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Editorial

Effect of Percutaneous Coronary Intervention on Quality of Life: A Consensus Statement from the Society for Cardiovascular Angiography and Interventions

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Percutaneous coronary intervention (PCI) decreases ischemic complications of acute coronary syndromes. The benefits of PCI in stable ischemic heart disease (SIHD) depend on its effect on quality of life (QoL), including angina, physical activity, and emotional well-being. PCI decreases angina and the need for anti-anginal medications, and increases exercise capacity and QoL, compared with baseline status and compared with medical therapy without PCI. These benefits are greater when QOL is markedly impaired by severe angina before the procedure. When considering treatment options for symptomatic SIHD, physicians should consider and provide objective data regarding QoL effects for each treatment strategy. QoL outcomes should be considered in clinical trials, appropriate use criteria, practice guidelines, and reimbursement policies for PCI.

Key words: stenting; percutaneous coronary intervention; quality of life; angina

INTRODUCTION

Patients have been treated successfully with percutaneous coronary intervention (PCI) for over 30 years. PCI decreases mortality in ST-elevation myocardial infarction (STEMI) [1–4] and reduces recurrent ischemic events (although not mortality) in patients with non-ST elevation acute coronary syndromes (NSTE-ACS) [5,6]. The benefit of PCI in STEMI and NSTE-ACS is accepted and a recent study concluded that 99% of PCI procedures performed for these clinical situations were appropriate [7]. However, the value of PCI in patients with stable ischemic heart disease (SIHD) has recently been questioned for several reasons. First, studies comparing PCI with medical therapy in patients with SIHD [8–11] demonstrate that PCI is similar but not superior to optimal medical therapy in preventing death or myocardial infarction (MI). Second, recent studies comparing PCI with medical therapy [8–11] demonstrated smaller than expected differences in angina relief, especially over several years of follow-up. Finally, exaggeration or overestimation of the alleged benefits of PCI in SIHD patients [7,12–17] may contribute to the recently reported inappropriate use of PCI [7,17].

Since PCI does not decrease the incidence of MI or death in SIHD patients, its major potential benefit may be in improving quality of life (QoL), which is worse

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TABLE I. Guidelines for PCI for Control of Symptoms

2011 ACC/AHA/SCAI PCI Guidelines to Improve Symptoms [19]

CLASS I

1. PCI to improve symptoms is beneficial in patients with 1 or more significant (≥70% diameter) coronary artery stenoses amenable to revascularization and unacceptable angina despite guideline-directed medical therapy (GDMT). (*Level of Evidence: A)*

CLASS IIa

1. PCI to improve symptoms is reasonable in patients with 1 or more significant (≥70% diameter) coronary artery stenoses and unacceptable angina for whom GDMT cannot be implemented because of medication contraindications, adverse effects, or patient preferences. (*Level of Evidence: C)*
2. PCI to improve symptoms is reasonable in patients with previous CABG, 1 or more significant (≥70% diameter) coronary artery stenoses associated with ischemia, and unacceptable angina despite GDMT. (*Level of Evidence: C)*

CLASS III: HARM

1. PCI to improve symptoms should not be performed in patients who do not meet anatomic (≥50% left main or greater than or equal to ≥70% non–left main stenosis) or physiological (e.g., abnormal fractional flow reserve) criteria for revascularization. (*Level of Evidence C)*

2010 European Society of Cardiology Guidelines on Myocardial Revascularization to Improve Symptoms [20]

CLASS I

1. Any stenosis >50% with limiting angina or angina equivalent, unresponsive to optimal medical therapy (OMT). (*Level of Evidence: A)*

CLASS IIa

1. Dyspnea/CHF and >10% left ventricular ischemia/viability supplied by >50% stenotic artery. (*Level of Evidence: B)*

CLASS III

1. No limiting symptoms with OMT. (*Level of Evidence C)*

"*Guideline-directed medical therapy (GDMT)* represents optimal medical therapy as defined by ACCF/AHA guideline recommended therapies (primarily Class I)."
"*Optimal medical therapy (OMT)* includes intensive lifestyle and pharmacological management."

in patients with SIHD compared with those without SIHD [18]. The benefits of PCI in improving QoL have been extensively studied and have influenced guidelines for performance of PCI (Table I), where QoL is clearly articulated as a primary goal and benefit of treatment [19,20]. The purpose of this article is to review the relevant literature describing the effects of PCI on QoL and recommend how QoL should be used in guiding therapeutic decisions.

METHODS OF ASSESSING QoL

Outcome metrics such as severity of angina, antianginal medication use, exercise duration, and recurrent angina after initial treatment have been used to assess QoL [21]. However, these outcomes are subject to confounding factors such as comorbid illnesses, physician practice patterns, and access to health care. For example, trials of stents often include angiographic follow-up in which target vessel revascularization may be performed in the absence of symptoms or QoL impairment. Conventional outcomes such as recurrent MI or angina relief may not accurately weight or quantify changes in QoL because they fail to take into account the patient's perception of physical, emotional, social, and psychological well-being. For example, a strategy based on medical therapy may relieve angina completely but at the cost of decreased QoL due to drug side effects or avoidance of valued activities [22]. Consequently, instruments that more comprehensively measure QoL by assessing the physical, psychological, social, and functional domains of a patient's life have been developed (Table II) [23]. These QoL measures are essential for the various medical specialties that focus on improving QoL as part of chronic disease management. In other medical specialties, studies have demonstrated that procedures can improve QoL [24–27]. Post-procedural QoL is influenced by many factors [28–31] including late procedural complications which lead to adverse clinical events (e.g., restenosis, recurrent angina, and hospitalization) [32,33].

