

Featured Topics

SCAI Statement on Ad Hoc Versus the Separate Performance of Diagnostic Cardiac Catheterization and Coronary Intervention

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Coronary intervention may be combined with diagnostic cardiac catheterization or performed separately. In the early years of angioplasty, performing these procedures separately was standard practice. Gradually, ad hoc intervention (performing diagnostic angiography and coronary intervention within the same session) has become more common, largely because of its convenience for patients and efficiency for physicians. However, the safety and potential cost savings of this approach remain uncertain. Criteria for the appropriate use of ad hoc intervention have not been established. Ad hoc intervention is reasonable for many, but not appropriate for all patients and should not be considered standard therapy. This document updates an earlier review of this topic and provides suggestions for the use of ad hoc intervention as a routine strategy. *Catheter Cardiovasc Interv* 2004;63:444–451. © 2004 Wiley-Liss, Inc.

Key words: angioplasty; stenting; costs

INTRODUCTION

As percutaneous coronary intervention (PCI) has become safer and easier to accomplish, it is now often performed at the time of diagnostic coronary angiography [1–9]. The forces behind this trend include convenience for the patient, efficiency for the physician, and possibly cost savings for payers. However, a randomized study comparing the safety and efficiency of separate versus so-called ad hoc procedures has never been performed. A position paper from the Society for Cardiovascular Angiography and Intervention published in 2000 endorsed an ad hoc strategy for some but not all patients [10]. This paper reviews this topic, including data from recent studies, and provides suggestions for laboratories in which ad hoc PCI is performed.

DEFINITIONS OF AD HOC AND SEPARATE PCI

Coronary intervention performed at the time of diagnostic catheterization has variously been termed “ad hoc” [11,12], “prima vista” [7], “combined” [6,9,13,14], and “single-stage” [15,16] PCI. Among published studies, there is no consistent definition of this process. The strictest definition of “ad hoc” PCI implies that the therapeutic procedure immediately follows diagnostic angiography without the patient being undraped and re-

moved from the procedure table. This differs from the de facto definition applied by Medicare to determine pay-

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TABLE I. Studies of Ad Hoc Versus Separate-Stage Intervention Including Rates of Success and Ischemic Complications

Study (year)	Number of Ad hoc/ Number of separate	Angiographic success		Death		Q-Wave-MI		CABG	
		Ad hoc	Separate	Ad hoc	Separate	Ad hoc	Separate	Ad hoc	Separate
O'Keefe et al. [4], 1989	120/404	89%	91%	0%	1.2%	0.8%	1.4%	1.6%	3.4%
O'Keefe et al. [6], 1991	73/5,351	94%	95%	0.5%	0%	0.9%	0.5%	2.3%	0.5%
Lund et al. [7], 1994	124/?	92.1%	88.4%						
Rozenman et al. [8], 1995	1,719/2,069	93.9%	92.9%	0.8%	1.3%	1.0%	1.3%	0.5%	0.3%
Kimmel et al. [9], 1997 ^b	6,152/29,548			0.29%	0.16%	0.73%	0.15%	1.3%	1.09%
Shubrooks et al. [12], 2000 ^b	1,748/2,388	93.7% ^a	93.6% ^a	0.6%	0.5%	2.0%	2.6%	0.9%	0.8%
Goldstein et al. [13], 2002 ^b	38,411/23,462			0.46%	0.56%				

^aClinical success is reported since angiographic success was not available.

^bStatistical analyses involved multivariate analysis.

ment, which requires only that the diagnostic and therapeutic procedures be performed on the same day. Using the Medicare definition, a patient could have a diagnostic procedure in the morning, leave the laboratory, and return later the same day for PCI. Most studies do not specify whether "ad hoc" implies same-session or same-day procedures. Furthermore, the majority of studies are retrospective and none identify the operators' reasons for using ad hoc versus separate-day strategies. The terms "separate" or "staged" are used to describe procedures that are done on different days.

