

# Percutaneous coronary intervention (PCI) in a 10-year period (2005–2015) – a single centre experience

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## Abstract

**Background:** Medicor was established as the third cardiovascular centre in Slovenia and started with percutaneous cardiovascular interventions in 2005. The purpose of our study was to describe the features and results of percutaneous coronary intervention (PCI) performed between 2005 and 2015.

**Methods:** Our retrospective descriptive study included consecutive patients undergoing PCI, who were enrolled in Medicor PCI Registry. Patient characteristics, coronary anatomy, PCI features, use of coronary stents, procedural success and complications were investigated. Special emphasis was put on patients undergoing unprotected left main PCI.

**Results:** A total of 1981 consecutive PCI procedures were performed. PCI patients were mainly men (73 %), their average age was  $65 \pm 10$  years and majority (94 %) had stable coronary disease with multivessel involvement (62 %). PCI was performed in 2978 lesions (1.50 lesion/patient) with an average diameter stenosis of  $85 \pm 10$  %. The target lesion was located either in the left anterior descending artery (42.9 %), right coronary artery (32.4 %), left circumflex artery (18.4 %), left main (3 %), and surgical grafts (2.3 %) or in the intermediate artery (1 %). Balloon angioplasty alone was performed in 9.6 % while other patients received 1 to 7 stents ( $1.44 \pm 0.86$  per patient). Until 2009, drug eluting stents (DES) penetration ranged between 20 % and 30 %. It then increased to 80 % in 2012 and 100 % in 2015. PCI was angiographically successful in 95.2 %. Because of PCI complications, 4 patients (0.2 %) required immediate open-heart surgery and 4 patients (0.2 %) surgical intervention at the femoral access site. Hospital mortality was 0 %. Stent thrombosis within 30 days was documented in 6 patients (0.3 %). In a subgroup of 58 patients undergoing unprotected left main PCI, provisional stenting was used in 88 %. DES penetration was 94 %. PCI was angiographically successful in all patients. Hospital and 30-day mortality rates were 0 %, 1-year mortality 1.7 % (95 % CI 0–11 %) and 5-year mortality 13.8 % (95 % CI 7–33 %). Target vessel revascularization at 5 years was 3.5 % (95 % CI 0–23 %).

**Conclusion:** PCI in patients with predominantly stable coronary artery disease performed in Medicor cardiovascular centre appears to be an effective and safe method of revascularization, which is also true for an intervention in unprotected left main.

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## Key words:

percutaneous coronary intervention; unprotected left main

## Cite as:

Zdrav Vestn. 2017; 86: 95–104.

Received: 28. 9. 2016

Accepted: 27. 2. 2017

**Cite as:** Zdrav Vestn. 2017;86: 95–104.

## Introduction

Private cardiovascular centre Medicor started with an open-heart surgery program in 2004 and performed 2.365 procedures by the end of 2015. First percutaneous coronary intervention (PCI), which was done in February 2005, was followed by percutaneous transluminal angioplasty of carotid/ peripheral arteries and percutaneous interventions for structural heart diseases. Registries of consecutive patients for each of these interventions were concomitantly established to allow continuous analysis of outcomes and comparison with similar cardiovascular centres worldwide. We have already reported our results on percutaneous closure of patent foramen ovale (1–2), atrial septal defect (3), alcohol septal ablation in hypertrophic cardiomyopathy (4) and retrograde ventricular septal defect closure (5). The aim of the present study is to continue this tradition and report results of PCI from

the first procedure in 2005 until the end of 2015. PCI, which was performed for the first time in Switzerland in 1977, is nowadays also in Slovenia a generally accepted method of coronary revascularization routinely performed in patients with acute coronary syndromes and stable coronary artery disease.

