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# **Changes in, and Predictors of, Quality of Life among Patients with Unstable Angina after Percutaneous Coronary Intervention**

**Running title: Quality of Life among Unstable Angina Patients**

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## **ABSTRACT**

**Rationale and objectives:** Changes in, and predictors of, quality of life (QoL) among unstable angina patients are informative for both clinical and public health practice. However, there is little research on this topic, especially in healthcare settings with limited resources. This study aims to detect changes in QoL and its associated factors among patients with unstable angina after percutaneous coronary intervention.

**Methods:** A longitudinal design was conducted with two repeated rounds of measurements, one month and three months after intervention, using the generic SF-36 questionnaire, in 120 patients from Vietnam National Heart Institute. A linear mixed-effects model was used to assess changes in patient QoL over time while adjusting for other covariates.

**Results:** Only 2 out of 8 QoL subscales (social functioning and emotional well-being) declined after one month, but these tended to rise again after three months, while scores of all other QoL subscales increased. Adjusting for covariates, QoL increased slightly after one month of intervention ( $\beta=0.65$ , 95%CI=-0.86-2.16) but improved by almost 6 QoL points after 3 months ( $\beta=5.99$ , 95%CI=4.48-7.50). Four confounders significantly associated with a decline in QoL were older age, being retired, living in rural areas, and having abnormal troponin level.

**Conclusion:** QoL of the patients with unstable angina improves significantly three months after intervention, rather than after one month. More attention should be given to patients, who are old, retired, live in rural areas and have abnormal troponin level.

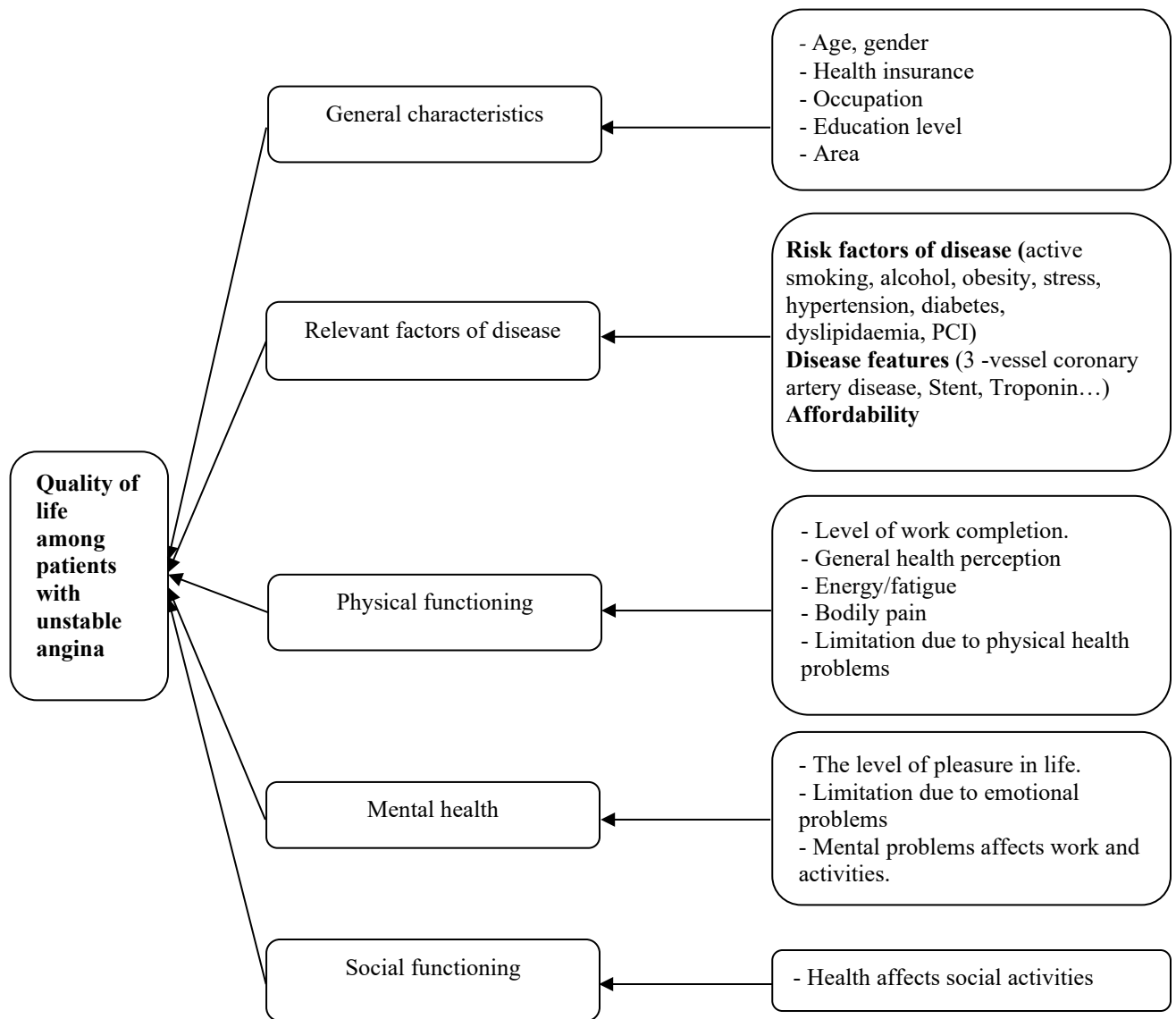
**Key words:** *Unstable angina; Percutaneous coronary intervention (PCI); Quality of life; SF-36; Vietnam*

