Comparison of Quality-of-Life Measures after Radial versus Femoral Artery Access for Cardiac Catheterization in Women: Results of the SAFE-PCI for Women Quality-of-Life Substudy

Short title: Hess et al.: QOL in SAFE-PCI for Women

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Abstract

Background: In the SAFE-PCI for Women trial, patient preference for radial access for future procedures was greater than for femoral access. We sought to assess whether radial or femoral access impacts formal measures of quality-of-life (QOL) among women undergoing cardiac catheterization.

Methods: We assessed QOL using European Quality of Life-5 Dimensions (EQ-5D) and EQ-Visual Analogue Scale (EQ-VAS) scores among 304 women randomized to radial or femoral arteriotomy in the SAFE-PCI for Women trial at sites with QOL substudy approval. Patient surveys were administered at baseline, hospital discharge, and 30-days (for PCI patients).

Results: Women randomized to both treatments had similar EQ-5D index and EQ-VAS scores at baseline, hospital discharge, and 30-day follow-up. After adjustment for baseline scores, there was no effect of assigned treatment on EQ-5D (discharge 0.004, 95% CI -0.03, 0.04; 30-day -0.03, 95% CI -0.09, 0.02) or EQ-VAS (discharge -1.31, 95% CI -4.74, 2.12; 30-day -2.10, 95% CI -8.92, 4.71) scores. At discharge, 60.5% versus 63.5% (p=0.60) of patients in radial and femoral groups were free from access site pain; at 30-days, rates were 85.7% versus 77.6% (p=0.30), respectively. Patient preference for the same access strategy for repeat procedures was greater in the radial versus femoral group (77.2% vs. 26.8%, p<0.0001).

Conclusions: Using established QOL instruments, we did not measure any difference in QOL or functional status according to access site strategy in women undergoing cardiac catheterization, yet patient preference for the radial approach was significantly greater. Other factors influencing patient choice for radial access should be investigated.

Clinical trial registration: NCT01406236 (http://clinicaltrials.gov/ct2/show/NCT01406236)

Key words: catheterization, angiography, trials, women

Bleeding is the most common complication of percutaneous coronary intervention (PCI),[1,2] and women are at higher risk than men for post-PCI bleeding and vascular complications.[3-5] Radial artery access for PCI has been shown to significantly decrease bleeding and access site complications compared with the femoral approach,[6-8] yet despite their higher bleeding risk, women are less likely than men to undergo radial PCI.[7,9] This is perhaps related to the fact that women have smaller radial arteries that may be more prone to spasm, potentially resulting in procedural failure and offsetting the benefit of the radial approach with respect to bleeding.

The Study of Access Site for Enhancement of Percutaneous Coronary Intervention for Women (SAFE-PCI for Women) was a multi-center, prospective randomized trial assessing the efficacy and feasibility of radial versus femoral PCI in women.[10] In the SAFE-PCI for Women trial, which was stopped early due to low event rates without concern for safety, there was no significant difference in the primary efficacy endpoint (post-procedure Bleeding Academic Research Consortium Types 2, 3, or 5 bleeding or vascular complications requiring intervention) according to access site among women undergoing PCI, but radial access did significantly reduce bleeding or vascular complications in the total cohort of women undergoing cardiac catheterization or PCI. Rates of access site crossover for procedure completion (primary feasibility endpoint) were higher for women assigned to radial versus femoral artery access. Interestingly, more women preferred radial access for their next procedure. Whether these variable outcomes between access site strategies affects formal measures of health status and quality-of-life (QOL), which may be important considerations in patient preference for access strategy, have not been well-studied, particularly among women. To explore the effect of radial

versus femoral artery access on QOL in women undergoing cardiac catheterization, we performed a prospective substudy as part of the SAFE-PCI for Women trial.

Methods

Study design and oversight

The design of the SAFE-PCI for Women trial has been previously described.[11,12] Briefly, women undergoing diagnostic angiography to evaluate ischemic symptoms with the possibility of PCI (excluding ST-segment elevation myocardial infarction) or those undergoing planned elective PCI were eligible for enrollment. Use of specific antithrombotic agents was not mandated, though unfractionated heparin (minimum 40 units/kg, maximum dose 5000 units) was recommended for diagnostic angiography in patients assigned to radial access, and bivalirudin was recommended for all PCI procedures. The planned sample size was 3,000 enrolled women, but the trial was stopped early at the recommendation of an independent data and safety monitoring board for low event rates without any safety concern. After obtaining written informed consent, a total of 1,787 women at 60 sites in the United States were randomized to radial or femoral access, 38.7% (n=691) of whom underwent PCI. A prospective quality-of-life substudy was planned among 300 patients enrolled in the trial. The main trial protocol was modified and re-presented for approval by the institutional review board at each participating site. After approval of the modified protocol and QOL substudy, all patients at approved sites were approached and included if they provided consent for participation in the QOL substudy.

