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Outcome reporting for surgical treatment of degenerative mitral valve disease: a systematic review and critical appraisal

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Abstract

OBJECTIVES: Standardized outcome reporting is of critical importance for performance monitoring, improvement of existing techniques and introduction of novel technologies. Whether outcome reporting for surgical treatment of degenerative mitral valve disease complies with the guidelines has not been assessed to date.

METHODS: A systematic review of PubMed, EMBASE, Web of Science and the Cochrane Library was conducted for articles published between 1 January 2009 and 7 March 2016. Inclusion criteria were adult patient population ($n \geq 200$) and surgical intervention for degenerative mitral valve disease. The quality of reported outcome was compared with the standard recommended by the guidelines on reporting morbidity and mortality after cardiac valve interventions.

RESULTS: Forty-two non-randomized clinical studies were included: 4 provided early and 38 provided early and late outcome data. Early echocardiographic outcome was reported in 49% of studies. Freedom from reintervention, the indication for reintervention and the follow-up echocardiographic outcome were reported in 97%, 59% and 79% of studies providing late outcome data, respectively. The Kaplan–Meier method was used to assess the freedom from recurrent mitral regurgitation in 60% (18/30) of studies, whereas 7% (2/30) of studies applied a longitudinal data analysis. Recurrent mitral regurgitation was most commonly defined as moderate (Grade 2+; 60%) or severe (Grade 4+; 37%) regurgitation.

CONCLUSIONS: There is a significant discordance between the guidelines-based recommendations and actual reporting of outcome for surgical treatment of degenerative mitral valve disease. Better adherence to the guidelines would raise the quality and generalizability of clinical data reporting.

Keywords: Mitral regurgitation • Mitral valve prolapse • Data reporting

INTRODUCTION

Following cardiac valve interventions, standardized early and late outcome reporting remains imperative to monitor patient- and valve-related outcome and to stimulate further developments in the field. The joint American Association of Thoracic Surgery (AATS), Society of Thoracic Surgery (STS) and the European Association of Cardio-Thoracic Surgery (EACTS) guidelines provide an excellent guide for standardized data reporting [1]. Strict adherence to the proposed definitions should ensure adequate comparability between studies.

Since the introduction of the guidelines in 2008 [1], several clinical studies have reported excellent early mortality and repair rates of <1% and >95%, respectively, in patients undergoing surgery for degenerative mitral valve disease [2–5]. These

results provide an important prognostic tool and influence our clinical decision-making. Nowadays, early surgical intervention for degenerative mitral valve disease is advocated when these high standards can be met [6, 7]. Besides early outcome, reporting on long-term repair durability is of utmost importance since recurrent mitral regurgitation (MR) is known to develop in a substantial amount of patients [3, 8, 9]. A proportion of these patients will undergo redo surgery with increased morbidity and mortality rates [10], while an even larger amount of patients will not be reoperated and will suffer the consequences of either an inaccurate repair or disease progression. However, it remains unclear whether the evidence on which our clinical decision-making and introduction of novel technologies is based complies with the standards of outcome reporting provided by the guidelines.

The aim of this systematic review is to study the concordance between the reported outcome in the current literature and the standards provided by the guidelines.

METHODS

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines [11] (Supplementary Material 1).

Search strategy

A systematic search of PubMed, EMBASE, Web of Science and the Cochrane Library was conducted for articles published between 1 January 2009 and 7 March 2016 (Supplementary Material 2). After removal of duplicates, titles and abstracts of the remaining articles were independently assessed for eligibility by 2 reviewers (A.T. and B.A.). When this was inconclusive, full-text articles were assessed. Any discrepancies regarding eligibility were discussed with the third review author (M.P.). The reference lists of relevant studies were searched to identify any other full-text article relevant to the review topic.