Utilities are an additional method for assessing patients' perspectives of their health status. These scales are determined by a variety of mechanisms (e.g., time trade-off, standard gamble or questionnaires mapped to societal-based utilities). Whereas it is impractical to measure utilities for every disease state, when available they can be integrated with survival to generate quality-adjusted life years (QALYs) that are important for economic analyses [49–51]. The QALY

TABLE II. Instruments Commonly Used to Evaluate Health Status and Quality of Life (QoL) in Patients With Stable Ischemic Heart Disease

Name of instrument	Description
Disease-specific quality of life/health status instruments	
Ferrans and Powers Quality of Life Index [34]	Measures both satisfaction and importance of various aspects of life. Importance ratings are used to weight the satisfaction response in four dimensions: health and functioning, socioeconomic, psychological/spiritual, and family
McMaster Health Index Questionnaire [35]	QoL measures based on physical, social and emotional functions. Measures are based on respondent's feelings and thoughts, but does not relate these to illness.
Medical Outcomes Study Short-Form 36 (SF-36) [36]	Consists of eight scaled scores, which are the weighted sums of the questions in their section measuring vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning and mental health. RAND-36 includes same items but is scored differently.
Short-Form 12 [37,38]	Shortened version of SF-36 and has been found to correlate well with the SF-36 summary scores in various disease states including angina
Nottingham Health Profile [39]	Evaluates six dimensions of health subjectively including: physical mobility, pain, social isolation, emotional reactions, energy, and sleep as well as statements about seven areas of life that are most affected by health status. Most useful for chronic and pronounced symptoms and for detecting treatment effects.
Psychological Well-Being Index [39,40]	Composed of six dimensions divided into 22 items: anxiety, depression, positive mood, vitality or energy, self-control repertories, overall health-related perceptions of illness. Suitable for evaluating the impact of symptoms on well-being and applicable for both healthy and patient populations.
Quality of Well-Being Scale [41]	Based on the societal preferences associated with a person's level of functioning at specific point in time. Averages values across three ratings of functioning: mobility, physical activity, social activity, and across one rating of symptomatic complaints that might inhibit function.
Sickness Impact Profile (SIP) [42]	Everyday activities in 12 categories (sleep and rest, emotional behavior, body care and movement, home management, mobility, social interaction, ambulation, alertness behavior, communication, work, recreation and pastimes, and eating) are measured. Scoring can be done at the level of categories and dimensions as well as at the total SIP level.
Swedish Health-Related Quality of Life Survey [43]	Consists of 61 items that form 11 multi-item scales assessing aspects of physical, mental, social and general health
Duke Activity Status Index (DASI) [44]	A 12-item scale measuring functional status. Asks questions about common activities and correlates with peak oxygen consumption.
Disease-specific quality of life/health status instruments	27 items assessing three factors: social functioning, physical functioning and emotional functioning.
MacNew Instrument (QoL after Myocardial Infarction Instrument (QLMI) or QLMI-2) [45]	
Seattle Angina Questionnaire (SAQ) [46]	Five scales to assess dimensions of coronary artery disease: physical limitation, angina stability, angina frequency, treatment satisfaction, and disease perception. Demonstrated to be responsive to both major changes in clinical status (i.e., improvement in angina-related problems as a result of angioplasty) and smaller changes in angina-related functional status.
Myocardial Infarction Dimensional Assessment Scale [47]	Covers seven areas of health status (physical activity, insecurity, emotional reaction, dependency, diet, concerns over medications and side effects).
Physical Activity Score [48]	Evaluates one dimension in estimating physical capacity for patients with angina pectoris

is a metric utilized in outcomes research that incorporates both longevity and QoL and provides a common scale to compare different therapies. Since many medical interventions are associated with a variety of clinical outcomes, the QALY is an invaluable common metric that affords the ability to compare very different interventions.

Health status measures can be generic, in that they are applicable to heterogeneous populations with varying diseases and comorbidities, or disease-specific (i.e., explicitly designed to assess the burden of SIHD, including the symptoms of angina and its associated limitations) [52–55]. One disease-specific tool for assessing angina is the Seattle angina questionnaire (SAQ) which is a 19-item self-administered questionnaire measuring five domains affected by angina: physical limitation, anginal stability, anginal frequency, treatment satisfaction, and disease perception. It was validated against measures such as physician diagnoses, nitroglycerin refills, and exercise duration and has

subsequently been shown to be prognostic of outcome [56]. The SAQ can distinguish treatment effect from the influences of comorbid illness and is more sensitive to subtle changes in clinical condition than are generic measurement tools [46,57].

Some symptoms of active ischemic heart disease (e.g., dyspnea/breathlessness, energy/fatigue) are not well captured in the current disease-specific scales but may be important to patients [58]. The absence of these dimensions from QoL measures may lead to underestimation of the benefits of therapies for SIHD.

Outcomes After PCI in Patients Presenting With STEMI/NSTE-ACS

Studies of outcomes after STEMI/NSTE-ACS have generally focused on adverse events such as recurrent MI, recurrent ischemia, and late revascularization rather than QoL. Since these outcomes are known to affect QoL, they are briefly summarized here.