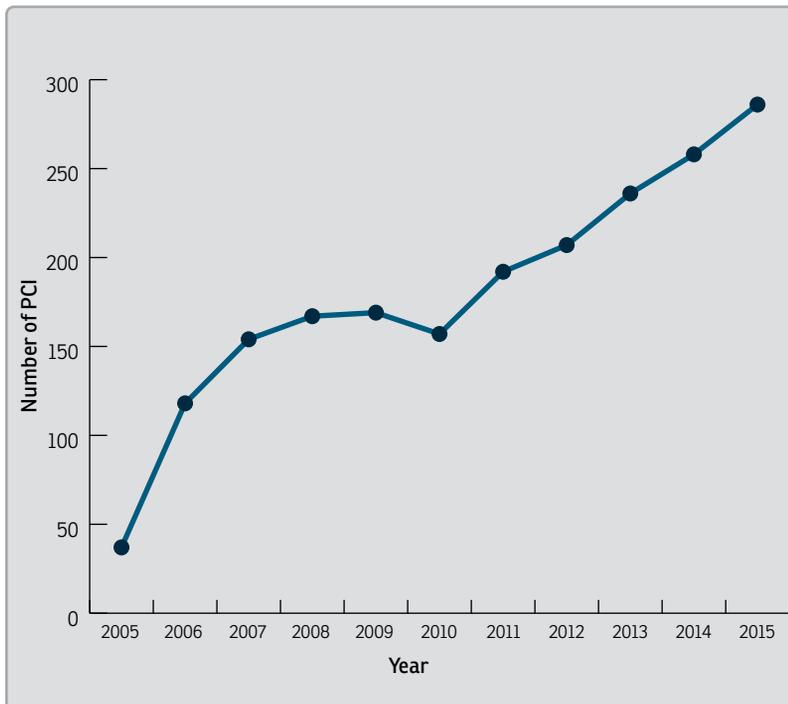
## Patients and methods

We conducted a retrospective, descriptive study enrolling consecutive patients undergoing PCI in Medicor between 9 February 2005 (first PCI) and 22 December 2015. Data were acquired from the PCI registry, which has been, as other Medicor registries, approved by the National Ethic Committee.

PCI was performed by one of the three interventional cardiologists with an annual volume of > 150 procedures including those in other institutions. One

**Table 1:** Percutaneous cardiovascular interventions in Medicor, 2005–2015.

	Number
Coronary angiography	5.322
Coronary angiography and fractional flow reserve (FFR)	290
Coronary angiography and percutaneous coronary intervention (PCI)	1.981
Percutaneous closure of patent foramen ovale (PFO)	154
Percutaneous closure of atrial septal defect (ASD)	30
Percutaneous closure of ventricular septal defect (VSD)	1
Percutaneous closure of left atrial appendage (LAA)	21
Alcohol septal ablation in hypertrophic cardiomyopathy	8
Angiography/carotid stenting (CAS)	1.601
Angiography/ Percutaneous transluminal angioplasty of vertebral/ subclavian artery	49
Angiography/Percutaneous transluminal angioplasty of lower extremity arteries	518
Implantation of permanent pacemaker	186
<b>Total</b>	<b>10.161</b>



**Figure 1:** Gradual increase in annual number of PCI in Medikor between years 2005 and 2015.

**Table 2:** Clinical characteristics of consecutive patients undergoing percutaneous coronary intervention (PCI)

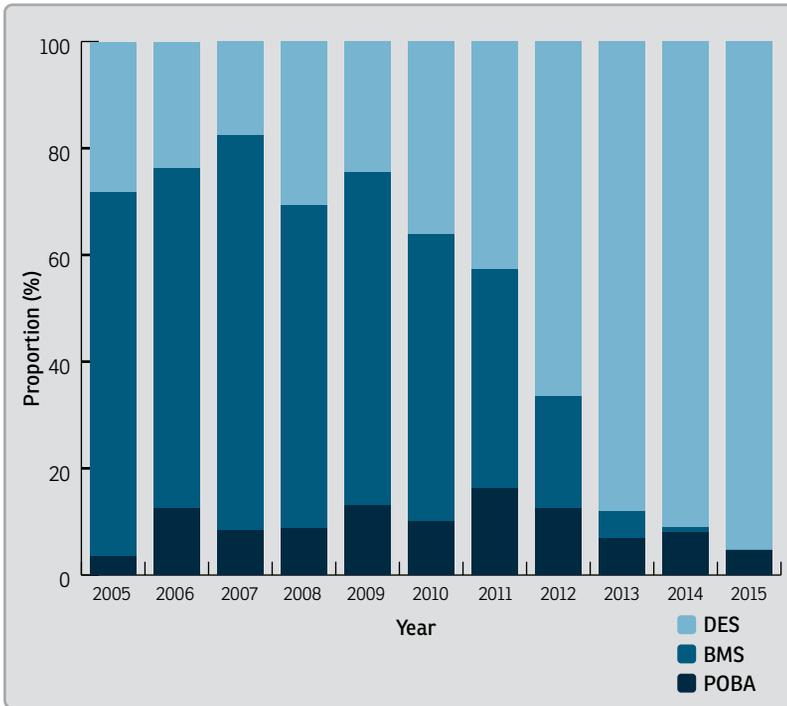
	n=1981
Age, years	65 ± 10 (30–90)
Male gender	1.443 (73 %)
<b>Indication</b>	
Exertional angina pectoris	1.626 (82,1 %)
Silent ischemia	40 (2 %)
Coronary spasm	1 (0,1 %)
Staged PCI	182 (9,2 %)
UA/NSTEMI	70 (3,5 %)
STEMI	44 (2,2 %)
Other	18 (0,9 %)
Left ventricular ejection fraction, %	57 ± 6 (15–70)
<b>Extent of coronary artery disease</b>	
One vessel	748 (37,8 %)
Two vessel	683 (34,5 %)
Three vessel	550 (27,7 %)

