Mathematical modeling for predicting the optimal size of ring annuloplasty in the repair of degenerative mitral valves

Laura Besola, Giosuè Salvatore Falcetta, Alessandro Fiocco, Chiara Mangifesta, Giacomo Ravenni, Michele Celiento, Danilo Ruggiero, Edoardo Merella, Federico Giorgi, Andrea Colli

Cardiac Surgery Unit, Department of Surgical, Medical and Molecular Pathology and Critical Care, University of Pisa, Pisa, Italy

Correspondence to: Prof. Andrea Colli, MD, PhD. Cardiac Surgery Unit, Department of Surgical, Medical and Molecular Pathology and Critical Care, University of Pisa, Via Paradisa, 2, 56126, Pisa, Italy. Email: colli.andrea.bcn@gmail.com.

Background: During mitral valve repair (MVRe), the sizing of the prosthetic ring/band often depends more on the surgeon's experience than objective methodology. The study aims to validate a mathematical approach based on transthoracic echocardiography to predict the optimal ring size in a surgical cohort.

Methods: Patients who underwent MVRe between July 2021 and July 2023 were retrospectively evaluated. Pre-operative echocardiography data were collected [including pre-operative coaptation length (CL0), anteroposterior (AP) diameter, anterior mitral leaflet (AML) length, posterior mitral leaflet (PML) length]. A dedicated formula was developed to predict the postoperative AP (pAP) diameter, ensuring a CL of 8 mm, according to the literature. Based on the calculated pAP, the optimal ring size was selected using the manufacturer's ring charts. A linear regression study tested the consistency between the predicted and implanted sizes.

Results: Fifty-four patients were included; six implanted a Flexible Band, 17 a Semirigid Band, and 31 a Semirigid Ring. In linear regression, there was an acceptable correlation between predicted/implanted sizes ($r=0.589$; $P<0.001$). Overall, the only factor influencing concordance was ring type. When analyzing the single ring groups, we found that correlation was impacted by ring type with an optimal correlation for Semirigid Rings ($r=0.745$, $P<0.001$), good for Semirigid Bands ($r=0.659$, $P=0.004$), and poor for Flexible Bands.

Conclusions: The proposed method is reliable in predicting the optimal ring size, with a CL >8 mm; however, the test's ability is influenced by the type of ring. Further studies are needed to validate the formula in a larger population and investigate its use in transcatheter annuloplasty.

Keywords: Mitral valve repair (MVRe); mitral valve disease; mitral annuloplasty; precision medicine

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Introduction

Mitral regurgitation (MR) is the most common heart valve disease requiring surgery in the United States and the second most common in Europe. As the population ages and grows, MR is expected to become even more prevalent (1). Surgical mitral valve repair (MVRe) is the preferred treatment for most patients with severe MR, as it is more durable than mitral valve replacement (MVR) (2).

During MVRe, ring annuloplasty using bands or rings is crucial for restoring annular dimensions and increasing leaflet coaptation length (CL) to prevent further dilatation and recurrence of regurgitation (3,4).

Importantly, to achieve a favorable outcome, it is fundamental to accurately select the size of the annuloplasty ring (5). Typically, ring size selection is based on intraoperative measurements of the anterior leaflet area and inter-trigonal distance, as well as the surgeon's judgment, which can be influenced by experience. This study aims to evaluate a new mathematical formula based on transthoracic