Primary PCI for STEMI has several advantages compared with fibrinolytic therapy. In pooled analyses, primary PCI is associated with reduced mortality, stroke, intracranial hemorrhage, reinfarction, and recurrent ischemia compared with fibrinolysis [2,59–62]. Analyses examining 12 month costs in terms of cost per event-free survivor found that expenditures were lower in the PCI cohorts than in the fibrinolytic-treated patients [63–66]. For STEMI, use of stents compared with balloon angioplasty is associated with early (i.e., 6 months) improvement in QoL as manifested as reduced angina frequency, less bodily pain, and improved disease perception [67].

A routine invasive strategy in patients with NSTE-ACS reduces (a) the composite risk of death or non-fatal MI [6,68] (particularly in patients with ischemic ECG changes, positive biomarkers, or advanced age), (b) severe angina [6,69], and (c) rehospitalization over the ensuing 1–2 years [6], as compared with an ischemia-guided approach. Compared with a non-invasive strategy, an invasive strategy reduces (a) duration of initial hospital stay [70,71], (b) readmission rate [71–73], (c) anginal symptoms [69,71,74], and (d) the number of required anti-anginal medications [71,74]. Studies have also demonstrated greater gains in QoL with an invasive strategy leading to PCI when appropriate compared with a strategy of medical therapy in ACS patients [74–77].

QoL After PCI in Patients With SIHD

Several types of studies have been used to evaluate the effect of PCI on QoL in SIHD patients. Observational cohort studies that compare baseline to post-PCI QoL provide the lowest quality of evidence, as they are subject to bias and placebo effect and likely exaggerate the true benefits of PCI (Table III). Observational studies that compare patients undergoing PCI to a cohort receiving medical therapy alone or coronary artery bypass graft (CABG) surgery (Table IV) provide higher quality evidence, but are still subject to bias. The highest quality evidence comes from randomized controlled studies comparing PCI to alternative treatments (Tables V and VI), although these are also subject to enrollment biases that may prevent conscription of the very patients who might benefit most, and to crossover that obscures the effects of the original treatment assignment.

Multiple studies have demonstrated that PCI improves QoL [9,10,52,54,55,58,78–86,89,93,103–110] and exercise capacity [78,79,85,86,111] compared with pre-PCI status. The magnitude of improvements in QoL correlated with improvements in outcomes following PCI [112].

Effect of PCI on QoL Compared With Medical Therapy

In studies of patients with SIHD, PCI has been more effective than medical therapy in relieving angina [8,11,87,94,97,106,113–119], reducing the use of anti-anginal drugs [117], and improving exercise capacity [8] and QoL [9,58,82,94,114] (Tables III and IV). Improved QoL with PCI compared with medical therapy (Table V) has been reported at late follow-up 5–8 years post procedure [114,118] but not at 3 years post procedure [113].

A meta-analysis of 14 randomized, controlled trials of PCI versus medical therapy in 7,818 patients enrolled from 1987–2005 showed that complete angina relief was superior with PCI (odds ratio: 1.69, 95% confidence interval: 1.24–2.30) [120] with the benefit limited to trials that enrolled patients before the year 2000. In pooled analysis of studies that enrolled patients after 2000, angina relief was similar for both therapies, which may be attributable to improved medical therapy. An alternative explanation is that the recent studies in this analysis enrolled patients with a low prevalence of significant angina at baseline. Specifically, two-thirds of patients in the Clinical Outcomes Utilizing Revascularization and Aggressive drug Evaluation trial [COURAGE] [113] had angina weekly or less frequently and 77% in the Open Artery Trial (OAT) [100] had no angina, perhaps rendering PCI—or any intervention—unlikely to improve angina symptom control. Non-randomized studies enrolling patients after 2000 with a higher prevalence of angina than COURAGE or OAT have demonstrated significantly better QoL with PCI compared with medical therapy [9,82,87,94,97,116–119].

TABLE III. Studies of Quality of Life (QoL) Post-Percutaneous Coronary Intervention (PCI) versus Pre-PCI in PCI Cohort Studies