*Legend: UA – unstable angina pectoris; NSTEMI – non-ST elevation myocardial infarction; STEMI – ST-elevation myocardial infarction*

cardiologist (MN) was active during the whole study period, one (HR) between 2006–2015, and one (IZ) between 2006–2011. In addition to interventional cardiologist, the PCI team consisted of a scrub nurse and an X-ray technician. Elective coronary patients were admitted on the day of the procedure and discharged the next morning. Patients with acute coronary syndromes were treated according to the valid Slovenian guidelines annually presented at the symposium »Akutni koronarni sindrom v Sloveniji«. Following PCI, the patient was admitted to the telemetry unit. At hospital discharge, every patient received verbal and written instructions about antiplatelet treatment and how to proceed in case of suspected stent thrombosis or restenosis.

Data regarding patient characteristics and PCI features were entered by each interventional cardiologists into the Medikor registry after completing the intervention. For each patient, general characteristics (age, gender), indication for PCI, left ventricular ejection fraction, extent of coronary artery disease, site/diameter of target stenosis, PCI features, stent characteristics/dimensions and final angiographic result were described. If there was a doubt about the significance of coronary stenosis, fractional flow reserve (FFR) using adenosine was performed since 2011. Intravascular ultrasound (IVUS) and optical coherence tomography (OCT) were not available at the time of the study. PCI was regarded as angiographically successful in the case of < 20 % residual stenosis, absence of coronary dissection/ thrombus and presence of normal anterograde coronary flow. Post PCI complications, hospital discharge and occurrence of stent thrombosis < 30 days after the PCI were followed.

A subgroup of patients undergoing PCI of unprotected left main (ULM) was



**Figure 2:** Proportion of balloon angioplasty alone (POBA), bare metal stents (BMS) and drug eluting stents (DES) between years 2005 and 2015.

analysed separately. ULM was defined as significant stenosis of the left main in the absence of patent surgical graft to distal parts of the left coronary tree. In addition to previously described variables, we also systematically followed long-term survival and the need for repeat revascularization.

Data are shown in tables and graphs. Numerical data are described as mean ± standard deviation and categorical as proportions in percentages. A 5-year survival and the need for repeat revascularization were analysed using Kaplan-Meier method.

## Results

Between 9 February 2005 and 22 December 2015, among 10.161 percutaneous cardiovascular interventions, 1981 PCIs were performed (Table 1). FFR was performed in 290 of 4,104 coronary angiographies (7.1%). Based on FFR, PCI was deferred in 224 patients (77%) and performed in 66 patients (23%).

Annual number of PCIs gradually increased from 34 in 2005 to 286 in 2015 (Figure 1). Patients undergoing PCI were mainly men (73%) at an average age of  $65 \pm 10$  years. The majority of patients (94%) had stable coronary artery disease with multivessel involvement in 62% (Table 2). PCI was performed in 2,978 lesions with an average diameter stenosis of  $85 \pm 10$ % (Table 3). Location of the target lesion was either in the left anterior descending artery (42.9%), right coronary artery (32.4%), left circumflex artery (18.4%), left main artery (3%), bypass grafts (2.3%) or on the intermediate artery (1%). Balloon angioplasty alone was performed in 9.6% while the rest of the patients received 1–7 stents which were either bare metal stents (BMS) or drug eluting stents (DES). The average number of implanted stents per procedure was  $1.44 \pm 0.86$ . The length of stented segment ranged from 8 to 122 mm ( $24.50 \pm 15.15$  mm). DES penetration, which ranged between 20–30% until 2009, increased to 80% in 2012 and to 100% in 2015 (Figure 2). PCI was angiographically successful in 95.2%.

