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Health-related quality of life of patients submitted to correction of heart valve diseases

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ABSTRACT

Introduction: The measurement of the health-related quality of life construct can reveal the positive repercussions on the lives of patients undergoing corrective valve procedures, as well as revealing points that prevent new surgical approaches. **Objective:** To identify the health-related quality of life of valvular heart disease in the perioperative period of conventional valve surgery. **Methods:** This is an integrative literature review. Searches were performed independently in four databases using controlled and uncontrolled descriptors. Eligibility criteria were: original articles that addressed the assessment of the health-related quality of life of valvular patients undergoing valve repair and/or valve prosthesis implantation; in Portuguese, English, and Spanish; with a time frame for convenience between 2015 and 2019. **Results:** 14 studies comprised the final review sample, despite being studies conducted in different countries and with different designs, it was possible to verify the improvement in health-related quality of life when evaluated through generic instruments in valvular patients after valve surgery. However, in studies in which the assessment of the construct occurred through specific instruments, the existence of factors that can interfere with the quality of life of patients undergoing valve implantation was revealed. **Conclusion:** It was noticed that there was generally an improvement in health-related quality of life after the surgical intervention.

Keywords: Quality of life; heart valves; heart valve prosthesis; heart valve prosthesis implantation; cardiac rehabilitation.

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INTRODUCTION

Valvular replacements and implants with biological and mechanical prostheses have increased substantially when compared to coronary artery bypass graft surgery. In Brazil, 7,891 conventional valve surgery interventions were performed in 2019, with 613 valve repairs and 7,278 valve prosthesis implants[1,2]. Valve implants with biological and mechanical prostheses are considered conventional valve surgical interventions, characterized by the replacement of the physiological valve with the valve prosthesis, which can be biological or mechanical[3-6].

The choice between the types of prostheses, biological and mechanical, depends on intrinsic factors of the patient, such as age over sixty years and the existence of comorbidities, such as congestive heart failure, renal failure, coronary artery disease, and pulmonary diseases. Besides extrinsic factors to the patient, related to the structures of the

prosthetic valves, since they have distinct characteristics regarding the structural form[7,8].

The main late complications related to surgical interventions and risks inherent to heart valve replacement, regardless of the material used, are thromboembolism, anticoagulation-related bleeding, endocarditis of the implanted valve, leakage, and implanted valve failure[3-6].

Given the magnitude of such complications, both in the perioperative context and after discharge, it is important to understand the repercussions of surgical treatment on the patient's life. Moreover, it is recommended that the patient be informed about the specifics of each procedure, as well as the care related to the postoperative period, contemplating aspects related to health-related quality of life, return to usual activities, potential complications in the mediate and late postoperative period, need for monitoring by a health professional due to care after the implant to avoid complications and improve health-related quality of life[9].

In the literature, the term Health-Related Quality of Life has emerged as a synonym for Quality of Life, from the individual's perception of health. The construct quality of life has been measured from the verification of the health-related quality of life in specific groups, using generic and/or specific instruments[10].

Thus, measuring health-related quality of life has become an important factor, because it can reveal the positive repercussions on the lives of patients undergoing corrective valve procedures, as well as reveal points for the prevention of new surgical approaches[3].

Due to the scarcity of studies summarizing the findings on health-related quality of life in valve patients after conventional valve surgery, we sought to identify the health-related quality of life of valve patients in the perioperative period of conventional valve surgery.

METHODS

This is an integrative literature review. This study adopted as a methodological reference the review process in six organizational phases, namely: identification of the theme and/or research question; establishment of criteria for inclusion and exclusion of studies and systematic search; definition of information to be extracted from the selected studies according to the guiding question; selection with subsequent evaluation of the studies included in the review; interpretation of the results found; and synthesis of knowledge[11].

To elaborate on the guiding question, the PICO strategy was used, in which "P" represents the word problem, "I" represents the word intervention, "C" represents the word comparison, and "O" represents the outcome or "Outcomes". Thus, the guiding question was Do valve patients undergoing conventional valve interventions have an improvement in health-related quality of life after the surgical procedure?