Author date	Study design	*N* (PCI patient)	QoL Tool(s)	Angina-Free (Pre-PCI/Post/PCI)	Summary of Status Post-PCI (compared with Pre-PCI)
PCI Cohort in Single Cohort Studies (PCI only)					
Bliley, 1993 [78]	Prospective cohort of PCI patients	40	Ferrans and Powers Quality of Life Index Cardiac Version	10% pre/72% post, $P < 0.0002$ at 6 weeks	Significant improvement in all domains of QoL at 6 weeks
McKenna, 1994 [79]	Prospective cohort of PCI patients	209	General Health Questionnaire	Angina improved in 72% of patients at 1 month	QoL improved at 2 and 11 months
Permanyer-Miralda, 1999 [80]	Prospective cohort of PCI patients	106	Nottingham Health Profile (NHP), DASI	0% pre/70% post at 3 years	NHP and DASI both statistically significantly improved at 1 month and 3 years ($P < 0.01$)
Seto, 2000 [81,82]	Prospective cohort of PCI patients	1445	SF-36, SAQ	nr	QoL improved in 58–75% of patients for different domains at 6 months
Spertus, 2004 [82]	Prospective cohort of PCI patients	1020	SAQ	nr	85% had "clinically significant improvement" at 1 year
Lowe, 2004 [83]	Prospective cohort of PCI patients " not appropriate for PCI"	21	SAQ	nr	No significant improvement in any domain at 1 year
Wong, 2007 [84]	Prospective cohort of Chinese PCI patients	78	SF-36, SAQ	nr	Statistically significant improvements in 6 of 8 SF36 and 5 of 5 SAQ domains at 1 and 3 months
Grantham, 2010 [85]	Prospective cohort of PCI patients with chronic total occlusion	125	SAQ	nr	"significant improvement" in QoL at 1 month
Melberg, 2010 [86]	Prospective cohort of PCI patients	609	SF-36	nr	"Significant improvement" in nearly all domains at 6 months
De Quadros, 2011 [87]	Prospective cohort of PCI patients	110	SAQ	5% pre/68% post ($P < 0.001$) at 1 year	"Significant clinical improvement" in >70% of patients in 4 out of 5 SAQ domains at 6 and 12 months
PCI Cohort in Multi-Cohort Studies					
Brorsson, 2001 [43]	Prospective cohorts of PCI and CABG patients	349	SWED-QUAL	3% pre/51% post ($P < 0.05$) at 4 years	Statistically significant improvements in all 5 domains of SWED-QUAL at 6, 21, and 48 months
Borkon, 2002 [88]	Prospective cohorts of PCI and CABG patients	252	SAQ	nr	All domains of SAQ improved at 6 and 12 months
Kattainen, 2005 [89]	Prospective cohorts of PCI and CABG patients	183	15D	nr	QoL significantly improved versus baseline at 6 and 12 months.
Loponen, 2009 [90]	Prospective cohorts of PCI and CABG patients	229	15D	2% pre/58% post at 3 years	QoL better at 6 months but not at 3 years; angina better at 6 months and 3 years
Van Dornburg, 2010, ARTS II [91]	Prospective cohorts of PCI and CABG patients	585	SF-36	7% pre/90% post at 3 years	Significant improvement in all 8 domains of SF-36 at 6 months and 3 years
Brooks, 2010 BARI-2D [92]	Prospective cohort of PCI patients and CABG patients	796	DASI, Rand scales	17% pre/60% post	Data not available for PCI group alone

ARTS, Arterial Revascularization Therapies Study; BARI-2D, Bypass Angioplasty Revascularization Investigation—2 Diabetes; CABG, coronary artery bypass graft surgery; DASI, Duke Activity Status Index; Nr, Not reported; PCI, Percutaneous coronary intervention; SAQ, Seattle Angina Questionnaire; SF-36, Short Form 36; SWED-QUAL, Swedish Quality of Life Survey.

TABLE IV. Studies of Quality of Life (QoL) Post-Percutaneous Coronary Intervention (PCI) versus Pre-PCI in PCI Arm of Randomized Studies

Author, date, trial name	Study design	*N*	QoL tool(s)	Angina-free (Pre-PCI/Post/PCI	Summary of status post-PCI (compared with pre-PCI)
Pocock, 2000, RITA-2 [58]	Randomized to PCI versus medical therapy	504	SF-36	nr	33% rated health at 1 year as "much better"; QoL better at 3 and 12 months
Strauss 1995, ACME [8]	Single vessel coronary disease randomized to PCI versus medical therapy	105	McMaster Health Index Questionnaire	23% pre/73% post at 6 months	Angina and QoL better at 6 months
Folland, 1997, ACME [93]	Two vessel coronary disease randomized to PCI versus medical therapy	51	McMaster Health Index Questionnaire	20% pre/53% post at 6 months	Angina and QoL better at 6 months
Pitt, 1999, AVERT [10]	Randomized to PCI versus atorvastatin	177	SF-36	Angina improved in 54% at 18 months	QoL improved at 6 and 18 months
Favarato, 2007, MASS II [94]	Randomized to PCI versus medical therapy	180	SF-36	nr	QoL improved at 6 and 12 months
Weintraub, 2008, COURAGE [9] [95]	Randomized to PCI versus medical therapy	1149	RAND-36 SAQ	21% pre/59% post at 3 years	QoL score improved approx 50% at 6, 12, 24, and 36 months
Wahrborg, 1999, CABRI [96]	Multi-vessel coronary disease randomized to PCI versus CABG versus medical therapy	74	Nottingham Health Profile (NHP)	nr	All 8 NHP domains improved at 1 year ($P < 0.01$)
Zhang, 2003, SoS Trial [97]	Multivessel coronary disease randomized to PCI or CABG	488	SAQ	nr	QoL improved at 6 months and 1 year ($P < 0.01$)
Thiele, 2009 [98]	Isolated proximal left anterior descending disease randomized to PCI or CABG	65	SF 36, McNew	nr	All 8 SF-36 and all 4 McNew domains improved at 1 year, all $P < 0.01$
Cohen, 2011, SYNTAX [99]	Multi-vessel or left main coronary disease randomized to PCI or CABG	903	SF-36, SAQ	22% pre/72% post at 12 months	QoL score improved significantly from approx 45 at baseline to approx 75 at 6 and 12 months

ACME, angioplasty compared with medical therapy; AVERT, atorvastatin versus revascularization treatment; CABG, coronary artery bypass graft surgery; COURAGE, clinical outcomes utilizing revascularization and aggressive drug evaluation; CABRI, coronary angioplasty versus bypass revascularization investigation; MASS II, medicine, angioplasty, or surgery study; NHP, Nottingham health profile; NR, not reported; PCI, percutaneous coronary intervention.