Selection criteria

Randomized clinical trials and non-randomized clinical studies were eligible for review. Inclusion criteria were degenerative mitral valve disease [with or without accompanying (non-)active infective endocarditis], surgical intervention regardless of the approach utilized (full or partial sternotomy and video-assisted or robot-assisted surgery), adult (≥ 18 years of age) study population and $n \geq 200$ patients. Only full-text articles published in peer-review journals were included. Aetiology other than degenerative mitral valve disease, with the exception of accompanying (non-)active infective endocarditis, resulted in exclusion. Depending on the duration of follow-up, studies were divided into early (follow-up period including only the index hospitalization) and late outcome (follow-up period extending beyond the index hospitalization) groups.

Data extraction

Data extraction was performed by 2 reviewers (A.T. and B.A.) using a standard data extraction form. Microsoft Office Excel (Microsoft, Redmond, WA, USA) was used for data extraction.

The following descriptive data were abstracted: first author, year of publication, country of origin, number of participants, mitral valve disease aetiology and degenerative entity, valve intervention details (treatment method, repair method and annuloplasty prosthesis type), antithrombotic management following valve intervention, structural valve deterioration and/or non-structural valve dysfunction, freedom from operated valve reintervention, indication for reintervention, operated valve endocarditis, thromboembolic and bleeding events and mortality (with the corresponding details on the cause of death). Additionally, the statistical methods applied were recorded. Outcome reporting was compared with the recommendations provided by the 2008 joint AATS/STS/EACTS guidelines for reporting mortality and morbidity after cardiac valve interventions [1].

RESULTS

The search strategy retrieved 1871 title-abstracts (Supplementary Material 2). Of these, 60 were eligible for full-text article assessment (Fig. 1). Ten pairs of articles were derived from the same study population; only the study encompassing the largest patient cohort within the same time period was included in all cases. Additional 8 articles were excluded due to no full-text article in English available (4 articles), the underlying aetiology of valve disease was unclear/not specified (2 articles) or inclusion of patients < 18 years of age (2 articles). We did not contact the authors for additional information.

Study characteristics

In total, 42 articles were included in the final review (Table 1). All articles were non-randomized clinical studies. There was 1 multi-centre study and 41 single-centre studies. Thirty-eight studies provided early and late outcome data, and 4 studies focused only on the early outcome. The median number of patients was 533 (range 200–5902) with a total of 37 425 patients included. The average age of patients at operation was 58.9 years and 12 469 (33%) patients were female.

Perioperative details on mitral valve repair

Thirty-five (83%) studies provided a description on the various surgical techniques utilized. Eighteen (43%) studies provided complete details on the type and size of annuloplasty prosthesis implanted. Only 22 (52%) studies reported the repair rate for the whole degenerative mitral valve surgery population during the study period. Details on antithrombotic management following surgical intervention were provided in 6 (14%) studies. All studies provided details on early mortality. Most commonly this was reported as in-hospital mortality or 30-day mortality; this was reported as such in 17 (40%) and 13 (31%) studies, respectively. Five (12%) studies defined early mortality as 30-day or in-hospital mortality and others as 60- or 90-day mortality. Five (12%) studies did not specifically define the early mortality end-point.

Mitral valve repair rate and residual mitral regurgitation

Among all studies reporting the rate of mitral valve repair during the study period, the repair rate varied from 44% to 100%. In 73% and 55% of these, the repair rate exceeded 90% and 95%, respectively.

Only 20 (49%) studies provided details on the early echocardiographic results of mitral valve repair and the eventual presence of residual MR (Table 1). Five of these reported only intraoperative echocardiographic results, while the remaining 15 studies provided details on pre-discharge echocardiography.

