ABSTRACT

Introduction

Coronary artery disease (CAD) is the leading cause of indoor morbidity in Sri Lanka. Percutaneous transluminal coronary angioplasty (PTCA) is becoming increasingly preferred method of coronary revascularization among stable CAD patients in Sri Lanka. Modern treatments, including angioplasty nowadays focus more on health related quality of life (HRQOL) as a means of measuring outcome of health care interventions among patients with CAD in a more patient-orientated manner compared to more objective traditional clinical outcomes such as morbidity, mortality and disability.

However, at present, due priority is not given to HRQOL as an outcome measure in the management of CAD patients in Sri Lanka. The present study was conducted with the objectives of validating a cardiovascular disease-specific HRQOL instrument to assess HRQOL among stable CAD patients and to determine the impact of coronary angioplasty on HRQOL, its correlates and house-hold expenditure incurred due to coronary angioplasty among same clinical group.

Methodology

The study comprised of four components. The first component was the validation of a heart disease specific HRQOL questionnaire to assess HRQOL among CAD patients. MacNew heart disease specific HRQOL questionnaire (MacNew) was selected at the end of a modified Delphi technique by a multi-disciplinary group of experts as the most relevant study instrument to meet the study objective. Translation of MacNew into Sinhala language (MacNew-S) was done according to translation strategy of the MacNew collaboration. Validity of the MacNew-S was assessed by triangulation method in the absence of a criterion. Judgment validity was assessed by form of content, face and consensual validity. Construct validity was explored by principal component analysis (PCA) and confirmed by confirmatory factor analysis (CFA) using robust maximum likelihood method and known group comparison.

The second component was a longitudinal study to assess impact of coronary angioplasty using percutaneous transluminal coronary angioplasty (PTCA) on HRQOL of stable CAD patients and to determine its correlates. Sample size was 260, when

calculated according to the formula for comparison of two means. HRQOL was measured at baseline and three months after PTCA among a sample of stable CAD patients using a combination of disease specific and generic tools to gain complimentary information on HRQOL. Study instruments used to assess HRQOL were validated 23 item MacNew-S in the Component I (the disease specific measure) and the World Health Organisation's quality of life- brief (WHOQOL-BREF) (the generic measure).

The third component was a cross-sectional study on house-hold health expenditure related to PTCA procedure. Data was collected peri-operatively during the hospital stay and at the first review visit.

The fourth component was a qualitative study to get insight into the physical and socio-economical aspects related to impact of PTCA. In-depth interviews using an interviewer guide as the research technique was employed among a group of purposively sampled patients three months after the PTCA.

Results

PCA results confirmed the original 3 factor model (*Physical, Emotional* and *Social*) of the MacNew with a 53.42 % of variance in HRQOL being explained by these three factors. Four items of the original questionnaire were deleted considering the appropriateness of factor loadings and content analysis resulting in 23 item MacNew-S to carry out CFA. Two out of three model fit criteria of thus selected model showed adequate fit [RMSEA 0.044 (90% CI =0.031 to 0.056) and NNFI 0.99]. Reliability in the form of internal consistency of the MacNew-S was found to be acceptable with Cronbach's α of the total scale being 0.92 with sub scale values ranging from 0.77- 0.91. Test retest reliability was also found to be satisfactory with a Spearman's rho of >0.9 for total and sub scales.

Response rate of the Component II was 100% with an attrition rate of 4.2%. Both MacNew and WHOQOL-BREF scores were negatively skewed. The median MacNew *Global* score at baseline and three months follow up were 4.91 (IQR: 4.08- 5.48) and 5.69 (IQR: 5.04-6.09) respectively. Wilcoxon signed rank test yielded statistically significant incremental benefits in all 3 domains of HRQOL when median baseline and post operative values were compared. Clinically significant improvement ($\geq$ +0.5) in MacNew Global HRQOL was observed in 61% (n=152) of the sample at three months

after PTCA. However, HRQOL in 4.8% (n=12) had deteriorated while in 34.2% (n=85) it has not changed to a level which can be considered as clinically important. The median change in Global HRQOL was 0.69 (IQR: 0.22-1.22). The highest median change was for the MacNew *Physical* domain (0.88; IQR: 0.38- 1.5) while the lowest was for the *Social* (0.67; IQR: -0.17- 1.33) domain.

Correlates of HRQOL identified in the current study concurred with the existing evidence. Multivariate correlates of higher baseline HRQOL were male sex (sex: β= 0.104, 95%CI =0.005 to 0.407, p=0.045), lesser baseline anginal frequency (anginal frequency: β= -0.332, 95%CI = -0.314 to -0.607, p<0.001) and good psychological well-being (GHQ 30≤ 8) (GHQ 30: β= -0.537, 95%CI = -0.113 to -0.080, p<0.001).

The current study identified high standard of living (SLI: β= 0.160, 95% CI= 0.365 to 0.029, p= 0.022), less baseline anginal frequency (anginal frequency: β = -0.145, 95% CI= -0.026 to -0.320, p= 0.021), good baseline psychological well-being (GHQ 30≤ 8) (GHQ 30: β = -0.160, 95% CI= -0.043 to -0.005, p= 0.016), lesser post-op anginal frequency (anginal frequency: β = -0.248, 95% CI= -0.571 to -1.324, p<0.001) and good post-operative psychological well-being (GHQ 30≤ 8) (GHQ 30: β = -0.522, 95% CI= -0.114 to -0.054, p<0.001) as multivariate correlates of higher post operative HRQOL at three months following PTCA.

When adjusted for confounding, correlates of incremental benefits in HRQOL three months following PTCA were post operative good psychological well-being (GHQ 30≤ 8) (GHQ 30: β= -0.546, 95% CI= -0.101 to -0.059, p<0.001) & lesser anginal frequency (anginal frequency: β = -0.284, 95% CI= -0.141 to -0.336, p<0.001) and baseline good psychological well-being (GHQ 30≤ 8) (GHQ 30: β= -0.526, 95% CI= -0.057 to -0.098, p<0.001) & higher anginal frequency (anginal frequency: β= 0.321, 95% CI= 0.232 to 0.094, p<0.001).

Even though health service is claimed to be free of charge at the point of service delivery, PTCA procedure in a Sri Lankan state sector health institution amount to a median total HHEH of Rs. 255,916 (IQR: Rs. 190,010- 343,200). while Expenditure on surgical appliances comprised of the majority of the total HHEH (95.2%) with a median of Rs. 250,000 (IQR: Rs. 185,000- 328,625). Catastrophic expenditures incurred among 92.5% of the patients undergoing PTCA at state sector hospitals resulting in adopting