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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

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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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Since its first inception over 3 decades ago, percutaneous coronary intervention (PCI) has become the most commonly performed cardiac intervention worldwide, with over 50% performed in the United States. The rising number of PCI procedures worldwide, combined with the escalating cost of health care, has led to significant logistic and financial constraints on healthcare facilities. Given the increased emphasis on measures to decrease medical care expenditure while upholding clinical efficacy and patient safety, same-day discharge after PCI in selected patients may lead to reduced healthcare costs and increased patient satisfaction. Over the past decade, continuous refinements of PCI procedures with the advent of coronary stents, miniaturization of PCI equipment, and the evolution of adjuvant pharmacology have substantially increased the success, improved short- and long-term safety of this technique, and reduced post-procedural length of stay (1–4).

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Abbreviations and Acronyms

ACS = acute coronary syndrome
CI = confidence interval
GPI = glycoprotein IIb/IIIa inhibitor
MACE = major adverse cardiovascular events
MI = myocardial infarction
ON = overnight hospitalization
OR = odds ratios
PCI = percutaneous coronary intervention
SDD = same-day discharge

A number of observational and a few randomized studies have described the safety of same-day discharge (SDD) in selected groups of patients (5–17), adding to several single-center reports extending back to the mid -90s, which suggested the feasibility and safety of this strategy (18–27). Individual reports have also highlighted potential financial savings with this approach, primarily by avoiding the cost of an overnight stay (28–30). Despite this, the practice of SDD after elective, uncomplicated PCI remains considerably variable worldwide, ranging from near routine in some parts of Europe, Asia, and Canada, to being rarely adopted in the United States. Reasons for this are multifactorial, including concerns about patient safety and short-term clinical outcomes, in addition to a perceived lack of fiscal incentive due to the current reimbursement structure of the United States healthcare system.

Many of the studies comparing SDD with overnight stay (ON) have shown no difference in the outcomes that were measured. This is either because both strategies are clinically equivalent, or because of Type II error. Pooling of data from all the studies may provide a large enough sample size to better evaluate whether SDD and ON are comparable with respect to patient outcomes. Accordingly, we undertook a systematic review and comprehensive meta-analysis of all available data comparing SDD after PCI with ON, to evaluate the impact of this strategy on clinical outcomes.

Methods

Eligibility, search strategy, and data collection. We performed this review and meta-analysis with standard protocols recommended by the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) (31) and the Quality of Reporting of Meta-analyses (QUOROM) groups (32) for randomized trials, and the Cochrane Collaboration and Meta-analyses of Observational Studies in Epidemiology (MOOSE) group (33) for observational studies. The medical literature databases were scrutinized for reports of studies with SDD after PCI. We performed a search of the PubMed database, EMBASE, and the Cochrane Library, using key words, such as "same-day," "same-day discharge," "outpatient," "day-case," "day-care," and "short stay" [AND] "PCI," "PTCA," "angioplasty," and "coronary angioplasty" (last update: 15 April 2011). There was no date or language restriction for our selection of publication. References of selected studies and all abstracts from international cardiology meeting programs (American College of Cardiology, American Heart Association, European Society of Cardiology, Transcatheter Cardiovascular Therapeutics, and Euro-PCR) were searched for relevant data.

For the purpose of this review and meta-analysis, inclusion criteria for studies were: 1) both randomized controlled trials and observational studies comparing SDD and ON following PCI; with 2) clinical and outcome data for up to 30 days following the index PCI procedure available for both SDD and ON groups separately; and 3) intent-to-treat or protocol-driven analysis. Exclusion criteria were: 1) studies reporting only in abstract format or conference presentation with no access to full data or manuscript; 2) studies reporting only outcome data on SDD patients, with no ON group as a comparator; 3) studies reporting on chronology of events but patients kept hospitalized overnight; and 4) studies with mixed outcome data between diagnostic and interventional procedures, or mixed outcome data for both the SDD and ON groups, with no possibility of separating individual outcomes. When study results were reported in abstract format and subsequently in a full paper, only results from the published manuscript were considered. Three evaluators (E.A., O.F.B., and O.C.) performed literature searches, and 2 (E.A. and O.F.B.) individually reviewed relevant articles, and extracted data independently. Discrepancies between datasets were resolved by consensus, if necessary after contact with authors.

Classification of studies and outcome definitions. We classified the studies on the basis of randomized or observational design. The primary outcomes for this study-level meta-analysis were the incidence of total complications, major adverse cardiovascular events (MACE), and rehospitalization within 30 days following PCI.

The definitions of complications were study specific (Table 1). Overall, it represents a summation of both cardiac and noncardiac complications, encompassing access site, bleeding and vascular complications, need for blood transfusion, and cerebrovascular events. MACE was defined as death, myocardial infarction (MI), or repeat revascularization. The definition of MI was as per the study author's definition, and most commonly defined using both typical symptoms, electrocardiogram, and enzymatic criteria (creatine kinase-MB, troponin, or both). Repeat revascularization was defined as the need for repeat PCI or coronary artery bypass grafting. Rehospitalization was defined as repeat hospital admission within 30 days of intervention for any reason related to the index procedure.

Bleeding complications. There was no standardized definition for bleeding across all studies included herein, and the total number of bleeding events was taken directly from papers, as defined by the authors. The largest randomized study (Bertrand et al. [12]) in this analysis offered a standardized definition according to REPLACE-2 (Randomized Evaluation in PCI Linking Angiomax to Reduced Clinical Events) criteria for major bleeding and used this as a component of the study's 7-event primary endpoint. Others defined this as major bleeding requiring blood transfusion, or hemoglobin drop of ≥2 g/dl.

Vascular complications. The definition covered a wide spectrum of access site complications commonly encountered in clinical practice, such as arteriovenous fistula, pseudoaneurysm, any complication requiring surgery, radial artery occlusion, local infection requiring antibiotics, moderate–severe hematoma, and major bleeding.