The trial was funded collaboratively by multiple partners, including Terumo Medical, Abbott Cardiovascular Systems, Medtronic Vascular, The Medicines Company, Lilly USA, Guerbet, ACIST Medical Systems, and the Duke Clinical Research Institute. The Food and Drug

Administration Office of Women's Health provided funding for the QOL substudy. The National Cardiovascular Research Infrastructure was funded by the National Heart, Lung, and Blood Institute (grant #1RC2HL101512-01). The Duke Clinical Research Institute served as the data coordinating center. The sponsors had no role in the design, analysis, or interpretation of the main study or QOL substudy. The authors are solely responsible for the design and conduct of this study, the drafting and editing of the manuscript, and its final contents.

Measurements of health status

We examined patient health status including QOL, symptoms, and functional capacity, at baseline (prior to cardiac catheterization) and at hospital discharge for all substudy patients and at 30-day follow-up for substudy patients who underwent PCI. Health status was assessed directly from patients using the European Quality of Life-5 Dimensions (EQ-5D) instrument, which includes five items addressing mobility, self-care, usual activities, pain or discomfort, and anxiety or depression.[13,14] For this study, three levels of responses were used. Individual domain scores were then summed into an index score relevant to the United States population using utility weights.[15] Utility weights represent preferences for a person's health state on a scale of -0.109 to 1 (the lowest score representing the worse possible health state, e.g. death; 1 representing the ideal health state). A patient's self-rated health was also quantified using the EQ visual analogue scale (EQ-VAS), a vertical scale with endpoints of "best imaginable health state" and "worst imaginable health state." Finally, we assessed patient preference for access site for future procedures and adapted questions from a prior study of vascular access to assess for differences in functional status and pain related specifically to the cardiac catheterization access site.[16] Site coordinators were provided instructions regarding administration of the questionnaire,

and questionnaires were filled out in person at baseline and at time of discharge from the hospitalization. As part of the SAFE-PCI for Women protocol, only patients undergoing PCI were scheduled to return for a follow-up visit at 30-days; therefore, QOL questionnaires were administered during these visits to PCI patients participating in the QOL substudy.

Statistical analysis

Baseline characteristics were compared between access site groups using the Chi-square test for categorical variables and the Wilcoxon test for continuous variables. Summary scores and individual domains for the EQ-5D and vascular access-specific tool were reported according to randomized access site and compared using Chi-square or Wilcoxon tests, where appropriate, with a p-value of <0.05 for statistical significance. Analyses were based on the intention-to-treat principle. No imputation was performed for missing data, and complete-case analyses were performed using all available data. Results of vascular access-specific questions were summarized as follows: patients were counted in the most severe category of pain/difficulty reported for either side (right or left) of the extremity in question (e.g., a patient reporting severe right hand pain, moderate left hand pain, mild right groin pain, and moderate left groin pain would be considered to have severe hand pain and moderate groin pain). Primary endpoints for our study were the summary EQ-5D United States preference-weighted index and visual analogue scale scores. Secondary endpoints included vascular access-specific responses. The primary analysis was performed using a standard linear regression model with a covariate for the randomization group, and the treatment effect was summarized using a point estimate and 95% confidence interval (CI) for the difference between treatment strategies. A sensitivity analysis was conducted according to actual treatment received. Generally, a difference of approximately

0.07 points in the summary index score for the EQ-5D instrument is considered clinically meaningful.[17] Assuming a common standard deviation of 0.20 points, a sample size of 300 patients (150 per treatment group) was calculated to provide 85% power to detect a clinically important difference of 0.07 points in the EQ-5D summary score.

