Ambulantní intervenční výkony

- proč určitě ano

Ivo Bernat

Kardiologické oddělení KKC FN Plzeň

Proč určitě ano ? ⇒ pro tyto výhody :

- Úspora nemocničních lůžkových kapacit
- Zkrácená doba pobytu pacienta v nemocnici
- Redukované požadavky na nemocniční personál
- Snížení počtu komplikací souvisejících s pobytem v nemocnici
- Možnost simulovat civilní prostředí na tzv. Kardiostacionáři s výrazně vyšším komfortem pro pacienta nevyžadujícím mj. klid na lůžku
- Zjednodušení logistiky péče o tyto nemocné

Inspirací pro všechny - Lounge v OLVG Amsterdam

1. Outpatient PCI

There is no *medical* need to keep the patient overnight with an optimal result following elective TRI in well selected patients, meaning:

- **NO BLEEDING COMPLICATIONS**
- **NO CARDIAC COMPLICATIONS**

BETWEEN 6 - 24 HOURS after PCI :

- *Laarman* et al. A pilot study of coronary angioplasty in outpatients. Br Heart J. 1994;72:12-5.
- *Kiemeneij* et al. Transradial Palmaz-Schatz coronary stenting on an outpatient basis: results of a prospective pilot study.J Invasive Cardiol. 1995;7:5A-11A.
- *Kiemeneij* et al. Outpatient coronary stent implantation. JACC 1997;29:323-7
- *Slagboom* et al. Actual outpatient PTCA: results of the OUTCLAS pilot study. CCI 2001;53:204-8.
- Ziakas et al. Safety of same day discharge radial PCI. Am Heart J 2003;146:699-704.
- *Slagboom* et al. Outpatient coronary angioplasty: feasible and safe. CCI 2005;64:421-7.

Laarman 2008

2.Outpatient PCI : Rationale

- All the advantages of TRI
- Patient comfort
- Beds available for sicker patients
- Safe
- Logistics
- Increases turn-over
- Reduces waiting lists
- Cost-effective

Laarman 2008

3. Outpatient PCI : Criteria

- Good result elective PCI
- No complications during PCI
- Clinically stable
- Uneventful course during 4-6 hours observation
    - Cardiac
    - Vascular
- No other medical reasons to keep the patient hospitalized (e.g. renal failure)
- Suitable psyco-social circumstances

Laarman 2008

4. Outpatient PCI

Requirements for outpatient PCI

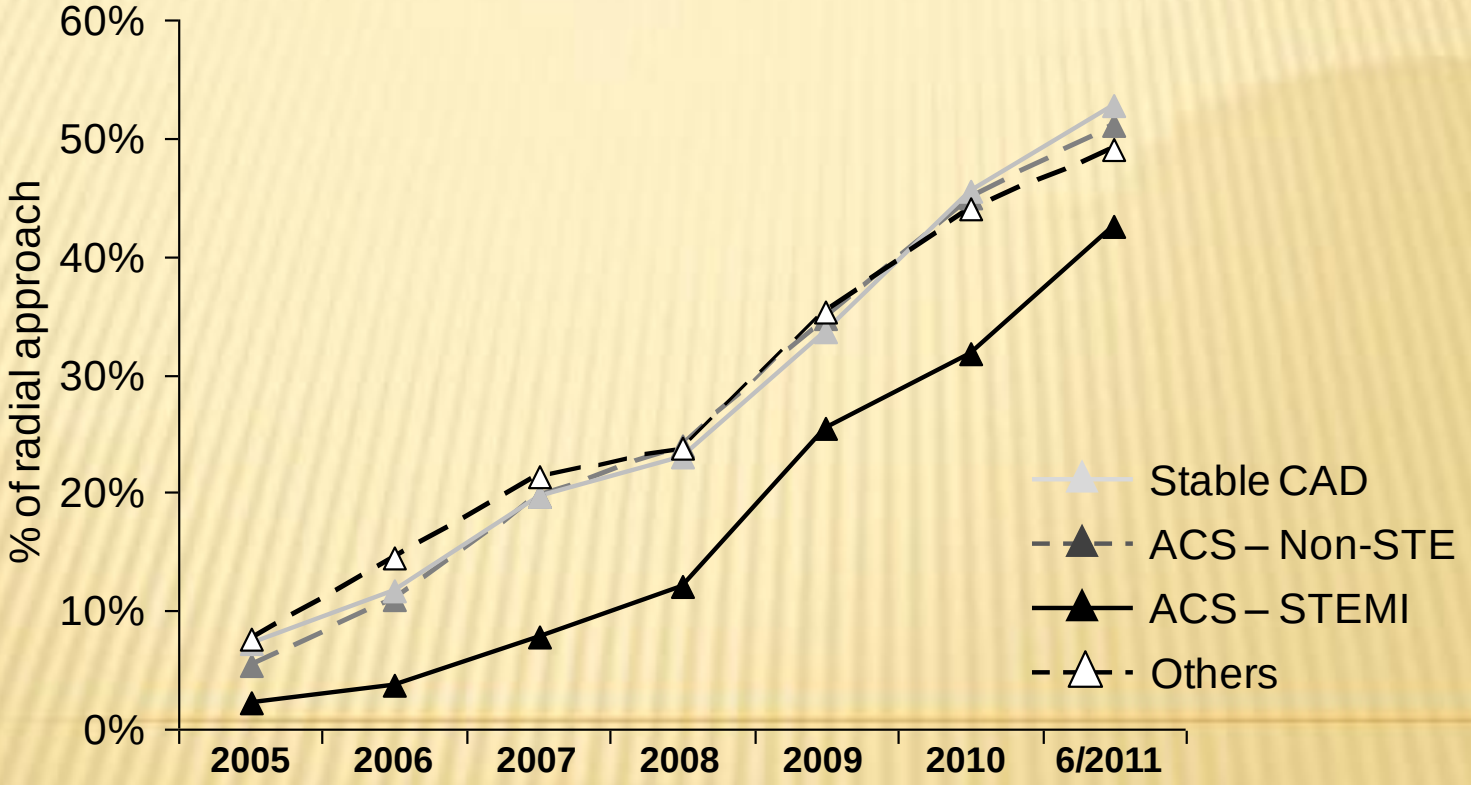
- Transradial approach
- Dedicated infrastructure (lounge)
- Dedicated and trained nursing and medical staff
- Optimal information before and after PCI

