

OUTPATIENT PERCUTANEOUS CORONARY INTERVENTIONS AT THE LATVIAN CENTRE OF CARDIOLOGY

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Cardiology in Latvia has experienced major changes since the separation from the Soviet Union. The era of interventional cardiology in Latvia began in 1990, when the first coronary angioplasty was performed (by Andrejs Ērglis and Andis Dombrovskis) at Latvian Centre of Cardiology, Pauls Stradins Clinical University hospital, which still remains the largest interventional cardiology centre in Latvia.

The concept of modern medicine lies in performing as minimal invasive interventions as possible, providing maximal physical and emotional comfort for the patient, reducing the time of patient hospital stay and time necessary for patient recovery and returning to his everyday activities. Due to the invasiveness and risk of potential complications, diagnostic coronary angiography or percutaneous coronary intervention (PCI) are commonly performed as inpatient procedures. However, with improved equipment, technology and the accumulation of experience, diagnostic coronary angiography has been increasingly done on an outpatient basis [1].

In Latvia, shortage of elective beds causes procedure cancellations and long waiting lists. Performing coronary interventions as day case procedures minimizes the problems of bed availability and

reduces overall cost. The 11th of July 2003 we initiated an interventional cardiology outpatient clinic at Latvian Centre of Cardiology. Initially the day clinic was operating 8 beds, the number of which increased to 20 in few years.

Nevertheless, PCI was still being performed as an inpatient procedure, with the average lengths of hospital stay ranging from 2 to 3 days. The two major reasons for keeping the patient under clinical observation is periprocedural myocardial damage, especially after complex coronary interventions and the risk of subacute closure of the target vessel. Therefore, at the beginning only coronary angiography was performed on outpatient basis, but since 2007 PCIs are also done as outpatient procedures. Since then the total number of outpatient PCIs has not changed significantly (figure 1); the number of outpatient PCIs at the Latvian Centre of Cardiology was 557, 527, 657 and

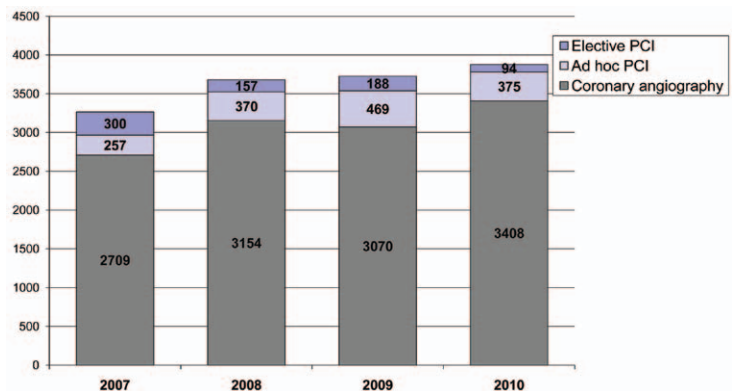


Figure 1. Procedures performed in outpatient clinic at Latvian Centre of cardiology by year.

469 in years 2007, 2008, 2009 and 2010, respectively.

Nonetheless, the majority of patients who are scheduled for coronary angiography in the outpatient clinic have stable angina pectoris, a history of previous myocardial infarction or unstable angina, intended heart valve operations or other elective surgical interventions.

The patients are referred to the outpatient day clinic by general practitioners or cardiologists. Prerequested examinations for patients are completed blood tests (complete blood count, creatinine, blood cholesterol, glucose), exercise test and echocardiography results. Previous medical records should also be presented to the attending doctor.

Generally, there are two categories of patients in whom PCI is done in our outpatient clinic. Firstly, these are patients scheduled for elective PCI and secondly, patients in whom critical coronary stenosis are detected during coronary angiography. Ad hoc outpatients PCIs were done 2 to 3 times more than elective outpatient PCIs (figure 1). A possible explanation for this is that technically easy PCIs are more often done as ad hoc procedures both on an outpatient or inpatient basis than staged as elective PCIs for another admission. Baseline characteristics from outpatient PCIs in 2009 are presented in table 1.