AD HOC VERSUS SEPARATE PCI IN PRESTENT ERA

Nine studies examined ad hoc balloon angioplasty before stenting became the dominant procedure [1–9]. Among these studies, 12–83% of the PCIs were classified as ad hoc. Studies that compared outcomes of separate PCI to outcomes of ad hoc PCI found no significant differences in angiographic success rates or complications (Table I) [2–4,6–9]. In two studies, ad hoc procedures were associated with an increased risk of complications in patients with unstable angina or other high-risk features [5,9]. Among the nine studies there was agreement that ad hoc PCI, as performed in these centers and on selected patients, was safe. However, these studies did not offer clear guidance on how to select appropriate patients for ad hoc PCI. Subsequent guidelines prepared by the Laboratory Standards Committee of the Society for Cardiovascular Angiography and Interventions attempted to address this issue [10].

STUDIES OF AD HOC VERSUS SEPARATE PCI IN STENT ERA

Adele et al. [11] performed an economic analysis of 395 patients undergoing ad hoc PCI, which included 191 (48%) who underwent stenting. Complications occurred

in 7.4% of the ad hoc group versus 4.2% when the procedures were performed separately, a difference that lacked statistical significance, although the study was not powered to identify differences in success or complication rates. Shubrooks et al. [12] reported the outcome of 4,136 PCIs performed in seven centers in 1997. Those with a prior PCI or requiring emergency procedures were excluded. Overall, 42% were performed ad hoc, but the use of ad hoc procedures varied from 7% to 77% among centers. The variation was attributed to differences in laboratory availability, operator availability, and operator preference. Stents were used in 72% of the ad hoc group and in 60% of those having separate procedures. Clinical success rate and ischemic complications were similar for ad hoc versus separate strategies. Vascular complications were lower in patients undergoing an ad hoc PCI procedure (0.6% versus 1.5%; $P = 0.006$). The authors emphasized "the importance of clinical judgment in deciding to proceed directly with PCI as opposed to medical or surgical options, of discussing this approach with patients before intervention, and of being certain that patients are appropriately prepared to proceed." The authors identified patients with multivessel disease and complex lesions as deserving of special consideration for staged intervention.

Goldstein et al. [13] evaluated data from the New York State Department of Health angioplasty database from 1995 to 1998, which included information from 33 centers using ad hoc PCI in 7–86% of procedures. The cohort included 38,411 patients undergoing ad hoc PCI and 23,462 patients undergoing separate procedures during the same hospitalization. Patients with staged interventions occurring in hospitals or admissions different than those of the initial cardiac catheterization ($n = 32,620$) were excluded. Stents were used in 63% of patients. Univariate and logistic regression analyses showed that ad hoc versus separate performance of PCI was not a predictor of mortality. The ad hoc strategy was associated with an increased risk of mortality in those

with congestive heart failure during the same admission (odds ratio = 1.6; $P = 0.04$) and Canadian Cardiovascular Society class IV status (odds ratio = 1.6; $P = 0.04$). The investigators concluded that overall mortality rates were similar for ad hoc and separate procedures, but that ad hoc PCI was associated with an increase in mortality for some high-risk subgroups.

SELECTION OF PATIENTS FOR AD HOC PCI

Guideline Recommendations

In the absence of randomized trials to guide selection of patients for ad hoc PCI, published guidelines have been based on observational series and the opinions of experts. The original angioplasty guidelines, published by the American College of Cardiology in 1988, advised against ad hoc coronary intervention [17]. However, in 1993, the revised angioplasty guidelines from the American College of Cardiology/American Heart Association stated that ad hoc coronary intervention is “particularly suitable” for patients with unstable angina that cannot be stabilized, patients with restenosis, and patients with acute myocardial infarction [18]. The 2001 revised guidelines [19], citing studies published before 1998 [2,4–6,8,9], reaffirmed the earlier recommendations from the 1993 guidelines and the 2000 Society for Cardiovascular Angiography and Intervention recommendations [10] stating that “ad-hoc coronary intervention is particularly suitable for patients with clinical evidence of restenosis 6 to 12 months following the initial procedure, patients undergoing primary angioplasty for MI, and patients with refractory unstable angina in need of urgent revascularization” [19].