Data synthesis and statistical analysis. Information on study design, sample size, population demographic characteristics, coronary angiographic characteristics, access site for PCI, procedural adjuvant pharmacotherapy, procedural success rate, outcome, and follow-up data were extracted and entered into a data sheet using a standardized protocol. The absolute numbers of events for each outcome of interest in every study were extracted for the SDD and ON groups, and entered into a statistical software program (the Cochrane Collaboration's Review Manager [RevMan], version 5.1.20, Nordic Cochrane Centre, Copenhagen, Denmark), which was used to synthesize the results. Differences in study characteristics, inclusion and exclusion criteria, procedural variables, and practice patterns mean that the true effect from each study is likely to vary, and a fixed-effects meta-analysis model would not account for this between-study variation. We therefore used the DerSimonian and Laird random effects model, with weights calculated using the Mantel-Haenszel method to better account for the differences between studies. Dichotomous outcomes data were measured and reported as odds ratio (OR), with their 95% confidence intervals (CIs) for randomized and observational studies. We examined heterogeneity across studies with the Cochran's Q statistic (based on the pooled OR) and the I^2 statistic test. An I^2 value of <25% was considered

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.

low heterogeneity, 25% to 50% moderate, and a value >50% was considered substantial heterogeneity. Funnel plots were constructed and inspected visually for evidence of publication bias (data not shown). The weight of each trial on the overall results of meta-analysis outcome was calculated as a percentage of the number of patients in that given trial over the total number included in each outcome analysis.

A sensitivity analysis was performed according to study design (randomized and observational) and population size to determine the effect of the largest study on the outcome of the meta-analysis.

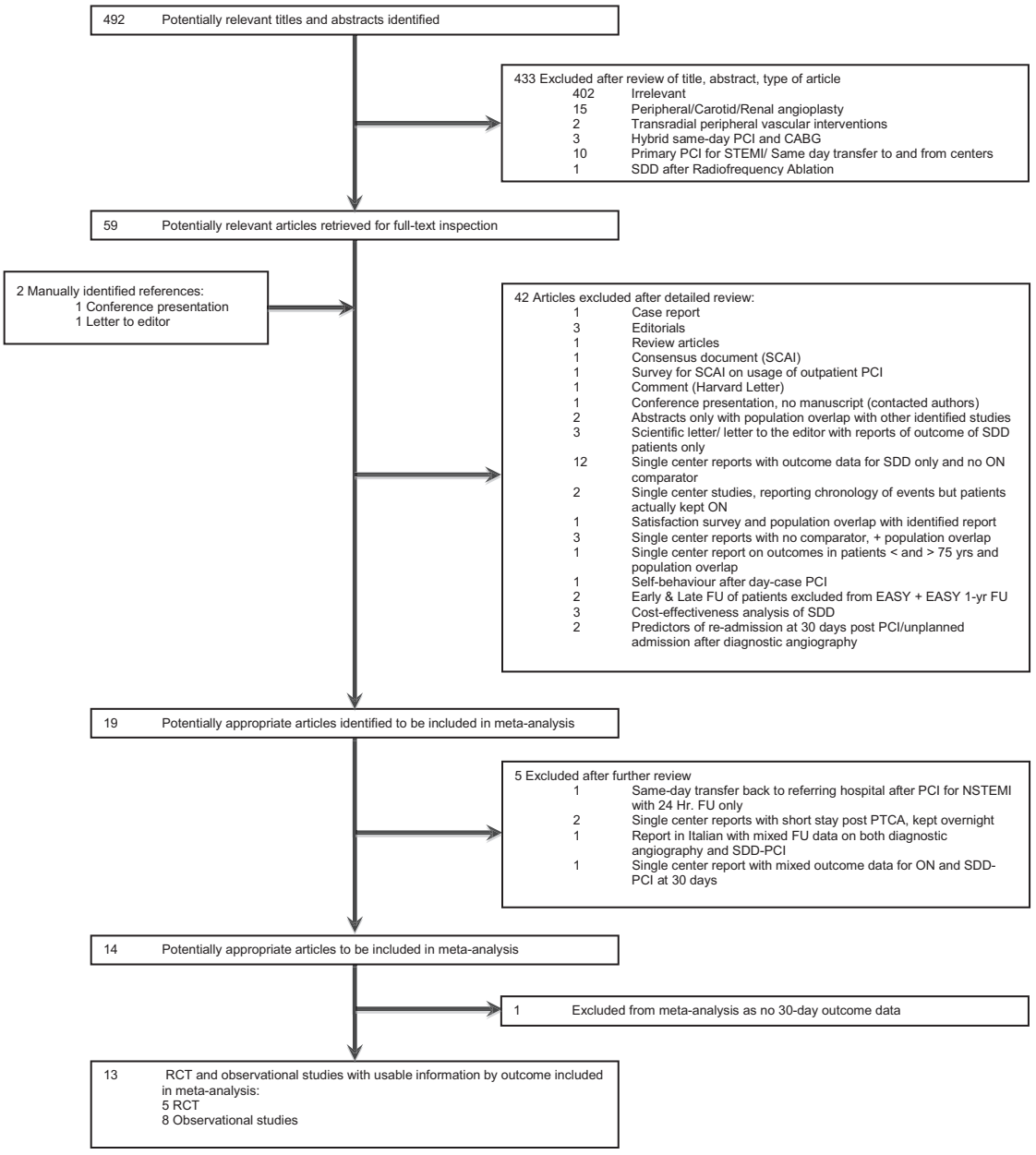

Figure 1. Flow Chart of Search Strategy and Studies Selection

PRISMA flow diagram showing literature search strategy, and selection process for inclusion in meta-analysis. CABG = coronary artery bypass grafting; EASY = Early Discharge After Transradial Stenting of Coronary Arteries study; ON = overnight stay; PCI = percutaneous coronary intervention; PTCA = percutaneous transluminal coronary angioplasty; RCT = randomized controlled trials; SCAI = Society for Cardiovascular Angiography and Interventions; SDD = same-day discharge; STEMI = ST-segment elevation myocardial infarction;

