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Article

Impact of Indexed Effective Orifice Area on the Quality of Life of Patients after Aortic Valve Replacement

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Abstract

Background: Improving health related quality of life is an important goal of aortic valve replacement. Inadequate effective orifice area of prosthesis according to the patient's body surface area may be associated with poor outcomes. In this study, we aimed to analyze impact of indexed effective orifice area (iEOA) on patients' quality of life after aortic valve replacement. **Methods**: A total of 138 patients who underwent isolated aortic valve replacement were included to the study. Quality of life assessment was performed with EuroQol Group EQ-5D-5L questionnaire. Patients were divided into three groups based on iEOA (Group 1 had an iEOA of <0.65 cm^2/m^2 (19 patients), Group 2 had an iEOA between 0.65–0.85 cm^2/m^2 (71 patients), and Group 3 had an iEOA of >0.85 cm^2/m^2). Mean EQ-5D-5L scores were compared among the groups statistically. **Results**: Mean EQ-5D-5L scores were lower in Group 1 than in Groups 2 and 3 (Group 1: 0.72 ± 0.18, Group 2: 0.83 ± 0.20, and Group 3: 0.86 ± 0.9, $p = 0.044$ and $p = 0.014$). The EQ-5D-5L score was significantly lower in patients with a $\geq$20 mmHg transvalvular gradient than those with a $<$20 mmHg (0.74 ± 0.25 *vs.* 0.84 ± 0.18, $p = 0.014$). **Conclusions**: Our results show that an iEOA <0.65 cm^2/m^2 is significantly associated with impaired postoperative health-related quality of life. Newer generation prostheses, transcatheter valve implantation, and root enlargement techniques should be kept in mind in preoperative planning.

Keywords

aortic valve surgery; quality of life; effective orifice area

Introduction

Aortic valve replacement (AVR), either via surgery or transcatheter, is the preferred treatment in patients with severe aortic valve disease and has satisfactory outcomes. However, operative results focusing on morbidity and mortality do not give enough information on a patient's physical, functional, emotional, and mental well-being. Postoperative improvement of health-related quality of life (HRQOL) is an important surgical goal and a major expectation for many patients.

An HRQOL analysis is based on patients' feedback about an operation's physical and mental outcomes. The early studies reporting on HRQOL in AVR patients were first published in 1997 [1–3]. In the following years, Shan *et al.* [4] undertook a review of HRQOL outcomes in elderly patients following AVR. They found noticeable improvements in cardiac symptoms and functional status in patients after AVR. Blokzijl *et al.* [5] also reported marked physical and mental improvement 1 year after AVR. However, they found that increasing age is a risk factor for postoperative deterioration of physical and mental HRQOL. Recently, Surman *et al.* [6] showed that AVR significantly improved patient-reported outcome measures and frailty at 3 months post-surgery, regardless of whether the surgical or transcatheter approach was used.

Indexed effective orifice area (iEOA) can be calculated by dividing the effective orifice area of the prosthesis by the patient's body surface area. Rahimtoola *et al.* [7] first described Prosthesis–patient mismatch (PPM) in 1978 as an inadequate prosthesis size according to the patient's body surface area. An iEOA of <0.85 cm^2/m^2 is generally regarded as the threshold for PPM in the aortic position, with values between 0.65 and 0.85 cm^2/m^2 classified as moderate PPM and those 0.65 cm^2/m^2 as severe PPM [8]. Various studies have analyzed the impact of PPM on postoperative outcomes [9–11].

In the present study, our aim to analyze the impact of iEOA on postoperative HRQOL following isolated AVR.

Material and Methods

Patients who underwent isolated AVR between January 2020 and January 2022 were reviewed. Istanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Research and Training Hospital's ethics committee approval was gained with the number of 2023/18. Following

the data analysis of 153 patients, 8 were excluded (5 were reoperated on, 2 were emergent cases, and 1 died in the hospital). A total of 145 patients were included in the study. The national death database revealed four patients had died of COVID-19, and the authors could not contact three patients by phone. Therefore, 138 patients were included in the HRQOL assessment. All patients were contacted by phone. Patients were informed about the study, and their consent was obtained before completing the HRQOL questionnaire. EuroQol Group EQ-5D-5L questionnaire was given to each patient. In addition, the patients were asked to compare their current health status to that before surgery.