Laarman 2008

Trend in the use of radial approach in CZ (PCI)

from the Czech National PCI Registry

2016 70%



Total : 5%……10%….17%…..21%…..32%…..42%….50%… **2016 70%**

SDD - Jednodenní katetrizace a intervence

V EU a USA je SDD dlouhodobě akceptován a podpořen množstvím dat, které jsou koncentrovány v :

1. konsensu tří pracovních skupin Evropské kardiologické společnosti z 2013 *Eurointervention*

   mj.přehled pre, post a procedurálních situací, které jsou rizikové a limitující pro SDD

2. kapitole (č.38) z 2016 *Topol-Textbook of Interventional Cardiology*

   hospitalizace, délka pobytu a plán propuštění po PCI s přehledem faktorů, kdy lze PCI v režimu SDD bezpečně provádět

3. dvou meta-analýzách z 2013 *JACC a JACC Cardiovasc Interv*

   re: při správném výběru pacienta nedochází v období 6-24 hodin po výkonu ke komplikacím a propuštění je proto bezpečné

EuroIntervention 2013; 8-online publish-ahead-of-print January 2013

editorial expedited publication

SPECIAL REPORT

Consensus document on the radial approach in percutaneous cardiovascular interventions: position paper by the European Association of Percutaneous Cardiovascular Interventions and Working Groups on Acute Cardiac Care** and Thrombosis of the European Society of Cardiology

Martial Hamon[1*#], MD; Christian Pristipino[2#], MD; Carlo Di Mario[3], MD, PhD; James Nolan[4], MD; Josef Ludwig[5], MD, PhD; Marco Tubaro[6], MD; Manel Sabate[7], MD, PhD; Josepa Mauri-Ferré[8], MD; Kurt Huber[9], MD; Kari Niemelä[10], MD; Michael Haude[11], MD; William Wijns[12], MD, PhD; Dariusz Dudek[13], MD; Jean Fajadet[14], MD; Ferdinand Kiemeneij[15#], MD, PhD

International experts: Gerald Barbeau[16], MD; Shigeru Saïto[17], MD; Sanjit Jolly[18], MD; Yves Louvard[19], MD; Tejas Patel[20], MD; Sunil V Rao[21], MD; Nicolaus Reifart[22], MD; Philippe Gabriel Steg[23], MD; Orazio Valsecchi[24], MD; Yuenjin Yang[25], MD