## INTRODUCTION

Unstable angina (UA) is an irregular type of angina pectoris<sup>1</sup> and a type of acute coronary syndrome (ACS).<sup>2</sup> Every year, in the U.S, more than one million people are hospitalized due to unstable angina and non–ST-segment elevation myocardial infarction (UA/NSTEMI),<sup>3</sup> and incidence is increasing in many countries. The burden of UA is high, as the first-year treatment cost of patients (\$12,058 per patient) is almost as high as that of myocardial infarction (\$15,540 for each survivor and \$17,532 for each death).<sup>4</sup> Even with a high cost intervention, health outcomes and long term prognosis may not improve.

Previously, survival rates, complication rates, and functional parameters were used as indicators of the efficacy of coronary artery disease (CAD) treatment.<sup>5</sup> Over the past years, however, the quality of life (QoL) of patients with chronic diseases such as cardiovascular disease has also become an important indicator of successful clinical practice.<sup>6</sup> Percutaneous coronary intervention (PCI) has been known as a breakthrough method that has become a frequently used revascularization strategy for patients with CAD.<sup>7</sup> QoL of patients with CAD may be evaluated using different instruments, including the Seattle angina questionnaire (SAQ)<sup>8</sup> and the physical activity score,<sup>9</sup> which are specific to coronary diseases. Others, such as the 36-item short form (SF-36),<sup>10</sup> the Nottingham health profile (NHP)<sup>11</sup>, and the Swedish quality of life survey (SWED-QUAL)<sup>12</sup> give a more generic assessment and allow comparisons with non-CAD populations. SAQ scores have been shown to predict 1-year mortality and ACS among outpatients with coronary disease, and might play a crucial part in stratifying the risk of such patients<sup>13</sup>. Some studies have also shown that PCI improves the QoL of CAD patients. A study of 65 patients receiving PCI found that QoL measured with the SF-36 improved significantly over time in six out of the eight domains and all other domains showed an increase at 3-month follow-up. Moreover, all five domains of SAQ improved significantly; however, the angina stability score at 3-month follow-up was lower than the baseline value.<sup>14</sup> A 2008 study comparing PCI and optimal medical therapy alone showed remarkable improvements in health outcomes during the follow-up period in the PCI group but these disappeared after 36 months.<sup>15</sup>