The misperception that PCI improves QoL only minimally may be fueled by a misunderstanding of the COURAGE [113] and Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI-2D) [92] treatment strategies. Since these studies compared medical therapy with revascularization as initial treatment strategies, crossover from medical therapy to revascularization therapy for relief of unacceptable symptoms was frequent (33% of patients in COURAGE and 42% of patients in BARI-2D). Because higher than anticipated crossover rates in clinical trials reduces the ability to detect differences in the treatment groups this may have obscured long-term differences in symptoms between the initial treatment assignment to PCI or medical therapy [92,113].

The writing group could find only two studies failing to show a benefit of PCI on QoL. Patients randomized to PCI versus exercise training reported similar improvements in angina [105]. In patients deemed unsuitable for any revascularization, salvage PCI did not improve QoL but slightly improved angina status compared with baseline [83].

Effect of PCI on QoL Compared With CABG

Many studies have compared PCI with CABG for angina control and QoL improvement (Table VI). Both procedures improve angina and QoL compared with baseline [88,91,94,96,97,99,121,122]. QoL is better after PCI than after CABG in the first months after the

TABLE V. Studies of Quality of Life (QoL) After Percutaneous Coronary Intervention (PCI) Compared With Medical Therapy

Author, date, trial name	Study design	*N*, (PCI/medical therapy)	QoL tool(s)	Angina-free (post-PCI/post medical therapy (MT)	Summary of status post-PCI (compared with Post MT)
Pitt, 1999, AVERT [10]	Randomized to PCI versus atorvastatin	177/164	SF36	nr	QoL similar at 6 and 18 months for PCI and MT. Both groups improved from baseline
Pocock, 2000, RITA-2 [77]	Randomized to PCI versus MT	504 /514	SF-36	65% PCI/ 47% MT ($P < 0.05$) at 1 year	QoL better than MT for PCI at 3 months and 1 year but not at 3 years.
Strauss, 1995, ACME [8]	Randomized to PCI versus MT for 1-vessel disease	105 /107	McMaster Health Index Questionnaire	nr	QoL scores better in PCI than in MT at 6-month
Folland, 1997, ACME [93]	Randomized to PCI versus MT for 2-vessel disease [93]	51 /50	McMaster Health Index Questionnaire	53% PCI/36% MT ($P = 0.09$) at 6 months	QoL similar for PCI and MT at 6 months.
Favarato, 2007, MASS II [94]	Randomized to PCI versus MT	180 /187	SF-36	nr	QoL better for PCI than MT at 12 months
Weintraub, 2008; Zhang, 2011, COURAGE [9] [95]	Randomized to PCI versus MT	1149 /1138	RAND-36 SAQ	53% PCI versus 42% MT ($P < 0.001$) at 3 months	Both groups improved from baseline. QoL better for PCI than MT at 3 and 6 months but similar at 12 months
Mark, 2009, OAT [100]	Post MI occluded infarct vessel randomized to PCI versus MT	1082 /1084	DASI SF-36	93% PCI / 88% MT ($P = 0.03$) at 24 months	QoL better with PCI at 6 months but not at 12 or 24 months by DASI; no difference by SF-36 at 6, 12, or 24 months

ACME, angioplasty compared with medical therapy; AVERT, atorvastatin versus revascularization treatment; BMS, bare metal stents; CABG, coronary artery bypass graft surgery; COURAGE, clinical outcomes utilizing revascularization and aggressive drug evaluation; DASI, duke activity status Index; DES, drug eluting stents; MASS, medicine, angioplasty, or surgery study; MI, myocardial infarction; nr, not reported; NHP, Nottingham health profile; PCI, percutaneous coronary intervention; OAT, occluded artery trial; PTCA, percutaneous transluminal coronary angioplasty; QoL, quality of life; RITA, randomized intervention treatment of Angina; SAQ, Seattle angina questionnaire; SF, short form. TIME, trial of invasive versus medical therapy in elderly patients with chronic symptomatic coronary artery disease.

procedure [88,90,99,109,123–126]. Return to work occurs earlier with PCI-treated patients compared with CABG, but at 3–5 months the rate is similar [40,124,127].

Fewer patients reported angina at 1 year follow-up with CABG compared with PCI in a collaborative analysis of data from 6,528 patients enrolled in 10 randomized trials of CABG versus PCI (14% versus 26%, $P < 0.001$) [128]. A systematic review of 23 randomized studies of CABG versus PCI reported that angina relief at 1, 3, and 5 years was better for CABG than PCI [129]; at 5 years the incidence of freedom from angina was 84% for CABG and 79% for PCI ($P < 0.001$). Most but not all observational studies document better angina relief and QoL with CABG at 6 months to 4 years of follow-up when compared with PCI [52,90,117,126,130].

Drug eluting stents (DES) compared with historic CABG controls were associated with better QoL at 1 year and similar QoL at 3 year follow-up [91]. The SYNergy Between PCI with TAXus and Cardiac Surgery (SYNTAX) trial demonstrated a small but significant reduction in angina frequency with CABG compared with DES at 6 and 12 months in patients who had frequent (i.e., daily or weekly) angina at baseline, but not in those with less frequent symptoms [99].

With long-term follow-up (e.g., >5 years), differences in angina-free status between PCI and CABG tend to decrease due to return of angina in CABG patients and cross-over to CABG in patients initially treated with PCI [102,131]. Findings during long-term follow-up stem, in part, from the fact that stent failure tends to occur over months, while vein graft attrition and related symptoms onset over years.