EuroIntervention 2013; 8-online publish-ahead-of-print January 2013

DAY-CASE ANGIOGRAPHY AND ANGIOPLASTY

The immediate ambulation of the patient, safety of the entry site and, for PCI patients, reliable immediate outcome of an optimal coronary stent procedure, theoretically allow patients to be discharged from the hospital after a few hours of uneventful observation. Day-case angiography is already routine practice after femoral access, especially when closure devices are used. Of course, early discharge should not prevent the attending physician from discussing the results with the patient. A radial approach facilitates the process and avoids prolonged hospital stays. Because of the potential risk of bleeding after anticoagulation, day-case angioplasty is less frequently practised with the femoral approach, and is often limited to unstable patients transferred back to admitting hospitals. The first outpatient transradial coronary stent implantation was reported in 1994[72]. Day-case angiography/PCI has several advantages[73]: patient preference, ease of ward management, shortened waiting lists, and enhanced cost-effectiveness. Overnight stay sometimes is prudent or required in selected groups meeting the following characteristics:

- Preprocedural: unstable angina pectoris, acute myocardial infarction, shock, heart failure, renal failure, severe comorbidities, poor social circumstances limiting family support after discharge.
- Procedural: transient vessel closure, arrhythmias or resuscitation during procedure, prolonged chest pain, persistent ECG changes, suboptimal PCI result, major or symptomatic side branch occlusion, entry site complication(s).
- Post-procedural: any cardiac or vascular complication within the 4-6 hour observation period.

Kdy NE :

EuroIntervention 2013; 8-online publish-ahead-of-print January 2013

If these criteria are applied consistently, outpatient PCI is safe[74-76]. However, these data stem from single-centre studies performed by expert operators at high-volume institutions. Therefore, at present, no definitive recommendations can be made based on published evidence; larger studies in the real world remain necessary to confirm the safety and efficacy of this technique.

Kdy ANO :

Stable patients undergoing transradial diagnostic studies without complications in the first 2-3 hours post procedure can be considered for early discharge. Stable patients with an optimal PCI result, optimal pharmacological treatment according to ESC guidelines and no cardiac or vascular complications during the procedure or up to 4-6 hours afterwards can be considered for outpatient treatment if performed at high-volume centres by experienced interventionalists. Close follow-up and immediate readmission should be possible for delayed complications.

Same-day PCI: Most Adverse Events Occur Within 6 Hours

N=450 TR-PCI 2004-2007

In-hospital Adverse Clinical Outcomes

Complications, n (%)	0-6 h	6-24 h	>24 h
Access site bleeding (minor)	11 (2.4%)	None	None
Access site bleeding (major)	None	None	None
Postprocedure infarction	8 (1.8%)	None	None
Repeat revascularization	4 (0.9%)	None	None
Ventricular tachycardia	1 (0.2%)	None	None
CABG	None	None	1 (0.2%)
Death	None	None	1 (0.2%)
Atrial fibrillation	None	None	1 (0.2%)
Stroke	None	None	1 (0.2%)

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STATE-OF-THE-ART PAPER

Same-Day Discharge Compared With Overnight Hospitalization After Uncomplicated Percutaneous Coronary Intervention

A Systematic Review and Meta-Analysis

Eltigani Abdelaal, MD,* Sunil V. Rao, MD,† Ian C. Gilchrist, MD,‡ Ivo Bernat, MD,§ Adhir Shroff, MD, MPH,‖ Ronald Caputo, MD,¶ Olivier Costerousse, PHD,* Samir B. Pancholy, MD,# Olivier F. Bertrand, MD, PHD*

Quebec City, Quebec, Canada; Durham, North Carolina; Hershey and Scranton, Pennsylvania; Pilsen, Czech Republic; Chicago, Illinois; and Syracuse, New York

Objectives This study sought to evaluate outcomes of same-day discharge (SDD) following percutaneous coronary intervention (PCI) versus overnight hospitalization (ON).

Background Although there are data on the safety and feasibility of SDD after PCI, ON continues to be prevalent.

Methods The Cochrane search strategy was used to search the PubMed database, EMBASE, and the Cochrane Library for relevant literature. Thirteen studies (5 randomized and 8 observational) of SDD after uncomplicated PCI versus ON met inclusion criteria. Data were pooled using a random effects model, and reported as odds ratios (OR) with their 95% confidence intervals (CI). The primary outcomes were incidence of total complications, major adverse cardiovascular events (MACE), and rehospitalization within 30 days after PCI.

Results A total of 13 studies, involving 111,830 patients were pooled. There was significant variation in the definition of outcomes across studies. For total complications, the strategy of SDD compared with ON after PCI had an estimated OR of 1.20 (95% CI: 0.82 to 1.74) in randomized and 0.67 (95% CI: 0.27 to 1.66) in observational studies. Similar results were found for MACE (randomized, OR: 0.99, 95% CI: 0.45 to 2.18; observational, OR: 0.59, 95% CI: 0.06 to 5.57) and rehospitalizations (randomized, OR: 1.10, 95% CI: 0.70 to 1.74; observational, OR: 0.62, 95% CI: 0.10 to 3.98) at 30 days post PCI.