The treatment strategy for elective PCI in patients with stable angina is based on the technical simplicity of coronary stenotic lesions. Elective outpatient PCIs should be low risk procedures. Patients scheduled for coronary diagnostics are evaluated differently, according to presence of critical stenosis or subtotal coronary occlusions. Immediate PCI is

Table - 1. Outpatient PCI characteristics at 2009

Characteristics	Value
Age, years, mean±SD	65.2 ± 9.0
Gender	
Male, n (%)	453 (69.0)
Female, n (%)	204 (31.0)
Stable angina pectoris, n (%)	597 (90.9)
Myocardial infarction in history, n (%)	248 (37.7)
Previous PCI, n (%)	191 (29.0)
Previous coronary artery bypass surgery, n (%)	8 (1.2)
Chronic heart failure, n (%)	324 (49.3)
Arterial hypertension, n (%)	581 (88.5)
Diabetes mellitus, n (%)	111 (16.9)
Dyslipidemia, n (%)	595 (90.5)
Stroke in history, n (%)	22 (3.3)
Chronic kidney disease, n (%)	8 (1.2)
Peripheral artery disease, n (%)	20 (3.1)
Active smoking, n (%)	131 (20.0)
Medical therapy before outpatient PCI	
Aspirin, n (%)	565 (86.0)
Clopidogrel, n (%)	160 (24.3)
Statins, n (%)	472 (71.8)
Medical therapy during outpatient PCI	
Heparin, n (%)	643 (97.8)
Enoxaparin, n (%)	14 (2.2)
GP IIb/IIIa inhibitors, n (%)	289 (44.0)
Eptifibatide, n (%)	97 (14.7)
Tirofiban, n (%)	193 (29.3)
Balloon angioplasty, n (%)	35 (5.4)
PCI with stent, n (%)	622 (94.6)
PCI with drug eluting stent, n (%)	222 (33.8)
Direct stenting, n (%)	271 (41.2)
Transferred to in-patient clinic, n (%)	5 (0.8)
Major bleeding, n (%)	2 (0.3)
Complex outpatient PCIs, n (%)	
Left main PCI, n (%)	6 (0.9)
Saphenous venous graft PCI, n (%)	2 (0.3)
Multivessel PCI, n (%)	42 (6.4)
Instant restenosis, n (%)	46 (7.0)
Bifurcation PCI, n (%)	46 (7.0)

offered if the stenosis is technically easy to treat in a patient with significant coronary complaints (unstable angina, accelerating angina or stable angina III or IV functional class according to Canadian Cardiovascular

Society functional classification of angina pectoris) and there is no heart valve pathology as evaluated by echocardiography and the patient is without any other known contraindications for PCI. The patient is informed about the risks and the necessity for immediate PCI. If the patient is able to understand the problem and consents to interventional treatment, PCI follows. The idea of the outpatient clinic is to admit stable individuals, nevertheless, sometimes patients with severe complaints and even unstable angina symptoms present.

With current stent technology, enhanced clinical expertise and potent antiplatelet drugs, the results of PCI are increasingly predictable with significant reduction in acute complications after the procedure [2]. Nevertheless, not every critical coronary stenosis is technically simple to manage and still the risk of periprocedural myocardial damage or abrupt vessel closure remains. Therefore, careful evaluation of the necessity of immediate PCI is crucial. Normally on outpatient basis we perform PCI for critical stenosis in cases with one or two vessel disease, choosing the most critical and technically simplest stenosis for immediate intervention and a staged PCI strategy for other coronary lesions. In situations when we diagnose critical bifurcation lesions, left main stenosis or complex multi-vessel disease, management strategy mainly depends on operator and patients actual coronary complaints. Every case is unique, and the treatment approach may differ from patient to patient. In some cases, we perform complex, immediate PCI in patients initially scheduled for outpatient coronary diagnostics, but generally, these patients are kept overnight in the hospital.

Left main (LM) critical stenosis covers special issue and the most appropriate treatment for this patient subgroup still remains unknown. However, recent progress in technique and equipment, including stents and use of intravascular ultrasound imaging together with modern and effective antiplatelet agents, has brought unprotected LM stenosis to the forefront of interventional cardiology. Despite improved results, LM PCI remains a high risk intervention, not only because of procedural risks, but also due to long

term concerns. Informed consent and full patient understanding are essential when considering patients for LM intervention. In case of immediate PCI it is difficult to explain all the risks, possible benefits and other treatment options to the patient and his family members. Immediate LM PCI should be done only if LM disease is critical and left untreated may provide high short term mortality risk. Moreover, it is of great importance that patients undergoing LM PCI have adequate medical records and available echocardiographic data.

Another concern regarding immediate PCI is the patient's actual medical therapy. Studies have suggested that pretreatment with statins might reduce the incidence of myocardial infarction after coronary intervention [7, 8]. Myocardial necrosis, assessed by creatine kinase (CK)-MB elevation, is relatively frequent after coronary intervention [9,10], although most patients remain asymptomatic with no changes in cardiac function. Nevertheless, a mild release of CK-MB is associated with higher mortality during follow-up [9,10]. The ARMYDA (Atorvastatin for Reduction of MYocardial Damage during Angioplasty) study showed that pretreatment with atorvastatin 40 mg/d for 7 days significantly reduced procedural myocardial injury in elective coronary intervention [11]. These results indicate that patient pretreatment with adjuvant pharmacological therapy before PCI is important and may influence long term results. However, in the outpatient clinic, the patients are not always on optimal medical therapy, including HMG-CoA reductase inhibitors (statins).