Freedom from structural valve degeneration/non-structural dysfunction and mitral valve reintervention

Thirty (79%) of the 38 studies from the late outcome group reported echocardiographic follow-up data. Only 8 (21%)

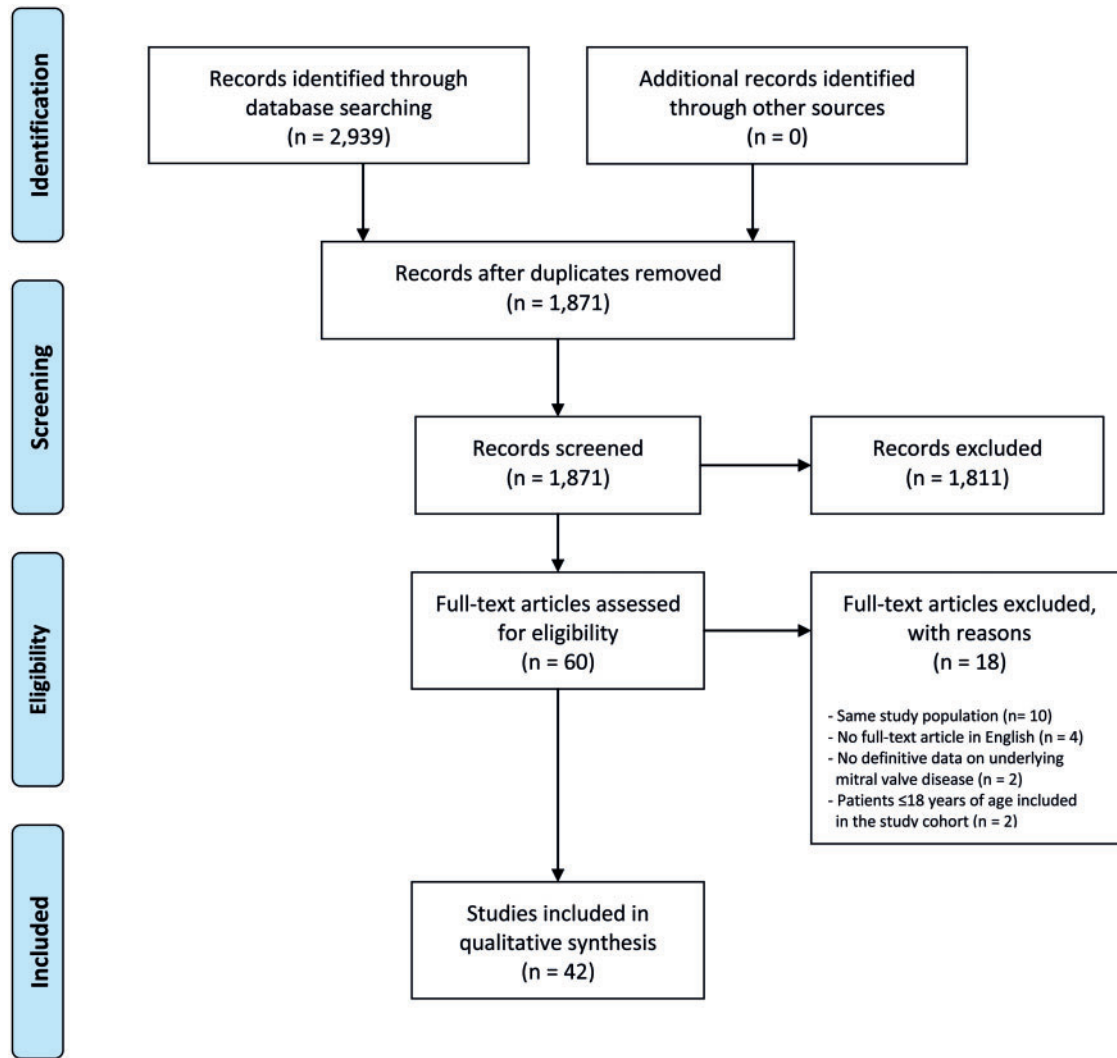


Figure 1: Prisma flow diagram.

studies provided echocardiographic follow-up data of $\geq 90\%$ of patients. Additionally, there was no clear consensus regarding the definition of recurrent MR, this was most commonly defined as freedom from moderate (Grade 2+; 60%) or severe (Grade 4+; 37%) MR. Moreover, 5 (17%) of the 30 studies provided only descriptive cross-sectional data on the status of recurrent MR and did not provide a time-related analysis. The most commonly utilized statistical method to assess the freedom from recurrent MR was the Kaplan–Meier method used in 18 (60%) studies. Longitudinal data analysis was performed in 2 (7%) studies. The definition of recurrent MR across studies, completeness of follow-up and statistical method of analysis are presented in Table 2.