The patients' preoperative echocardiographic features and demographic, operative, and postoperative data were taken from the institutional database. The prosthetic valve's effective orifice area was obtained from the manufacturer's data. The iEOA was calculated by dividing the prosthetic valve's effective orifice area by the patient's body surface area. Patients were divided into three groups according to the iEOA: Group 1 had an iEOA of <0.65 cm^2/m^2 (19 patients), Group 2 had an iEOA between 0.65–0.85 cm^2/m^2 (71 patients), and Group 3 had an iEOA of >0.85 cm^2/m^2 (48 patients).

The present study aimed to analyze the impact of the iEOA and the patients' demographic data, preoperative echocardiographic features, and operative data on the patients' HRQL, assessed statistically with the patients' reported health status and postoperative EQ-5D-5L questionnaire scores.

All statistical analyses were performed using IBM SPSS® Statistics software version 26.0 (IBM Corp., Armonk, NY, USA). Continuous data were presented as mean $\pm$ standard deviation or median (interquartile range) based on the distribution of the data. The normality of the distribution was assessed using the Kolmogorov–Smirnov test. Categorical data were presented as frequencies and percentages. The differences in the continuous variables between the groups were assessed using the Student's *t*-test for normal distributions or the Mann–Whitney U test for non-normal distributions.

One-way analysis of variance followed by Tukey's range test were used to compare the mean values among the three groups. Correlations were assessed with the Spearman's rank correlation coefficient. The statistical significance was set at $p < 0.050$ and $p < 0.001$.

Results

One hundred thirty-eight patients (50 female, 88 male) were included in the study. The median age was 62 years (min.50–max.68). All patients underwent AVR under cardiopulmonary bypass. Median sternotomy was used in 127 patients, and 8 patients were operated via j sternotomy and 3 patients were operated via right atrial thoracotomy. A bioprosthetic valve was used in 41 patients, and a mechanical valve in 97 patients. The median aortic cross-clamp time was 72.50 min (range: 59, 75–87 min), and the cardiopulmonary bypass time was 106.7 $\pm$ 40.74 min (81.50–122.50). Table 1 summarizes the patients' demographic parameters. The mean follow-up time was 20.41 $\pm$ 9.13 months (13–38 months).

Table 1. A correlation of patients demographic, echocardiographic and operative characteristics and EQ-5D scores.

Parameter	Mean	*p* value	Test
Age	57.78 $\pm$ 14.3	0.684	Spearman's
Gender (F/M)	50/88	0.513	MWU
Preoperative EF	54.70 $\pm$ 9.64	0.089	Spearman's
Preoperative Gradient	47.65 $\pm$ 14.88	0.948	Spearman's
CPB Time	106.7 $\pm$ 40.74	0.575	Spearman's
Cross Clamp Time	72.50	0.681	Spearman's
Prosthesis type*	41/97	0.997	MWU
Postoperative EF	53.58 $\pm$ 8.14	0.045	Spearman's
Postoperative Gradient	14.32 $\pm$ 6.4	0.070	Spearman's

F/M, Female/Male; EF, Ejection Fraction; CPB, Cardiopulmonary Bypass; *, Bioprosthesis/Mechanic valve; MWU, Mann Whitney U.

The mean iEOA was significantly different among the groups (Group 1: 0.62 $\pm$ 0.02, Group 2: 0.75 $\pm$ 0.05, and Group 3: 0.99 $\pm$ 0.11, $p < 0.001$). Patients were significantly younger in Group 1 in comparison with Group 3 (53.66 $\pm$ 14.27 *vs.* 61.56 $\pm$ 13.71, $p = 0.034$). The gender distribution was similar among the groups.

Mean EQ-5D-5L scores were lower in Group 1 than in Groups 2 and 3 (Group 1: 0.72 $\pm$ 0.18, Group 2: 0.83 $\pm$ 0.20, and Group 3: 0.86 $\pm$ 0.9, $p = 0.044$ and $p = 0.014$). Fig. 1 shows correlation between iEOA and EQ-5D-5L scores. Fig. 2 shows the mean values for each dimension of the EQ-5D-5L.