The studies were selected after searches in the databases, without the use of filters: Medical Literature Analysis and Retrieval System Online (Medline), via Pubmed; Scopus, via Elsevier; Web of Science and Embase, using the controlled descriptors of the Medical Subject Headings for the Medline search and the Emtree for the Embase search, as well as non-controlled descriptors (keywords) in the Web of Science and Scopus databases. All controlled and uncontrolled descriptors were combined with Boolean operators, AND and OR, as described in Table 1. The searches were conducted between March and April 2020 by the researchers independently, using an instrument developed for them.

The eligibility criteria were original articles that addressed the assessment of the health-related quality of life in patients undergoing valve repair and/or implantation of prosthetic valves; in Portuguese, English, and Spanish languages; with a temporal cut for convenience between 2015 and 2019; articles available in full that had in their titles at least one of the descriptors used in the search, being selected for reading the abstracts. After reading the abstracts, those articles that showed the assessment of the health-related quality of life in patients after conventional valve surgery using validated instruments were selected for reading in full.

The Preferred Reporting Items for Systematic Review and Meta-Analyses[12] flowchart was used to describe the search process, as shown in Figure 1.

Excluded were those in which health-related quality of life was assessed through a qualitative approach or that presented the assessment of the health-related quality of life in patients undergoing valve surgery through minimally invasive procedures. Before reading in full, the selected articles were entered into the Mendeley reference manager to separate duplicate studies.

After this step, data were extracted from an instrument developed by the authors, which allowed the descriptive analysis of the data, containing the variables of characterization (authors' names, year of publication, database, and level of evidence) and specific variables focused on the assessment of the health-related quality of life in the perioperative context, which composed the summary table with the evidence.

The selected studies were classified according to the level of scientific evidence proposed by the Oxford Centre for Evidence-Based Medicine[13]. The search strategy was maintained throughout the process; no manual search was performed in journals indexed in these databases, and there was no selection of references from the studies selected to compose the final sample.

RESULTS

After the search, 3,572 articles were found, and 60 studies were selected for reading in their entirety, 14 of which comprised the final sample. The main information extracted from the original articles selected for this review is presented in Table 2, according to the eligibility criteria already mentioned.

Table 1: Combinations of keywords used

Bases	Combinations
Medline MeSH	("Life of Quality") OR ("Health-Related Quality of Life") OR ("Health-Related Quality of Life") OR ("HRQOL") AND ("Heart Valve Prosthesis Implantation") OR ("Heart Valve Prosthesis").
Scopus Password	("Heart Valve Prosthesis Implantation") OR ("Heart Valve Prosthesis") AND ("Life of Quality") OR ("Health-Related Quality of Life") OR ("Health-Related Quality of Life") OR ("HRQOL").
Web of Science Password	("Heart Valve Prosthesis Implantation") OR ("Heart Valve Prosthesis") AND ("Life of Quality") OR ("Health-Related Quality of Life") OR ("Health-Related Quality of Life") OR ("HRQOL").
Embase Emtree	("Heart Valve Diseases") OR ("Disease, Heart Valve") OR ("Diseases, Heart Valve") OR ("Valve Disease, Heart") OR ("Valve Diseases, Heart") OR ("Valvular Heart Diseases") OR ("Disease, Valvular Heart") OR ("Diseases, Valvular Heart") OR ("Heart Disease, Valvular") OR ("Heart Diseases, Valvular") OR ("Valvular Heart Disease") AND ("Heart Valve Replacement") AND ("Life of Quality") OR ("Health-Related Quality of Life") OR ("Health-Related Quality of Life") OR ("HRQOL").