Freedom from mitral valve reintervention was reported in 37 (97%) of the 38 studies from the late outcome group (Table 1). Only in 22 (59%) of these studies, details on the indication for reintervention were provided.

Early and late mortality and morbidity

Complete early mortality data were reported in 41 (98%) studies (Table 1). Of the 38 studies from the late outcome group, the late

mortality rate was reported in 36 (95%) studies. However, the cause of death was defined in only 8 (22%) of these.

Other valve-related morbidity was inconsistently reported; the freedom from infective endocarditis was reported in 6 (16%), the freedom from bleeding-related complications in 6 (16%) and the rate of thromboembolism occurrence in 8 (21%) studies. The functional clinical status (NYHA class) was reported in 11 (29%) studies.

DISCUSSION

To the best of our knowledge, this is the first review to explore the current state of outcome reporting on surgical treatment for degenerative mitral valve disease. Our review revealed a significant diversity in the selection and definition of relevant patient- and valve-related end-points in the recent literature. Notably, 52% of studies failed to provide early echocardiographic results of mitral valve repair. Moreover, recurrent MR was defined inconsistently with a high variation in the completeness of follow-up between studies.

Standardization of data reporting remains a crucial task to support consistency in study design and allows critical interpretation

Table 1: Study characteristics and the primary parameters reported

Author	Country	Number of patients	Early mortality	Late mortality	Details on late mortality	Predischarge and/or early echocardiography	Follow-up echocardiography and RMR occurrence	Freedom from reoperation	Indication for reoperation	Freedom from thrombo-embolic event	Freedom from bleeding event	Freedom from operated valve endocarditis
Early outcome group												
1 Loulmet et al. [20]	USA	1918	1		0							
2 Perier et al. [21]	Germany	842	1		1							
3 Suri et al. [22]	USA	301	1		1							
4 Yazdchi et al. [23]	USA	5902	1		1							
n (%)	8963	4 (100)			3 (75)							
Late outcome group												
5 Anyanwu et al. [24]	USA	668	1	1	0		1	1	0	0	0	0
6 Ben et al. [25]	Israel	572	1	1	0		1	1	0	0	0	0
