, all the staff involved in the work of the Registry agree that it has greatly facilitated the daily work (the time required for data entry has shortened, the visibility of data is better, it is easier to search for information, all the data are in electronic format) and the database is being created resulting in easier monitoring of the laboratory work for invasive and interventional cardiology, each interventional cardiologist separately and it will become the foundation for the future scientific research. Furthermore, the upgrade of the Registry with data on pharmacotherapy before and after the intervention is implemented. In the forthcoming months we shall try to make the Registry compliant with the CARD project standards, introduce clinical monitoring and clinical outcome of patients not only in-hospital clinical outcome, but also after 30 days and 12 months.

Based on the experience we have gained, we believe that the PCI Registry, in fact, complements new technologies introduced in the treatment of CHD. Systematic and continuous collection of data on patients, interventions and outcomes, pharmacotherapy, and clinical follow-up, enables statistical and epidemiological workup and evaluation of the data which are used to reach conclusions on compliance with clinical guidelines, quality of these guidelines, quality of work in the Laboratory and Cardiovascular Disease Institute and the new treatment possibilities. Consequently, we can see that the Registry will result in potentially positive improvements in the quality of clinical care for patients and better outcome of treatment, as well as better utilization of available financial resources in the treatment of CHD.

The fact is however, that the establishment of this Registry is only a step towards a common goal, establishment of the national PCI registry and the participation of the Republic of Croatia in the European registry of patients with acute coronary syndrome.

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