The 2001 guidelines also stated: “However, ad-hoc percutaneous revascularization should not be performed in patients in whom the angiographic findings are unanticipated or the indication, suitability, or preferences for percutaneous revascularization is unclear. Patient safety should be the paramount consideration when contemplating ad-hoc intervention is considered [sic]. This Committee endorses the recommendations from the SCA&I that ad-hoc PCI be individualized and not be a standard or required strategy for all patients” [19]. The most recent guidelines identify three groups in whom ad hoc PCI seems appropriate.

Unstable Patients

The indication for PCI is often strongest in patients who are highly symptomatic. Accordingly, patients with unstable or progressive symptoms of myocardial ischemia are appropriate candidates for ad hoc PCI. Although earlier studies suggested complications were higher in unstable patients treated by the ad hoc strategy [5,9], more recent

data suggest that rapid triage of unstable patients to the catheterization laboratory with aggressive antithrombotic therapy followed by ad hoc PCI results in superior 30-day outcomes compared to prolonged antithrombotic treatment for 3–5 days before angiography [20].

Restenotic Lesions

Patients suspected of having restenosis based on symptoms or abnormal stress tests are often well suited for ad hoc PCI. Their experience with a prior PCI facilitates the informed consent process. The results of PCI for restenosis are predictable and the risk of complications is low. Unless coronary brachytherapy is planned, patients with suspected restenosis seldom require two separate procedures.

Low-Risk Patients With Simple Lesion Morphology and Compelling Symptoms

These patients have a favorable benefit/risk ratio for ad hoc PCI. Recent studies provide algorithms for identifying low-risk patients and certain lesion classification schemes are helpful predictors of the procedure risk associated with specific lesion morphologies [21–25]. The guidelines appropriately emphasize that when patients are stable and lesions have high-risk morphology, or the indications for PCI are neither clear nor compelling, PCI as a separate procedure may be the more appropriate strategy.

APPROPRIATE SELECTION OF PATIENTS FOR SEPARATE INTERVENTION

In some situations, PCI performed separately from diagnostic angiography may be the most prudent strategy. Data are lacking to identify which patients and what circumstances require this approach. However, some situations in which separate procedures would be appropriate are as follows.

Patients in Whom Risk of Adverse Outcome Is High With an Ad Hoc Strategy

Goldstein et al. [13] identified congestive heart failure during admission and Canadian Cardiovascular Society class IV angina as characteristics associated with an increased risk of mortality when ad hoc PCI is performed. When these variables are present, it may be prudent to perform PCI separately, especially if the patient’s status can be improved before proceeding to intervention.

Patients at High Risk for Procedure-Related Death

Shaw et al. [22] analyzed the American College of Cardiology National Cardiovascular Data Registry and

identified several characteristics associated with a greater than twofold risk of procedure-related death, including age > 50, left ventricular ejection fraction < 30%, complex lesion morphology, and renal failure. Some of these characteristics can be considered during informed consent discussions before diagnostic procedure. Others, such as lesion number and complexity, will be unknown until after the diagnostic study. When information revealed during the diagnostic study defines a risk of PCI higher than previously estimated, it may be wise to delay intervention until this is discussed with the patient without the influence of sedatives. This is especially important when the overall risk of death or major complications is unusually high.

Patients at Risk for Renal Failure

Several factors complicate decision-making in patients with or at risk for renal insufficiency. Separating the diagnostic and interventional procedures to minimize dye load in patients with known renal dysfunction might be prudent, especially when the diagnostic catheterization has required unusually large doses of contrast. McCullough et al. [26] found that when the dye load was under 100 ml, renal complications rarely occurred, so performing separate procedures to keep each under that limit might be a reasonable strategy. Some data suggest that the second contrast load should be delayed for at least 72 hr to minimize the risk of contrast-induced nephropathy [27]. Strategies to minimize contrast-induced nephropathy include pretreatment with vigorous hydration and acetylcysteine [28]. Separate intervention may be most appropriate for patients with renal dysfunction not adequately pretreated with these therapies. Finally, some treatments (e.g., venovenous hemofiltration) must be coordinated and initiated before the PCI [29].