In recent years, there has been an increasing use of clopidogrel 600 mg loading dose before elective PCI, mostly triggered by the ARMYDA-2 trial [14]. The pre-treatment with 300 clopidogrel 3-24 hours before PCI was not associated with significant risk reduction in the prospective randomized Clopidogrel for the Reduction of Events During Observation trial [12]. Subgroup analyses, however, suggested that longer intervals between the loading dose and PCI may reduce events. No treatment differences were observed in patients receiving a 600 mg loading dose 2-3 h before PCI vs. those receiving the

same loading dose 12 h before PCI in the Intracoronary Stenting and Antithrombotic Regimen-Rapid Early Action for Coronary Treatment (ISAR-REACT) trial [13]. For immediate PCI, we use 600 mg clopidogrel loading dose and a GP IIb/IIIa inhibitor, at least a bolus dose, in order to cover the gap until acceptable platelet inhibition by clopidogrel is obtained.

The development of procedures via a transradial approach [3] and the femoral vascular closure devices [4-6] have contributed to the decreased length of hospital stay and made it possible to perform outpatient interventions. Nonetheless, transradial coronary intervention (TRI) is considered as the most suitable for a same-day discharge procedure because of the advantage of effective compression hemostasis. Furthermore, puncture site complications rarely occur with the radial approach and its indication widens with the accumulation of operator experience of performing TRI. At our outpatient clinic an average of 70-80%

are TRI interventions (figure 2 and 3). The interventional cardiology day clinic employs 13 interventional cardiologists and each of them is trained to perform TRI.

After discharge from either outpatient or inpatient interventional clinic, we recommend an exercise test at one, three, six and twelve months after PCI. Latvia is a small country with Riga geographically centrally located, which makes it possible for patients to reach us for every exercise test. This follow-up routine has the advantage that the interventional cardiologists will receive feedback from their patients, and that the interventional cardiologists are more available for the patients. We believe that a close relationship with the patient is of importance for confidence building, knowledge and compliance, which is crucial for good long term results. Moreover, we have established a program for patient monitoring - a telephone survey at one, six and twelve months after PCI.

Latvia is a geographically small country with low population density, but with huge countryside areas, sometimes difficult to reach, which increases possible risks of those coronary patients who live there. Therefore another aspect for outpatient intervention is patient overnight location. We strongly recommend staying in or close to Riga during the night after intervention, especially in case of outpatient PCI.

Although, till nowadays safety and efficacy of ad hoc PCI remain a matter of discussion, these procedures are still performed increasingly worldwide and in our outpatient clinic. Krone et al. analyzed 68,528 patients with stable angina from 2001-2003 and reported that PCI success was dependent on patient/lesion related factors and not on the performance of ad hoc PCIs per se [15,16]. Main concern rises about inappropriate rush and underevaluation of indication for PCI when it is performed at the same laboratory visit as diagnos-

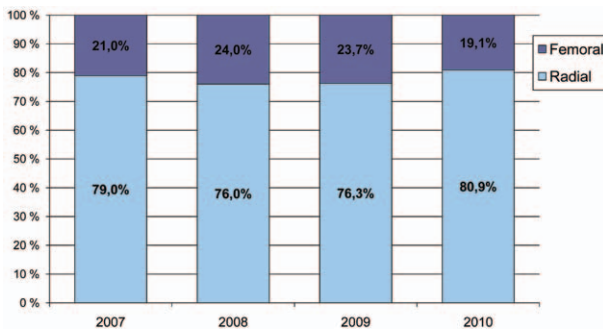


Figure 2. Arterial approach used for coronary angiographies in outpatient clinic at Latvian Centre of cardiology by year.