7 Brown et al. [26]	USA	511	1	1	0		1	1	0	0	0	0
8 Chan et al. [27]	Canada	625	1	1	0		1	1	1	0	0	0
9 Coutinho et al. [28]	Portugal	501	1	1	0		0	1	1	0	0	0
10 Coutinho et al. [29]	Portugal	382	1	1	0		0	1	1	0	0	0
11 Deneshmand et al. [30]	USA	989	1	1	1		0	0	0	0	0	0
12 David et al. [31]	Canada	606	1	1	1		1	1	1	1	1	1
13 David et al. [3]	Canada	847	1	1	1		1	1	1	1	1	1
14 David et al. [32]	Canada	337	1	1	1		1	1	1	1	1	1
15 Galloway et al. [33]	USA	1601	1	1	0		1	1	0	0	0	0
16 Gillionov et al. [34]	USA	4586	1	1	0		1	1	0	0	0	0
17 Gillionov et al. [35]	USA	3057	1	1	0		1	1	1	0	0	0
18 Goldstone et al. [4]	USA	525	1	1	0		1	1	1	0	0	0
19 Jouan et al. [9]	France	200	1	1	0		1	1	1	0	0	0
20 Kanemitsu et al. [18]	Japan	226	1	1	1		1	1	1	1	1	1
21 Kitai et al. [36]	Japan	298	1	1	0		1	1	0	1	1	0
22 Kuperstei et al. [37]	Israel	549	1	1	0		1	1	0	0	0	0
23 Lange et al. [38]	Germany	397	1	1	0		1	1	1	1	1	0
24 Mazine et al. [39]	Canada	200	1	1	1		0	1	1	0	0	0
25 Miceli et al. [40]	Italy	703	1	1	0		1	1	0	0	0	0
26 Murashita et al. [41]	Japan	654	1	0	0		1	1	1	0	0	0
27 Nardi et al. [42]	Italy	305	1	1	1		1	1	1	0	0	1
28 Nifong et al. [43]	USA	540	1	1	1		0	1	1	0	0	0
29 Nozohoor et al. [44]	Sweden	270	1	0	0		0	1	1	0	0	0
30 Okada et al. [19]	Japan	514	1	1	0		1	1	0	1	0	0
31 Ragnarsson et al. [45]	Sweden and Denmark	201	1	1	0		1	1	1	1	1	1
32 Schwartz et al. [46]	USA	1012	1	1	0		1	1	0	0	0	0
33 Seeburger et al. [47]	Germany	1230	1	1	0		0	1	0	0	0	0
34 Suri et al. [15]	USA	1218	1	1	0		1	1	0	0	0	0
35 Suri et al. [48]	USA	487	1	1	0		1	1	1	0	0	0
36 Tabata et al. [49]	Japan	700	1	1	0		1	1	1	0	0	0
37 Tabata et al. [5]	Japan	212	1	1	0		1	1	1	0	0	0
38 Vaccarion et al. [50]	Argentina	254	1	1	0		0	0	0	0	0	0
39 Vrancic et al. [51]	Argentina	255	1	1	0		1	1	0	0	0	0
40 Yaffee et al. [52]	USA	1612	1	1	0		1	1	0	0	0	0
41 Yoo et al. [53]	South Korea	299	1	1	0		1	1	1	0	0	0
42 Zhou et al. [54]	France	319	1	1	0		1	1	1	0	0	0
n (%)	28 462	38 (100)	36 (95)	8 (21)	17 (45)	30 (79)	37 (97)	22 (58)	8 (21)	6 (16)	6 (16)	6 (16)
Combined	n (%)	37 425	42 (100)			20 (48)						

1: reported; 0: not reported. Empty entries indicate does not apply.
RMR: recurrent mitral regurgitation.

Table 2: Recurrent MR definition as reported across studies providing long-term echocardiographic follow-up data