Although the effect of PCI on QoL in CAD patients has been established in developed countries, there is little research concerning this area in developing countries, including Vietnam. As Vietnam moves into the epidemiological transition and experiences a growing burden of non-communicable disease (NCD), research on the optimal treatments for conditions such as Angina, and rapid implementation of best practice from high-income countries, is essential to prepare the Vietnamese health system for better management of the growing epidemic of NCDs. This study aimed to compare QoL among patients with unstable angina after PCI and examine factors associated with QoL improvement after PCI. Our study adopts Lawton's theoretical framework<sup>16</sup> (see Fig. 1), which is regarded as appropriately for explaining factors associated with patients' QoL after myocardial infarction. On theoretical grounds, Lawton distinguishes four domains of QoL: 'Behavioral competence', which includes physical health, daily activities, cognitive functioning and social behaviour; 'Objective environment', including material possessions, social support, and network; 'Domain-specific perceived QoL', the degree of satisfaction with all important (life) domains, such as social functioning, leisure activities, living accommodation, and income; and 'Psychological well-being', the weighted evaluated level of a person's competence and perceived quality in all domains of contemporary life. Lawton recommends a hierarchical reference with 'behavioral competence' and 'perceived quality of life' as central domains, 'environment' as a prerequisite or catalyst, and 'psychological well-being' as the ultimate outcome.<sup>17</sup> These behavioral competencies are the aspects of functioning that are strongly influenced by illness. Given the scope of this study as well as the complex nature of the intervention delivered to our participants, this theoretical model for our study is adapted and presented as hereinafter.



**Figure 1. Theoretical framework for quality of life among patients with unstable angina**

## **METHODS**

**Research design and location.** In a longitudinal study with two repeated surveys after the baseline, we used face-to-face interviews and telephone calls with the same patients with unstable angina before and one month and three months after PCI for outcome measurements at the National Heart Institute, Vietnam.

**Sample size and participants.** We used the convenience sampling method to recruit participants. All patients who visited the Vietnam Heart Institute from September 2016 as baseline to February 2017 as post line and met criteria were included. Those who were diagnosed with unstable angina (UA), received PCI in the Vietnam National Heart Institute and agreed to participant were interviewed. The patient was excluded if s/he had associated chronic diseases such as cancer and

COPD, or died after intervention. A total of 127 eligible participants, 120 patients participated in this study, which gave a response rate of 94.5%. All 120 participants were followed at one month and 3 months after PCI.

### **Measurement and data collection**

Version 1.0 of the SF-36<sup>18</sup> was translated into Vietnamese by a professional translator and then translated back into English by another. No significant difference between the two translations was detected. The survey consisted of 36 questions related to eight health notions including physical functioning, role limitations due to physical health problems, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, bodily pain and general health perceptions, divided into two groups of physical and mental health.<sup>10</sup> The responses were scored following the RAND scoring method.<sup>19</sup> The 36-Item Health Survey 1.0 included the same set of items as the SF-36. In this research, we used the RAND 36-Item Health Survey scoring process consisting of 2 steps. Firstly, pre-coded numeric values were recoded according to the scoring scale described hereinafter. Responses 1 to 5 for items number 1, 2, 20, 22, 34, and 36 were recoded to values of 100, 75, 50, 25, and 0, respectively. Responses 1 to 3 for items number 3 to 12 were recoded to values of 0, 50, and 100, respectively. Responses 1 and 2 for items from 13 to 19 would be recoded to values of 0 and 100, respectively. Responses 1 to 6 for items number 21, 23, 26, 27, 30 were recoded to values of 100, 80, 60, 40, 20, and 0, respectively. Responses 1 to 6 for items number 24, 25, 28, 29, 31 were recoded to values of 0, 20, 40, 60, 80, and 100, respectively. Responses 1 to 5 for items number 32, 33, 35 were recoded to values of 0, 25, 50, 75, and 100, respectively. All the items were scored so that that a higher score indicates a better state of health-related QoL. In addition, each score of items ranged from 0 to 100, with 0 indicating the lowest and 100 the highest possible score. Scores are represented as percentage of the total possible score achieved.<sup>19</sup> Secondly, items in the same scale were averaged together to create 8 sub-scale scores that yield eight health concepts. If the respondent missed one of the two items, the person's score was set to be equal to that of the non-missing item.<sup>19</sup>