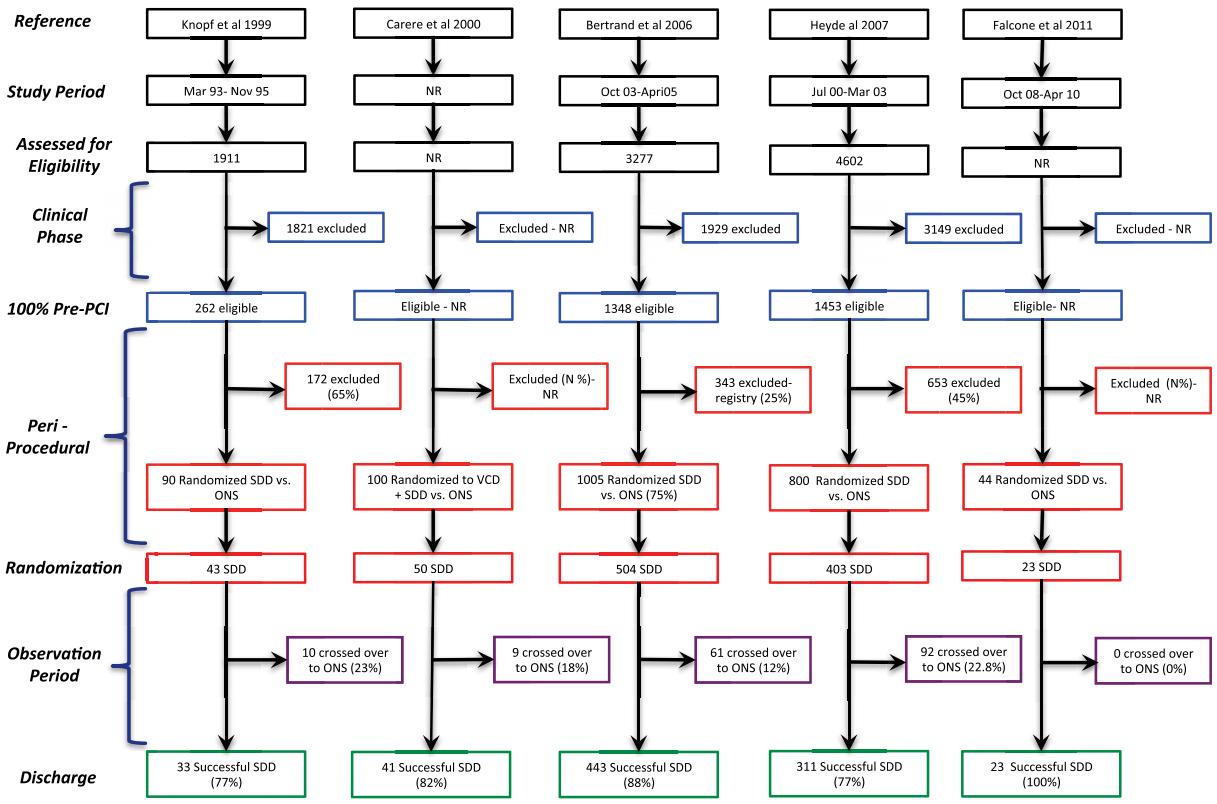

Figure 2. Selection Process for Eligibility for SDD in Randomized Trials

Flow diagram illustrating the selection process for same-day discharge (SDD) in randomized trials included in the meta-analysis. This systematic selection process usually combines clinical, procedural, and periprocedural criteria, and final triage based on clinical stability and other factors (e.g., social) during the observation period. In a randomized study design, approximately 80% to 88% of patients initially assigned for SDD are discharged. NR = not reported; other abbreviations as in Figure 1.

Results

A total of 13 studies conducted between 1999 and 2011 were included in the meta-analysis (Fig. 1). Five studies were randomized trials, and 8 were observational studies. Twelve studies were single-center (n = 4,182 patients), and 1 was a large U.S. multicenter observational study (N = 107,018 patients). Three studies were conducted in the United States, 3 in Canada, 5 in Europe, and 2 in Asia. Baseline characteristics and procedural data of study populations are shown in Table 2. Our comprehensive review involved a total of 111,830 patients (2,039 enrolled in randomized trials, and 109,791 in observational studies), with 4,179 (3.7%) in the SDD, and 107,651 (96.3%) in the ON group. The mean age for the entire meta-analysis population was 62 ± 4.9 years. Of these, 64% were men, 32% were diabetic, 82% had systemic hypertension, 79% had dyslipidemia, 39% had prior PCI, and 23% had prior coronary artery bypass grafting. Patients in randomized trials (n = 2,039) were slightly younger (60 ± 2 years vs. 63 ± 6 years), and more often men (79% vs. 64.5%) than in observational studies.

Twelve studies (n = 110,825) examined elective PCI in stable angina, but a small proportion also included unstable angina (Braunwald Class 1 and 2). A single randomized trial (EASY [Early Discharge After Transradial Stenting of Coronary Arteries]) with 1,005 patients, examined SDD after PCI in unstable angina and acute coronary syndrome (ACS) with elevated troponin, which represented 25% of study population (12). Khater et al. (14) also included low-intermediate risk ACS patients (using Thrombolysis In Myocardial Infarction risk scoring) in their single-center study of 150 patients. A total of 96% were treated via the femoral approach, whereas transradial access was used in 3%, and a minority of 0.36% had brachial access. When the large observational study of Rao et al. (16) was excluded, radial access was used in 45% of the remaining population, reflecting the current lower utilization of radial access in the United States compared with Europe, Asia, and Canada. Multivessel PCI was performed in 16% of patients, whereas 37% had angiographic Type B or C lesions.