Patients Transferred to Another Institution for PCI

Patients undergoing diagnostic procedures in a hospital without PCI capabilities must be transferred for intervention. This occurred in 18% of the cases in the New York State Department of Health database for 1995–1998 [13]. Occasionally patients may be transferred from one interventional facility to a larger one if additional expertise (e.g., experience treating complex lesions) or equipment (e.g., brachytherapy) is available only at the larger facility. The time delay required for transfer often precludes ad hoc PCI.

Patients Without Informed Consent

Informed consent must be obtained before the procedure, when the patient has time to consider information carefully without pressure or sedation [30]. Only in the setting of an extreme emergency should this standard be

relaxed. A noninterventional invasive cardiologist may not be fully aware of the details and risks of PCI in a particular patient. In this case, an interventionist asked to perform ad hoc PCI may appropriately delay the PCI to be sure the patient and family have been fully informed about risks. This is especially important when complex lesion anatomy predicts a high risk of complications. When diagnostic angiography shows coronary disease that could be treated appropriately with either bypass surgery or PCI, it may be appropriate to delay PCI until the advantages and disadvantages of both therapies have been discussed with the patient in an unpressured environment.

Patients Requiring Brachytherapy

At present, brachytherapy remains the only proven strategy for treating in-stent restenosis. Brachytherapy requires the combined efforts of radiation oncologists, radiation physicists, and interventional cardiologists. If the radiation oncologist or physicist is not available when diagnostic catheterization identifies in-stent restenosis, then brachytherapy must be performed as a separate procedure when radiation personnel are available. When possible, patients with likely in-stent restenosis should be scheduled when brachytherapy can be performed at the same sitting.

Patients Who Would Benefit From Additional Preinterventional Treatment

The strategy of delaying PCI to allow pretreatment with clopidogrel is controversial at present. Potential risks include interim myocardial infarction [20] and increased bleeding if bypass surgery is performed within the next 5 days. However, in high-risk patients, clopidogrel given several hours before intervention may decrease the risk of procedure-related myocardial infarction [31–33]. In low-risk patients, clopidogrel given several hours before the procedure may obviate the need for glycoprotein IIb/IIIa inhibitors and their attendant small risks of bleeding or thrombocytopenia [34]. For some patients, the benefits of delaying PCI to start clopidogrel may outweigh its risks.

REQUIREMENTS FOR PROGRAMS USING ROUTINE AD HOC INTERVENTION

Programs routinely performing ad hoc PCIs must have a systematic approach to this treatment strategy, which includes the following elements [35].

Pretreatment

Pretreatment with aspirin before PCI is essential to decrease ischemic complications. When the possibility of PCI is high, pretreatment with clopidogrel may be appropriate

before diagnostic angiography [20,31–34], although this may delay subsequent cardiac surgery if that is deemed necessary. Adequate hydration and perhaps acetylcysteine in patients with renal insufficiency are important because of the greater dye load anticipated [28].

Risk Assessment

The risks of PCI must be assessed before diagnostic angiography if ad hoc PCI is anticipated. Risk assessment requires a comprehensive assessment of the patient's history, including diagnostic studies and current laboratory findings. Several methods exist for assessing the risks of PCI based on clinical data available before diagnostic angiography [22–25].

Informed Consent

Informed consent for PCI must be obtained before patients undergo diagnostic angiography if ad hoc PCI is anticipated. Any clinical characteristics that suggest the patient may be at increased risk for complications of PCI should be identified and discussed with the patient beforehand. For some patients, this will require more than a “boilerplate” discussion by a physician's assistant and will require a face-to-face conversation with the interventionist. If a noninterventional invasive cardiologist is to perform diagnostic angiography, someone familiar with the details and techniques of PCI should discuss interventional options with the patient before the diagnostic procedure.

Laboratory Scheduling Flexibility

Cardiac catheterization laboratories and physicians must have the flexibility to delay schedules by an hour or more to accommodate unscheduled ad hoc PCIs.

