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Selecting Instruments to Measure Quality of Life after Acute Coronary Syndrome: A Literature Review

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Abstract--- *Quality of life (QoL) is an important aspect to describe the quality of patient care. The use of valid and reliable instruments is a major concern for measuring the quality of life in post-acute coronary syndrome patients. The purpose of the paper was to select existing tools to measure the quality of life after acute coronary syndrome. A review was performed of literature published from 2000-2019, with the following keywords: acute coronary syndrome, quality of life, and psychometric properties or validity. Scopus, MEDLINE, CINAHL, Science Direct, and Proquest were the primary databases utilized for the search of the literature. The criteria to consider when selecting the existing instrument were a match to objective, psychometric evidence, validity, and reliability. The full texts of 10 articles were found for the evaluation and psychometric after acute coronary syndrome. We identified these assessment tools with different psychometric reported two to eight domains of QoL. The number of items contained in the questionnaires ranges from 6 to 74, and all the tools are self-administered. Most of the tools had not reported complete and desirable psychometric properties. Heart quality of life (HeartQoL) is an appropriate instrument to measure the quality of life after acute coronary syndrome patients. Developing a tool for different societies with varied cultural and social characteristics is suggested because socio-cultural factors can influence the quality of life.*

Keywords--- *Post-Acute Coronary Syndrome; Psychometric Properties; Quality of Life; Validity; Reliability*

I. INTRODUCTION

Acute coronary syndrome (ACS) is a life-threatening disease with high morbidity and mortality (Hoekstra, 2018). An acute coronary syndrome is a condition that arises because of a sudden reduction in blood flow to the heart, which includes unstable angina pectoris, Non-ST-Elevation myocardial Infarction (NSTEMI), and ST-Elevation Myocardial Infarction (STEMI [1–3].

Quality of life is essential to assess the quality of care in patients. Patients aged 60 years or older described their quality of life as the lowest [4]. ACS patients in phase I rehabilitation experience low quality of life in physical and mental aspects [5]. Females also tend to have a worse quality of life compared to men.

There are several instruments to measure the quality of life, which are divided into tools to assess the quality of life in general and specific diseases. The disease-specific tools address complaints that are characteristic of certain conditions, whereas generic instruments require aspects beyond the particular illness. Disease-specific instruments are, however, considered more sensitive and thus better suited to measuring changes in disease-related elements [6]. However, currently, no precise tools are known to measure the quality of life in patients post-acute coronary syndrome. The purpose of this paper is to select an appropriate instrument to measure the quality of life in patients after acute coronary syndrome.

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II. METHOD

This literature review was performed in 2020 by searching Scopus, MEDLINE, CINAHL, Science Direct, and Proquest database. The keywords were "acute coronary syndrome," "quality of life," and "psychometric properties, or "validity" or "reliability. We retrieved English language articles published from 2000-2019. In the sampling stage, we selected all the studies reporting validation of the quality of life-specific questionnaires. The inclusion criteria were at least one measure of reliability or validity based on the COSMIN criteria (complete reporting validity, reliability, responsiveness, and interpretability) [7, 8]. Articles without available full texts and with incomplete psychometric properties and non-English publications were excluded.