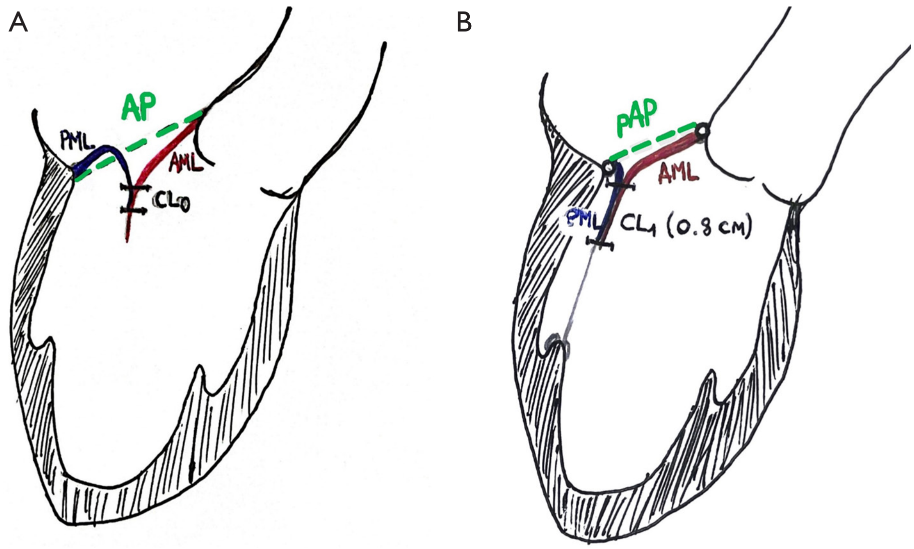

Figure 1 Graphical representation of the proposed formula and relative measurements: (A) before ring implant and (B) after ring implant. AML, anterior mitral leaflet length; AP, preoperative anteroposterior mitral annulus diameter; CL0, pre-operative coaptation length; CL1, postoperative coaptation length set at 8 mm; pAP, postoperative anteroposterior mitral annulus diameter; PML, posterior mitral leaflet length.

echocardiographic (TTE) measurements to predict the prosthetic ring size needed for surgical annuloplasty.

Methods

We retrospectively included patients who underwent surgical MVRe for degenerative MR (DMR) at the Cardiac Surgery University of Pisa between July 2021 and July 2023 and presented preoperative high-quality 2-dimensional (2D) TTE datasets. Patients with functional and mixed MR were excluded. All patients underwent 2D-TTE at baseline and postoperatively, and standard echocardiography data were collected. In addition, four preoperative measurements were made off-line in the parasternal long axis (P-LAX) view for the specific purpose of this study: anterior mitral leaflet (AML) and posterior mitral leaflet (PML) length, pre-operative coaptation length (CL0), and anteroposterior mitral annulus diameter in telesystole (AP). An ideal postoperative CL of 8 mm was set as the desired one according to previously published data that showed that CL between 6 and 10 mm can provide the optimal outcomes in terms of MR recurrence (5). The following formula was developed (*Figure 1*) to predict the final postoperative AP (pAP) diameter, ensuring a CL of 8 mm:

$$pAP = \frac{(AML-8)+(PML-8)}{(AML-CL0)+(PML-CL0)} \times AP \qquad [1]$$

Based on the calculated pAP, the optimal ring size was selected using the manufacturer's ring charts (specific to the model), which show the AP diameter corresponding to each ring size. The obtained ring size was then compared to the actual implanted size. The prediction was considered successful if the predicted size was between±1 of the implanted size.

All measurements were obtained three times by the same expert echocardiographer, and expected sizes were chosen blindly with respect to the actually implanted sizes.

The Pearson correlation coefficient (PCC) test was used to assess the correlation between the implanted and predicted sizes in the overall population. A Bland-Altman plot was obtained on the ring-type stratified population. Chi-squared and two-tailed *t*-tests were used, as appropriate, to assess variables that might influence the difference between the implanted and predicted sizes. Based on available literature and clinical experience, the following variables were chosen: BSA, sex, AML and PML length, AP diameter, and left ventricle end-diastolic volume (LVEDV), as well as leaflet resection or chordal implantation. Significance was set at 0.05, and all data analyses were performed using SPSS software, version 28 (SPSS Inc., Chicago, IL, USA).

Results

Fifty-four patients fulfilled the inclusion criteria. Mean

Table 1 Overall population and stratified population correlation test

Variables	Values
Age (years)	64±13
BMI (kg/m^2)	24.4±3
BSA (m^2)	1.8±0.2
Diabetes mellitus	4 (7.4)
Smoke	17 (31.5)
Ex	11 (20.4)
Active	6 (11.1)
CAD	7 (13.0)
One vessel disease	4 (7.4)
Two vessel disease	2 (3.7)
Three vessel disease	1 (1.8)
EuroScore II	2±1.9
STS score	1.4±1.3
Arterial hypertension	26 (48.1)
Dyslipidemia	16 (29.6)
PAD	12 (22.2)
COPD	3 (5.5)
Previous stroke	1 (1.9)
Malignancy	3 (5.5)
NYHA	
1	14 (25.9)
2	25 (46.3)
3	11 (20.4)
4	4 (7.4)
Preoperative radiotherapy	2 (3.7)
Dialysis	0 (0.0)
Preoperative cardiac rhythm	
SR	46 (85.2)
AF	8 (14.8)
PPM	0 (0.0)
Previous CABG surgery	6 (11.1)
Creatinine (mg/dL)	1±0.2
eGFR (mL/min/1.73 m^2)	76.7±28.5
Hb (g/dL)	12.6±1.8