We used femoral access in the majority of patients with manual compression for haemostasis. None of the patient died during PCI. Four patients (0.2%), who underwent urgent open-heart surgery due to PCI complication, survived and were discharged from the hospital (Table 4). Four patients (0.2%), who required surgical intervention because of the complication on the access site, were also discharged from the hospital alive. In-hospital mortality was therefore 0%. Acute or subacute stent thrombosis within 30 days from the PCI was documented in 6 patients (0.3%).

Among 1981 patients undergoing PCI, there were 88 patients (3%) with significant left main stenosis, including 58 pa-

**Table 3:** Features of percutaneous coronary intervention (PCI)

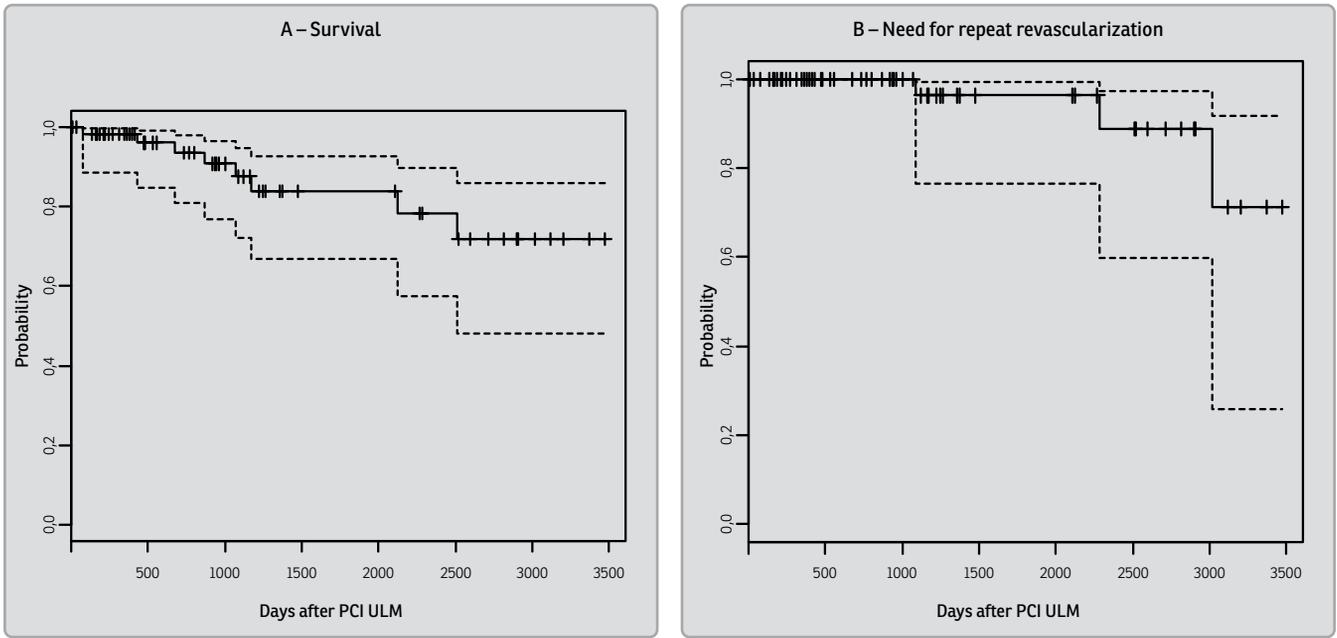
Number of patients	1.981
Target stenoses treated by PCI	2.978
Target stenoses/patient	1.50
<b>Location of stenosis</b>	
Left main coronary artery	88 (3 %)
LAD-diagonal branches	1.276 (42,9 %)
LCX-marginal branches	549 (18,4 %)
Intermediate artery	30 (1 %)
RCA-PDA/PLA	966 (32,4 %)
SVG	56 (1,9 %)
LIMA/RIMA	13 (0,4 %)
Diameter stenosis, %	85 ± 10
Chronic total occlusion (CTO)	128 (4,3 %)
<b>PCI technique</b>	
POBA	285 (9,6 %)
BMS	1.026 (34,4 %)
DES	1.667 (56 %)
Stent diameter, mm	3,02 ± 0,46 (2,25–5,0)
Stent length, mm	17,04 ± 5,73 (8–38)
Length of stented segment, mm	24,50 ± 15,15; (8–122)
Stents/patient	1,44 ± 0,86 (1–7)
Successful PCI, %	2.834 (95,2 %)
<b>Hemostasis at puncture site</b>	
Manual compression	1.354 (68,4 %)
Angioseal	564 (28,5 %)
Perclose	12 (0,6 %)
Exoseal	3 (0,1 %)
Transradial band	48 (2,4 %)