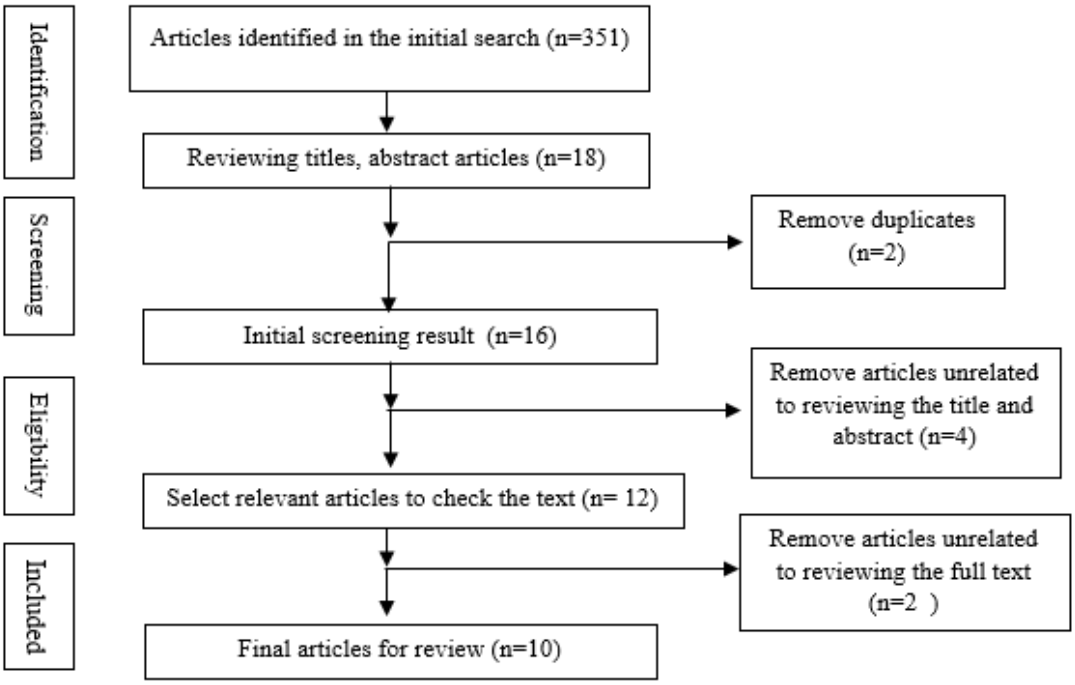

Figure 1. Chart of study process

III. RESULT

The initial search yielded 351 articles; after the second evaluation, 18 relevant articles were obtained. Then, duplicate articles were excluded, and the number of articles decreased to 16. In the review of the articles, only the articles on design, complete psychometric measures of tools, and construction of QOL related tools were retained in the study (n=10). Finally, the full texts of 10 articles were considered for evaluation and psychometric after acute coronary syndrome. The QoL tools were analyzed using the COSMIN checklist [7, 8] (Table 1). We identified these assessment tools with different psychometric properties reported two to eight domains of QOL. The domains of the instrument included physical, emotional, social [9–11], physical limitation (PL), angina stability (AS), angina frequency (AF), treatment satisfaction (TS), and quality of life (QoL) [12], mobility, self-care, usual activities, pain/discomfort, and anxiety/depression [13–15]. The number of

items contained in the questionnaires ranges from 14 to 27, and all the questionnaires are self-administered. These tools were criticized in detail based on the COSMIN checklist in Table 2, and their psychometric properties were explained.

Based on the literature, there are several instruments to measure the quality of life in patients with cardiovascular disease. The following is a brief explanation of the instruments and results from previous studies relating to the validity and reliability of each instrument.

- European Quality of Life (EQ-5 Dimension)

The European Quality of Life Group developed it in 1987. The EQ-5D was first published in 1990, and its five dimensions have remained unchanged since 1991. EQ-5D is a generic HRQoL instrument to measure health outcomes. The validity of the EQ-5D has been assessed within many different patient groups and within the general population in different countries. The EQ-5D scale is a short and easy HRQoL instrument compared with the MacNew disease-specific instrument [13]. It is used to measure the patient's health status directly. This instrument consists of 5 items addressing mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. 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) [20]. Each dimension of the EQ-5D is divided into three degrees of severity as "no problem", "some problems", or "major problems" [13].

- MacNew Heart Disease Health-related Quality of Life

The English-language MacNew evolved from the interview version of the Quality of Life after Myocardial Infarction instrument. TheMacNew heart disease quality of life questionnaire is designed to evaluate the quality of life in heart diseases. It is simple to administer and well-accepted by patients. The MacNew scale has been translated into more than 20 languages [13]. The MacNew questionnaire was designed to evaluate how daily activities and physical, emotional, and social functioning are affected by coronary heart disease and its treatment [9] in a 2-week timeframe. It consists of 27 items that fall into three domains (physical limitations, emotional, and social function) with a global HRQoL score. Domain scores are calculated by taking the average of the responses to the items in each domain. Possible scores range from 1 to 7, with a higher score indicating a better HRQoL [13, 17]. The reliability of the English version shows Cronbach's α values between 0.93 and 0.95 and is thus considered very good. Its validity and sensitivity to change are generally satisfactory. Reliability was demonstrated by using internal consistency and the intraclass correlation coefficients for the three domains in the Dutch, English, Farsi, German, and Spanish versions of the MacNew. With internal consistency and intraclass correlation coefficients =>0.73, reliability is high. The validity of the MacNew was examined with factor analysis, and three core underlying factors, physical, emotional, and social, were identified, explaining 63.0 – 66.5% of the observed variance and replicated in the translations with psychometric data. The construct validity of the MacNew was further demonstrated by extensive substantiation of the logical relationships, defined a priori, between items and other comparison tools. The MacNew is responsive and sensitive to changes in HRQL following various interventions for patients with heart disease with 11 of 13 effect size statistics >0.80. Taking an average of 10 minutes or less to complete, the respondent-burden for the MacNew is low, and its acceptability is demonstrated by response rates of over 90%. Normative data are available for patients with myocardial infarction, angina, and heart failure in the English version [9].