The high reliability of this scoring method for each of eight scales has been identified, with Cronbach's alpha ranging from 0.78 to 0.93.<sup>19</sup> The International QoL Assessment project has translated and validated the SF-36 for use in 45 countries.<sup>20</sup> In this study, we also verified the suitability of the SF-36 based on our pilot study after translation and adaptation to the Vietnamese language and culture. The pilot research was conducted on 10 patients, and the results showed that all the scales were technically reliable and feasible for the main survey. In the main survey, the selected patients were interviewed face-to-face when they visited Vietnam Heart Institute (about 80% of the patients) or via telephone when any of them did not come at repeated surveys (20%). The main predictor of interest is the QoL of patients across rounds (i.e., baseline, 1<sup>st</sup> and 3<sup>rd</sup> months of follow up)

Key selected characteristics. The demographic factors covered age (years), gender (male or female), educational level (lower level representing under or equal to high school or higher level including college or university and post-graduate level), marital status (single or married), occupation (retired or not retired/farmers), region (rural or urban), past coronary intervention before the current intervention (yes or no), hypertension (yes or not), hyperlipidaemia (yes or no), diabetes mellitus (yes or no), the number of stents inserted (1, 2, and 3 stents), smoking history (yes or no before the onset of UA), alcohol intake history (yes vs. no before the onset of UA), and troponin T (under or over 0,01 ng/ml).

**Statistical analysis.** The frequencies and percentages for categorical variables, and means and standard deviations (SD) for quantitative variables were used to describe the data. We calculated mean scores and standard deviations for eight subscales of the SF-36 at pre-intervention, one month, and three months after the intervention. In each of the eight subscales, higher scores indicated a better state of health-related QoL. As a repeated measures design, we used a mixed-effects model with random intercept to detect factors associated with QoL. Each individual had three observations, one at baseline, one at 1 month and the other at 3 months, with correlation



assumed between observations within the same individual. All analyses were conducted using Stata version 16 (Stata Corporation, College Station, TX)

**Research ethics.** All subjects received verbal descriptions of the purpose and methods and their right to refuse participation at any time. They were reassured that their participation was voluntary and anonymous, and the refusal would not affect their treatment or nursing care. The protocol was approved by the Research Assessment Board from the Institute for Preventive Medicine and Public Health at Hanoi Medical University according to Decision No. 5403/QD-DHYHN dated 06/12/2016.

## **RESULTS**

### **Key selected characteristics of the research patients**

Out of the 127 patients initially enrolled in the study, the number of patients who completed all assessment periods before and after 1 month and 3 months was 120 patients, a participation rate of 120/127 (94.5%). The mean age of the subjects was 66.6 (SD = 9.8) years, with patients mainly in the 60+ age group (77.5%). Most were male and had an education level of high school or less (74.2%). Just over half were retired (53.3%), there was a similar proportion of people living in rural and urban areas. The proportion of patients who smoked and drank alcohol were 52.5% and 39.2%, respectively. The prevalence of hypertension and diabetes were 57.5% and 33.3%, respectively. More than thirty percent were diagnosed with dyslipidaemia, and 64.2% of the patients had received coronary intervention before the current intervention. Patients who had 1, 2 and 3 stents accounted for 45.0%, 34.2% and 20.8%, respectively (table 1).