Results

Study population

Between September 2011 and July 2013, a total of 1,787 women were randomized in SAFE-PCI for Women; of these, 17.0% (n=304) were included in the QOL substudy from December 2012 to July 2013. Among the 304 QOL participants, 33.9% (n=103) underwent PCI; by trial design, only PCI patients were subsequently seen for 30-day follow-up and administered the QOL questionnaire at that time (Figure 1). Although patients in the substudy were generally representative of the overall trial population (Table I), there were greater proportions of patients with a history of smoking or diabetes and presentation with stable coronary artery disease in the QOL population. Among patients in the QOL substudy, characteristics were well balanced between the radial versus femoral access treatment groups.

Quality of life outcomes

Table II shows individual components of the EQ-5D instrument according to access site. At discharge, more women undergoing femoral artery access had difficulty walking, while more women undergoing radial artery access had difficulty with self-care, though neither comparison was statistically significant. Primary QOL endpoints, including the summary EQ-5D index score, according to the assigned treatment group are shown in Table III. The EQ-5D United States

preference-weighted index scores for women randomized to radial versus femoral access were similar at baseline, hospital discharge, and 30-day follow-up. After adjusting for baseline EQ-5D scores, there was no significant effect of randomized catheterization access site on EQ-5D score (Figure 2A). EQ-VAS scores at each time point were also similar between radial and femoral groups (Table II). After accounting for baseline EQ-VAS score, we found no significant effect of assigned treatment group on EQ-VAS scores (Figure 2B). Analyses were repeated according to actual treatment received (radial or femoral, Figures 2A and 2B), site radial volume (≤50, 51–100, 101–150, >150 cases, data not shown), and age (≤65 or >65 years old, data not shown) with similar results for both EQ-5D and EQ-VAS scores.

Vascular access-specific outcomes

Secondary endpoints pertaining to vascular access site were assessed according to treatment group. As shown in Figure 3A, rates of freedom from access site pain at hospital discharge for radial versus femoral groups were 60.5% (n=75) versus 63.6% (n=84, p=0.60). Other measures of discomfort and functional status assessed at hospital discharge were also similar between treatment groups, with the exception of greater difficulty using one's hand for routine activities among patients in the radial group. Patient satisfaction with the procedural approach was high with both approaches. At 30 days, rates of freedom from access site pain for patients assigned to radial versus femoral increased to 85.7% (n=42) versus 77.6% (n=38, p=0.30). Again, there was no significant effect of assigned treatment on any of the 30-day secondary endpoints (Figure 3B). When asked about access site preference for a repeat procedure during their 30-day follow-up, 77.2% (n=44) of patients assigned to radial preferred the radial

approach, while 26.8% (n=15, p<0.0001) of patients assigned to femoral preferred femoral access.

Discussion

The SAFE-PCI for Women trial randomized women eligible for PCI to radial versus femoral artery access and found no difference in the primary endpoint of bleeding or vascular complications requiring interventions among women undergoing PCI. In this pre-specified QOL substudy, we found that arterial access site did not affect established measures of QOL by hospital discharge or 30-days post-procedure. We also were unable to measure a significant benefit of radial over femoral access for improved post-procedure pain or functional status. However, patient preference for the same access strategy for repeat procedures was significantly greater among patients assigned to radial compared with femoral treatment, a finding consistent with the main SAFE-PCI for Women study, despite differences in the incidence of diabetes, smoking, and acute clinical presentations among the QOL cohort. These data suggest that in contemporary practice, patient preference for the radial approach among women undergoing cardiac catheterization appears to be based on factors other than those captured by established QOL instruments.

Data examining the potential impact of radial artery access on QOL are limited. Compared with the femoral approach, post-catheterization functional status and QOL might be expected to be better after radial artery access, due to the associated reductions in bleeding/vascular complications and the elimination of post-procedural bed rest. In support of this hypothesis, some studies have reported patient preference for the radial over femoral approach.[16,18] To date, only one randomized trial comparing the two approaches has assessed