Ability to Assess Intermediate Lesions in Catheterization Laboratory

Lesions of intermediate severity may be found during diagnostic catheterization. Invasive assessment to determine their hemodynamic significance may be performed by intravascular ultrasound or pressure-wire measurements of fractional flow reserve [36]. In patients with intermediate lesions and no objective evidence of ischemia, ad hoc intervention should be undertaken only if both equipment and experienced operators are available to invasively identify hemodynamically important lesions.

COST COMPARISONS OF AD HOC VERSUS SEPARATE INTERVENTION

O'Keefe et al. [6] reported in 1991 on charges associated with ad hoc versus separate PCI and found significantly lower charges with ad hoc procedures. However,

their charge data may not have accurately represented actual costs, and findings from the present era may not apply to the stent era. Adele et al. [11] found that ad hoc PCI for stented patients, but not angioplastied patients, was significantly less costly than staged procedures. Specifically, the cost of the average ad hoc stent procedure was \$8,808, but when performed separately from a diagnostic procedure, the cost combined was \$10,737. When stratified into those with stable angina, unstable angina, and postmyocardial infarction, the cost differential between separate diagnostic and stent procedures compared with ad hoc PCI was lower in the group with stenting. In contrast, the average ad hoc balloon angioplasty cost was not different from the average cost of separate diagnostic angiography and angioplasty in all groups. Adele et al. [11] concluded that there were significantly lower costs with an ad hoc strategy when stenting was used.

Professional Fees

Interventionists should make decisions about ad hoc intervention based on patient safety and preference rather than on reimbursement [37]. However, current Medicare payment policy dictates that diagnostic angiography performed on the same day as PCI is reimbursed at 50% of the usual rate. Diagnostic angiography followed by ad hoc PCI is assigned 18.2 relative value units (RVUs), whereas when performed on different days, the two procedures have a total of 21.5 RVUs, an increase of 18% (Table II). The decrement of 3.3 RVUs for ad hoc PCI supposedly represents the efficiency gained by doing only one informed consent process, one arterial access procedure, one set of diagnostic angiograms, one review of baseline angiograms, one report, and one postprocedure family discussion. This reduction of 3.3 RVUs is probably fair, considering the work saved by doing diagnostic catheterization and PCI at the same sitting. However, the opportunity to avoid this discount by staging interventions may influence physician behavior.

These issues become even more complicated when the diagnostic procedure is particularly complex. For example, the codes and RVUs for a complex diagnostic catheterization including left ventriculography, coronary angiography, vein graft angiography, arterial graft angiography, and aortography total 7.74 compared with 4.1 RVUs for a simple diagnostic procedure involving just coronary angiography (Table III). If the complex diagnostic procedure were combined with coronary stenting, the 50% discount would reduce reimbursement RVUs by 3.87, compared with a 2.05 RVUs reduction for the simple diagnostic procedure. The decrement in RVUs is greater for the complex procedure. Furthermore, this Medicare policy penalizes physicians who perform only diagnostic procedures. Such a physician is not fully re-

TABLE II. Medicare Reimbursement to Physicians for Ad Hoc Versus Separate Interventions

CPT code	Procedure	Physician work RVUs for diagnostic catheterization and coronary stenting performed on different days	Physician work RVUs for diagnostic catheterization and coronary stenting performed on same day
93510	Left heart catheterization, retrograde, from the femoral artery; percutaneous	4.33	2.165
93543	Injection procedure during cardiac catheterization; for selective left ventricular or left atrial angiography	0.29	0.145
93545	Injection procedure during cardiac catheterization; for selective coronary angiography	0.40	0.20
93555	Imaging supervision, interpretation, and report for injection procedure(s) during cardiac catheterization; ventricular angiography	0.81	0.405
93556	Imaging supervision, interpretation and report for injection procedure(s) during cardiac catheterization; selective coronary angiography	0.83	0.415
92980	Transcatheter placement of an intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel	14.84	14.84
	Total	21.5	18.17

CPT, current procedural terminology.