**Table 1: Participants' characteristics**

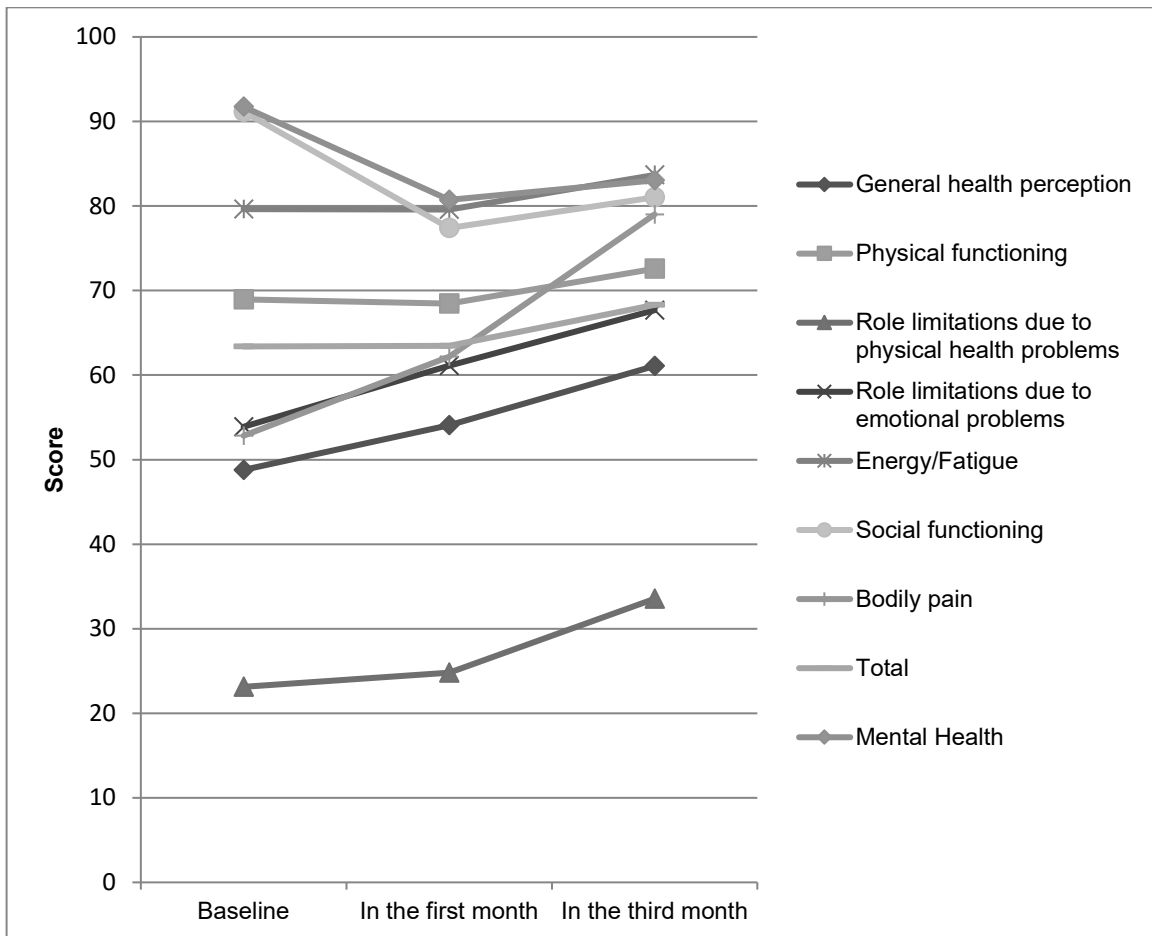
<b>Characteristics</b>	<b>N (%)</b>
<b>Age, mean (SD)</b>	66.59 (9.8)
<b>Age group</b>	
< 60	27 (22.5)
≥ 60	93 (77.5)
<b>Education</b>	
High school or below	89 (74.2)
College/University	31 (25.8)
<b>Sex</b>	
Female	31 (25.8)
Male	89 (74.2)
<b>Occupation</b>	
Non-retirement	56 (46.7)
Retirement	64 (53.3)
<b>Place of residence</b>	
Urban	55 (45.8)
Rural	65 (54.2)
<b>Smoke</b>	
No	57 (47.5)
Yes	63 (52.5)
<b>Drink</b>	
No	73 (60.8)
Yes	47 (39.2)
<b>Hypertension</b>	
No	51 (42.5)
Yes	69 (57.5)
<b>Diabetes</b>	
No	80 (66.7)
Yes	40 (33.3)
<b>Dyslipidemia</b>	
No	83 (69.2)
Yes	37 (30.8)
<b>Troponin</b>	
Normal	35 (29.2)
Abnormal	85 (70.8)
<b>The past coronary intervention</b>	
No	43 (35.8)
Yes	77 (64.2)
<b>Number of stents</b>	
1	54 (45.0)
2	41 (34.2)
3	25 (20.8)

The distribution of QoL scores by patient characteristics is shown in table 2. Overall, the QoL scores for all groups increased from the baseline to the third month after PCI.