- Seattle Angina Questionnaire Quality of Life (SAQ QoL)

The SAQQoL scale assesses how the patient perceives their coronary artery diseases (CAD) to be impacting his or her QoL. It has been widely used to assess disease-specific health status in patients with ischemic heart disease (IHD). It was initially developed in a predominantly male population. The SAQ demonstrates similar psychometric properties in men and women with CAD [12]. The SAQ is a 19-item self-administered questionnaire measuring health status in patients with IHD. It has five domains: physical limitation (PL), angina stability (AS), angina frequency (AF), treatment satisfaction (TS), and quality of life (QoL). All domain scores and a summary score (SS; derived from the PL, AF, and QoL domains) range from

0 to 100, with higher scores indicating less angina, fewer physical limitations due to angina, and better QoL. The 7-item version excludes the TS and AS domains [12].

- Heart Quality of Life (HeartQoL)

The HeartQol questionnaire is a relatively new tool for measuring health-related quality of life among patients with ischemic heart disease [11]. The development of a scale to measure the quality of life of this instrument was based on three special conditions instruments: (1) MacNew Heart Disease HRQoL (developed for patients with MI), (2) Minnesota Living with Heart Failure, and (3) Seattle Angina Questionnaire.

Heart Qol is a reliable and valid 14-item IHD-specific core HRQL questionnaire for patients with angina, MI, or ischemic heart failure. The HeartQoL questionnaire was developed and validated in a cohort of 6384 patients with IHD who live in 22 countries and speak one of 15 languages. An independent group of 730 patients either undergoing PCI (350) or referred to CR (380), from 10 countries speaking one of eight languages. This instrument consists of 14-items with a 10-item global and physical (items 1-8, 13, and 14) and a 4-item emotional subscale (items 9-12) scored from 0 (poor HRQL) to 3 (better HRQL). Three different response scales were used depending on the item: No (3); a little (2); some (1); and a lot (0) [11]. The Heart Qol-P questionnaire indicated good internal consistency (the Cronbach alpha for the total score and each subscale was between 0.80 and 0.95). The Heart Qol-P questionnaire also has acceptable properties for its use in prediction of quality of life amongst Persian speaking populations [10].

IV. DISCUSSION

The results showed that several tools had been designed for measuring QoL for heart-disease patients with myocardial infarction [10, 11, 17] angina, heart failure [17], patients undergoing cardiac rehabilitation [6]. Health-related quality of life in patients with ACS is challenging to define [13]. There are several disease-specific tools to measure HRQoL for heart diseases, such as the MacNew Heart disease quality of life [6, 9, 16], Seattle Angina Questionnaire (SAQ) [12], and HeartQoL [10, 11]. SF-12 and Euro-QoL (EQ-5D) are generic tools to assess the quality of life.

Based on the COSMIN criteria, it seems that some of them ultimately reported dimensions of the concept, the number of items, and their psychometric properties such as validity, reliability. The criteria for the COSMIN checklist are the primary basis and foundation for assessing the applications of the instrument [7, 8]. Some tools required little time and were accessible toto fulfill the instrument. Several instruments had been translated before the validity test (Heart Qol, MacNew). For responsiveness (sensitivity to changes), three of the five tools tested responsiveness, which is required to evaluate the impact of clinical trials and interventions. For example, MacNew, SAQ, and HeartQoL have responsiveness. These results were consistent with those of the COSMIN checklist, where the definition of responsiveness is the ability of an instrument to detect change over time in the construct to be measured, and it is related to validity.

For assessing reliability, two of the five tools had both good stability and internal consistency (MacNew, and Heart QoL). Heart QoL has high reliability compared with other tools. Heart QoL-P is a disease-specific instrument to measure Acute Myocardial Infarction (AMI) patients' quality of life in Iran, and it is recommended for other Persian speaking countries [10]. The HeartQoL questionnaire has several objectives, including assessing baseline HRQL, making between-diagnosis comparisons of HRQL, and evaluating a change in HRQL in patients with angina, MI, and heart failure undergoing interventions designed to improve patient HRQL. It can reduce the cardiovascular burden on patients who live with heart disease and their families [11].