The postoperative ejection fraction (EF) was similar between the groups, but the postoperative mean transvalvular gradient was significantly higher in Groups 1 and 2 than in Group 3 (16.67, 14.88, 12.47 mmHg, $p = 0.012$ and $p = 0.043$).

The postoperative EF was positively correlated with the EQ-5D-5L scores ($p = 0.045$). The postoperative transvalvular mean gradient was not associated with decreased HRQOL ($p = 0.070$). However, the EQ-5D-5L score was significantly lower in patients with a $\geq$20 mmHg transvalvular gradient than those with a $<$20 mmHg (0.74 $\pm$ 0.25 *vs.* 0.84 $\pm$ 0.18, $p = 0.014$).

The patients' self-assessment comparing their current and preoperative health status revealed that while 73.2% of patients reported a significant improvement in their health status, 11.5% reported a worsening, and 15.3% declared they had no change postoperatively (Fig. 3).

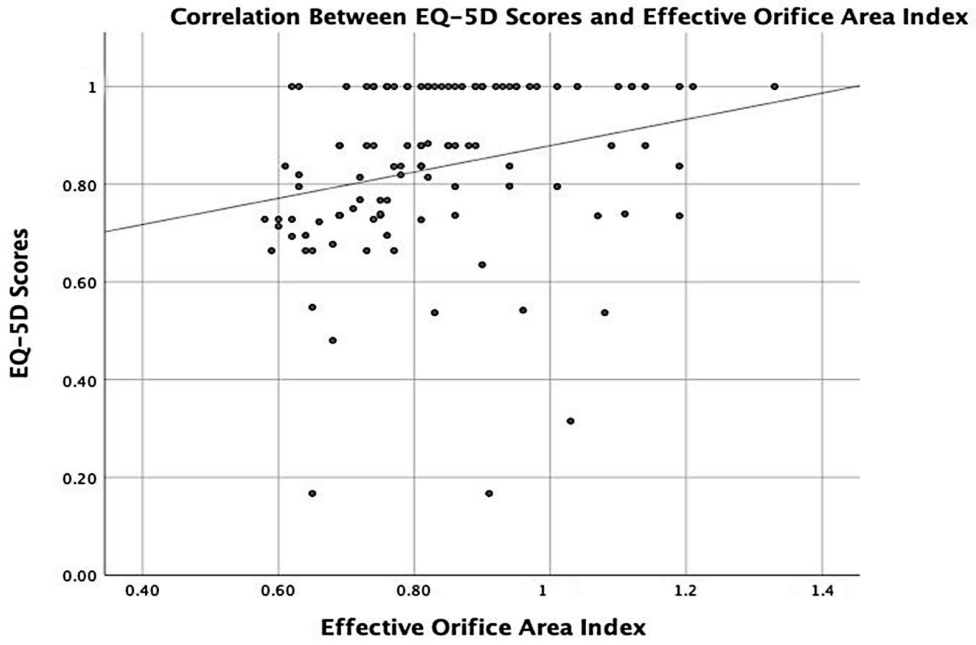

Fig. 1. Correlation between iEOA and EQ-5D-5L scores.

