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Percutaneous coronary intervention with or without on-site coronary artery bypass surgery: A systematic review and meta-analysis

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ABSTRACT

Background: Current American Heart Association guidelines recommend against the performance of elective or primary percutaneous coronary intervention (PCI) without on-site surgical backup (i.e. a class III and IIb recommendation respectively). Despite this, numerous centers have already implemented PCI programs with no on-site surgery backup (NSOS).

Methods: To evaluate the necessity for on-site surgical backup (SOS) when performing PCI we performed a systematic review and meta-analysis. English-language articles published from 1966 through December 2010 were retrieved using keyword searches of Medline and Scopus, supplemented by letters to authors and reviews of all bibliographies. Article inclusion and data extraction was performed by two independent reviewers. We identified 18 articles published between 1992 and 2009 which contained reported events on 1,150,200 patients.

Results: The combined odds ratio calculated using a random effects model for death with NSOS was 0.93 (95% CI, 0.80–1.09). In studies with data reported for primary PCI and elective PCI the OR for death was 0.91 (95% CI, 0.84–1.00) and 1.04 (95% CI, 0.67–1.63). A lack of effect of SOS was maintained when analysis was performed by study type or by either primary or elective PCI. No differences in rates of emergency coronary artery bypass grafting, post procedural myocardial infarction, target vessel revascularization, or cerebrovascular accidents were observed between SOS and NSOS centers.

Conclusion: Both primary and elective PCI can safely be performed at NSOS centers without an increase in mortality or PCI related complications. AHA/ACC guidelines should reflect the lack of benefit conferred by on-site surgical backup. In establishing PCI programs, adequate operator/center volumes, patient selection, and geographic/population considerations should take precedence rather than the availability of on-site surgical backup during PCI.

1. Introduction

Coronary angiography and percutaneous coronary intervention (PCI) has become the standard of care for evaluating and treating obstructive coronary artery disease [1,2]. Historically, balloon angioplasty was restricted to sites with surgical backup onsite (SOS) as early balloon-only techniques carried a significant rate of complications requiring emergency coronary artery bypass graft surgery (eCABG) [3]. However, with contemporary technology, including the near universal deployment of coronary stents, the need for eCABG has been reduced to only 0.3–0.4% of all cases [1,3]. Moreover, given the well established value of timely access to a catheterization laboratory, approximately 13% of centers offering PCI do so in a NSOS setting [4].

However, current AHA/ACC guidelines recommend against the performance of elective PCI without on-site surgical backup (Class III recommendation) and only recommend primary PCI in centers which meet specific volume criteria (Class IIb recommendation) [2]. These recommendations are largely derived from a single observational study which reviewed medicare records for 2 years and noted increased mortality in patients receiving PCI at NSOS centers [5]. In contrast, numerous observational studies have reported comparable outcomes in NSOS centers when performing either elective or primary PCI [6–8]. Given the implications in providing health services and the current recommendations of the AHA/ACC, we performed a meta-analysis to more precisely estimate the mortality benefit, if any, associated with surgical backup. Moreover, we sought to determine if benefit could be demonstrated in the subgroups of patients receiving either elective or primary PCI.

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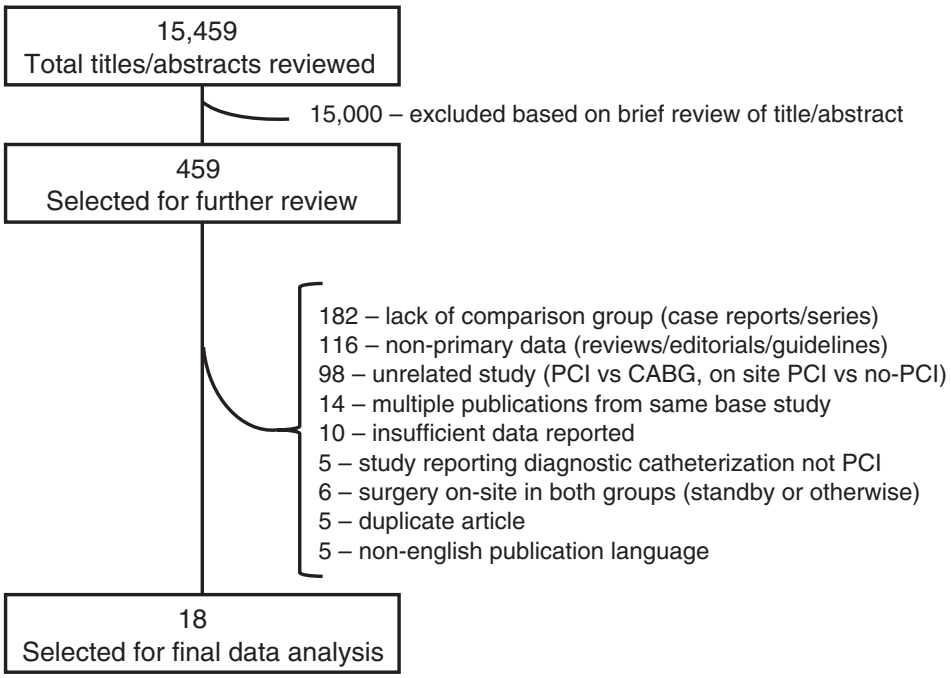

Fig. 1. Flow diagram of included studies for the meta-analysis.