Culture is an essential aspect of the quality of life. It defines the goal of living in health and illness and affects the personal perception of these both, QoL, thoughts, and feelings [21]. Cultural adaptation is significant in the use and design of tools. Further research is required to appraise cross-cultural adaptability of the translated instrument based on the demographic population in a different country and also examine its validity and reliability.

V. CONCLUSION

Quality of life in patients after ACS is critical because it impacts the recovery process and increases physical and mental well-being. Based on the COSMIN checklist, Heart QoL is an appropriate instrument to assess the quality of life after acute coronary syndrome. Developing a tool for different societies with varied cultural and social characteristics is suggested because socio-cultural factors can influence the quality of life. Future studies must investigate the cross-cultural validity of the scale in the countries.

CONFLIC OF INTEREST

The authors declare that there is no conflict of interests.

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APPENDIX

Table 1. Summary of the final articles reviewed

Authors, year	The purpose of the study	Principal findings
[16]	Measuring HRQL in a group of Iranian patients with CAD and documented MI.	The result showed that trivial rates of missing data confirmed the acceptability of the tool. The principal component analysis revealed that the three domains, emotional, social, and physical, performed as well as in the original studies. Internal consistency was high and comparable to other studies. The test-retest analysis showed a significant correlation between the emotional and physical domains.
[9]	Reviewing evidence concerning the measurement properties of the MacNew Heart Disease Health-related Quality of Life [MacNew] Questionnaire	The result showed that reliability was demonstrated by using internal consistency and the intraclass correlation coefficients for the three domains in the Dutch, English, Farsi, German, and Spanish versions of the MacNew. With internal consistency and intraclass correlation coefficients, reliability is high. The Validity of the MacNew was examined with factor analysis, and three core underlying factors, physical, emotional, and social, were identified. Construct validity of the MacNew was further demonstrated by extensive substantiation of the logical relationships, defined a priori, between items and other comparison tools. The MacNew is responsive and sensitive to changes in HRQL following various interventions for patients with heart disease. Normative data are available in the English version for patients with myocardial infarction, angina, and heart failure
[11]	Reporting on the interim psychometric properties of the HeartQoL	The result showed that the HeartQoL questionnaire comprises 14-items with physical and emotional subscales and a global score (range 0–3, poor to better HRQL). Cronbach's α was consistent; convergent validity correlations between similar HeartQoL and SF-36 subscales were significant; discriminative validity was confirmed with predictor variables: health transition, anxiety, depression, and functional status.
[17]	Evaluating the psychometric properties of the Chinese version of the MacNew in a cohort of Hong- Kong patients diagnosed with CHD	The results warrant recommending the use of the MacNew as an outcome measure to enhance treatment evaluation in Chinese patients with CHD and diagnosis of myocardial infarction, angina or heart failure, substantiating previous psychometric data on the MacNew in many different studies in patients speaking seven different languages
[18]	Determining the construct and criterion validity of the 12-item short-form questionnaire (SF-12) in coronary patients with either acute myocardial infarction or unstable angina in Spain	The validation result was as expected: female patients and those with poor education level, worse mental health, unstable angina, cardiovascular risk factor, and co-morbidity obtained a lower score in the SF-12. The correlations between SF-36 and SF-12 summary scores were high. The equivalence between the SF-12 and SF-36 was good.
[13]	Examining the validity of the EQ-5D scale in routine clinical practices in patients with ACS as compared to the MacNew Heart Disease Quality of Life instrument	The correlation coefficients of the EQ-5D index score with the MacNew subscales ranged from 0.557 to 0.721, with EQ-5D VAS score ranging from 0.297 to 0.484 ($p<0.001$ for all of them). According to the stepwise regression model, MacNew global score was found to be a significantly effective factor on the EQ-5D index score
[6]	Investigating the psychometric properties of the German version of the	Two items had more than 7% missing data. We observed neither floor nor ceiling effects. Cronbach's α of the scales ranged from 0.78 (physical scale) to 0.95 (global