**Table 2: Distribution of overall QoL score by patients' characteristics at baseline, the first and the third month after PCI**

<b>Characteristics</b>	<b>QoL – Baseline</b> <i>Mean (SD)</i>	<b>QoL – 1<sup>st</sup> month</b> <i>Mean (SD)</i>	<b>QoL – 3<sup>rd</sup> month</b> <i>Mean (SD)</i>
<b>Overall</b>	63.41 (13.8)	64.06 (7.6)	69.40 (6.7)
<b>Age group</b>			
< 60	71.42 (13.9)	68.35 (7.2)	72.89 (8.0)
≥ 60	61.09 (13.0)	62.82 (7.2)	68.39 (6.0)
<b>Education</b>			
High school or below	63.32 (13.6)	63.92 (7.2)	69.40 (6.1)
College/University	63.67 (14.8)	64.47 (8.6)	69.41 (8.5)
<b>Sex</b>			
Female	59.40 (10.8)	62.50 (6.7)	67.99 (6.1)
Male	64.81 (14.5)	64.61 (7.8)	69.89 (6.9)
<b>Occupation</b>			
Non-retirement	65.67 (16.3)	65.79 (7.9)	71.08 (7.0)
Retirement	61.44 (11.0)	62.56 (7.0)	67.93 (6.2)
<b>Place of residence</b>			
Urban	64.39 (13.5)	64.35 (7.8)	69.71 (7.0)
Rural	62.58 (14.1)	63.83 (7.4)	69.14 (6.5)
<b>Smoke</b>			
No	60.24 (11.3)	62.30 (7.0)	68.38 (6.1)
Yes	66.28 (15.3)	65.66 (7.8)	70.33 (7.2)
<b>Drink</b>			
No	61.41 (13.0)	62.90 (7.4)	68.65 (6.5)
Yes	66.53 (14.6)	65.87 (7.6)	70.57 (7.0)
<b>Hypertension</b>			
No	66.14 (14.8)	65.56 (8.0)	70.48 (6.9)
Yes	61.39 (12.8)	62.96 (7.1)	68.60 (6.5)
<b>Diabetes</b>			
No	64.99 (13.6)	65.41 (7.6)	69.73 (7.1)
Yes	60.25 (13.9)	61.38 (6.8)	68.75 (5.9)
<b>Dyslipidemia</b>			
No	62.17 (14.6)	63.65 (7.5)	69.36 (6.6)
Yes	66.20 (11.7)	64.99 (7.8)	69.50 (7.1)
<b>Troponin</b>			
Normal	65.06 (10.4)	64.78 (6.2)	70.48 (6.3)
Abnormal	62.73 (15.0)	63.77 (8.1)	68.96 (6.9)
<b>The past coronary intervention</b>			
No	66.58 (14.0)	65.06 (8.3)	69.29 (6.9)
Yes	61.64 (13.5)	63.51 (7.1)	69.46 (6.7)
<b>Number of stents</b>			
1	63.56 (13.2)	63.88 (7.0)	69.13 (6.3)
2	62.44 (15.1)	64.33 (8.2)	69.27 (7.5)
3	64.70 (13.3)	64.03 (7.9)	70.21 (6.4)

Figure 2 summarizes trends in health-related QoL at baseline, 1 month and 3 months after PCI using eight subscales. The scores of 6 out of 8 subscales including general health perception, physical functioning, energy/fatigue, bodily pain, role limitations due to physical health and emotional problems significantly increased at 1 and 3 months from intervention. The two other subscales, social functioning and emotional well-being had a drop in QoL after 1 month and tended to rise again after 3 months.