QOL as the primary outcome using formal instruments. In their single-center trial, Cooper et al. randomized 200 patients undergoing diagnostic cardiac catheterization, 69% of whom were male, to radial or femoral access.[16] They found that measures of bodily pain, walking ability, and QOL were better in the radial group at 1 day and 1 week post-procedure. Importantly, this trial was performed in an era where femoral bleeding complications were higher than in the contemporary era. A more recent substudy of 103 Polish patients presenting with ST-segment elevation myocardial infarction randomized to radial versus femoral access found that QOL was significantly better in the radial arm.[19] Whether similar results from these studies apply to women, who are at higher risk for bleeding and vascular complications, has not been previously studied. On the one hand, reductions in bleeding and vascular complications in this high-risk population may favor the radial approach, while on the other hand, greater risk of radial artery occlusion and smaller radial arteries that are more prone to spasm might result in greater endothelial damage and perhaps more residual discomfort.[20,21] In addition, there may be sex-specific differences in patient perception of what constitutes a meaningful and important outcome after cardiac catheterization and what factors may contribute to these outcomes. Therefore, we took advantage of this unique prospective opportunity to examine the effect of radial versus femoral access on patient-centered outcomes in SAFE-PCI for Women.

In our study, we were unable to measure a difference in post-procedural QOL according to access site strategy. Several explanations related to study design might account for these results, which differ from those from prior studies.[16,19] Cooper et al. studied 1-day and 1-week outcomes among patients at their institution undergoing diagnostic angiography only, and radial procedures were performed preferentially in the non-dominant arm using 5 and 6 French, 23 cm-long arterial sheaths. In contrast, SAFE-PCI for Women included 60 sites and studied patients

undergoing both diagnostic and PCI procedures, the latter of which is associated with higher risk for bleeding and complications and also longer procedure time. In SAFE-PCI for Women, there were no recommendations against performing procedures in the dominant hand, and in modern-day practice, short 6 French sheaths are common, and use of the right radial artery is preferred for operator convenience.[22] Patients undergoing catheterization through the dominant versus non-dominant wrist may be more likely to notice discomfort and loss of function. Furthermore, we examined longer-term outcomes at 30-days, though interpretation of these results is limited by small sample size.

An important difference is that both previous trials reporting significant improvement in post-procedure QOL after radial versus femoral access studied mixed male and female populations, whereas our study population was all female. We found that women undergoing radial artery access reported more significant impairment of the accessed limb at discharge than women undergoing the femoral approach. Some of this may have reflected strict post-radial procedure instructions to refrain from using the accessed arm for 24 hours rather than true "impairment." However, women have smaller radial arteries and may have more residual pain after a radial procedure perhaps due to spasm and endothelial damage. Despite the reported increase in post-procedure impairment, more women preferred radial over femoral access for the next procedure. This perceived benefit of radial artery access in women suggests that an opportunity exists to design a better QOL questionnaire for cardiac catheterization/PCI and that established QOL surveys used in these studies, which may adequately capture important effects of radial access for men, may not identify factors perceived to be meaningful by women.

Rapid advances in cardiac catheterization and PCI technique, equipment, and concomitant medications may have also contributed to the lack of demonstrable benefit of access

strategy for QOL in SAFE-PCI for Women. Compared with the 1990s, when Cooper et al. performed their study, developments in catheterization equipment and technique have likely improved the experience for patients undergoing both femoral and radial procedures. Increased use of vascular closure devices and other hemostasis devices in lieu of heavy sandbags or prolonged manual compression could reduce leg and back discomfort associated with the femoral approach. Newer catheters that require less manipulation and hydrophilic radial sheaths may reduce radial spasm and arterial damage, and use of preventive strategies such as antithrombotic agents and the technique of "patent hemostasis" may reduce radial artery occlusion.[20,23-26] Importantly, there is a greater overall awareness of procedural bleeding; combined with technical improvements, this has led to much lower bleeding rates, as reported in the main SAFE-PCI for Women results.[10] Due to all of these factors, it may be increasingly difficult to demonstrate significant differences between study treatments using traditional QOL instruments. Finally, in SAFE-PCI for Women, we examined an overall lower-risk population with low rates of adverse clinical events, which may have reduced any potential effect of access site strategy on patient perception of QOL measures. Perhaps any true benefit of radial over femoral artery access regarding QOL may need to be studied in higher-risk populations, such as high-risk non–ST-segment elevation myocardial infarction patients or patients presenting with ST-segment elevation myocardial infarction.