Conclusions There is considerable heterogeneity across published studies comparing SDD with ON. This, coupled with the low event rate and wide corresponding CIs, suggest that an adequately powered multicenter randomized trial comparing SDD with ON would require a very large sample size (>17,000). Until such a trial is completed, SDD after uncomplicated PCI seems a reasonable approach in selected patients. (J Am Coll Cardiol Intv 2013;6:99–112) © 2013 by the American College of Cardiology Foundation

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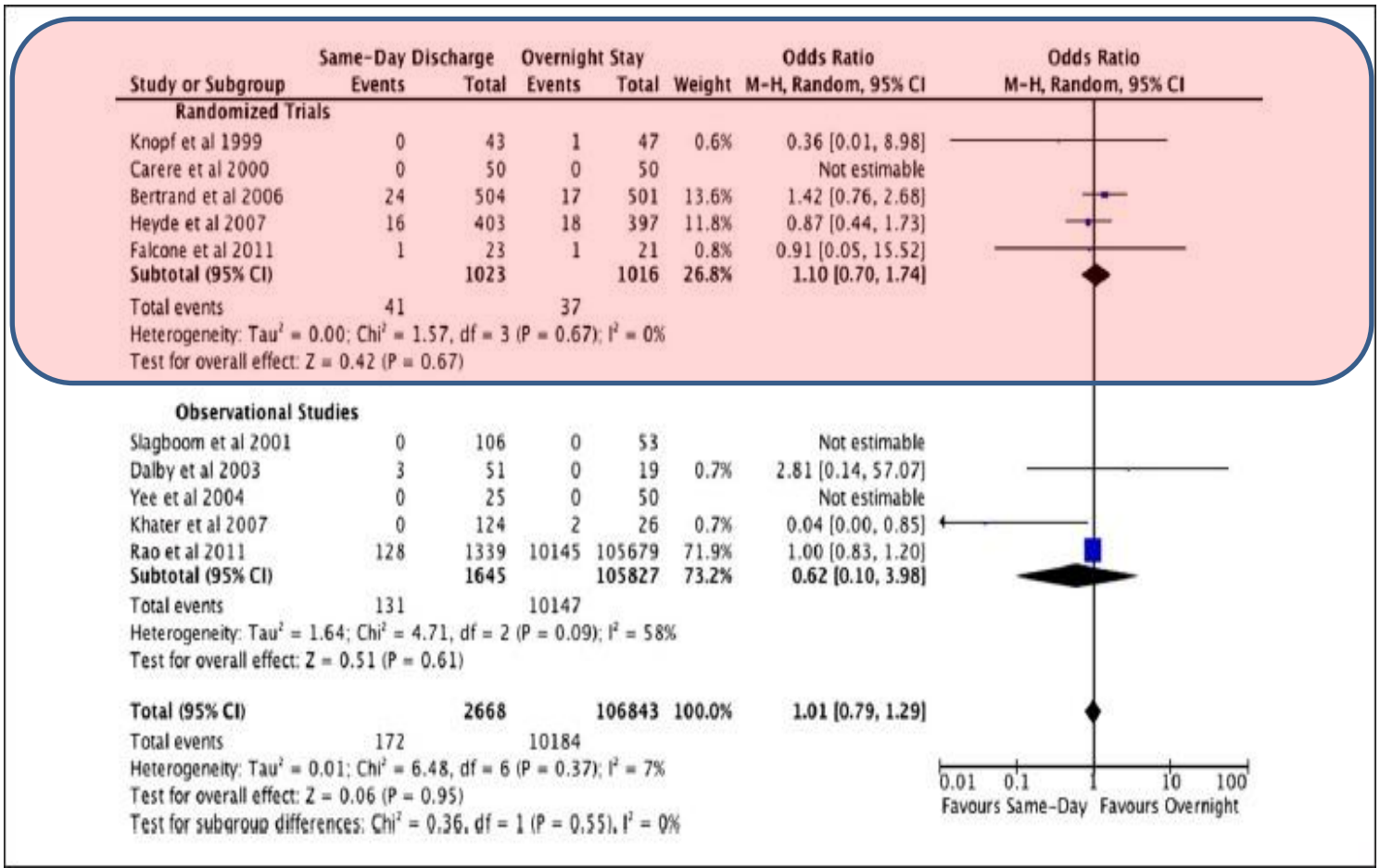