Data are presented as mean ± standard deviation or n (%). AF, atrial fibrillation; BMI, body mass index; BSA, body surface area; CABG, coronary artery bypass grafting; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; Hb, hemoglobin; NYHA, New York Heart Association; PAD, peripheral artery disease; PPM, permanent pacemaker; SR, sinus rhythm; STS, Society of Thoracic Surgeons.

age was 64±13 years and most were men (64%). Their body surface area was 1.8±0.2 m^2, and 26 (48.1%) had hypertension, while the majority (85.2%) were in sinus rhythm at presentation. Complete data are shown in *Table 1*. All patients had severe DMR at baseline TTE, vena contracta width (VCW) was 6.6±1.3 mm; an effective regurgitant orifice area (EROA) of 0.5±0.2 cm^2; and regurgitation volume of 74±21.4 mL. Patients presented with only mildly dilated left ventricles [LVEDV of 136±46 mL, left ventricle end-systolic volume (LVESV) of 52±30 mL] and preserved left ventricular ejection fraction (61%±6%) (*Table 2*).

Thirty-three patients (61.1%) presented with leaflet prolapse, involving the AML in four (7.4%) cases, PML in 23 (42.6%), and both leaflets in six (11.1%); 21 (38.9%) patients had PML flail. Mean systolic and diastolic AP diameter were 38.2±5.7 and 34.6±6 mm, respectively; while mean AML and PML length were 24.5±4 and 18.8±3.7 mm, respectively (*Table 2*).

All patients underwent surgery through a traditional full median sternotomy performed by the same surgeon. In all patients, annuloplasty was performed; 17 (31.5%) received a CG Future Band (Semirigid Band), 31 (57.4%) a Simulus Ring (Semirigid Ring), and six (11.1%) a SimuPlus Band (Flexible Band) (Medtronic, Minneapolis, MN, USA).

During surgery, additional PML resection was performed in 18 (33.3%) patients while PML augmentation was performed in one patient (1.8%). Thirty patients (55.5%) received artificial chords: three (10%) on the AML, 26 (86.7%) on the PML, and one on both (3.3%). Commissuroplasty was performed in three (5.5%) patients (*Table 3*).

In the overall population, the predicted ring size was well correlated with the actual implanted size (PCC r=0.589, P<0.001). When performing the analysis after dividing the population according to the implanted ring model, the predicted size well correlated with the implanted size for the Semirigid Band and the Semirigid Ring (PCC r=0.659; P=0.004 and PCC r=0.745; P<0.001 respectively) but not for the Flexible Band (PCC r=−0.048; P=0.928) (*Table 4* and Figure S1). In the overall population, the linear regression analysis showed that the ring type was the only variable to influence the predicted-implanted size difference (Table S1). In the per-model analysis, LVEDV tended to have an influence on implanted-predicted size difference for the Semirigid Ring group (r=0.363, P=0.068) (Table S2). No variable influencing the difference in Semirigid Band was found (Table S3). The Flexible Band group was not tested