In addition to patient preference for the radial approach, other potential advantages of radial over femoral artery access exist and should motivate operators to consider this strategy for cardiac catheterization. Multiple studies have associated radial artery access with improved safety via significant reductions in access site-related bleeding and complications compared with the femoral approach.[6-8] Several analyses have also supported the use of radial over femoral

access to reduce healthcare costs associated with catheterization procedures, with estimated cost-savings from ~$300 for diagnostic procedures to >$800 for PCI procedures.[16,27-29] Finally, from a training perspective, there is a learning curve associated with learning to perform radial procedures.[30] Though we did not demonstrate a measurable QOL benefit with radial access, maintaining a "radial first" mentality to approach procedures with the radial artery as the default access site and initial selection of less complex patients undergoing elective procedures, remain important strategies to overcoming the learning curve and improving operator proficiency with the radial approach.

Limitations

Several limitations of this study should be acknowledged. First, based on the difference in EQ-5D scores that is typically considered clinically meaningful (0.07 with a standard deviation of 0.20), we calculated a sample size of 300 patients necessary to detect a significant difference with 85% power. Although we achieved the requisite initial sample size to meet these parameters, not all patients completed hospital discharge questionnaires, and per trial protocol, only PCI patients were required to return for 30-day follow-up. As a result, we may have been underpowered to detect a true effect of access strategy on 30-day outcomes. Second, the EQ-5D instrument is widely applicable to a broad range of health conditions, and we also included questions designed to examine outcomes related to the access site and catheterization procedure. However, neither the QOL survey nor our questions were validated specifically in cardiac catheterization/PCI populations or in women. Therefore, we may not have captured important sex-specific factors that relate to differences in QOL associated with arterial access strategy. Finally, although we demonstrated patient preference for radial over femoral artery access for

future procedures, we did not specifically ask women to explain their rationale for this preference; such knowledge might provide insight into measurable QOL differences for future studies.

Conclusions

In conclusion, among women undergoing cardiac catheterization, we were unable to measure a benefit of radial versus femoral artery access on post-procedure QOL using currently available QOL measurement tools, functional status at hospital discharge, or at 30-day follow-up. Despite these findings, patient preference for the same access strategy for repeat procedures was significantly greater among patients assigned to radial compared with femoral treatment. Factors other than those collected on established QOL surveys that may affect female patient preference for access site should be further investigated.

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Figure Legends

Figure 1. Flowchart of patient selection

Shown is a diagram of patient selection for SAFE-PCI for Women patients participating in the quality-of-life substudy. Per trial protocol, only patients undergoing PCI were scheduled for routine 30-day follow-up and were expected to complete 30-day QOL questionnaires.

PCI, percutaneous coronary intervention; *SAFE-PCI for Women*, Study of Access Site For Enhancement of Percutaneous Coronary Intervention for Women; *QOL*, quality-of-life

Figure 2. The effect of arterial access site on quality-of-life measures

This forest plot depicts the estimated difference in: A) EQ-5D score; and B) EQ-VAS score for femoral compared with radial artery access after adjusting for baseline EQ-5D and EQ-VAS scores, respectively. Results for both analyses of patients according to assigned treatment and actual treatment received are included.

CI, confidence interval; *EQ-5D*, European Quality of Life-5 Dimensions; *EQ-VAS*, European Quality of Life-Visual Analog Scale

Figure 3. Vascular access site-related outcomes according to assigned treatment

Shown are outcomes related to vascular access site for patients assigned to radial or femoral artery access at: A) hospital discharge; and B) 30-day follow-up. Unless otherwise indicated, all p-values for pair-wise comparisons are >0.05.

Table I. Baseline patient characteristics

	Patients in overall study (n=1,787)	**Radial (n=146)**	**Femoral (n=158)**	**p-value***
Median age (25th, 75th percentiles), years	64.4 (56.5, 73.2)	61.3 (55.4, 72.3)	63.3 (55.8, 70.8)	0.94
Median BMI (25th, 75th percentiles), kg/m^2	30.3 (26.2, 34.9)	30.1 (26.7, 35.0)	31.0 (25.4, 36.7)	0.73
Current or recent smoking	459 (25.7)	46 (31.5)	50 (31.7)	0.98
Hypertension	1424 (79.7)	117 (80.1)	130 (82.3)	0.63
Previous MI	335 (18.8)	26 (17.8)	28 (17.7)	0.98
Previous CABG	97 (5.4)	8 (5.5)	10 (6.3)	0.75
Peripheral arterial disease	105 (5.9)	11 (7.5)	8 (5.1)	0.37
Diabetes mellitus	627 (35.1)	57 (39.0)	60 (38.0)	0.84
Clinical presentation				0.58
Non-ACS	806 (45.1)	71 (48.6)	76 (48.1)	
NSTEACS	974 (54.5)	74 (50.7)	82 (51.9)	
STEMI	6 (0.3)	1 (0.7)	0 (0.0)	
Median procedure duration (25th, 75th percentiles), min	44.0 (31.0), 64.0)	56.5 (37.0, 80.0)	45.0 (32.0, 73.0)	0.17