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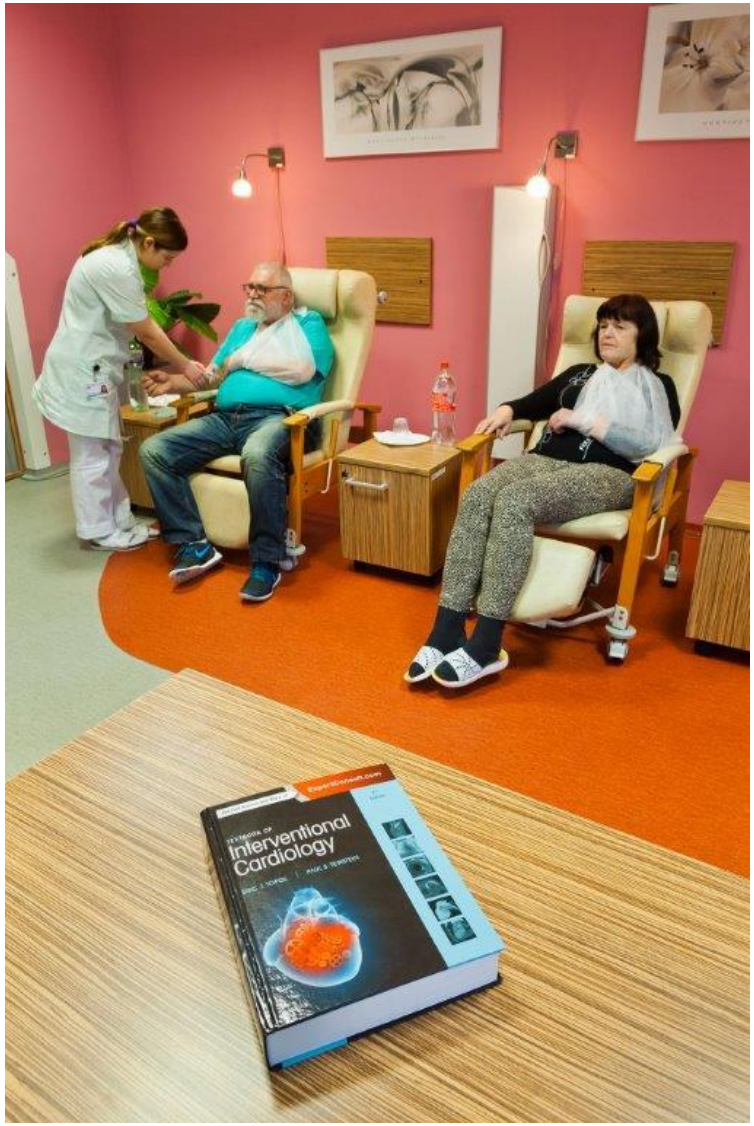
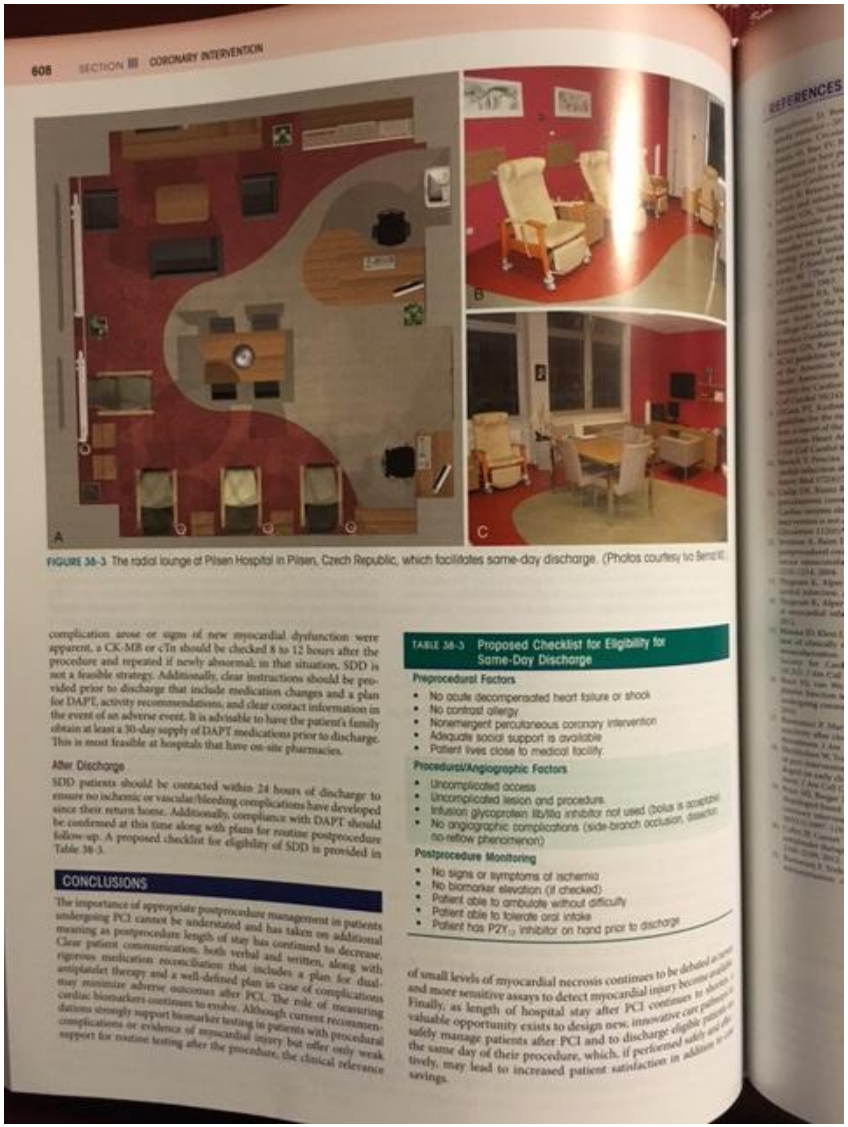
Table 1. Definition of Complications and MACE per Study Included in Meta-Analysis