Table 2. Baseline Characteristics of Included Studies

Variable	Knopf 1999 (5)	Carere 2000 (6)	Koch 2000 (7)	Slagboom 2001 (8)	Dalby 2003 (9)	Yee 2004 (10)	Slagboom 2005 (11)	Bertrand 2006 EASY Study (12)	Heyde 2007 EPOS Study (13)	Khater 2007 (14)	Chung 2010 (15)	Rao 2011 (16)	Falcone 2011 ABDCD-PCI (17)
Demographics													
Patients, total	90	100	1,015	159	70	75	644	1,005	800	150	660	107,018	44
SDD	43	50	922	106	51	25	375	504	403	124	214	1,339	23
ON	47	50	87	53	19	50	269	501	397	26	446	105,679	21
Men, total	57	83	745	124	57	65	490	790	648	123	562	67,392	31
SDD	26	44	—	85	41	21	290	395	327	99	181	863	15
ON	31	39	—	39	16	44	200	395	321	24	381	66,529	16
Age, yrs	58	—	60	—	65.1	—	60	60.5	62	58	—	73	—
SDD	57	62	—	63	65.3	55.9	60	60	62.1	58	59.7	73	60.6
ON	59	59	—	62	64.6	56.5	60	61	61.1	57	61.7	73	57.0
DM, total	18	—	130	21	11	13	85	165	121	60	180	35,627	20
SDD	7	—	—	12	9	4	54	83	65	50	60	443	11
ON	11	—	—	9	2	9	31	82	56	10	120	35,184	9
HTn, total	50	—	418	46	39	32	238	539	320	66	388	89,223	40
SDD	22	—	—	25	26	9	139	263	165	56	128	1,075	20
ON	28	—	—	21	13	23	99	276	155	10	260	8,848	20
Prior MI total	28	—	516	62	18	—	227	443	285	34	265	—	11
SDD	14	—	—	38	13	—	129	219	130	31	107	—	4
ONS	14	—	—	24	5	—	98	224	155	3	158	—	7
Prior CABG total	12	—	57	18	14	—	54	—	28	—	—	25,119	—
SDD	5	—	—	12	10	—	37	—	13	—	—	303	—
ON	7	—	—	6	4	—	17	—	15	—	—	24,816	—
Prior PCI total	47	—	263	51	14	—	155	200	168	—	—	42,988	20
SDD	22	—	—	34	10	—	89	107	84	—	—	578	10
ONS	25	—	—	17	4	—	66	93	84	—	—	42,410	10

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Table 2. Continued

Variable	Knopf 1999 (5)	Carere 2000 (6)	Koch 2000 (7)	Slagboom 2001 (8)	Dalby 2003 (9)	Yee 2004 (10)	Slagboom 2005 (11)	Bertrand 2006 EASY Study (12)	Heyde 2007 EPOS Study (13)	Khater 2007 (14)	Chung 2010 (15)	Rao 2011 (16)	Falcone 2011 ABDCD-PCI (17)
Procedural data													
Brachial access, total	0	0	0	0	0	0	0	0	0	0	0	405	0
SDD	0	0	0	0	0	0	0	0	0	0	0	5	0
ON	0	0	0	0	0	0	0	0	0	0	0	400	0
Femoral access, total	90	100	1,015	0	70	75	322	0	800	150	0	104,552	44
SDD	47	50	922	0	51	25	177	0	403	126	0	1,290	23
ON	43	50	87	0	19	50	145	0	397	24	0	103,262	21
Radial access, total	0	0	0	159	0	0	322	1,005	0	0	660	1,680	0
SDD	0	0	0	106	0	0	198	504	0	0	214	42	0
ON	0	0	0	53	0	0	124	501	0	0	446	1,638	0
Sheath size, F	8	8	6	6	6–8	6–7	6	5–6	5–6	6–8	5–8	—	—
SDD	8	8	6	6	6–8	6–7	6	5–6	5–6	6–8	5–6 in 98.6	—	—
ON	8	8	6	6	6–8	6–7	6	5–6	5–6	6–8	5–6 in 89.9%	—	—
Type B2/C lesion, total	—	—	951	27	43	45	184	641	927	118	481	37,882	0
SDD	—	—	—	14	27	13	67	321	453	94	128	442	0
ON	—	—	—	13	16	32	117	320	474	24	353	37,440	0
MV PCI total	11	—	117	0	0	0	—	317	141	43	37	17,474	—
SDD	2	—	—	0	0	0	—	149	71	34	6	189	—
ON	9	—	—	0	0	0	—	168	70	9	31	17,285	—
Lesions, total	106	—	1,510	180	82	—	814	—	1,240	—	—	—	—
Procedural anticoagulant													
Heparin, %	100	100	100	100	100	100	100	100	100	100	100	40.5	—
GPI, %	0	0	0	0	0	0	—	100	6.4	8.7	0	23.1	0
Bivalirudin, %	0	0	0	0	0	0	0	0	0	0	0	50.6	0
Hemostasis													
VCD total	0	50	0	0	68	75	0	0	0	—	0	53,834	44
SDD	0	50	0	0	50	25	0	0	0	—	0	871	23
ON	0	0	0	0	18	50	0	0	0	—	0	52,963	21
Length of hospital stay post-PCI, h													
SDD	8–10	11	4	4–6	6	10	4–6	4–6	—	10	4–6	—	3
ON	23	22	FM	FM	FM	FM	FM	FM	FM	FM	FM	—	FM

Summary of demographic characteristics of meta-analysis population, procedural data, and average hospital length of stay is shown.

CABG = coronary artery bypass grafting; DM = diabetes mellitus; FM = following morning; GPI = glycoprotein IIb/IIIa inhibitor; HTn = hypertension; MI = myocardial infarction; ON = overnight stay; PCI = percutaneous coronary intervention; SDD = same-day discharge; VCD = vascular closure device.