*Legend: LAD – left anterior descending artery; LCX – left circumflex artery; RCA – right coronary artery; PDA – posterior descending artery; PLA – posterolateral artery; SVG – saphenous vein graft; LIMA – left internal mammary artery; RIMA – right internal mammary artery; POBA – balloon angioplasty only alone; BMS – bare metal stent; DES – drug eluting stent*

tients (66 %) undergoing UML PCI. The lesion was diffuse or involved distal left main in 65 % (Table 5). One stent strategy was used in 88 %. Wire recrossing and kissing balloon inflation was used in 34 %. Second side-branch stent was deployed in 12 %. DES penetration was 94 %. PCI was angiographically successful in all patients. Long-term follow up was available in 57 of 58 patients (98 %). Hospital and 30-day mortality were 0 %, 1-year mortality 1.7 % (95 % CI 0–11 %) and 5-year mortality 13.8 % (95 % CI 7–33 %) (Figure 3A). Three out of 8 patients who died underwent autopsy while in the remaining 5 patients the cause of death was established from their medical documentation. Coronary death was documented in 2 patients (25 %) while the rest of the deaths were non-cardiac. Repeat revascularization at 5 years was 3.5 % (95 % CI 0–23 %) (Figure 3B).

## Discussion

We demonstrated that PCI in cardiovascular centre Medicor, which was mainly performed in elective coronary patients (94 %), was a very effective and safe revascularization method. Our hospital mortality was 0 %, angiographic success rate was 95 %, need for urgent open heart surgery was 0.2 %, need for surgical repair at the access site 0.2 % and stent thrombosis within 30 days 0.3 %. Unfortunately, we do not have a systematic long-term follow-up in terms of repeat revascularization and survival except for a subgroup of patients undergoing ULM PCI. We could therefore not compare the effectiveness of BMS versus DES in our patients. Since we do not systematically follow-up periprocedural troponin levels, we also do not have data



**Figure 3:** Kaplan-Meier curves of survival (A) and need for repeat revascularization (B) in patients undergoing unprotected left main PCI (PCI ULM). Dotted lines indicate 95 % confidence interval.

on the incidence and size of periprocedural myocardial infarction.

Despite using femoral access in the majority of patients, only few patients (0.2 %) required surgical repair due to complication. Low complication rate was probably related to the fact that puncture was performed by the experienced interventional cardiologist, who always performed femoral angiography if closure device was attempted. If manual compression was chosen, it was performed by two experienced and trained medical technicians. Transradial access, however, is nowadays becoming predominant also in Medigor, and elective coronary angi-

ography and PCI are gradually becoming outpatient procedures.

Our PCI results, which are comparable with those published in the literature, were achieved despite a relatively small annual PCI volume (< 400). This argues for the hypothesis that an experienced interventional cardiologist with a large annual procedural volume together with an experienced nurse and x-ray technician may also have very good PCI results in a relatively small centre. In this context, it is also important to emphasize that Medigor closely followed developments in stent technology and moved from BMS and first generation DES to

**Table 4:** Complications of percutaneous coronary intervention (PCI).

	<b>n=1.981</b>
Death during PCI	0 (0 %)
Urgent open-heart surgery due to PCI complication	4 (0,2 %)
Surgical intervention due to puncture site complication	4 (0,2 %)
Hospital mortality	0 (0 %)
Stent thrombosis <30 days from PCI	6 (0,3 %)
Acute (<24 hours)	2 (0,1 %)
Subacute (Day 1–39)	4 (0,2 %)