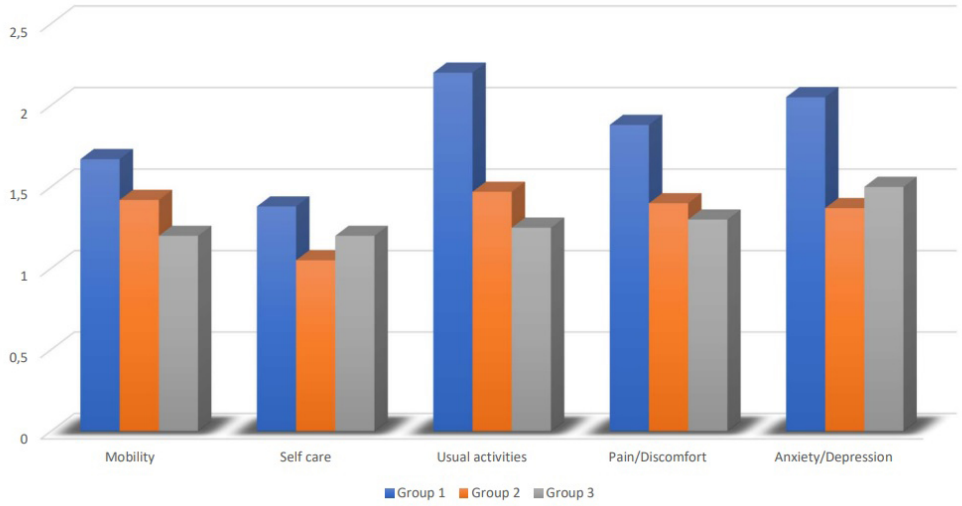

Fig. 2. Graphic shows the sum of the mean values for each of the 5 EQ-5D-5L dimensions for groups.

Discussion

The present study analyzed the factors affecting postoperative outcomes and HRQOL following AVR. Our results showed that the iEOA is significantly associated with patients' HRQOL. A strong linear correlation was found between the iEOA, postoperative EQ-5D-5L scores, and the patients' HRQOL. The postoperative EF and the transvalvular mean gradient were also significantly correlated with HRQOL. Although mean iEOA was higher in patients who underwent AVR with bioprosthetic valves, HRQOL was similar to patients who underwent AVR with a mechanical prosthesis.

The World Health Organization (WHO) defines health as "not only the absence of disease and infirmity but also the presence of physical, mental, and social well-being". According to the WHO's HRQOL definition, any generic HRQOL instrument should include physical, psychological, social, functional, and well-being measures [12]. The

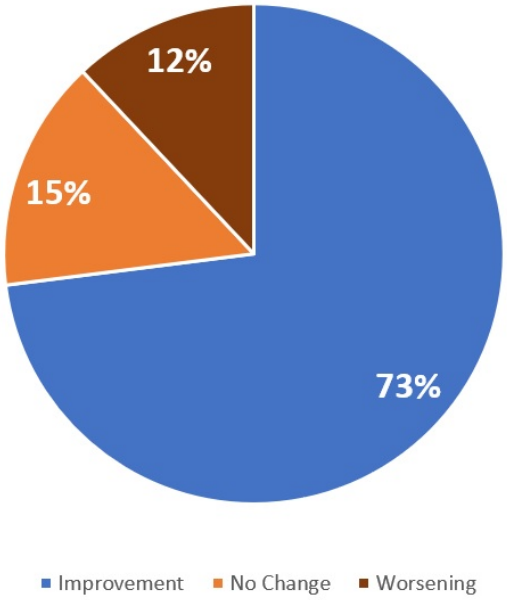

Fig. 3. Pie chart of the patients reported health status change.

EQ-5D-5L questionnaire is a well-designed instrument for HRQOL assessment and includes mobility, self-care, usual activities, pain and discomfort, and anxiety and depression [13]. In this study, the mean values for each dimension were higher in Group 1. However, the most noticeable difference appeared in usual activities (e.g., work, study, housework, family, and leisure), followed by anxiety and depression (Fig. 2).

Eisenmann *et al*. [14] analyzed the long-term impact of PPM (an iEOA <0.85 cm^2/m^2) after mechanical AVR in 75 patients. Prosthesis–patient mismatch was found in 37% of patients. Compared with the non-PPM group, the PPM group contained fewer patients in Class I of the New York Heart Association Functional Classification, and their mean 36-Item Short Form Survey physical component summary score was found to be significantly lower [14]. In this study, moderate PPM was found in 51.4% of patients, severe PPM was found in 13.8% of patients, and PPM was not found in 34.8% of patients. For the severe PPM patients (Group 1), mean EQ-5D-5L scores were significantly lower than for patients with moderate PPM (Group 2) and no PPM (Group 3). The mean EQ-5D-5L scores were lower in the moderate PPM group compared with the non-PPM group, but the difference was not significant. Eisenmann *et al*. [14] reported that the transvalvular gradient was higher in the PPM group. In the present study, the authors also found a higher mean transvalvular gradient in the severe and moderate PPM groups compared with the non-PPM group, and the postoperative transvalvular gradient correlated with the HRQOL scores.