Table 3. Summary of Selection Criteria for SDD in Meta-Analysis Studies

First Author, Year (Ref. #)	Patients Total N	Selection Criteria for SDD			
		Pre-Procedural	Procedural	Post-Procedural	Discharge
Knopf et al., 1999 (5) randomized	90	Age <80 yrs Stable/unstable angina, or recent MI >5 days No illness requiring medical care No communication barrier	Non–CABG-related target lesion No LMS disease, SVG lesion, proximal LAD disease, acute occlusions, nonballoon interventions, no luminal thrombus	Successful procedure before 3 PM	NR
Carere et al., 2000 (6) randomized	100	Elective or urgent PCI ± stenting (provided operator felt SDD possible). Creatinine <150 μmol/L BP = <180/100 No PVD or pre-existing femoral hematoma	NR	Those randomized to vascular suture closure with Prostar-Plus	NR
Koch et al., 2000 (7) observational	1,015	Consecutive patients undergoing elective PTCA. No planned IABP; no acute MI or UA class 3	Successful uncomplicated PTCA with no MACE No angiographic exclusion criteria Angiographic criteria, poor LV, previous CABG were not exclusions	Stable clinical condition during observation	NR
Slagboom et al., 2001 (8) observational	159	Stable/unstable angina (class 1 and 2) No acute MI Adequate collateral hand blood supply No non-PTCA reason to remain hospitalized	Sheath ≤6-F Type A and B lesions (no type C lesion or CTO) No expected HD collapse in case of occlusion; no intracoronary thrombus No dissection, thrombus, SB occlusion	Successful uncomplicated PTCA Clinically stable patient No access site complication	NR
Dalby et al., 2003 (9) observational	70	Elective PCI. Noncomplex cases No significant comorbidities	Noncomplex lesions Successful uncomplicated PCI with stenting No periprocedural arrhythmia	Stable clinical condition No periprocedural or vascular access complications	Patient socially able and willing to go home Arrangements made for next morning review for vascular access inspection and renal function
Yee et al., 2004 (10) observational	75	Elective PCI for stable angina, Age 18–75 yrs No bleeding disorder, anticoagulation, systemic or local infection (VCD) No PVD	Clean femoral puncture Single lesion with a VD >3 mm, and lesion length ≤23 mm Sheath ≤8-F	Successful PCI, and adequate hemostasis Stable clinical condition No CP, ECG changes, or enzymatic increase No GPI	NR
Slagboom et al., 2005 (11) observational	644	Stable/unstable angina class 1 and 2), No acute MI, nor UA class 3 No non–PTCA-related reason for hospitalization	Type A and B lesions No expected hemodynamic collapse in case of reocclusion No IC thrombus, SB occlusion or dissection	Optimal PTCA result No access site complications	NR
Bertrand et al., 2006 (12) randomized	1,005	Ad hoc PCI procedures Age >18 yrs No recent MI (<72 h) LVEF >30% No condition precluding SDD No intolerance to aspirin or thienopyridines INR ratio <2.0	Successful coronary stenting by TRA approach No transient vessel closure or HD collapse during PCI	After successful ad hoc stenting, randomized to only abciximab bolus Adequate hemostasis	Able and willing to go home Adequate social support

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In 4 of 5 randomized, and 7 of 8 observational studies, the anticoagulant of choice in 100% of patients was unfractionated heparin (UFH). In the EASY randomized trial, all patients received abciximab (bolus only in SDD patients vs. bolus plus a 12-h infusion in the ON group) in addition to UFH (12). In the EPOS (Elective PCI in Outpatient

Table 3. Continued

First Author, Year (Ref. #)	Patients Total N	Selection Criteria for SDD			
		Pre-Procedural	Procedural	Post-Procedural	Discharge
Heyde et al., 2007 (13) randomized	800	Patients scheduled to undergo elective PCI eligible for enrollment if they remained at home before the procedure and did not have an ACS, No long-term systemic anticoagulation	Use of GC ≤6-F No elective use of GPI There were no angiographic exclusion criteria	Pts. who met inclusion criteria, randomized to SDD after decision to perform PCI, but before the start of PCI	Patients must live ≤60 min away from medical center
Khater et al., 2007 (14) observational	150	Adults ≥18 yrs old Creatinine ≤2 mg/dl Diagnoses of stable angina or low–intermediate risk ACS using TIMI risk score.	Documented single or multivessel CAD amenable for PCI Utilization of GPIs was left to the operator's discretion.	Ambulatory, HD stable, Not receiving GPI No major complications or bleeding	Adequate home supervision and social support
Chung et al., 2010 (15) observational	660	Pts. referred for elective/ad hoc TRA PCI LVEF >30% No CKD (creatinine >2.0 mg/dl)	No LMS disease Uncomplicated PCI	HD stable	Ability to reach an emergency dept. within 40 min (home <40 km from hospital)
Rao et al., 2011 (16) observational	107,018	107,018 pts ≥65 yrs undergoing elective PCI procedures at 903 U.S. sites participating in the CathPCI registry between November 2004 and December 2008 Exclusion: UA, NSTEMI, or STEMI; emergency, urgent, or salvage procedures; CPR en route to the cath lab Cardiogenic shock	Successful PCI with stenting	1,339 who were discharged on the same-day as their PCI	NR
Falcone et al., 2011 (17) randomized	44	Age ≤75 yrs Type A or B lesion >2 h post PCI No acute MI INR <2, plt >100,000, HCT >25% No CKD LVEF >30%	No other anticoagulation beside heparin or bivalirudin used during PCI PCI native vessel No evidence of thrombus Implantation of <3 stents No dissection or SB occlusion during PCI Femoral access site amenable to VCD	Successful PCI and femoral VCD Stable for 2 h post-procedure	Residence <30 min from hospital

A 4-step selection process for SDD (clinical, procedural, post-procedural, and discharge or social) and criteria employed in randomized and observational studies.

ACS = acute coronary syndrome; BP = blood pressure; CKD = chronic kidney disease; CP = chest pain; CPR = cardiopulmonary resuscitation; CTO = chronic total occlusion; ECG = electrocardiogram; GC = guiding catheter; GPI = glycoprotein IIb/IIIa inhibitor; HCT = hematocrit; HD = hemodynamic/hemodynamically; IABP = intra-aortic balloon pump; INR = international normalized ratio; LAD = left anterior descending artery; LMS = left main stem; LV= left ventricle/ventricular; LVEF = left ventricular ejection fraction; MACE = major adverse cardiovascular events; NR = not reported; NSTEMI = non–ST-segment elevation myocardial infarction; Pt = patient; PTCA = percutaneous transluminal coronary angioplasty; PVD = peripheral vascular disease; SB = side branch; STEMI = ST-segment elevation myocardial infarction; SVG = saphenous vein graft; TIMI = Thrombolysis In Myocardial Infarction; TRA = transradial access; UA = unstable angina; VD = vessel diameter; other abbreviations as in Tables 1 and 2.