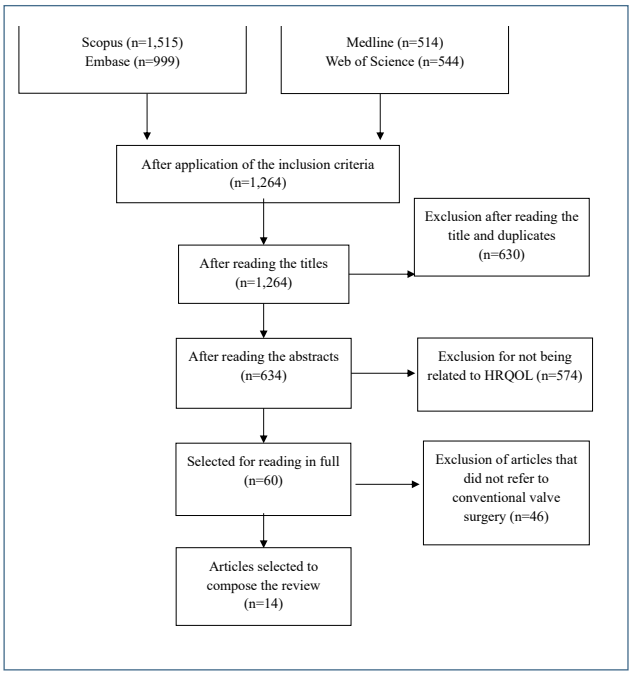

Figure 1: Flowchart[12] adapted for the selection of the studies

Regarding the databases, one article was selected from Embase, four articles from Medline, two articles from Scopus, and seven articles from Web of Science, totaling 14 articles to compose the final sample. As for the geographical distribution of the selected studies, two were carried out in the American continent, with Canadian participants[14,15]; three in Asia, with Chinese participants[16-18]; and nine in Europe, being one in Croatia[19], one in the Netherlands[20], one in Portugal[21], one in England[22], two in Denmark[23,24], two in Germany[25,26] and one in the Czech Republic[27].

Regarding the methodological design, four randomized clinical trials were found[14-15,20,23], while the others were observational studies, called cohort or cross-sectional studies by the respective authors[16-18,21,22,24-27].

Regarding the level of evidence, four had the level of evidence one[14,15,20,23], since they were clinical trials, while the others were considered the level of evidence three[16-19,21,22,24-27], because they were observational studies, with or without follow-up after conventional valve surgery. Was noticeable heterogeneity among the numbers of participants, since the study with the smallest number of participants had 25 patients[16] and the largest managed to access 742 patients[24].

About the data collection of the selected articles, the evaluation of the health-related quality of life during the pre-and postoperative periods was identified, as well as the evaluation of the construct by follow-up only in the postoperative period.

The selected articles contemplated mostly surgical interventions, with access to the mitral valve, followed by access to the aortic valve and tricuspid valve. Plastics were referenced in nine of the selected studies, and valve implants were described in all selected studies. It is noteworthy that in only two, the authors specified the type of valve prosthesis used, biological and/or mechanical[16,19], as shown in Table 2.

Regarding the instruments to assess health-related quality of life, the use of generic instruments was identified, 36-Item Short-Form General Health Survey (SF-36)[16-22,24,26,27], 12-Item Short-Form General Health Survey (SF-12)[14,25], 6D health utility index (SF-6D)15,21, European Quality of Life - 5 Dimensions (EQ-5D)[14,22,23] and Minnesota Living with Heart Failure[14], and the SF-36 was used in eleven studies. Regarding the use of specific instruments, it was evident the measurement of the construct by the Heart QoL Questionnaire[24] and by the Valve-specific Qol Questionnaire[20,27], the latter being considered a complementary questionnaire to the assessment of the health-related quality of life by a generic instrument.

Regarding the follow-up evaluation of the health-related quality of life, the studies mostly assessed the construct throughout the perioperative context. However, in five studies[23,24,26,27] the assessment of this construct was performed only in the postoperative period, at different times during the first year after valve surgery.