ACS, acute coronary syndrome; *BMI*, body mass index; *CABG*, coronary artery bypass grafting; *MI*, myocardial infarction; *NSTEACS*, non–ST-segment elevation acute coronary syndrome; *PCI*, percutaneous coronary intervention; *STEMI*, ST-segment elevation myocardial infarction

*p-values are for comparisons of patients in the quality of life sub-study randomized to radial versus femoral

Table II. Discharge and 30-day EQ-5D scores according to access site

		Discharge			30-Day		
Variable		**Radial**	**Femoral**	**p-value**	**Radial**	**Femoral**	**p-value**
Mobility	No problems with walking	93 (69.9)	92 (64.8)	0.19	33 (63.5)	39 (76.5)	0.15
	Some problems with walking	40 (30.1)	47 (33.1)		19 (36.5)	12 (23.5)	
	Confined to bed	0 (0.0)	3 (2.1)		94 (64.4)	107 (67.7)	
Self-care	No problems with self-care	116 (87.2)	131 (92.9)	0.11	50 (96.2)	49 (96.1)	0.98
	Some problems with washing or dressing myself	17 (12.8)	10 (7.1)		2 (3.9)	2 (3.9)	
Usual activities	No problems performing usual activities	82 (61.7)	92 (65.3)	0.68	34 (65.4)	36 (70.6)	0.35
	Some problems performing usual activities	50 (37.6)	47 (33.3)		16 (30.8)	15 (29.4)	
	Unable to perform usual activities	1 (0.8)	2 (1.4)		2 (3.9)	0 (0.0)	
Pain/discomfort	No pain/discomfort	66 (50.0)	80 (56.3)	0.28	29 (55.8)	31 (60.8)	0.40
	Moderate pain/discomfort	60 (45.5)	52 (36.6)		19 (36.5)	19 (37.3)	
	Extreme pain/discomfort	6 (4.6)	10 (7.0)		4 (7.7)	1 (2.0)	
Anxiety/depression	Not anxious or depressed	97 (72.9)	98 (69.0)	0.61	37 (71.2)	29 (56.9)	0.31
	Moderately anxious or depressed	30 (22.6)	39 (27.5)		14 (26.9)	21 (41.2)	
	Extremely anxious or depressed	6 (4.5)	5 (3.5)		1 (1.9)	1 (2.0)	

EQ-5D, European Quality of Life-5 Dimensions

Table III. Quality of life summary measures

Measure	Radial	Femoral	p-value
EQ-5D Index Score			
Baseline			
Number of patients	142	156	0.92
Median (25^{th}, 75^{th} percentiles)	0.83 (0.76, 0.86)	0.83 (0.73, 1.0)	
Mean	0.81±0.16	0.80±0.20	
Hospital discharge			
Number of patients	132	140	0.98
Median (25^{th}, 75^{th} percentiles)	0.83 (0.77, 1.0)	0.84 (0.77, 1.0)	
Mean	0.83±0.17	0.82±0.18	
30-days			
Number of patients	52	51	0.60
Median (25^{th}, 75^{th} percentiles)	0.84 (0.78, 1.0)	0.84 (0.78, 1.0)	
Mean	0.83±0.18	0.87±0.15	
Visual Analogue Scale score			
Baseline			
Number of patients	144	156	0.53
Median (25^{th}, 75^{th} percentiles)	70.0 (51.5, 80.0)	70.0 (50.0, 82.5)	
Mean	66.7±17.5	67.2±20.6	
Hospital discharge			
Number of patients	134	143	0.15
Median (25^{th}, 75^{th} percentiles)	75.0 (60.0, 85.0)	80.0 (65.0, 90.0)	
Mean	72.0±18.6	74.1±19.8	
30-days			
Number of patients	52	50	0.85
Median (25^{th}, 75^{th} percentiles)	78.5 (62.5, 86.5)	80.0 (60.0, 90.0)	
Mean	73.4±20.4	74.5±18.6	

All abbreviations can be found in Table II.