In patients with left main or single vessel proximal left anterior descending artery disease, PCI (compared with CABG) produced similar QoL at 6–12 months [98,132–134] but more frequent angina at 5 years [11].

TABLE VI. Selected Studies of Quality of Life (QoL) After Percutaneous Coronary Intervention (PCI) Compared With Coronary Artery Bypass Surgery (CABG)

Author, date, trial name	Study design	*N* (PCI/CABG)	QoL tool(s)	Angina-free (post-CABG/Post PCI)	Summary of status post-PCI (compared with Post-CABG)
Brorsson 2001, Sweden [52]	Cohort with chronic stable angina and 1- or 2-vessel disease	252/349	SWED-QUAL	57% CABG/51% post PCI at 4 years	QoL better with CABG at 6 months but similar at 4 years on all scales.
Brorsson, 2002, Sweden [101]	Cohort with chronic stable angina	256/757	SWED-QUAL		QoL better with CABG at 6 and 21 months ($P < 0.05$) in 4 of 5 domains
Pocock, 1996, RITA [55]	Randomized to PCI versus CABG	510/501	NHP	78% CABG/ 69% PCI (($P = 0.007$) at 2 years	QoL borderline significantly better for CABG than PCI at 6 months and 2 years
Wahrborg, 1999, CABRI [96]	Multivessel CAD randomized to PCI or CABG or medical therapy	74/80	NHP	nr	QoL similar for PCI and CABG at 1 year
Borkon, 2002 [88]	Cohort undergoing PCI or CABG	252 /223	SAQ	nr	Angina frequency and QoL better for CABG than PCI at 6 and 12 months
Zhang, 2003, SoS Trial [97]	Multivessel CAD randomized to PCI versus CABG	488 /500	SAQ	nr	Angina frequency and QoL better with CABG at 6- and 12-months.
Favarato, 2007, MASS II [94]	Multi-vessel coronary disease randomized to PCI or CABG or medical therapy	180/175	SF-36	nr	QoL for CABG better than PCI at 1 year. QOL for CABG and PCI better than with medical therapy at 1 year
Hlatky, 2004, BARI [102]	Multi-vessel coronary disease randomized to PCI versus CABG versus medical therapy	465/ 469	DASI and Rand Mental Health Inventory 5 Scale	nr	QoL better for CABG than PCI through 3 years but similar from 3–10 years
Thiele, 2009 [98]	Isolated proximal left anterior descending disease randomized to PCI versus CABG	65/65	SF 36, McNew	CABG 74% /PCI 81% ($P = 0.05$) at 12 months	QOL similar for PCI and CABG
Van Dornburg, 2010, ARTS II [91]	DES cohort (compared with historical controls randomized to BMS versus CABG)	583 = (DES) 483 = (BMS) 492 = (CABG)	SF-36	CABG 87.0%/ PCI with DES 90.0% / 80% PCI with BMS at 12 months	QoL better after DES than CABG up to 1 year and similar at 3 years
Cohen, 2011, SYNTAX [99]	Multi-vessel or left main coronary disease randomized to PCI versus CABG [99]	903 /897	SF-36 SAQ	Similar at 1 and 6 months; CABG 76% versus PCI 72%, $P = 0.05$ at 1 year	QoL better for PCI at 1 month and worse for PCI at 12 months compared with CABG

ACME, angioplasty compared with medical therapy; ARTS, arterial revascularization therapies study; BARI, bypass angioplasty revascularization investigation; BMS, bare metal stents; CABG, coronary artery bypass graft surgery; CABRI, Coronary Angioplasty versus Bypass Revascularization Investigation; CAD, coronary artery disease; COURAGE, clinical outcomes utilizing revascularization and aggressive drug evaluation; DASI, duke activity status index; DES, drug eluting stents; NHP, Nottingham health profile; NS, not significant; OAT, occluded artery trial; PCI, percutaneous coronary intervention; PTCA, percutaneous transluminal coronary angioplasty; QoL, quality of life; RITA, randomized interventions treatment of angina; SAQ, Seattle angina questionnaire; SF, short form, SoS, stent or surgery; SYNTAX, SYnergy between PCI with TAXUS and CABG.

QoL After PCI in Specific Patient Subsets

Gender. QoL is better in men who undergo revascularization for CAD as compared with similarly treated women [87,92,94,117,135,136]. This finding is due in part to the facts that men report better QoL at baseline compared with women, and baseline QoL is a strong predictor of post-revascularization QoL. Another contributing factor is that women have more recurrent angina after PCI than men [137,138].

Elderly. Elderly patients with symptomatic CAD have improved QoL with PCI and derive a similar or greater improvement than younger patients, despite having a higher risk profile at presentation [81,82,85,104,108 139–141]. Neither of the age-specific

subgroups in the SYNTAX trial (<75-year old versus >75-year old) had differences between PCI and CABG in the SAQ angina frequency subscale at 6 or 12 months; there was no interaction between age and angina status. [99].

Diabetes. The BARI 2D trial showed improvement in angina with PCI compared with medical therapy, but otherwise similar QoL measurements [92,115]. The SYNTAX trial did not demonstrate significant differences in QoL scores for CABG versus PCI-treated diabetic patients [99].

Prior CABG. In a retrospective study of patients with recurrent ischemia following CABG, PCI of the native vessel or bypass graft significantly improved angina compared with baseline [142].