Regarding the type of procedure performed, it was observed the performance of mitral valve prosthesis implants[14,15,18,20], aortic[19-22,25-27], tricuspid[16,17] and studies without distinction as to the location of the valve prosthesis to be replaced[23,24], in some studies there was a comparison between implants and valve repair[14,15,17,23,24], which revealed early improvement in health-related quality of life in patients undergoing valve repair only (Table 2).

Of the studies selected for the review, ten[14-22,25] allowed us to verify the improvement in health-related quality of life after

Table 2: Synthesis of the studies included in the review according to authors, database, level of evidence, periods of assessment of the health-related quality of life

Authors LE	Database and country of origin	Delineation	Preoperative	Postoperative
Kidler et al. 2015[22] LE: 3	Scopus England	The observational study was performed pre- and postoperatively after valve surgery.	For the SF-36 the scores of all domains were lower than 50 points and for the EQ-6D they were lower than 75 points.	Improvement in all domains by SF-36 and EQ-5D.
Ren et al. 2015[17] LE: 3	Medline China	Cohort	By the SF-36, the worst evaluated domains were Functional Capacity and Physical Appearance, in both investigated groups.	In the plastics, without the use of a ring, there was an improvement in the domains: Physical Aspect, Emotional Aspect, Social Aspect, and General Health. In the surgeries with the use of the ring, there was an improvement in all domains, except pain.
Sibilitz et al. 2015[24] LE: 3	Web of Science Denmark	An observational study was conducted with patients six to twelve months after valve surgery.	Not applicable.	According to the SF-36, there was an improvement in all domains, except for the pain domain. Regarding the Heart QoL Questionnaire, the physical component obtained a score of 2.0.
Goldstein et al. 2016[14] LE: 1	Medline Canada	A randomized clinical trial at preoperative, one month, six months, and the first and second year after valve surgery.	The SF-12 scores for the Physical and Mental components were lower than 50 points, the Minnesota scores were lower than 50 points, and the EQ-5D scores were between 50 and 60 points in the evaluated groups.	In the plastic surgeries, by SF-12 and EQ-5D there was an increase in scores between the first and sixth month after surgery. While in the valve implants, by the SF-12 there was an improvement in the quality of life-related to health from the sixth month and by Minnesota improvement between the first and sixth month, both after conventional valve surgery.
Tsang et al. 2016[16] LE: 3	Embase China	An observational and longitudinal study, carried out preoperatively and six months after valve intervention	By the SF-36, the best-evaluated domains were Functional Capacity and Emotional Aspect. However, the worst domains were Vitality and General Health.	All domains were better rated by the participants six months after the conventional valve intervention.
Zacek et al. 2016[27] LE: 3	Web of Science The Czech Republic	A cross-sectional study was conducted with patients starting six months after valve surgery.	Not applicable.	By SF-36, vitality was the worst, and functional capacity was the best domain evaluated by the different groups studied. By the Valve-Specific Qol Questionnaire, fear of possible valve failure, reoperation, and continuous anticoagulant use was considered disruptive factors.
Kottmaier et al. 2016[26] LE: 3	Web of Science Germany	Cohort study, conducted with patients starting six months after valve surgery.	Not applicable.	By the SF-36, vitality was the worst evaluated domain, and the social aspect was the best evaluated by the different groups studied. By the Valve-Specific Qol Questionnaire, the continuous use of anticoagulants was considered a disturbing factor.
Petersen et al. 2016[25] LE: 3	Web of Science Germany	An observational study was conducted with patients preoperatively, one and six months after valve surgery.	By the SF-12, the physical component scored less than 40 points and the mental component score less than 50 points.	Through the SF-12, there was an improvement in the two components evaluated, however, the values were higher as of the third month after the surgical intervention.
Luksic et al. 2017[19] LE: 3	Medline Croatia	An observational and longitudinal study was performed preoperatively and up to twelve months after valve intervention.	By the SF-36, the worst evaluated domains were Functional Capacity and Physical Appearance, in both investigated groups.	All domains obtained better evaluations, with Functional Capacity and Physical Aspects standing out.
Hansen et al. 2017[23] LE:1	Web of Science Denmark	A randomized controlled trial with patients undergoing valve surgery.	Not applicable.	The EQ-5D showed improvement in all the components evaluated in the two investigated groups.
Korteland et al. 2017[20] LE: 1	Web of Science Netherlands	Randomized controlled clinical trials performed pre- and postoperatively after valve surgery.	In the SF-36, the physical aspect scored less than 50 points in both investigated groups.	The SF-36 showed improvement in all domains in the investigated groups.