	Author	Degree of MR reported				Follow-up conducted in $\geq 90\%$ of patients at risk	Method
		Mild $\geq 1+$	Moderate $\geq 2+$	$\geq 3+$	Severe $\geq 4+$		
1	Anyanwu <i>et al.</i> [24]	○	○	○	●	NS	Kaplan–Meier
2	Ben <i>et al.</i> [25]	●	●	●	●	NS	Descriptive
3	Brown <i>et al.</i> [26]	○	●	○	○	NS	Descriptive
4	Chan <i>et al.</i> [27]	○	●	●	○	NS	Kaplan–Meier
5	David <i>et al.</i> [31]	○	●	○	●	NS	Kaplan–Meier
6	David <i>et al.</i> [3]	○	●	○	●	1	Parametric survival model
7	David <i>et al.</i> [32]	○	●	○	○	1	Parametric survival model
8	Galloway <i>et al.</i> [33]	○	○	○	● ^a	NS	Life table analysis
9	Gillionov <i>et al.</i> [34]	●	●	●	●	0	Longitudinal regression model for repeated measurements
10	Gillionov <i>et al.</i> [35]	○	●	○	○	0	Longitudinal regression model for repeated measurements
11	Goldstone <i>et al.</i> [4]	○	●	○	○	0	Kaplan–Meier
12	Jouan <i>et al.</i> [9]	○	○	●	○	NS	Kaplan–Meier
13	Kanemitsu <i>et al.</i> [18]	○	●	○	○	0	Kaplan–Meier
14	Kitai <i>et al.</i> [36]	○	○	○	●	NS	Descriptive
15	Kuperstei <i>et al.</i> [37]	○	●	○	○	1	Descriptive
16	Lange <i>et al.</i> [38]	○	○	○	●	0	Kaplan–Meier
17	Miceli <i>et al.</i> [40]	○	○	●	○	0	Kaplan–Meier
18	Murashita <i>et al.</i> [41]	○	○	○	●	NS	Kaplan–Meier
19	Nardi <i>et al.</i> [42]	○	○	●	○	1	Kaplan–Meier
20	Okada <i>et al.</i> [19]	○	●	●	○	0	Kaplan–Meier
21	Ragnarsson <i>et al.</i> [45]	○	●	○	○	0	Kaplan–Meier
22	Schwartz <i>et al.</i> [46]	○	○	○	● ^a	NS	Kaplan–Meier
23	Suri <i>et al.</i> [15]	○	●	○	○	0	Kaplan–Meier
24	Suri <i>et al.</i> [48]	○	●	○	○	1	Kaplan–Meier
25	Tabata <i>et al.</i> [49]	○	●	○	○	1	Kaplan–Meier
26	Tabata <i>et al.</i> [5]	○	●	○	○	1	Kaplan–Meier
27	Vrancic <i>et al.</i> [51]	○	●	○	○	0	Kaplan–Meier
28	Yaffee <i>et al.</i> [52]	○	○	○	●	NS	Life table analysis
29	Yoo <i>et al.</i> [53]	○	○	●	○	1	Cox proportional hazard regression model
30	Zhou <i>et al.</i> [54]	○	○	●	○	0	Descriptive
n (%)		2 (7)	18 (60)	9 (30)	11 (37)		

●: reported; ○: not reported; 1: yes; 0: no; NS: not specified.

^aOnly cumulative freedom from reoperation or severe MR reported.

MR: mitral regurgitation.

of study results. Previously, the Valve Academic Research Consortium has published guidelines for end-point definitions following transcatheter aortic valve implantation and transcatheter mitral valve repair or replacement [12–14]. We have decided, however, to compare the current body of literature on the results of reconstructive mitral valve surgery to the guidelines provided by Akins *et al.* [1]. The latter are better suited for studies focused on patients undergoing surgical intervention and are generally of use in this population. Furthermore, the less extensive profile of end-points (that encompasses the most relevant end-points following cardiac valve intervention) covered in the guidelines by Akins *et al.* make it more convenient to use. The results of our systematic review highlight the need for consistency in the definition of relevant patient- and valve-related end-points.

Early results of mitral valve repair

Currently, several different surgical techniques and various annuloplasty devices are in use when mitral valve repair is performed.

Our review revealed that several studies failed to describe the techniques used upon performing valve repair. A comprehensive description of the repair techniques will allow for better interpretation of the study results and further stimulate the translation of study results into clinical practice.

Currently, the mitral valve repair rate is reported as a quantitative measure of the total mitral surgery cohort. However, residual MR can be seen on postoperative echocardiography despite a successful intraoperative result. Reporting the early echocardiographic results of valve repair will provide further insight into early and late repaired valve performance and allow for better appreciation of the early performance of valve repair.

Freedom from structural valve degeneration/non-structural dysfunction and mitral valve reintervention

Following successful repair, technical failure of valve repair or degenerative mitral valve disease progression is responsible for the

recurrence of MR in a considerable amount of patients [3, 8, 9]. The guidelines define more-than-mild MR as recurrent MR (either non-structural dysfunction or valve deterioration in origin) [1]. While the clinical course and effect of recurrent MR might not yet be fully understood, a recent study from Suri *et al.* [15] demonstrated that recurrence of more-than-mild MR significantly impairs patient survival. This effect on the clinical outcome provides additional rationale for adherence to the guideline-proposed definition on recurrent MR.