Table 2 Preoperative transthoracic echocardiography data

Variables	Values
MR grade	
Trivial/mild	0 (0.0)
Moderate	2 (3.7)
Severe	52 (96.3)
Leaflet prolapse	33 (61.1)
AML	4 (7.4)
PML	23 (42.6)
Bi-leaflet	6 (11.1)
Leaflet flail	21 (38.9)
Number of involved scallops	
One	28 (51.8)
Two	15 (27.8)
Multiple	11 (20.4)
TR grade	
Trivial	1 (1.8)
Mild	48 (88.9)
Moderate	5 (9.3)
AR grade	
Trivial	41 (75.9)
Mild	13 (24.1)
VCW (mm)	6.6±1.3
EROA (cm^2)	0.5±0.2
Regurgitant volume (mL)	74±21.4
Mean gradient (mmHg)	1.8±1.2
AP annular diameter (mm)	
Systolic	38.2±5.7
Diastolic	34.6±6
Leaflet length (mm)	
AML	24.5±4
PML	18.8±3.7
Mitral peak Doppler E-wave	
E/e’	12.6±4.8
E/A	1.8±1
Pulmonary arterial hypertension	43 (79.6)
LAD (mm)	45±7
LAV (mL)	86±32
Indexed LAV (mL/m^2)	44±19
LVEDV (mL)	136±46
Indexed LVEDV (mL/m^2)	69±26
LVESV (mL)	52±30
Indexed LVESV (mL/m^2)	28±14
LVEF (%)	61±6

Data are presented as mean ± standard deviation or n (%). AML, anterior mitral leaflet; AP, anteroposterior; AR, aortic regurgitation; LAD, left atrial diameter; LAV, left atrial volume; LVEDV, left ventricle end-diastolic volume; LVEF, left ventricle ejection fraction; LVESV, left ventricle end-systolic volume; MR, mitral regurgitation; PML, posterior mitral leaflet; TR, tricuspid regurgitation; VCW, vena contracta width.

Table 3 Procedural data

Variables	Values
AML augmentation	0 (0.0)
PML augmentation	1 (1.8)
AML resection	0 (0.0)
PML resection	18 (33.3)
Neochordae implantation	30 (55.5)
AML	3 (10.0)
PML	26 (86.7)
Both	1 (3.3)
Commissuroplasty	3 (5.5)
Alfieri stitch	0 (0.0)
Semirigid Ring	31 (57.4)
Semirigid Band	17 (31.5)
Flexible Band	6 (11.1)
Cardiopulmonary bypass time (min)	111±45
Cross-clamp time (min)	84±36
Intraoperative SAM	0 (0.0)

Data are presented as mean ± standard deviation or n (%). AML, anterior mitral leaflet; PML, posterior mitral leaflet; SAM, systolic anterior motion.

Table 4 Overall population and stratified population correlation test

Variables	PCC	P value
Overall population	0.589	<0.001
Flexible Band	−0.048	0.928
Semirigid Band	0.659	0.004
Semirigid Ring	0.745	<0.001

PCC, Pearson correlation coefficient.

for linear regression because of the small sample size.

Discussion

It has been demonstrated with the clinical experience of the transapical neochord implantation that an annuloplasty is not always necessary if there is a non-dilated mitral valve (MV) annulus, meaning in other words that there is a significant coaptation reserve index (6-8).

However, besides the previous scientific observations, in clinical practice, 99% of the MV repairs worldwide are performed with an annuloplasty device.

The rationale behind this is to reduce the anteroposterior dimension, consequently improving the CL between the anterior and posterior leaflets in order to increase durability of the repair over time. In general, the CL achieved postoperatively is significantly longer than that seen in natural conditions, 8–10 versus 2 mm (9,10).

Annuloplasty device selection during MVRe surgery is a complex process influenced by several factors that an experienced surgeon can take into consideration, but so far has been more in correlation with art than science. In the general practice, the ring size is not determined on echo measurements but only by sizer testing during cardioplegic arrest based on the intertrigonal distance, intercommissural distance, and the surface area of the anterior leaflet (11).

The aim of the present study was to explore the possibility of transforming the art of choosing an annuloplasty device into a mathematical formula for selecting the appropriate device size.

The main finding of the study is that the proposed formula can quite accurately predict the appropriate annuloplasty ring needed to achieve a CL of at least 8 mm in patients undergoing MVRe for DMR.

The overall analysis revealed an overall moderate correlation between the implanted and predicted ring sizes, with a PCC r value of 0.589 (P<0.001), indicating that the formula provides a quite reliable tool for surgeons to plan annuloplasty based on preoperative TTE findings.