Continue...

Table 2: Continuation.

Authors LE	Database and country of origin	Delineation	Preoperative	Postoperative
Coelho et al. 2018[21] LE: 3	Scopus Portugal	The observational study was performed preoperatively, three, six, and twelve months after valve surgery.	The SF-36 scores were lower than 50 points and the SF-6D scores were lower than 40 points.	By the SF-36 in general with scores higher than 70 and by the SF-6D with values higher than 40 points, after the conventional valve surgery intervention.
Ferket et al. 2019[15] LE: 1	Medline Canada	A randomized clinical trial at preoperative, one month, six months, and the first and second year after valve surgery.	The SF-6D scores were between 65 and 68 for plastics and implants, respectively.	The best evaluations with values higher than 68 were observed only from the sixth month on.
Hong et al. 2019[18] LE: 3	Web of Science China	An observational study was conducted with patients preoperatively, one, three, six, and twelve months after valve surgery.	In the SF-36, the physical aspect and vitality scores were lower than 50 points in the investigated groups.	The SF-36 showed improvement in all domains in the investigated groups.

Key: SF-36: 36-Item Short-Form General Health Survey; SF-12: 12-Item Short-Form General Health Survey; EQ-5D: European Quality of Life - 5 Dimensions, SF- 6D: SF-6D health utility index; LE: level of evidence.

conventional valve surgery, from follow-up through outpatient follow-up up to one year after the intervention.

In the preoperative period, it was observed in general the impairment of the domains, Vitality[14,18], General Health[16], Functional Capacity[16,17,19,] and Physical Aspect[18], by SF-36. However, the evaluations by components, by SF-36, SF-12, SF- 6D, and Minnesota Living with Heart Failure, revealed impairment in the physical and mental components, with scores below 50 points[14,18,20-22,25].

Postoperatively, an improvement in health-related quality of life was evidenced in all studies with outpatient follow-up. It was observed that the improvement occurred mostly from the sixth month after valve surgery. However, some situations may influence the assessment of the construct, because when there was a comparison between valve repair and valve prosthesis implantation, the domain pain, measured by the SF-36, was the domain with the worst scores in patients undergoing valve prosthesis implantation[17,24,26,27].

Four of the selected studies assessed health-related quality of life only postoperatively at different times (three, six, and twelve months). The domains, assessed by the SF-36, and the components, assessed by EQ-5D and SF-36 and SF-12, showed improvement in health-related quality of life[23-24,26,27], however, the domains pain and vitality were the worst evaluated in some studies[24,26,27].

Regarding the health-related quality of life in patients undergoing biological or mechanical valve prosthesis implantation, it was observed that there was improvement according to the reports of the authors of articles selected to compose this review, when the construct was assessed using generic instruments, however, when the construct was assessed by specific instrument Heart QoL Questionnaire and the Valve- specific QoL Questionnaire, it was perceived the existence of factors related to the type of prosthetic valve implanted, which came to impair the quality of life-related to health[20,24,26,27], according to the assessments highlighted in Table 2 in the assessment from the generic instruments.

DISCUSSION

The review in question identified an improvement in the health-related quality of life of patients with valve disease after conventional valve surgery, which allows us to infer that the surgical treatment[28] was perceived by patients with valve disease as positive when assessed by generic instruments. However, in studies in which the assessment of the health-related quality of life was performed by generic and specific instruments, we noticed gaps in the assessment of the construct.