**Figure 2. SF-36 scores at baseline, in the first month and in the third month after PCI**

Table 3 shows the results of the mixed-effects model for factors associated with patient's QoL. After one month of PCI, the QoL of the patients did not show a significant difference from baseline, QoL increased significantly by almost 6 points at 3 months ( $\beta = 5.99$ ; 95% CI = 4.48 to 7.50;  $P < 0.001$ ). Older, retired, and rural patients and patients with abnormal level of troponin had reduced QoL ( $\beta$ 's were -0.27, -3.45, -4.45, and -3.49, respectively).

**Table 3: Mixed-effects model of factors associated with QoL**

	<b>Coefficient</b>	<b>95% CI</b>	<b>P-value</b>
QoL at baseline	Ref	Ref	
1 month follow-up	0.65	-0.86 to 2.16	0.397
3 month follow-up	5.99	4.48 to 7.50	<b>0.000</b>
<b>Age</b> ( <i>year</i> )	-0.27	-0.43 to -0.12	<b>0.001</b>
<b>Education</b> ( <i>higher vs. lower High school</i> )	-0.89	-4.22 to 2.44	0.601
<b>Sex</b> ( <i>male vs. female</i> )	2.12	-1.95 to 6.19	0.306
<b>Occupation</b> ( <i>retired vs. non-retired</i> )	-3.45	-6.73 to -0.17	<b>0.039</b>
<b>Place of residence</b> ( <i>rural vs. urban</i> )	-4.45	-7.68 to -1.21	<b>0.007</b>
<b>Smoke</b> ( <i>yes vs. no</i> )	1.21	-2.48 to 4.89	0.521
<b>Drink alcohol</b> ( <i>yes vs. no</i> )	1.45	-1.91 to 4.81	0.397
<b>Hypertension</b> ( <i>yes vs. no</i> )	-0.59	-3.67 to 2.48	0.705
<b>Diabetes</b> ( <i>yes vs. no</i> )	-0.97	-3.96 to 2.01	0.524
<b>Troponin</b> ( <i>abnormal vs. normal</i> )	-3.49	-6.55 to -0.42	<b>0.026</b>
<b>Past coronary intervention</b> ( <i>yes vs. no</i> )	-1.78	-4.59 to 1.03	0.215

## DISCUSSION

This study compared the quality of life (QoL) of patients with unstable angina before and after being treated with PCI and investigated the factors associated with improvement after treatment. The results indicated that PCI led to improved QoL in most of the health concepts categorized by the SF-36 questionnaire except for the social functioning and mental health aspects. The findings are comparable with a study by Wong et al<sup>14</sup> which demonstrated an increase in all the eight domains after one month of PCI, and even after 3 months in several domains. Before the intervention, the patients reported experiencing significant problems with daily activities due to their physical limitations, moderate bodily pain, and fatigue. This is in line with another study on Australian and Danish populations showing quite similar pre-intervention QoL score to our results.<sup>21</sup> Their study also indicated 27% of the patients reporting a decrease in the subscale of mental health, which reaffirmed the patient's decline of mental health QoL score in our result<sup>21</sup>. This decrease in the mental health aspect of QoL would be due to unstable mental status and fear of post-operation complications, which led them to fall into stress and anxiety shortly after the intervention. This condition would improve over time as the patient's health stabilized again. Our results reflected this situation as the QoL score for mental health, and social functioning aspects dropped remarkably one month from intervention and started to rise again after three months, even

if it was still lower than before the intervention. The QoL of patients with coronary heart disease may be significantly affected by patients' mental health even where methods of intervention are physically beneficial as found in a study by Staniūtė and Brožaitienė<sup>22</sup>, and more attention to mental and social support after intervention may be warranted.

Our results also indicated that some demographic factors were associated with the QoL improvement resulting from PCI. As expected, older people and people in rural areas had lower QoL across the time period of the study. Associations of access to healthcare with QoL between rural and urban settings were also founded after controlling individual and household factors in a recent study in China by Zhang et al.<sup>23</sup> It is because they may have more difficulty to access to better facilities for health care. In Vietnam, the health system that serves the elderly is limited which could affect health care. This result was found in several previous studies showing higher mortality rates after PCI in older than in younger patients. In fact, in several interventions, advanced age was associated with worse short-term prognosis and higher rates of complications.<sup>24-26</sup> The justification for this would be that multiple comorbidities, including chronic kidney diseases, that older patients often suffer from, were increased risk factors for PCI.<sup>27</sup> Besides, in the study by Shanmugasundaram, physiological factors were also considered to influence on the outcome after PCI, age caused an increase vascular stiffness, which in turn results in hypertension, left ventricular hypertrophy, and decreased left ventricular function.<sup>27</sup> Even myocardial diastolic function becomes impaired with aging, and endothelial dysfunction is more common.<sup>27</sup>