**Table 5:** Percutaneous coronary intervention (PCI) in patients with unprotected left main stenosis between years 2006–2015

	<b>n = 58</b>
Age, years	66 ± 13
Male gender	40 (69 %)
Stable coronary artery disease	50 (86 %)
Acute coronary syndrome	8 (14 %)
<b>Indication</b>	
Prohibitive CABG risk	24 (41 %)
Patient refused CABG	5 (9 %)
Heart team decision for PCI	21 (36 %)
Rescue PCI	8 (14 %)
<b>Location of left main stenosis</b>	
Ostial	16 (28 %)
Mid shaft	4 (7 %)
Whole/distal	38 (65 %)
Diameter stenosis	75 ± 15 %
FFR confirmation (<0.80)	8 (14 %)
Multivessel disease	38 (66 %)
<b>PCI features</b>	
One stent only	51 (88 %)
Wire recross and kissing balloons	20 (34 %)
Second stent in the side branch	7 (12 %)
T-stenting	5 (9 %)
T and protrusion (TAP)	2 (3 %)
DES	60 (94 %)
Successful PCI	58 (100 %)
PCI of additional coronary arteries	32 (55 %)

Legend: CABG – coronary artery bypass grafting; FFR – fractional flow reserve; DES – drug eluting stent

second generation DES as soon as they became available. It is well known that second generation DES reduce in-stent restenosis by more than 50 %, and even more importantly, also significantly reduce the incidence of stent thrombosis. Low incidence of stent thrombosis in our patients was probably also related to systematic education of patients about

the importance of regular dual antiplatelet treatment and written instructions at hospital discharge. We would also like to emphasize that herein described PCI results were achieved without advanced intravascular imaging including IVUS and OCT, which are financially unattainable due to the lack of reimbursement from the Slovenian national insurance system.

This is also true for some PCI methods including rotablation and cutting balloons, which may in some patients be essential. On the other hand, we systematically used distal protection in PCI of saphenous vein grafts. Despite the previously described financial restrictions, we introduced FFR of angiographically intermediate lesions (50–70 %) already in 2011, which is in accordance with current revascularization guidelines of the European Society of Cardiology (6). FFR also proved to be very useful in our hands because we were able to safely defer PCI using FAME trial criteria (7) in 77 % of patients.

We put special emphasis on patients undergoing ULM PCI, which was performed only by one interventional cardiologist who cumulatively – including his work in other institutions – performed 147 such interventions in years 2006–2015. The results show very good angiographic PCI success and low long-term mortality, which was 13.8 % (95 CI 7–33 %) at 5 years and is comparable to PCI groups of recent large international randomized trials. A 5-year mortality was 12.8 % in SYNTAX (8), 5.7 % in PRECOMBAT (9) and 12 % in NOBEL study (10). Our mortality at 3 years (8.6 %) is also almost identical as in the very recent EXCEL trial (11). It is important to emphasize that among our patients undergoing ULM PCI, there were 41 % of patients with prohibitive CABG risk due to concomitant comorbidities and 14 % of patients with life-saving rescue interventions. The fact that such patients with

expected higher mortality were not included in the previously described randomised studies further confirms that our results are comparable with those reported by the best PCI centres. Since only 25 % of our deaths during the follow-up were coronary, we believe that non-cardiac comorbidities represented the main cause of death, which is also in accordance with low incidence of repeat revascularization at 5 years (3.5 %, 95 % CI 0–23 %). This incidence is again lower or comparable with that in SYNTAX (26.7 %), PRECOMBAT (12.4 %) and NOBEL (16.2 %) studies. It is, however, important to emphasize that our revascularization was clinically driven and not based on routine repeat coronary angiography as in the described randomised trials.

## Conclusion

PCI performed at Medicor cardiovascular centre in patients with predominantly stable coronary artery disease is an effective and safe revascularization method, which is also true for ULM PCI.

## Acknowledgment

The authors would like to thank all nurses in the catheterization laboratory, x-ray technicians, doctors and nurses on the medical ward for their excellent care and management of patients before, during and after PCI. We are especially grateful to Medicor head nurse Mrs. Jasmina Grahovac.

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