Other Subgroups. Data regarding QoL after PCI in patients with chronic kidney disease or congestive heart failure is lacking.

Factors Affecting QoL After PCI

Not all patients who undergo PCI experience improved QoL [8,55,107,143]. Post-PCI QoL is affected by several factors (Table VII).

Increased frequency of angina and greater extent of myocardial ischemia at baseline correlate with greater improvements in QoL after PCI [9,82,85,96,99,145,15], as do post-PCI freedom from angina [55,80,89,152 158,159] and freedom from repeat revascularization post-PCI [153]. However, patients attach limited importance to repeat PCI for restenosis [160]. A time trade-off study demonstrated that patients would be willing to sacrifice less than a week of life out of an expected 10-year life span to avoid an episode of restenosis [161].

In randomized trials, cardiac rehabilitation reduces hospital readmission and clinical event rates and improves QoL after PCI [146,147]. Non-smoking status after PCI correlated with better QoL compared with smoking [92,144,146] and patients that quit have better health status outcomes than those that continue smoking [144,150]. Co-morbidities (e.g., depression, congestive heart failure, increasing body mass index and neuropathy) [54,80,92,162], lower socioeconomic status [153], and unemployed status [55,154] after PCI correlate with lower QoL.

Sexual activity is a component of QoL [155]. Sexual dysfunction is more prevalent in patients with SIHD [163], but it is unclear whether it is improved by PCI [164]. Patients with erectile dysfunction may be unable to take phosphodiesterase inhibitors (e.g., sildenafil) because they have angina treated with long-acting nitrates or sub-lingual nitroglycerine. PCI that removes the need for nitrates and allows use of phosphodiesterase inhibitors to treat erectile dysfunction might improve sexual functioning and QoL in selected patients [165].

Ethical Principles in Decisions Regarding Therapy and QoL

The fundamental principles of medical ethics are beneficence ("do good, avoid harm"), autonomy, and distributive justice [166]. The first two are most relevant to PCI and QoL. Beneficence represents the duty of the physician to provide care that produces the greatest benefit to the patient. Autonomy describes the physician's responsibility to help the patient make informed decisions. These principles should influence how physicians conduct informed consent discussions and advise patients about preferred therapies [167].

Informed Consent. The physician has the responsibility for presenting treatment options and the pros and cons of each alternative [167]. This may require inquiry into the patient's values to identify important preferences. The physician should discuss the likelihood of survival, MI, stroke, repeat revascularization procedures, and QoL associated with the treatment options. This discussion should be personalized for each patient to include anticipated risks and benefits. For many patients, the treatment options carry similar risks of death and MI and therefore QoL assumes relatively greater importance. In these cases, physicians should explain that for some but not all patients QoL is most improved by PCI or CABG in the most symptomatic patients, and least improved with revascularization in patients who are asymptomatic or only mildly symptomatic.

Advising Patients on Choice of Strategy. For most patients, survival dictates the choice of treatment strategy. When survival is similar among various strategies, patients usually base decisions on their perceptions of how each strategy affects QoL.

Given a choice, most patients prefer a strategy that is easier in the short-term (e.g., PCI) over a strategy that is more complicated in the short-term (e.g., CABG), even when the more complicated strategy produces better long-term results (e.g., less angina or better QoL). Since most patients make these value judgments—so called temporal discounting—without this understanding [168], the physician should make patients aware of the trade-offs they are considering.

Cardiologists face several challenges to their objectivity when making treatment recommendations. First, patients and physicians frequently over-estimate the benefit of revascularization procedures compared with noninvasive medical therapies [12,13–15,169]. Second, physicians express more regret about adverse

TABLE VII. Studies Identifying Predictors of Post-Percutaneous Coronary Intervention (PCI) Quality of Life (QoL)

			Factors Correlating with Poor Post-PCI Quality of Life		
Author, date, reference	Population	*N*	Baseline poor health status	Other factors	Improvement in QoL correlates with severity of baseline angina
McKenna, 1994 [79]	Post-PCI	209	nr	Restenosis/ revascularization	nr
Nash, 1999 [54]	Post-PCI	1182	+	Prior CABG, elderly	nr
Permanyer-Miralda, 1999 [80]	Post-PCI	106	+	Post-PCI angina, dyspnea, restenosis/ revascularization	nr
Taira, 2000 [145]	Post-PCI	1432	nr	Continued smoking post-PCI	nr
Bourassa, 2000 [146]	Post PCI or CABG in BARI Trial	1095	nr	nr	+
Belardinelli, 2001 [147]	Post-PCI	118	nr	Randomization to no exercise training	nr
Rumsfeld, 2001 [127]	Post-PCI or CABG	389	+	COPD, CKD, diabetes, current smoker	nr
Higgins, 2001 [148]	Post-PCI	99	nr	Randomization to no cardiac rehab	nr
Brorsson, 2001 [149]	Post-PCI or CABG	601	nr	Female, heart failure	nr
Jamieson, 2002 [150]	Post-PCI or CABG	301	+	Female elderly	nr
Borkon, 2002 [88]	Post-PCI	252	nr	Restenosis/ revascularization	nr
Haddock, 2003 [151]	Post-PCI	271	nr	Current smoker	nr
Zhang, 2003 [97]	Post-PCI	488	nr	Restenosis/ revascularization	nr
Zhang, 2004 [136]	Post-PCI in SOS Trial	388	nr	Female	nr
Hlatky, 2004 [152]	Post-PCI or CABG in BARI Trial	934	nr	nr	+
Spertus, 2004 [82]	Post-PCI	1518	+	Age	+
Spertus, 2005 [153]	Post-PCI	1027	nr	High risk for restenosis	nr
Denvir, 2006; Leslie, 2007 [154,155]	Post-PCI	1346	nr	Low socioeconomic status, unemployment	nr
Hofer, 2006 [124]	Post-PCI	432	nr	Depression, anxiety	nr
Favarato, 2007 [94]	Post-PCI	180	nr	Female	nr
Weintraub, 2008 [9]	Post-PCI in COURAGE	1149	nr	nr	+
Kriston, 2010 [156]	Post-PCI or CABG	493	nr	Sexual dysfunction, depression	nr
Grantham, 2010 [85]	Post-PCI	125	nr	nr	+
Brooks, 2010 [92]	Post-PCI or CABG in BARI-2D Trial	2368	nr	Female, elderly, angina, smoking, heart failure	nr
Rittger, 2011 [157]	Post-PCI	95	nr	Elderly	nr
De Quadros, 2011 [87]	Post-PCI	110	+	nr	+

