Quality of Life Patients After PCI with Drug-Eluting Stents

Sharapova Nozima Erkinjonovna

Teacher of the Department Fundamental Medicine Disciplines Asia International University

Annotation: This article focuses on evaluating the quality of life in patients with coronary artery disease after undergoing percutaneous coronary intervention (PCI) with drug-eluting stents (DES). PCI is widely used as an alternative revascularization method to improve patients' quality of life. The study utilized the Seattle Angina Questionnaire (SAQ) to assess disease-specific health status, including angina frequency, physical limitations, and factors impacting overall quality of life. A total of 1,800 patients were observed over 12 months to monitor quality indicators. The results compared PCI with coronary artery bypass grafting (CABG). Findings revealed that PCI improved health-related quality of life during the initial month; however, at 6 and 12 months, CABG demonstrated superiority in reducing angina symptoms. This study highlights PCI's potential to enhance quality-of-life outcomes, even in cases of complex arterial disease, providing valuable insights into its effectiveness for long-term management of coronary artery conditions.

Keywords: PCI, anginafrequency subscale, stents, paclitaxel-eluting stents, angina, balloon angioplasty.

Introduction

Health status (which includes symptoms, functional limitations, and quality of life) was assessed directly from patients with the use of standardized, written questionnaires at baseline and at 1, 6, and 12 months after randomization (details are provided in the Supplementary Appendix, available at NEJM.org). The baseline questionnaires were completed before the patients underwent randomization. Subsequent questionnaires were completed in person at the time of scheduled follow-up visits or were sent by mail.Disease-specific health status was assessed with the use of the Seattle Angina Questionnaire (SAQ), which is a 19-item questionnaire that measures five domains of health status related to coronary artery disease: angina frequency, physical limitations, quality of life, angina stability, and treatment satisfaction.3,4 Scores range from 0 to 100, with higher scores indicating fewer symptoms and better health status.

The prespecified primary end point of the quality of-life analysis was the score on the SAQ anginafrequency subscale. All scores on other scales were considered to be secondary end points. Baseline characteristics were compared between treatment groups with the use of the chi-square test for categorical variables and Student's t-test for continuous variables. For the primary analysis, mean quality-of-life scores were compared between groups at each time point by means of analysis of covariance in order to adjust for baseline scores. Categorical analyses of the primary end point were also performed in which patients were classified as having no angina (SAQ anginafrequency score of 100) versus any angina and in which patients were classified as having an increase from baseline in the SAQ angina-frequency score of 20 points or more (which was considered to be substantial improvement) versus an incre**ase of less than 20 points.**

Between March 2005 and April 2007, a total of 1800 patients with three-vessel or left main coronary artery disease were randomly assigned to PCI with paclitaxel-eluting stents (903 patients) or CABG (897 patients). There were no significant differences between the two groups in baseline characteristics or quality-of-life scores (Table 1). At baseline, approximately 12% of the patients reported experiencing daily angina during the month before randomization, whereas approximately 20% reported no angina.

The overall rate of response for quality-of-life assessments among surviving patients was more than 90% at all time points (96.2% at baseline, 90.5% at 1 month, 90.3% at 6 months, and 90.5% at 12 months). The rates of response for individual subscales were similar.

Methodology

This study was a randomized clinical trial comparing PCI with paclitaxel-eluting stents and CABG in 1800 patients with three-vessel or left main coronary artery disease. Health status was assessed at baseline and at 1, 6, and 12 months using validated tools, including the Seattle Angina Questionnaire (SAQ) and SF-36.

The primary endpoint was the SAQ angina-frequency score, with secondary endpoints covering other SAQ domains and general health metrics. Baseline characteristics were analyzed using chi-square and t-tests, while ANCOVA was applied to adjust for baseline scores in follow-up comparisons.

Subgroup analyses identified factors influencing quality-of-life improvements, using multivariable models to account for demographics, disease severity, and baseline health status. This approach provided comprehensive insights into the comparative effects of PCI and CABG on patient outcomes.

