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Transcatheter or surgical treatment of paravalvular leaks: A meta-analysis of 13 studies and 2003 patients

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ABSTRACT

Background: Significant paravalvular leak is a rare but serious complication of heart valve replacement, leading to symptomatic heart failure and hemolysis. Due to the paucity of comparative data between surgical and transcatheter paravalvular leak correction, we performed a systematic review and meta-analysis of available studies.

Methods: Studies comparing transcatheter and surgical treatment of paravalvular leak were systematically identified. Short-term all-cause mortality was the primary outcome. Technical and procedural success, 30-day persistence of significant paravalvular leak, length of hospital stay and long-term mortality, persistence of symptoms and paravalvular leak were the main secondary endpoints.

Results: Thirteen studies with 2003 patients were included, treating in most of the cases a mitral prothesis. Transcatheter closure was associated with lower short-term mortality rate (30 days OR 0.28, 95 % CI 0.18–0.42, $p < 0.001$) compared to surgical treatment. Technical and procedural success did not differ among the two groups. 30-day and long-term rates of persistence of moderate or severe paravalvular leak were higher in the transcatheter group (OR 3.56, 95 % CI 1.49–8.49, $p = 0.004$ and OR 2.20, 95 % CI 1.27–3.81, $p = 0.005$ respectively). Long-term death and re-hospitalization events did not differ among the two treatment modalities. The mean difference in days of length of stay was significantly lower in the transcatheter group (mean difference −9.66, 95 % CI −12.37 to −6.94, $p < 0.001$).

Conclusion: Transcatheter closure of paravalvular leaks is associated with lower short-term mortality rates but higher persistence of moderate-severe paravalvular leak and heart failure symptoms at short and long-term follow-up compared to surgical treatment.

1. Introduction

Paravalvular leak (PVL) is not an unfrequent complication after heart valve replacement procedures. This condition occurs in 2–10 % and 7–17 % of aortic and mitral valve replacements respectively[1–3]. Numerous procedural and patient factors have been associated with PVL development[4]. Although the majority of PVLs are subclinical, about 3 % of patients develop severe heart failure, hemolysis or a combination of both requiring re-intervention[5–7]. Surgical repair is the cornerstone in the treatment of symptomatic PVL. Nevertheless, repeat surgical repair is associated with high mortality and a high risk of re-leakage. Thus, few patients are referred to a second surgical correction. Furthermore, mortality increases progressively with the number of re-operations, up 37 % after the third re-operation[4]. The development of catheter-based treatment for structural heart diseases and the need to reduce morbidity and mortality in the treatment of paravalvular leaks has driven medical professionals along with the medical industry to introduce less invasive treatment—catheter-based PVL closure— into clinical practice[8]. Moreover, transcatheter closure of PVL will become more frequent due to the expanding indication of transcatheter aortic valve replacement (TAVR) to younger and lower-risk patients. Actually patients with a long expectancy of life should not be exposed to the detrimental long term

Abbreviations: PVL, Paravalvular Leak.

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effects of regurgitation consequently increasing the rates of referral to PVL. Due to low significant PVL incidence and paucity of reported data on hard endpoints, up to date there are no large comparison studies between percutaneous and surgical interventions. In order to summarize and analyse available evidence on PVL treatment, we performed a systematic review and meta-analysis of the published studies on surgical and transcatheter treatments of PVL, aiming to compare the safety and effectiveness of these techniques.

2. Methods

2.1. Research, eligibility criteria and selection strategy

This analysis was performed following the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines[9] and registered on PROSPERO (CRD42024510950). The following online databases were evaluated for articles published from inception to February 2024: PubMed/ MEDLINE, Google Scholar and Scopus. The subsequent terms, following a PICO strategy (population, intervention, control, outcomes), were searched: (paravalvular) AND ((leak) OR (regurgitation)) AND ((surgical treatment) OR (surgery) OR (reintervention) OR (reoperation)) AND (((transcatheter) OR (percutaneous)) AND ((treatment) OR (closure))). We excluded from the research reviews, meta-analyses and case reports. No language restriction was applied. For the final inclusion in the analysis, titles of records through database search were identified, followed by the removal of duplicates. Abstracts were selected and, after analysis of full texts, when available, screened for eligibility. Studies were included in the final analysis if: 1) Comprehended patients with paravalvular leaks; 2) The population was stratified according to two different treatments (transcatheter and surgery); 3) Reported clinical outcomes per group at both short and longer-term follow-up. Two investigators (R.I,G.D.P.) screened the searched the databases and performed data extraction independently. Disagreements were resolved by a third author, who also checked the extracted data for accuracy (F.D.A).

A flow diagram is reported in Fig. 1 and full research strategy is reported in TableS1. Ethical approval was not requested and no language restriction was applied.