BARI, bypass angioplasty revascularization investigation; BARI-2D, bypass angioplasty revascularization investigation—2 diabetes Trial; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; COURAGE, Clinical outcomes utilizing revascularization and aggressive drug evaluation trial; nr, not reported; PCI, percutaneous coronary intervention; QoL, quality of life; SoS, stent or surgery trial.

outcomes associated with inaction (not performing PCI) than complications associated with performing PCI (the ''chagrin factor'') [170] even though the outcome may be the same (i.e., death of the patient). Third, the reimbursement model for United States health care incentivizes performance of procedures. Therefore, the physician must accurately advise the patient about the pros and cons of each treatment alternative and help the patient arrive at the treatment decision most consistent with the patient's values and preferences [128].

CONCLUSIONS AND RECOMMENDATIONS

1. While the overiding goal in performing PCI in patients with STEMI and NSTE-ACS is to reduce morbidity and mortality, appropriate early cardiac catheterization and PCI is associated with improved QoL in patients without serious comorbidities.
2. PCI for treatment of SIHD improves QoL and angina, compared with baseline, and compared with medical therapy, with the following limitations:

   a. QoL improvement after PCI is proportional to the severity of angina before PCI and adequacy of revascularization.
   b. Some co-morbidities limit QoL before and after PCI and may minimize any improvement in QoL resulting from PCI.
   c. QoL benefits of PCI over medical therapy decrease over time due to cross-over from medical therapy to PCI, the efficacy of optimal medical therapy, and restenosis or progression of atherosclerosis.
3. QoL after PCI compared with CABG is better in the short-term (months), worse in the intermediate term (1–5 years), and probably similar in the long-term (>5 years) due to bypass graft failure, progression of atherosclerosis in native vessels, and cross-over from PCI to CABG.
4. Many SIHD patients and physicians tend to overestimate the benefits of revascularization procedures and underestimate the safety and effectiveness of medical therapy.
5. When there is equipoise in the risks/benefits of medical therapy compared with PCI, the preferences of the fully informed patient should play a major role in treatment decisions.
6. Policymakers should consider QoL issues and allow for patient preferences when developing clinical trials, appropriate use criteria, practice guidelines, and reimbursement policies for PCI.
7. The importance of QoL issues should be considered in all aspects of PCI care from the physician's initial assessment of potential benefit through the public reporting of results.
8. Additional research is needed to accomplish the following:
   a. Prospectively document the baseline and follow-up QoL in SIHD patients treated with medical therapy alone versus medical therapy with PCI versus medical therapy with CABG, including specific subgroups such as women, diabetics, the elderly, and those with chronic kidney disease, heart failure, or prior CABG.
   b. Identify subgroups of SIHD patients for whom PCI is particularly effective in improving QoL (e.g., patients with QoL limited only by severe angina) and for whom PCI is relatively *ineffective* in improving QoL (e.g., patients with minimal angina or with baseline poor QoL due to multiple intractable co-morbidities). Build prediction models of health status outcomes that could better inform patients and physicians of likely outcomes of medical therapy, PCI, and CABG.
   c. Identify optimal methods of educating patients and physicians about expected outcomes of different treatment options and integrate optimal education methods into routine informed consent processes.

New innovations in revascularization and medical therapy will require ongoing reassessment of QoL after PCI. For example, most of the studies cited here did not use DES; reductions in restenosis due to DES may further improve QoL post-PCI. Additional insights into post-PCI QoL are expected from the proposed International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) Trial randomizing 8,000 patients with moderate ischemia on stress testing to catheterization and revascularization versus optimal medical therapy.

In summary, PCI decreases mortality and ischemic events and improves QoL in patients with STEMI and NSTE-ACS. In SIHD patients, PCI may improve symptoms and QoL, with the greatest benefits in patients with few co-morbidities, severe angina, and potential for complete revascularization. SIHD patients with severe co-morbidities or minimal ischemic symptoms benefit minimally from PCI. For many SIHD patients, an initial treatment strategy of PCI is superior to medical therapy in improving QoL in the short-term. QoL differences between PCI versus CABG vary as time elapses after the procedure. QoL differences among these treatment strategies are small enough and individual patients' responses to treatment are variable enough that patient preferences must be considered in choosing treatment strategies for SIHD.

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