Study) randomized trial (13) and in 2 of the observational studies, investigators permitted variable use of a glycoprotein IIb/IIIa inhibitor (GPI). In the large observational study of Rao et al. (16), 40.5% of patients received UFH, 50.6% bivalirudin, whereas 23.1% received a GPI.

Of the 2,039 patients in randomized trials, 1,023 (50.2%) were assigned to SDD after PCI, and 1,016 (49.8%) to ON. Of the 1,023 assigned to SDD, 851 (83%) were successfully discharged home the same day of PCI, whereas 172 (17%) developed an indication for extended observation, and crossed over to an overnight stay (Fig. 2). Reasons for this included procedural-related complications, such as major coronary dissection not suitable for stenting, in-lab transient vessel closure with hemodynamic collapse, intracoronary thrombus, pericardial effusion, procedural arrhythmia, wire perforation, chest pain, or issues with the access site (e.g., hematoma, delayed hemostasis). Very few were due to social reasons or to patient refusal after randomization.

Where reported, the average length of stay after PCI in the majority of studies ranged between 4 and 11 h for SDD, with ≥77% of patients sent home between 4 and 8 h post-procedure, and 1 day for ON, with very few patients kept longer for various clinical indications. Selection criteria for SDD varied significantly between individual studies (Table 3), with the majority agreeing on the following criteria: elective PCI for stable or unstable angina,

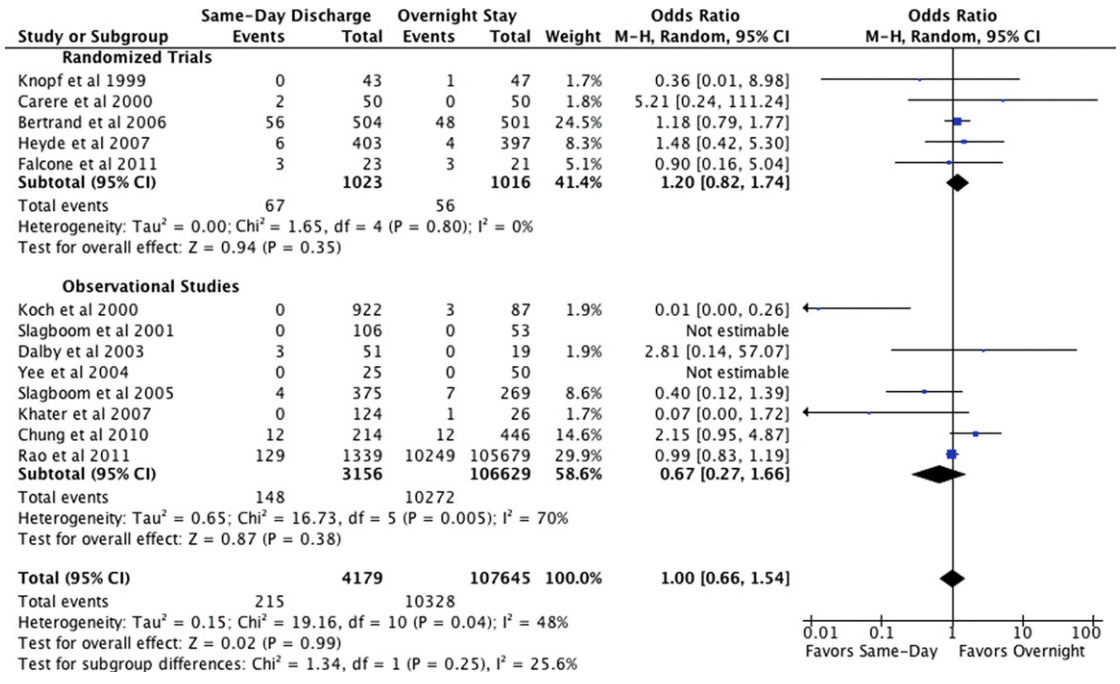

Figure 3. Forest Plot of the Incidence of 30-Day Total Complications

Meta-analysis of pooled data from randomized and observational studies showing the incidence of total complications at 30 days post PCI, using a Mantel-Haenszel (M-H) random effects model. Outcomes data were measured and reported as odds ratio (OR), with their 95% confidence intervals (CI). Heterogeneity across studies denoted by the I^2 statistic test. An I^2 value of <25% was considered low heterogeneity, 25% to 50% moderate, and a value >50% was considered substantial heterogeneity. The weight of each trial on the overall results of meta-analysis outcome is displayed as a percentage. PCI = percutaneous coronary intervention.

low–moderate risk ACS, successful uncomplicated PCI, stable clinical condition post-PCI, and patients' willingness to go home with the ability to reach the emergency department within a reasonable time (40 to 60 min), and adequate social support.

In the randomized trials, the total number of complications in the SDD group was 67 of 1,023 (6.5%) versus 56 of 1,016 (5.5%) for the ON group (OR: 1.20, 95% CI: 0.82 to 1.74). The total number of complications reported in the SDD group in the observational data were 148 of 3,156 (4.7%) versus 10,272 of 106,629 (9.6%) for the ON group, (OR: 0.67, 95% CI: 0.27 to 1.66) (Fig. 3). To assess the influence of the Rao et al. study (16) with the largest population size, we performed a sensitivity analysis by removing this study from the forest plot. For the remaining pooled observational studies, total complications in the SDD group was 19 of 1,817 (1.0%) versus 23 of 950 (2.4%) in the ON group (OR: 0.4, 95% CI: 0.07 to 2.14). At 30 days, the incidence of MACE in the SDD versus the ON group in randomized trials was 13 of 1,023 (1.3%) versus 13 of 1,016 (1.3%) (OR: 0.99, 95% CI: 0.45 to 2.18), and in observational studies 10 of 1,817 (0.6%) versus 11 of 950 (1.2%) (OR: 0.59, 95% CI: 0.06 to 5.57) (Fig. 4). Finally, the incidence of rehospitalizations within 30 days after PCI between the SDD and ON groups in randomized trials was 41 of 1,023 (4.0%) versus 37 of 1,016 (3.6%) (OR: 1.10, 95% CI: 0.70 to 1.74) and in observational studies 131 of 1,645 (8.0%) versus 10,147 of 105,827 (9.6%) (OR: 0.62, 95% CI: 0.10 to 3.98), respectively (Fig. 5). When Rao et al. (16) was excluded, the incidence of rehospitalization in observational studies was 3 of 306 (1.0%) in the SDD versus 2 of 148 (1.4%) in the ON group (OR: 0.34, 95% CI: 0.01 to 22.57).