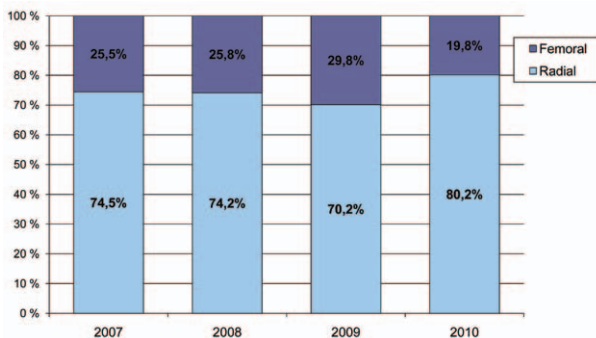


Figure 3. Arterial approach used for percutaneous coronary interventions in outpatient clinic at Latvian Centre of cardiology by year.

tic coronary angiography. However, there are several advantages of ad hoc PCI which include cost effective use of materials and resources during a single catheterization laboratory visit instead of adding a second scheduled hospital stay after diagnostic angiography. There are also important benefits for the patient who will gain a shorter length of overall hospital stay and greater satisfaction, as performing both procedures together is simpler and creates less anxiety. Objectively, the patient suffers less radiation exposure, a lower risk of contrast nephropathy (especially in patients with baseline renal insufficiency) [15-17], and there are potentially easier arterial access site management and less complications expected, since the same access is used for both procedures. Feldman et al. [18] demonstrated that there were no differences between ad hoc and staged PCI patients with respect to in-hospital mortality, major adverse cardiac events, or renal failure, but that staged patients trended toward a higher rate of site access site injury (adjusted OR: 1.34, 95% CI: 0.99 to 1.81).

However, potential disadvantages include an abbreviated informed consent process (particularly for interventions for which there is an alternative intervention) and the need for immediate decision making regarding the appropriateness of the procedure. The Society for Cardiac Angiography and Intervention Statement on Ad Hoc versus the Separate Performance of Diagnostic Cardiac Catheterization and Coronary Intervention states that it is reasonable for many, but not appropriate for all patients, and should not be considered standard therapy [15-18].

The most unlikely coronary complication following PCI is abrupt vessel closure. The systematic use of stents and potent antiplatelet agents have revolutionized the acute success rates of PCI by eliminating the risks of acute vessel closure within the first 24 h following a successful procedure. *Knopf et al* [19] reported a series of 90 patients randomly assigned to same-day discharge or overnight hospitalization. No complications occurred after discharge, and a satisfaction survey conducted with patients and relatives showed a high degree of comfort and preference for the same-day

discharge strategy. *Olivier et al* randomized 1005 patients after a bolus of abciximab and uncomplicated transradial percutaneous coronary stent implantation either to same-day home discharge and no infusion of abciximab (group 1, n=504) or to overnight hospitalization and a standard 12-hour infusion of abciximab (group 2, n=501) and concluded that same-day home discharge after uncomplicated transradial coronary stenting and bolus only of abciximab is not clinically inferior, in a wide spectrum of patients, to the standard overnight hospitalization and a bolus followed by a 12-hour infusion [20]. At Outpatient clinic at Latvian Centre of Cardiology patients are under observation 7 to 8 hours after PCI. If during this time period any complications develop or patient has discomfort in the chest, we consider transfer to the inpatients clinic. Only uncomplicated PCIs are discharged on the same day. Unfortunately data about 24 hour outcomes are not available, however, all patients discharged on the same day, are informed about the risks of coronary and puncture site complications. Moreover, strong recommendations are given to stay in Riga overnight and return to hospital immediately if discomfort in chest area or bleeding complications appear.

Ad hoc PCI is safe and feasible when performed in carefully selected cases even on outpatient basis. However, at least 6 to 8 hour observation period is suggested and accurate identification of those patients who can safely be discharged early is essential. Nevertheless, larger randomized studies would be helpful to define ischemic risks after PCI as well as the optimal length of an observation period.

References:

1. Block PC, Ockene I, Goldberg RJ, Butterly J, Block EH, Degon C, et al. A prospective randomized trial of outpatient versus inpatient cardiac catheterization. *N Engl J med* 1988;319:1251-5.
2. Roubin GS, Cannon AD, Agrawal SK, Macander PJ, Dean LS, Baxley WA, et al. Intracoronary stenting for acute and threatened closure complicating percutaneous transluminal coronary angioplasty. *Circulation* 1992;85:916-27.
3. Kiemeneij F, Laarman GJ, de Melker E. Transradial artery coronary angioplasty. *Am Heart J* 1995;129:1-7.