In addition, another factor that was related to the QoL improvement resulting from PCI was occupation. It may be true that retirees be more likely not to improve their QoL after the treatment than the working people (workers, freelancers, farmers, home-makers, etc.). One justification for this is that people being retired would undergo a series of emotional and the salary level changing<sup>28</sup> as a result of workplace separation. The study of Isabelle Hansson et al also showed that retirees reported having an increase in life satisfaction and a higher degree of autonomy due to sufficient financial capacity after one year of retirement.<sup>29</sup> This could be

explained by the fact that older people with stable financing are able to focus more on their regular health care and participate in social and cultural activities which might enhance their psychological as well as physical QoL. The working group would have less time to recover from the intervention than the retirees since they had to return to their job duties as soon as they could. This elucidates the similarity of QoL improvement between the groups on the end of the first month after the treatment, and the higher likelihood of QoL improvement of the retirees compared to other occupation groups after three months. Given this result, it is necessary for further research to investigate the impact of this factor on PCI outcome.

Our study also found a factor that had impact on the effectiveness of PCI was the place of residence. The elderly living in rural area were less likely to improve their QOL after PCI than the people living in urban area. This result was similar with the finding of the previous study.<sup>30</sup> They found that ST-elevation myocardial infarction (STEMI) guidelines recommend reperfusion by PCI with less than or equal to 90 minutes from time of first medical contact (FMC). This strategy is challenging in rural areas with a lack of nearby PCI-capable hospitals.<sup>30</sup> Another study in China<sup>31</sup> detected that people living in rural areas had limited access to medical services. In cases of high-impact conditions, such as acute myocardial infarction, rural residents are less likely to receive evidence-based therapies and may experience worse outcomes. We found that abnormal troponin was associated with the setback of PCI outcomes, but other sub-clinical factors are not, consistent with a study by Prasad et al.<sup>32</sup> which found that patients with an elevated troponin after PCI had elevated short-term mortality risk. The association between an elevation in troponin and efficacy of cardiovascular diseases treatment was supported by our study.

This study has several limitations. Some of the interviews were partly conducted via telephone, which limited the collection of comprehensive information as we could not observe the facial expression of the interviewees, and some of the questions might have been difficult for them to understand compared to direct face-to-face interaction. The sample may not representative of the concerned population. However, as a longitudinal design with repeated measures on the same

patients over time, the results could present a valid case for informing both clinical and public health practice.

The results of this study have several implications for care and follow up in angina patients. Firstly, an observed drop in the social functioning and emotional well-being after technical intervention may help clinical practitioners and public health specialists in designing interventions that target QoL in UA patients undergoing PCI. Health care service providers and caregivers are expected to deliver proper rehabilitation methods and guide lifestyles which can provide the patients with the best recovery after PCI. In addition, healthcare service providers should establish counselling programs that enhance the knowledge and practices about post-operation care of patients. Efforts should also be made to raise patients' awareness on the adverse impact of smoking and diabetes on the severity of unstable angina as well as the efficacy of PCI treatment.

## **CONCLUSIONS**

There was an improvement in QoL among patients with unstable angina after PCI except for two domains, the patient's mental well-being and social functioning QOL scores after PCI which declined after the baseline. Our findings suggest a search for appropriate care and other methods which could support the recovery of patients as well as improve their social functioning and mental health. Given some limitation of our current study, further research such as randomized control trial or quasi-experiment designed with two arms will not only help to confirm causality, but also inform more effective policy strategies to improve QoL of patients with UA. A longitudinal study is also needed to detect a long-term improvement in QoL.



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