Discussion

In this systematic review and comprehensive meta-analysis, we show that many carefully selected and risk-stratified groups of patients undergoing elective or ad hoc PCI for low–intermediate risk ACS have been managed successfully with an SDD strategy. Still, due to the low event rate, the significant variation in the definition of outcomes across studies, and wide confidence intervals around the pooled point estimates, a definitive resolution of a statistically significant hazard or benefit to the SDD approach cannot be determined based on the totality of presently available data.

With the advancement of operative techniques and surgical equipment over the past few years, a number of

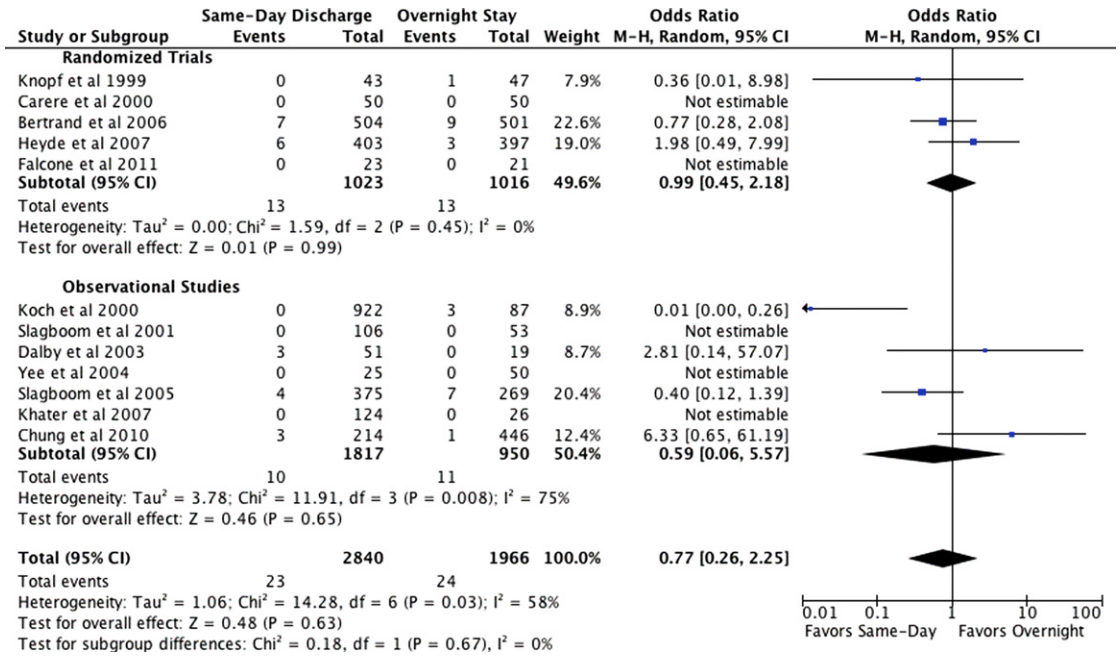

Figure 4. Forest Plot of the Incidence of 30-Day Total MACE

Meta-analysis of pooled data from randomized and observational studies showing the incidence of total major adverse cardiovascular events (MACE) at 30 days post-percutaneous coronary intervention (PCI), using a Mantel-Haenszel random effects model. Abbreviations as in Figure 3.

noncardiac disciplines have evaluated the benefits and safety of SDD (34–36). This practice has also been extended to selected vascular procedures performed under general anesthesia and to interventional peripheral, renal, and carotid angioplasty (37). With significant accomplishments in safety and success, PCI techniques have likewise progressed to the point that SDD after PCI is not uncommon in many countries, without reported issues of safety.

Hesitance in changing current practice could broadly be attributed to 4 potential challenges. First, the biggest hurdle seems to be the medicolegal concerns from the medical community, hospitals, and care providers, which relate to the safety of SDD. Second, there may be concerns on the part of physicians, nurses, and hospitals that an SDD strategy may not provide enough time to educate patients about their underlying disease and/or their PCI procedure. Third, there is a misconception that current payment systems, such as in the United States, provide a disincentive to hospitals and physicians to change practice and discharge patients the same day as their procedure. Fourth, some patients may be reluctant to accept an SDD strategy after uncomplicated PCI.

Despite the spreading adoption of SDD after PCI practices worldwide, the present comprehensive systematic review and meta-analysis of all available clinical data involving 111,830 patients cannot scientifically resolve the ultimate question: whether SDD after uncomplicated PCI in a selected subgroup of patients is as safe as or safer than ON. To scientifically resolve this question, assuming similar results for total complications as obtained in this meta-analysis and a noninferiority design according to the Blackwelder equation, a large sample size would be required. Indeed, if there is truly no difference between ON and SDD strategies, then 17,812 patients would be required to be 90% sure that the upper limit of a 1-sided 95% confidence interval will exclude a difference in favor of the ON strategy of more than 1%.