4. Wilentz JR, Mishkel G, McDermott D, Ravi K, Fox JT, Reimers CD. Outpatient coronary stenting using the femoral approach with vascular sealing. *J Invasive Cardiol* 1999; 11:709-17.
5. Carere RG, Webb JG, Buller CE, Wilson M, Rahman T, Spinelli J, et al. Suture closure of femoral arterial puncture sites after coronary angioplasty followed by same-day discharge. *Am Heart J* 2000;139:52-8.
6. Dalby M, Davies J, Rakhit R, Mayet J, Foale R, Davies DW. Feasibility and safety of day-case transfemoral coronary stenting. *Catheter Cardiovasc Interv* 2003;60:18-24.
7. Herrmann J, Lerman A, Baumgart D, et al. Preprocedural statin medication reduces the extent of periprocedural non-Q-wave myocardial infarction. *Circulation*.2002;106:2180-2183.
8. Chan AW, Bhatt DL, Chew DP, et al. Early and sustained survival benefit associated with statin therapy at the time of percutaneous coronary intervention. *Circulation*.2002;105:691-696.
9. Brener SJ, Ellis SG, Schneider J, et al. Frequency and long-term impact of myonecrosis after coronary stenting. *Eur Heart J*. 2002;23:869 - 876.
10. Nallamothu BK, Bates ER. Periprocedural myocardial infarction and mortality: causality versus association. *J Am Coll Cardiol*. 2003;42:1412-1414.
11. Vincenzo Pasceri, Giuseppe Patti, Annunziata Nusca, Christian Pristipino, Giuseppe Richichi, Germano Di Sciascio and on behalf of the ARMYDA Investigators. Randomized Trial of Atorvastatin for Reduction of Myocardial Damage During Coronary Intervention: Results From the ARMYDA (Atorvastatin for Reduction of MYocardial Damage during Angioplasty) Study. *Circulation* 2004;110:674-678.
12. Steinhubl SR, Berger PB, Mann JT, Fry ETA, DeLago A, Wilmer C, Topol EJ, for the CREDO Investigators. Early and sustained dual oral antiplatelet therapy following percutaneous coronary intervention: a randomized controlled trial. *JAMA* (2002) 288:2411-2420.
13. Kandzari DE, Berger PB, Kastrati A, Steinhubl SR, Mehilli J, Dotzer F, ten Berg JM, Neumann FJ, Bollwein H, Dirschinger J, Schomig A. Influence of treatment duration with a 600-mg dose of clopidogrel before percutaneous coronary revascularization. *J Am Coll Cardiol* (2004) 44:2133-2136.
14. Patti G, Colonna G, Pasceri V, Pepe LL, Montinaro A, Di Sciascio G. Randomized trial of high loading dose of clopidogrel for reduction of periprocedural myocardial infarction in patients undergoing coronary intervention: results from the ARMYDA-2 (Antiplatelet therapy for Reduction of MYocardial Damage during Angioplasty) study. *Circulation* (2005) 111:2099-2106.
15. Krone, RJ, Shaw RE, Klein LW, Blankenship JC, Weintraub WS; American College of Cardiology - National Cardiovascular Data Registry. Ad hoc percutaneous coronary interventions in patients with stable coronary artery disease--a study of prevalence, safety, and variation in use from the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR). *Catheter Cardiovasc Interv*. 2006 Nov;68(5):696-703.
16. Good, CW, JC Blankenship, TD Scott, KA Skelding, PB Berger, and GC Wood. "Feasibility and Safety of Ad Hoc Percutaneous Coronary Intervention in the Modern Era." *The Journal of Invasive Cardiology*. 21.5 (2009): 194-200.
17. Hannan, E.L, Z Samadashvili, G Walford, D.R Holmes, A Jacobs, S Sharma, S Katz, and III S. B. King. "Predictors and Outcomes of Ad Hoc Versus Non-Ad Hoc Percutaneous Coronary Interventions." *Jacc: Cardiovascular Interventions*. 2.4 (2009): 350-356.
18. Feldman DN, Minutello RM, Gade CL, Wong SC. Outcomes following immediate (ad hoc) versus staged percutaneous coronary interventions (report from 2000 to 2001 New York State Angioplasty registry). *Am J Cardiol* 2007;99:446-9.
19. Knopf WD, Cohen-Bernstein C, Ryan J, Heselov K, Yarbrough N, Steahr G. Outpatient PTCA with same day discharge is safe and produces high patient satisfaction level. *J Invasive Cardiol* 1999;11:290-5.
20. Bertrand, OF, De Larochelière, R, JRodés-Cabau, J, Proulx, G, Gleeton, O, Nguyen, CM, Déry, JP, Barbeau, G, Noël, B, Larose, E, Poirier, P, Roy, L, for the Early Discharge After Transradial Stenting of Coronary Arteries (EASY) Study Investigators. A Randomized Study Comparing Same-Day Home Discharge and Abciximab Bolus Only to Overnight Hospitalization and Abciximab Bolus and Infusion After Transradial Coronary Stent Implantation. *Circulation*. 2006;114:2636-2643.