However, the accuracy of the formula was influenced by the type of annular device we used. Indeed, we found significant differences when analyzing the single ring models: for the Flexible band, a high difference was reported between the predicted and actually implanted sizes (r=−0.048; P=0.928), with a strong tendency to predict a smaller size than the one selected. We believe that a possible explanation lies in the flexibility of the band. This flexibility may alter its ideal shape, resulting in changes to its geometry and dimensions once the sutures are tightened. In contrast, the semi-rigid band and semi-rigid ring consistently maintained their geometry, and their correlation with the predicted size was strong (r=0.659; P<0.001). Another possibility to consider is that this finding may be influenced by statistical bias, given the very small sample size of the Flexible Band. In general, the formula tended to over-estimate the size, in particular for the complete semirigid ring. Moreover, we have to remember that the formula is set to obtain a CL of 8 mm, but in our real practice, the actual CL the surgeon aimed to was usually 10 mm or more, and to do so, a smaller ring was chosen; particularly in the case of complete rings, which are usually preferred when a superior AP diameter reduction is desired.

Apart from LVEDV, none of the other included variables influenced the predicted-implanted size concordance. This might be explained because when the patient presents a dilated ventricle and therefore a very dilated annulus, the surgeon prefers the largest available annuloplasty device. The formula we used in our study differs from previously proposed methods (12,13) because it takes into account all the factors that surgeons typically consider when sizing a ring during surgery. Unlike other methods, our formula is specifically designed to achieve a preset CL of 8 mm, which is considered optimal for ensuring a longer durability of the repair (5). Anyway the desired CL can be set depending on the surgeon preference. Other methods assume that the surgeon's choice of ring size is correct, regardless of the observed postoperative CL. Furthermore, our approach is founded on straightforward 2D-TTE measurements that can be easily obtained. This sets it apart from other suggested methods that depend on complex preoperative analysis using specialized software or even 3D-printed models of the MV, which cannot be readily and swiftly utilized by the surgeon in the operating room (14,15).

We believe that a less experienced surgeon may benefit from a formula that helps to make this subjective process more objective and possibly more teachable, with a relatively less demanding learning curve to become proficient.

In addition, advancements in transcatheter annuloplasty techniques have been made in recent years (16,17). One crucial factor for a successful procedure is accurately determining the appropriate ring size before the surgery, as it's not possible to take measurements during the procedure. Therefore, developing reliable and straightforward methods to predict the optimal ring size for a durable repair is crucial. It's possible that more precise measurements, using multi-phase cardiac CT-scan and transesophageal echocardiography, could improve the accuracy of our formula.

Our work is limited to annuloplasty sizing only; on the contrary, McCarthy *et al.* (18) presented a more complex and extensive quantitative algorithm for repairing the MV, utilizing measurements to reconstruct the leaflets using resection techniques and determine the optimal ring size.

In our clinical practice, unlike McCarthy's group, ePTFE chord implantation is the preferred technique to perform the leaflet repair. This makes it more complex to include chord length and the number of implanted chords into the ring predictor system. Makhdom *et al.* and Pitsis *et al.* have identified a possible algorithm to measure the chord length to be implanted upfront (19,20). However, as stated by Tirone David, "the problem with chordal replacement with ePTFE is to determine the appropriate length of the neochords. Although numerous techniques have been described, none is easily reproducible by the learning surgeon" (21). Indeed, as observed during beating heart transcatheter procedures, the required chordal length to achieve optimal coaptation can be significantly influenced by the rate of anteroposterior reduction achieved with the annuloplasty device.

We can speculate that to fully replicate the MV repair process—which includes annuloplasty sizing and leaflet plasty, that surgeons currently perform using their knowledge, experience, and personal skills—we would likely need an AI-based imaging tool. This tool would need to accurately identify and measure anatomical structures and, drawing from a comprehensive library of preoperative and postoperative cases, create simulations of potential technical solutions for MV repair (22).

Conclusions

The suggested formula can effectively predict the ring size for surgical MV repair to correct DMR with a strong correlation. However, its reliability varies based on the type of ring model used, with the best results achieved with complete semirigid rings. Ring sizing can be challenging for some patients and is significantly influenced by the surgeon's experience. Consequently, this proposed method could serve as a valuable tool during MVRe, especially for patients with limited intraoperative exposure of the MV. Further studies and the inclusion of a larger patient population are necessary to confirm the formula's effectiveness and to expand its application to preoperative planning for transcatheter annuloplasty.

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Footnote

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