TABLE III. Medicare Reimbursement to Physicians for Ad Hoc Versus Separate Interventions for a Complex Diagnostic Cardiac Catheterization

CPT code	Procedure	Physician work RVUs when diagnostic catheterization and coronary stenting performed on different days	Physician work RVUs when diagnostic catheterization and coronary stenting performed on same day
93510	Left heart catheterization, retrograde, from the femoral artery; percutaneous	4.33	2.165
93543	Injection procedure during cardiac catheterization; for selective left ventricular or left atrial angiography	0.29	0.145
93545	Injection procedure during cardiac catheterization; for selective coronary angiography	0.40	0.20
93555	Imaging supervision, interpretation, and report for injection procedure(s) during cardiac catheterization; ventricular angiography	0.81	0.405
93556	Imaging supervision, interpretation, and report for injection procedure(s) during cardiac catheterization; selective coronary angiography	0.83	0.415
93539	Injection procedure during cardiac catheterization for arterial conduits (e.g., internal mammary artery)	0.40	0.20
93540	Injection procedure during cardiac catheterization for venous bypass grafts	0.43	0.215
93544	Injection procedure during cardiac catheterization for aortography	0.25	0.125
	Total	7.74	3.87

CPT, current procedural terminology.

imbursed for a diagnostic catheterization due to the 50% reduction rule, while the interventionist receives full reimbursement for doing less work than would be required by a separate intervention. This situation is another example in which current payment policy provides incentives for performing coronary intervention as a separate procedure. Considering the current equipoise between separate and ad hoc PCI, reimbursement policies should provide neither an incentive nor a penalty for either strategy.

SHOULD AD HOC INTERVENTION BE ROUTINE STRATEGY?

In 1995, Hill [15] concluded that “patient care will likely be compromised if we are forced by reimburse-

ment or other factors to make single-stage angiography and PTCA standard practice.” Hill [15] recommended that ad hoc intervention “should not be mandated, nor should physicians be penalized if they feel that further discussion with either colleagues or the patient is necessary before proceeding.” However, others argued that ad hoc intervention “should be the new standard, and every effort should be made to apply this new standard to serve patients better and reduce health care costs” [16]. Since then, published commentaries have generally been neutral, suggesting that both strategies are safe but acknowledging the lack of randomized data. It has frequently been recommended that clinical judgment be the prevailing factor to triage patients into one of these strategies.

Rozenman et al. [8] reported the results from an interventional program that had developed protocols to facil-

itate and encourage ad hoc PCI. With these protocols in place, ad hoc PCI was performed in 83% of all interventions. Shubrooks et al. [12] reported on seven institutions, in which the rate of ad hoc PCI ranged from 7% to 77% of all interventions and data from 33 hospitals in the New York State database show the rate of ad hoc PCI to vary from 7% to 86% [13]. These data highlight the continuing wide variation in the use of ad hoc PCI.

We are unaware of any formal guidelines regarding appropriateness of ad hoc versus separate PCI procedures; thus, the principles proposed by the Society for Cardiovascular Angiography and Intervention in 2000 still seem appropriate [10]. It is the responsibility of the interventionist to make certain that before ad hoc PCI is considered, full informed consent is obtained before diagnostic catheterization, the results of diagnostic catheterization do not require reevaluation of the risks and benefits of PCI because of new information, the decision for PCI does not require further consultations regarding appropriateness, and it is in the patient's best interests to proceed.

At present, there is no justification for any third-party payer to insist on ad hoc PCI as a routine strategy. First, data suggesting that ad hoc PCI reduces total costs are very limited. It would be inappropriate to base policy decisions on these limited data. Second, ad hoc PCI in some patients may increase the risk of mortality [13]. Third, survey data of ad hoc PCI identified no centers where it is performed in excess of 90% of procedures. Finally, in certain circumstances as described above, a separate PCI procedure may be appropriate to optimize the patient's care or ability to make autonomous well-informed decisions [38].

In summary, ad hoc PCI is appropriate for many patients. Laboratories should have protocols in place to ensure that patients are well informed and optimally prepared for possible intervention. However, for some patients, ad hoc intervention is not appropriate and it should not be considered standard practice by patients, physicians, or insurers.

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