First Author, Year (Ref. #)	Study Design*	Number of Centers	Population Total N	Definition of Complications
Knopf et al., 1999 (5)	1	1	90	Death, MI, urgent revascularization, acute vessel dissection/occlusion, cardiac arrhythmia, AV fistula with repair, recurrent chest pain
Carere et al., 2000 (6)	1	1	100	Need for vascular surgery, external bleeding, hematoma, blood transfusion
Koch et al., 2000 (7)	0	1	1,015	Death, MI, urgent revascularization during hospitalization, pericardial effusion, or any complication requiring prolonged hospitalization
Slagboom et al., 2001 (8)	0	1	159	Cardiac death, MI, urgent revascularization, MI, UA, major access site complication, major bleeding
Dalby et al., 2003 (9)	0	1	70	Death, MI, TVR
Yee et al., 2004 (10)	0	1	75	MACE, vascular access site complications
Slagboom et al., 2005 (11)	0	1	644	Cardiac death, urgent revascularization, MI, rehospitalization, major access site complications and bleeding
Bertrand et al., 2006 (12)	1	1	1,005	Death, MI, urgent revascularization, major bleeding, repeat hospitalization, severe thrombocytopenia, and access site complications
Heyde et al., 2007 (13)	1	1	800	Cardiac death, MI, stroke, urgent revascularization, access site complications
Khater et al., 2007 (14)	0	1	150	Death, MI, urgent revascularization, access site complications
Chung et al., 2010 (15)	0	1	660	Death, MI, urgent revascularization, stroke, bleeding, transfusion, rehospitalization, access site complication
Rao et al., 2011 (16)	0	903	107,018	Death, rehospitalization, bleeding, access site complications
Falcone et al., 2011 (17)	1	1	44	Death, MI, stroke, rehospitalization, access site complications

Significant heterogeneity of the definition of outcomes and complications was noted between studies *0 = observational study; 1 = randomized.
AV = arteriovenous; MACE = major adverse cardiovascular events; MI = myocardial infarction; TVR = target vessel revascularization; UA = unstable angina.

Topol 2015 - 7thTextbook of Interventional Cardiology





608 SECTION III CORONARY INTERVENTION

FIGURE 38-3 The radial lounge at Pilsen Hospital in Pilsen, Czech Republic, which facilitates same-day discharge. (Photos courtesy Ivo Šeruga.)

complication arose or signs of new myocardial dysfunction were apparent, a CK-MB or cTn should be checked 8 to 12 hours after the procedure and repeated if newly abnormal; in that situation, SDD is not a feasible strategy. Additionally, clear instructions should be provided prior to discharge that include medication changes and a plan for DAPT, activity recommendations, and clear contact information in the event of an adverse event. It is advisable to have the patient's family obtain at least a 30-day supply of DAPT medications prior to discharge. This is most feasible at hospitals that have on-site pharmacies.

After Discharge

SDD patients should be contacted within 24 hours of discharge to ensure no ischemic or vascular/bleeding complications have developed since their return home. Additionally, compliance with DAPT should be confirmed at this time along with plans for routine postprocedure follow-up. A proposed checklist for eligibility of SDD is provided in Table 38-3.