The evaluations were reflected by domains, when the SF-36 was used, revealing the preoperative impairment of health-related quality of life in functional capacity[17,19], physical aspect[17-19], vitality[16,18], general health status[16], and pain[17], with significant improvement postoperatively, except in the pain domain.

The pain domain obtained the worst assessment in the two studies included in this review. These findings may be related to the type of procedure performed, because in the study in which the pain domain obtained the worst evaluations, the participants underwent tricuspid valvuloplasty with ring[17] or implantation of biological or mechanical valve prosthesis[24] which may justify the increased pain threshold expressed by the participants of the studies, possibly justified by the manipulation of the organ to perform the valve surgery, both by the use of a valve ring and by the implantation of the valve prosthesis itself.

Regarding the evaluation by components, there was a predominance of scores lower than 50 points in the preoperative period, also by SF-36, by SF-12, and by Minnesota Living with Heart Failure, with improvement in the evaluation of the physical component and the mental component after valvuloplasty[14]. As for the valve implants, in studies that allowed the comparison between pre- and postoperative, the improvement was evidenced from the third month after the surgical intervention[18,20-22,25].

Regarding the type of surgical procedure, there was a better evaluation of the health-related quality of life in patients undergoing valve repair when compared to those undergoing valve

prosthesis implantation, without specification of the type of prosthesis used in the surgical intervention performed[14,15,17,23-25].

On aspects related to the influence of the type of prosthetic valve implanted, biological or mechanical, no differences were identified related to the measurement of health-related quality of life through the generic instruments used[14,26]. However, aspects related to the assessment of this construct were evidenced by the Valve-specific Qol Questionnaire, which revealed gaps in the assessment of the construct, from the moment the participants highlighted the oral anticoagulation therapy (OAT) as a factor that may compromise the improvement of health-related quality of life[20,26,27].

The fear of possible failure of the prosthesis and the possibility of reoperation due to the durability of the valve were negative points highlighted by patients undergoing implantation of biological valve prosthesis[20,27]. Regarding individuals undergoing mechanical valve prosthesis implantation, the continuous use of oral anticoagulants was considered a negative factor, which may interfere with the quality of life related to health[26] due to the need for monetization of the International Normalized Ratio (INR) to prevent thrombotic events during drug therapy.

The choice between the types of prostheses, passes through intrinsic factors to patients with valve disease, such as age over sixty years and the existence of comorbidities (congestive heart failure, renal failure, coronary artery disease, and lung diseases), in addition to factors related to valve structures, because the biological prostheses structurally similar to physiological prostheses have a higher risk of structural deterioration after the first five years of implantation. On the other hand, mechanical prostheses have greater durability, however, the patient requires specific care aimed at continuous oral anticoagulation, and outpatient follow-up is of great importance after surgery to avoid ischemic events or episodes of bleeding[7,8,29].

The limitations of the study considered the fact that some articles included in the final sample, did not allow the comparison of health-related quality of life in individuals undergoing different valve surgery, whose information gap may not reflect the reliable assessment of the construct investigated. Thus, it is suggested the performance of observational studies with assessments by follow-up, aiming to measure the health-related quality of life using generic and specific instruments to verify potential gaps in perioperative care for patients with valve disease submitted to conventional valve surgery.

Conclusion

From the synthesis of the selected studies, it was possible to identify the improvement in health-related quality of life after conventional valve surgery when assessed only by generic instruments, however, in studies in which the construct was assessed by generic and specific instruments concomitantly, it revealed some weaknesses in the assessment of the health-related quality of life because the use of specific instruments made it possible to reveal elements that may impair health-related quality of life in the postoperative period.

In general, the domains related to the physical conditions of patients with valve disease showed the lowest scores, both in the comparison between pre-and postoperative periods and in the evaluation by postoperative follow-up in patients undergoing mechanical valve prosthesis implantation. On the other hand, the domains related to emotional conditions were lower in patients with valve disease who had undergone biological valve prosthesis implantation. Whereas, those who underwent only valvuloplasty showed improvement in physical and emotional conditions.

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