In this meta-analysis, and by definition, patients in randomized trials who were discharged the same day as their PCI had a similar risk profile to those hospitalized overnight. In particular, no clinically important differences in medical comorbidities, procedural characteristics, multivessel PCI, high-risk lesions, access site, or use of vascular closure devices were observed between the 2 groups (Table 2). By contrast, patients in observational studies who were discharged home the same day of their PCI were a highly selected population as evaluated by the operators. Although it is likely that individual centers have created their local protocols for SDD after PCI, our review highlights the lack of standardized selection criteria for this strategy and the lack of standardized definitions of outcomes used across studies. Existing recommendations in the Society for Cardiovascular Angiography and Interventions statement (38) (endorsed by the American College of Cardiology) on SDD

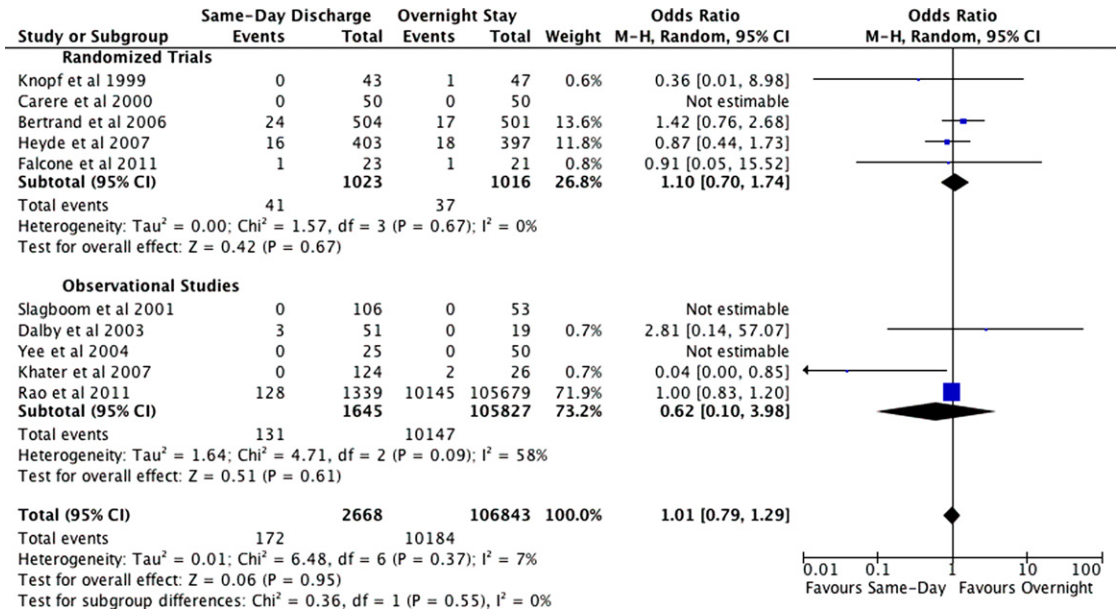

Figure 5. Forest Plot of the Incidence of 30-Day Rehospitalization

Meta-analysis of pooled data from randomized and observational studies showing the incidence of rehospitalization at 30 days post-percutaneous coronary intervention (PCI), using a Mantel-Haenszel random effects model. Abbreviations as in Figure 3.

may be more conservative than what current "real-world" practice may be (39). Central to many discussions over the merits of SDD versus ON care is an assumption that more hospitalization, although clearly more expensive, is also by definition safer. No trials have attempted to look at the hazard of hospitalization in this patient population, but a recent systematic database review has suggested the risk from an overnight stay in the hospital includes 0.4% of skin ulcer formation, 3.4% suffering adverse drug reactions, and 11.1% of infection (40).

Complications after PCI include ischemic events, such as periprocedural MI and acute stent thrombosis, as well as bleeding and vascular complications. In the contemporary PCI era, there are several strategies to minimize both types of complications. Coronary stents have reduced the risk for abrupt closure, and potent antiplatelet and anticoagulant combinations reduce the risk for periprocedural MI. Appropriate dosing antithrombotic medications, or the preferred use of radial access, can reduce bleeding and vascular complications (41–43). Some observational studies suggest that the use of femoral closure devices in selected patients may also be associated with a reduction in vascular complications (44); however, the exact clinical benefit remains controversial. Given the myriad options to optimize PCI safety and efficacy, an SDD strategy may be a natural evolution of post-procedural care. Key to the success of this strategy, however, is judicious patient selection. Moreover, patient education regarding late complications that may occur after PCI is an integral part of an SDD program. A multidisciplinary team approach of all healthcare providers involved in patient pathways, as well as hospital administrators, is needed to build a successful SDD program.

Some investigators also reported patients' preference for and satisfaction with SDD strategy after PCI (13,45). It is clear that patients' education on the safety of outpatient PCI in selected patients is pivotal in ensuring the success of such a program. Because PCI is no longer considered a criterion for inpatient admission by default, the reimbursement scheme for elective PCI in the United States has shifted towards Ambulatory Payment Classification billing, instead of the Diagnosis-Related Group reimbursement system for inpatient procedures (38). Furthermore, in 2010, the U.S. Centers for Medicare & Medicaid Services extended its Recovery Audit Contractor program to all 50 states, with heightened scrutiny of hospital billing practices and inappropriate admissions related to procedures, which might have a noticeable impact on shifting current PCI practice toward shorter lengths of stay.

Study limitations. To the authors' knowledge, this systematic review and meta-analysis represents the most current and comprehensive analysis of available studies on SDD after PCI. Some of the observational studies included in this meta-analysis are of extremely small size, and the influence of the largest multicenter study to date (Rao et al. [16]) of >100,000 patients should be noted. An inherent limitation of any meta-analysis is that of publi-

cation bias. Although we included all randomized studies to date on this analysis, there was a large presence of single-center observational data (both retrospective and prospective). Other important issues such as patient satisfaction, quality of life, and costs were not addressed in those studies. They should be further studied in future comparative studies.

Conclusions

Considerable heterogeneity exists across published studies comparing SDD after PCI with ON, with significant variation in the populations studied, as well as the definition of outcomes. Despite a large sample size from pooling of randomized and observational studies, the point estimates for the OR between SDD and outcomes had wide CIs. With current heterogeneity between studies and wide CIs, an adequately powered multicenter randomized trial comparing SDD with ON would require a very large sample size. Until such a trial is completed, SDD after uncomplicated PCI seems a reasonable approach in selected patients.

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Key words: day-care ■ outpatient ■ PCI ■ same-day.