TABLE 38-3 Proposed Checklist for Eligibility for Same-Day Discharge

Preprocedural Factors
- No acute decompensated heart failure or shock
- No contrast allergy
- Nonemergent percutaneous coronary intervention
- Adequate social support is available
- Patient lives close to medical facility

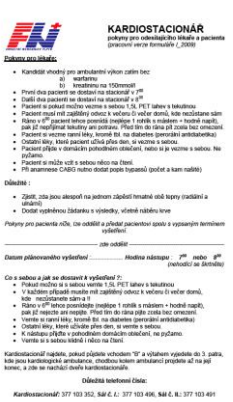
Procedural/Angiographic Factors
- Uncomplicated access
- Uncomplicated lesion and procedure
- Infusion glycoprotein IIb/IIIa inhibitor not used (bolus is acceptable)
- No angiographic complications (side-branch occlusion, dissection, no-reflow phenomenon)

Postprocedure Monitoring
- No signs or symptoms of ischemia
- No biomarker elevation (if checked)
- Patient able to ambulate without difficulty
- Patient able to tolerate oral intake
- Patient has $P2Y_{12}$ inhibitor on hand prior to discharge

CONCLUSIONS

The importance of appropriate postprocedure management in patients undergoing PCI cannot be understated and has taken on additional meaning as postprocedure length of stay has continued to decrease. Clear patient communication, both verbal and written, along with rigorous medication reconciliation that includes a plan for dual-antiplatelet therapy and a well-defined plan in case of complications may minimize adverse outcomes after PCI. The role of measuring cardiac biomarkers continues to evolve. Although current recommendations strongly support biomarker testing in patients with procedural complications or evidence of myocardial injury but offer only weak support for routine testing after the procedure, the clinical relevance of small levels of myocardial necrosis continues to be debated as more and more sensitive assays to detect myocardial injury become available. Finally, as length of hospital stay after PCI continues to shorten, a valuable opportunity exists to design new, innovative care pathways to safely manage patients after PCI and to discharge eligible patients on the same day of their procedure, which, if performed safely and effectively, may lead to increased patient satisfaction in addition to cost savings.

REFERENCES



KARDIOSTACIONÁR
pokyny pro odesílajícího lékaře a pacienta
(pracovní verze formuláře z_0909)

Pokyny pro lékaře:

- Kandidát vhodný pro ambulantní výkon zatím bez
  a) warfarinu
  b) kreatininu na 150mmol/l
- První dva pacienti se dostaví na stacionář v 7[00]
- Další dva pacienti se dostaví na stacionář v 8[00]
- Pacient si pokud možno vezme s sebou 1,5L PET láhev s tekutinou
- Pacient myslí mít zajištěný odvoz k večeru či večer domů, kde nezůstane sám
- Ráno v 6[00] pacient lehce posnídá (nejlépe 1 rohlík s máslem + hodně napití), pak již nepřijímat tekutiny ani potravu. Před tím do rána již zcela bez omezení.
- Pacient si vezme ranní léky, kromě Bl. na diabetes (perorální antidiabetika)
- Ostatní léky, které pacient užívá přes den, si vezme s sebou.
- Pacient přijde v domácím pohodlném oblečení, nebo si je vezme s sebou. Ne pyžamo.
- Pacient si může vzít s sebou něco na čtení.
- Při anamnéze CABG nutno dostat popis bypassů (počet a kam našité)

Důležité !

- Zjistit, zda jsou alespoň na jednom zápěstí hmatné obě tepny (radiální a ulnární)
- Dodat vyplněnou žádanku s výsledky, včetně nátěru krve

Pokyny pro pacienta níže, lze oddělit a předat pacientovi spolu s vypsaným termínem vyšetření.

..... zde oddělit .....

Datum plánovaného vyšetření** ..... **Hodina nástupu : 7[00] nebo 8[00]
(nehodící se škrtněte)

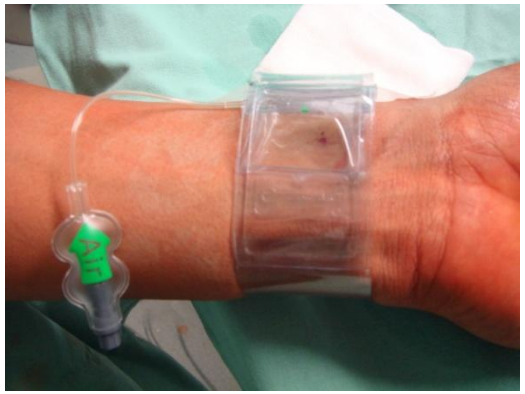
Co s sebou a jak se dostavit k vyšetření ?:

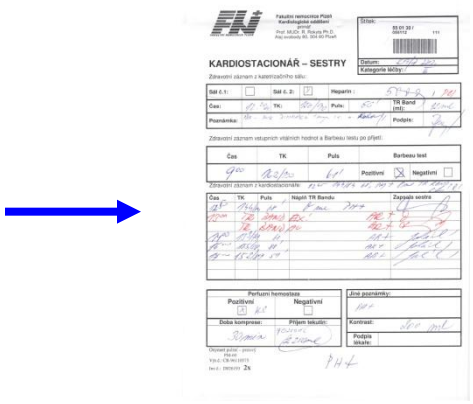
- Pokud možno si s sebou vemte 1,5L PET láhev s tekutinou
- V každém případě musíte mít zajištěný odvoz k večeru či večer domů, kde nezůstanete sám a ti
- Ráno v 6[00] lehce posnídejte (nejlépe 1 rohlík s máslem + hodně napití), pak již nejezte ani nepijte. Před tím do rána jíjte zcela bez omezení.
- Vemte si ranní léky, kromě Bl. na diabetes (perorální antidiabetika)
- Ostatní léky, které užíváte přes den, si vemte s sebou.
- K nástupu přijďte v pohodlném domácím oblečení, ne pyžamo.
- Vemte si s sebou klidně i něco na čtení.

Kardiostacionář najdete, pokud půjdete vchodem "S" a výtahem výjedete do 3. patra, kde jsou kardiologická ambulance, chodbou kolem ambulancí projdete až na její konec, a zde se nacházejí dveře kardiostacionáře.

Důležitá telefonní čísla:

Kardiostacionář: 377 103 352, ***Sál č. I.:*** 377 103 496, ***Sál č. II.:*** 377 103 491





KARDIOSTACIONÁŘ – SESTRY

„Lounge“ FN Plzeň - počty pacientů

• 6-12/2009	301	72 **PCI**	výměna TKS -	0
• 2010	706	179		36
• 2011	708	155		76
• 2012	748	161		89
• 2013	821	177		105
• 2014	853	162		108
• 2015	825	184		94
• 2016	817	179		99

2009-2016: 5809 **1263 PCI** **5202 SKG** 607 výměn

Situace v ČR

- Selektivní koronarografie >50 000 ročně
- PCI >20 000 ročně
- Radiální přístup nyní >70%
-
- Polovina výkonů je plánovaných
- Podstatnou část z nich lze provádět v režimu SDD
- Situace v ČR v současnosti - viz data zaslaná D.Horákovi z PCI center za 2016

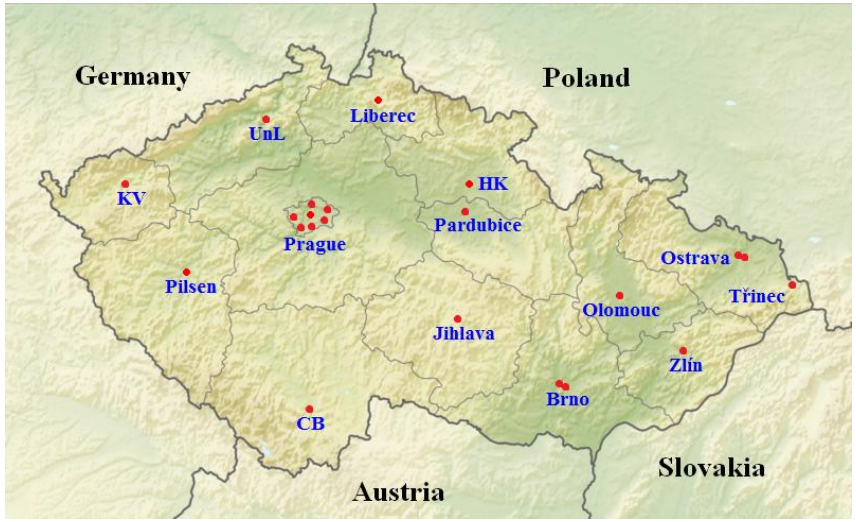
Situace v ČR

- Jednodenní katetrizace a intervence je v řadě PCI center v ČR již zavedeným systémem péče pro významnou část pacientů podstupujících tyto výkony

- Při dodržení bezpečnostních kriterií, používání jednotné terminologie a způsobu vykazování ji lze doporučit pro všechna PCI centra v ČR jako bezpečnou a pro pacienty výhodnou.

Závěr:

Všechna PCI centra v České republice mají dlouhodobě zavedený režim 24/7 pro akutní výkony.



Pro podstatnou část plánovaných výkonů pak na druhé straně není v současnosti již žádný racionální medicinský důvod, proč by neměly být prováděny v režimu jednodenních katetrizací a intervencí, tj. v režimu „Same day discharge“.