Results and Discussion

Because PCI is performed to improve patients' quality of life, analyses were conducted to identify baseline patient characteristics associated with changes in quality of life. These included the demographic, clinical, and disease severity variables listed in Table 1. Baseline health status variables were also incorporated, including the SAQ Angina Frequency and Physical Limitation scores. To facilitate interpretation of patients' health status, baseline Angina Frequency and Physical Limitation scores were each grouped into 4 ranges: Angina Frequency scores were grouped into daily angina (SAQ scores0 to 30), weekly angina, (31– 60), monthly angina (61–99), or no angina (100). Physical Limitation scores were grouped as severe limitation (0 –25), moderate limitation (26 –50), mild limitation (51–75), or slight to no limitation (75). Baseline characteristics associated with 1-year change in quality of life were evaluated using both univariate and multivariable models. Univariate associations were estimated using linear regression or 1-way ANOVA. To provide a patient-level assessment of quality-of-life benefit, an additional analysis was conducted to describe the proportion of patients who experienced a clinically significant (10-point) change in the SAQ Quality-of-Life scale by baseline frequency of angina and category of physical limitation. Independent effects were then estimated by the construction of 3 general linear models. The first model included only the patients' demographic (age, race, and sex) and clinical (previous revascularization, previous MI, hypertension, diabetes, hyperlipidemia, chronic obstructive pulmonary disease, renal insufficiency, and heart failure) characteristics. The second model added disease severity characteristics (number of diseased vessels and ejection fraction) to the first model. The final model included demographic, clinical, and disease severity characteristics along with the patients' baseline health status (SAQ Physical Function and Angina Frequency scores). This order of model development provides a description of the incremental contribution from adding disease severity variables to the patient characteristics (model 2) and health status to patient and disease severity characteristics (model 3). To describe the strength of association between model variables and outcome, a coefficient of multiple determination (R^2) was used.

In this trial, we compared the outcomes of CABG with those of PCI with the use of paclitaxel-eluting stents among patients with three-vessel or left main coronary artery disease. Both PCI and CABG led to significant improvements in disease-specific and general health status over the course of 12 months. With respect to the primary quality-oflife end point — the score on the SAQ anginafrequency subscale — the extent of improvement was slightly greater with CABG than with PCI at 6 and 12 months, with a mean between-group difference of 1.7 points at both time points. There were no consistent differences in the scores on any other components of the SAQ at these later time points. In contrast, there were marked benefits with PCI as compared with CABG in general health-related quality of life as assessed by the SF-36 as well as EQ-5D utility weights at 1 month, but these differences had largely disappeared by 6 months.

Subgroup analyses showed that the benefits of CABG with respect to relief from angina were consistent over a broad range of patient characteristics. There was, however, evidence of heterogeneity according to the frequency of angina at baseline. Among patients with daily or weekly angina, CABG was associated with greater relief from angina than was PCI at both 6 months and 12 months, whereas there was no significant between-group difference in relief from angina among the two thirds of the study population with less frequent angina at baseline. Numerous previous studies have examined health-related quality of life after PCI or CABG. These studies, in which PCI was performed with the use of either balloon angioplasty or baremetal stents, have generally shown that CABG results in superior relief from angina over the course of the first 1 to 3 years after the initial revascularization.[16-20] Our study shows that despite our inclusion of patients with more complex coronary artery disease than those in previous trials, the continued evolution of PCI techniques, including the use of drug-eluting stents, has narrowed the gap in health-related quality of life between patients who undergo PCI and those who undergo CABG.

This study provides an important step toward understanding the predictors of quality-of-life improvement after PCI. It is hoped that this information will allow clinicians to prospectively understand the degree of postprocedural benefit patients are likely to experience, thereby supporting medical decision-making and augmenting physicians' ability to convey anticipated benefits to patients. This is an especially important contribution in light of evidence that patients often overestimate the likely benefits of PCI.[26] Although further research should replicate this work, it appears that substantially less benefit, from the patients' perspectives, should be anticipated when PCI is performed in asymptomatic individuals.

Conclusion

This study demonstrates that both percutaneous coronary intervention (PCI) with paclitaxel-eluting stents and coronary artery bypass grafting (CABG) significantly improve health-related quality of life in patients with three-vessel or left main coronary artery disease. However, CABG provides slightly better relief from angina, particularly for those with more frequent symptoms at baseline, and offers more sustained long-term benefits. On the other hand, PCI showed advantages in general health status early after the procedure, though these benefits diminished over time.

Overall, the choice between PCI and CABG should be guided by individual patient characteristics, including the severity of symptoms, disease progression, and patient preferences. While PCI offers a less invasive option with quicker recovery, CABG remains the gold standard for patients with significant, frequent angina. Further studies are needed to deepen our understanding of long-term outcomes and refine strategies for optimal patient management in coronary artery disease.

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