2. Methods

2.1. Literature search

We identified the population, intervention, comparison and outcome of interest in development of our initial research question. Specifically, we were interested in populations receiving percutaneous coronary interventions (PCI). The intervention of interest was the availability of cardiac surgery backup on-site (SOS) versus PCI at centers with no on-site surgery backup (NSOS). The comparison of interest was mortality between SOS and NSOS centers. Specifically, we did not set out to compare PCI at NSOS centers versus thrombolytic therapy for primary/emergent cases as the evidence favoring PCI over thrombolytic therapy was felt to be sufficient. The primary outcome of our analysis was overall mortality. Secondary end-points of PCI related complications were also assessed — specifically peri-procedural myocardial infarction (MI), cerebrovascular accidents (CVA), need for emergent coronary artery bypass grafting (eCABG), and need for target vessel revascularization (TVR). Data was extracted from the published results available. If a study did not report the primary endpoint of mortality the communicating author was contacted to request additional information. If authors could not provide mortality data then the study was excluded. However, if the primary endpoint data was available and only the secondary endpoint data lacking, the missing data was requested and the study was included regardless as to whether the authors were able to provide the secondary endpoint data or not.

Given the limited number of randomized control trials, we sought to identify both randomized and observational studies addressing the use of PCI in both SOS and NSOS settings. We performed a computerized literature search of MEDLINE and SCOPUS up until December 31st 2010 for English language studies. Searches using permutations of the search terms percutaneous coronary intervention, PCI, coronary artery bypass grafting, CABG, surgery, backup, site, on-site and off-site were performed. Secondarily, additional references were identified using the related article feature in Pubmed, and all references of identified studies as well as citing articles were identified utilizing the SCOPUS database. This practice was repeated for each article selected to ensure inclusion of all relevant studies. In this manner, a total of 15,459 titles and abstracts were identified and reviewed for potential study eligibility. From this initial cohort of manuscripts, abstracts were reviewed by a single individual who removed duplicates and studies not relevant to the study question. From this, 459 articles were collected for full review.

Two reviewers independently evaluated the full text versions of the identified studies for eligibility, with any discrepancies being resolved by consensus, to yield a final list of 18 articles for extraction. The inclusion criteria were as follows: (1) population receiving either elective or primary PCI, (2) studies compared SOS to NSOS centers and (3) studies were required to report mortality data. The exclusion criteria were the following: (1)

Table 1
Study data.

					Surgery on-site						No surgery on-site					
Reference	Year	Study design	Type of intervention	Length of follow-up	N	Death	MI	CVA	eCABG	TVR	N	Death	MI	CVA	eCABG	TVR
Hubner et al	1992	Cohort	n/a	n/a	14024	96	231	n/a	291	n/a	1006	3	19	n/a	12	n/a
Weaver et al	1997	Cohort	Primary	1 year	592	65	n/a	n/a	83	41	472	52	n/a	n/a	66	38
Tebbe et al	1997	Cohort	n/a	n/a	27166	280	447	n/a	104	n/a	54,440	578	830	n/a	138	n/a
Wennberg et al	2004	Cohort	Both	In-hospital	617686	20,393	n/a	n/a	n/a	8321	8168	492	n/a	n/a	n/a	160
Sanborn et al	2004	Cohort	Primary	In-hospital	24890	1195	299	174	n/a	n/a	1057	44	16	4	0	n/a
Wharton et al	2004	Cohort	Primary	1 year	71	6	1	0	0	n/a	499	17	1	9	2	n/a
Melberg et al	2006	RCT	Elective	6 months	299	0	3	0	0	6	304	1	3	1	0	19
Peels et al	2007	RCT	Primary	30 days	103	1	n/a	n/a	n/a	n/a	96	2	0	0	0	0
Shiraishi et al	2007	Cohort	Primary	In-hospital	993	98	n/a	n/a	1	n/a	792	83	n/a	n/a	3	n/a
Carlsson et al	2007	Cohort	Both	30 days	25,525	562	n/a	77	40	n/a	8838	124	n/a	35	4	n/a
Frutkin et al	2008	Cohort	Elective	1 year	3317	155	19	11	1	11	1090	29	4	0	2	5
Pereira et al	2008	Cohort	Both	In hospital	6123	126	33	58	56	n/a	7112	127	28	188	158	n/a
Kutcher et al	2009	Cohort	Both	In-hospital	299,425	3632	n/a	n/a	1110	n/a	8736	151	n/a	n/a	26	n/a
Singh et al	2009	Case control	Both	In-hospital	2509	29	4	2	7	24	2509	21	12	12	5	18
Hannan et al	2009	Case control	Primary	30 days	1729	33	n/a	n/a	6	n/a	1729	40	n/a	n/a	1	n/a
Anis et al	2009	Cohort	Primary	1 year	1562	147	79	n/a	n/a	170	781	67	52	n/a	n/a	76
Tebbe et al	2009	Cohort	Both	In-hospital	12,465	224	75	12	25	n/a	10,683	214	53	11	21	n/a
Pride et al	2009	Case control	Primary	In-hospital	1768	67	18	11	n/a	95	1655	55	15	7	n/a	78

N — sample size, MI — myocardial infarction, CVA — cerebrovascular accident, eCABG — emergency coronary artery bypass grafting, TVR — target vessel revascularization.