Older age is a well-known risk factor for mortality and morbidity after cardiac surgery [15]. However, studies have shown no statistically significant difference in HRQOL between older and younger patients. The impact of PPM on HRQOL may be more pronounced in older patients who are more likely to have comorbidities that limit their daily activities. On the other hand, decreased daily activities due to comorbidities and aging may also alleviate the impact of PPM. This study's cohort was relatively younger, with a median age of 62, and age was not found to be correlated with EQ-5D-5L scores and HRQOL.

The relationship between early mortality and PPM is controversial. Several studies report that PPM is not correlated with early mortality but may affect long-term survival [16–18]. Mohty *et al*. [19] analyzed the impact of PPM on mortality in a large follow-up study of 2576 patients, and they demonstrated that severe PPM might increase mortality in patients younger than 70 years, those with a body mass index <30 kg/m^2, and those with a left ventricular EF of $<50\%$. Recently, Dahlbacka *et al*. [20] reported that PPM is associated with increased 5-year mortality in patients >70 years. This study has not focused on mortality, but accumulated data may indicate that avoiding severe PPM in high-risk patients should be part of the treatment strategy.

The postoperative mean transvalvular gradient ≥ 20 mmHg is considered a severe condition and was found to be associated with poor outcomes [21]. In the present study's cohort, a postoperative high transvalvular gradient was diagnosed in 27 patients. The mean EQ-5D-5L score of these

patients was found to be significantly lower than the patients whose transvalvular gradient was <20 mmHg. Detailed analysis of the EQ-5D-5L showed that mobility and usual activities were the most impaired dimensions.

In conclusion, iEOA is an important prognostic factor after AVR. Our results show that an iEOA between 0.65–0.85 cm^2/m^2 may not affect HRQOL. However, an iEOA <0.65 cm^2/m^2 is significantly associated with impaired HRQOL. Improved HRQOL is one of the most important goals of AVR. Newer generation prostheses, transcatheter valve implantation, and root enlargement techniques should be kept in mind in preoperative planning.

Conclusions

Our findings provide compelling evidence that an indexed effective orifice area (iEOA) measuring less than 0.65 cm^2/m^2 is strongly correlated with diminished postoperative health-related quality of life. This underscores the importance of considering alternative interventions, such as newer generation prostheses, transcatheter valve implantation and root enlargement techniques, during the preoperative planning stage. By incorporating these alternatives cardiac surgeons can aim to enhance patient outcomes and improve overall postoperative well-being in individuals who require intervention for aortic stenosis.

Abbreviations

AVR, Aortic Valve Replacement; CPB, Cardiopulmonary Bypass; EF, Ejection Fraction; HRQOL, Health Related Quality of Life; iEOA, Indexed Effective Orifice Area; MWU, Mann Whitney U; PPM, Patient Prostheses Mismatch; WHO, World Health Organization.

Availability of Data and Materials

Data of this study will be available immediately following publication and no end date. In present study, all of the individual participant data collected during the trial after deidentification. No personal data was used in article.

Author Contributions

MG: Conception, design and drafting the article; EY: Statistical analysis, drafting the article; SG: Statistical analysis, analysis and interpretation of data; LY: Data collection, analysis and interpretation of data; TM: Data collection, analysis and interpretation of data; EKa: Design and drafting the article; EKu: Design and drafting the article; UA: Design and drafting the article. All authors discussed the results and commented on the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work to take public responsibility for appropriate portions of the content and agreed to be accountable for all aspects of the work in ensuring that questions related to its accuracy or integrity.

Ethics Approval and Consent to Participate

Istanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Research and Training Hospital's ethics committee approval was gained with the number of 2023/18. Patients were informed about the study, and their consent was obtained before completing the HRQOL questionnaire.

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Conflict of Interest

The authors declare no conflict of interest.

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