Authors, year	The purpose of the study	Principal findings
	MacNew Heart Disease Health-related Quality of Life Questionnaire (MacNew) in patients undergoing cardiac rehabilitation.	scale). Confirmatory factor analysis failed to reproduce the proposed factor structure (CFI = 0.882; TLI = 0.871; RMSEA = 0.074). We, therefore, drafted our own model (CFI = 0.932; TLI = 0.921; RMSEA = 0.064) and observed a correlation pattern largely conforming to the hypotheses with generic health-related quality of life instrument. The effect sizes we noted between the start and end of rehabilitation fell between 0.66 and 0.74; at the 6-month follow-up they ranged from 0.69 to 0.92
[19]	Comparing different value sets for the EQ-5D-3L and assessing how well they reproduce patients' reported results	EHS-VAS had smaller MAEs and higher ρ in all the patients and in the inpatient group and correlated best with MacNew global score. EHS-VAS more accurately reflected Quality-adjusted survival. At admission, younger, better-educated patients reported lower VAS than the EHS-based value set. EHS-based estimates were mostly able to reproduce patient-reported valuation. Economic utility measurement is conceptually different, produced results less strongly related to patients' reports, and resulted in about 20% longer quality-adjusted survival.
[12]	Validating the SAQ and its subdomains in women with Ischemic Heart Disease	Comparable correlations between the SAQSS and the Canadian Cardiovascular Society class were demonstrated in both men and women (−0.48 for men, −0.46 for women). Similar correlations between the SAQPL scale and treadmill exercise duration and Short Form-12 (SF-12) Physical Component Summary were observed in women and men (0.34–0.63 and 0.40–0.63, respectively). SAQAS scores were significantly lower for both men and women with acute syndromes compared with one month later. All SAQ scales demonstrated excellent reliability (intraclass correlation ≥0.78) in both men and women with stable CAD and were very sensitive to change after the percutaneous coronary intervention (≥15-point difference in scores, standardized response mean ≥ 0.67). The SAQSS was similarly predictive of 1- year mortality and cardiac re-hospitalizations for both men and women.
[10]	Validating the HeartQoL for Persian speaking populations	The two-factor structure of the HeartQoL-P was supported by the outputs of the confirmatory factor analysis and good internal consistency measures (total score α = 0.94) (physical subscale (10 items) α = 0.95) and emotional subscale (4 items) α = 0.80)). No ceiling or floor effects were observed for the overall Heart Qol-P'score.

Table 2. Tools measuring the quality of life in post-acute coronary syndrome patients

Test	Country of origin	Scaling	Domains	Number of items	Validity			Reliability		Interpretability	Responsiveness
					V1	V2	V3	R1	R2		
Mac New	Dutch, English, Farsi, German, and Spanish versions	7-point Likert scale: (7: good HRQoL) and- the minimum 1 (poor HRQoL).	three domains: Physical (10 items), emotional (14 items) and social (3 items)	27 items	√	√	√	√	√	-	√
	Hongkong	7-point scoring scale: 1 (low HRQL) to 7 (high HRQL)	three domains (physical, emotional, and social)	27 items	-	√	-	√	√	√	√
	Iran	7-point scoring scale: 1 (low HRQL) to 7 (high HRQL)	three domains (physical - 12 items, emotional- 14 items, and social- 3 items)	26 items	-	√	-	√	√	-	-
	German	7-point scoring scale: 1 (low HRQL) to 7 (high HRQL)	three domains (physical-5 items, emotional-12 items, and social-11 items)	27 items	-	√	√	-	√	√	-

Test	Country of origin	Scaling	Domains	Number of items	Validity			Reliability		Interpretability	Responsiveness
					V1	V2	V3	R1	R2		
Euro Qol (EQ-5D)	Turkey	Index score ranges from -0.59 to 1 and includes a worse-than-death measure (negative score), outside the range of 0 (dead) to 1 (perfect health)	five domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression	not explained	-	√	-	-	√	-	-
SAQ QoL	USA	All domain scores and a summary score range from 0 to 100, with higher scores indicating less angina, fewer physical limitations due to angina, and better QoL	five domains: physical limitation (PL), angina stability (AS), angina frequency (AF), treatment satisfaction (TS), and quality of life (QoL)	19 items	-	√	√	√	-	-	√
SF-12	Spain	Not explained	Not explained	Not explained	-	√	√	-	-	√	-
Heart QoL	22 Countries	4-point Likert scale (0: poor HRQoL – 3 better HRQoL)	two domains: Global and Physical (10 items) Emotional (4 items)	14 items	√	√	√	√	√	-	√
	Iran	4-point Likert scale (0: poor HRQoL – 3 better HRQoL)	two domains: Global and Physical (10 items) Emotional (4 items)	14 items	√	√	-	-	√	√	√

V1: Content Validity; V2: Criterion Validity; V3: Construct Validity; R1: Stability; R2: Internal Consistency