A considerable proportion of studies, however, defined recurrent MR as freedom from moderate-to-severe or severe regurgitation. This will directly lead to under-reporting of the incidence of recurrent MR and hamper the critical assessment of valve repair durability. Adherence to the guidelines on this point is of critical importance to provide meaningful results and identify the potential risk factors of recurrent MR. Moreover, the freedom from recurrent MR was assessed with the Kaplan-Meier method in a small majority of studies (60%). For the purpose of uniform data reporting, utilizing the same statistical method across studies allows for a general appreciation of the performance of the surgical technique. However, the Kaplan-Meier method is a time-to-event analysis and based on the condition at last follow-up while the grade of MR is a dynamic biomarker which is subject to various factors (e.g. the fluid volume status, left ventricular function, blood pressure, etc.) and may vary in severity over time. Hence, the Kaplan-Meier method cannot illustrate the time-dependent changes in the severity of MR. Despite its limitations, the Kaplan-Meier method will arguably provide sufficient evidence on valve repair performance when a simple comparative analysis of 2 or more different groups is attempted.

Several other methods of longitudinal data analysis are available and are superior to the Kaplan-Meier analysis when analysing longitudinal data of time-related events with serial assessments [1]. Based on our review, these statistical methods have not yet been widely adopted in the current literature on surgical treatment of mitral valve disease. Such statistical methods have been reported for longitudinal echocardiographic assessment of valve function after surgical treatment of aortic valve disease and can be easily adapted to the mitral valve [16]. Further studies should aim to explore the clinical usefulness of such data analysis to further determine the risk factors of mitral valve repair failure and the clinical consequences hereof.

The studies identified focused primarily on freedom from recurrent MR as determined by echocardiography. None of the studies provided a cumulative freedom from structural valve degeneration/non-structural dysfunction assessment. According to the guidelines, this includes valve stenosis and all cases of non-structural valve dysfunction [1]. Although the rate of these events is expected to be low, they can significantly add to the observed morbidity and mortality and hamper the health-related quality of life. This is in line with recent reports that have demonstrated that dynamic mitral valve stenosis following valve repair might actually not be an uncommon finding [17].

Parallel to echocardiographic findings, freedom from re-intervention rates and details on the indication for re-intervention provide invaluable information on the performance and durability of mitral valve repair. However, only freedom from re-intervention presents a poor indicator of valve performance,

as it underestimates the rate of MR recurrence [3, 9, 18, 19]. Moreover, indications for re-intervention as well as single-centre approach to recurrent MR differ significantly and might depend on single-centre experience in re-repairing mitral valves with residual of recurrent MR. Freedom from re-intervention alone is therefore an insufficient measurement of valve repair durability. It does, however, provide valuable insight into the operated valve performance and mechanism of valve repair failure and aids in the assessment of the probability of mitral valve re-repair.

Limitations

Some studies included in the review were designed to assess specific short- and/or long-term outcomes in cohorts of patients undergoing surgery for degenerative mitral valve disease. It is possible that these studies have omitted certain end-points included in our analysis as they were not relevant to the study question. However, we applied a guideline and evidence-based approach when selecting our study parameters. Selective study assessment would incorporate a possible bias and limit the interpretability of our results.

CONCLUSIONS

Current outcome reporting for surgical treatment of degenerative mitral valve disease demonstrates significant heterogeneity of the definition of several clinically important end-points. Moreover, data on valve- and patient-related outcome, foremostly, echocardiographic freedom from valve dysfunction, are often missing. This importantly affects the value of presented results and limits their interpretation. Because clinical decisions and evolution of clinical care are derived from the published results, high standard of data reporting is crucial.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *ICVTS* online.

Conflict of interest: none declared.

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For references [20–54], please refer to [Supplementary Material 3](#).

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