2.2. Outcomes and data selection

The primary outcome was 30-day all-cause mortality. Secondary outcomes were the length of hospital stay, 30-day study-defined technical success, procedural success, stroke, infections, major bleedings,

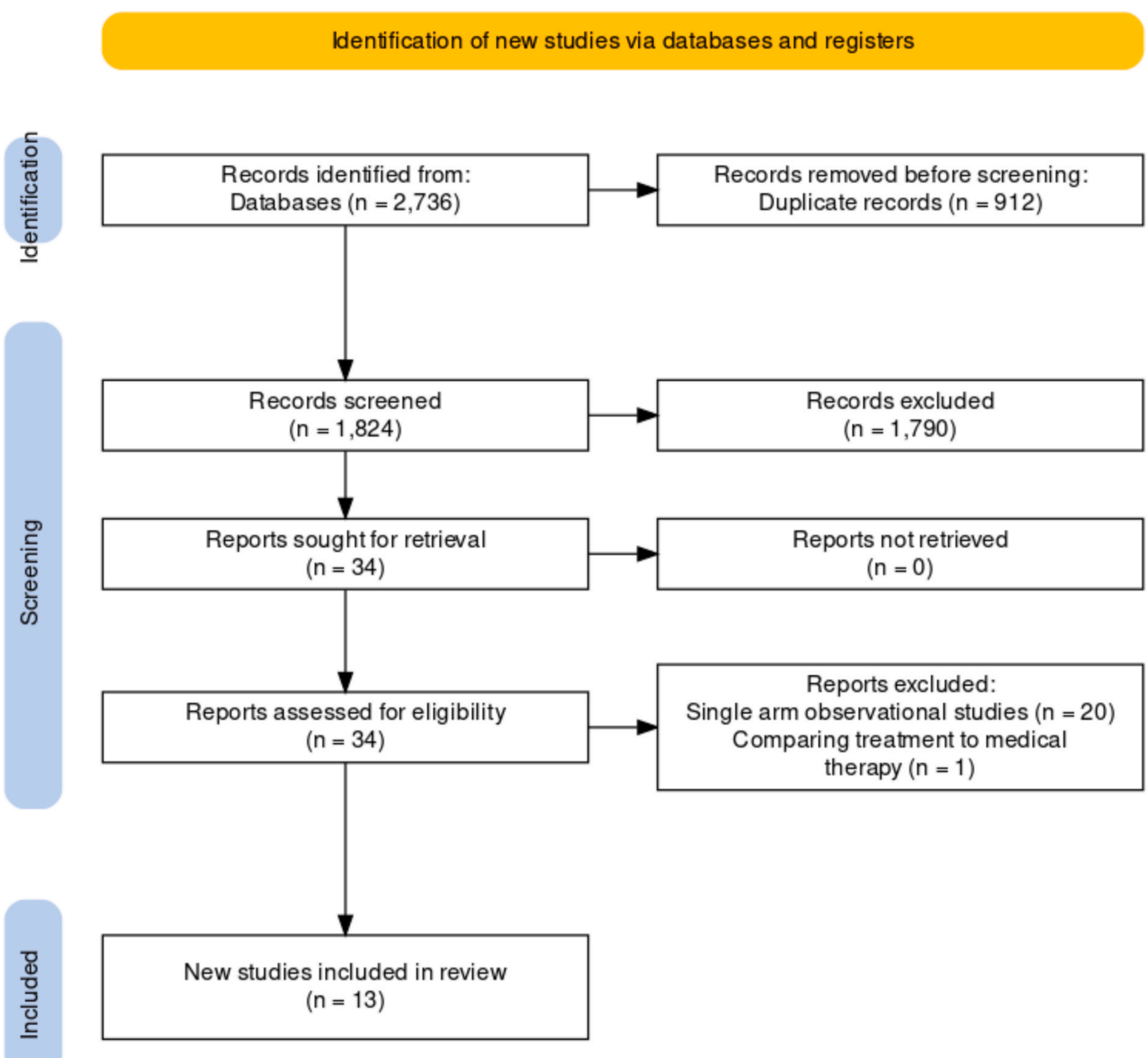

Fig. 1. PRISMA flowchart for study search.

acute kidney injury, re-intervention, persistence of moderate or more PVL and long-term all-cause mortality, re-hospitalization, haemolysis, persistence of NYHA class 3 or superior and of PVL moderate-severe. After 30 days of follow-up, we selected the events reported for the longest follow-up.

2.3. Assessment of risk of bias

The included studies were evaluated for risk of bias through The Risk of Bias in Non-Randomized Studies of Interventions tool (ROBINS-I) [10]. Severity scale was used to identify in each domain and in the overall analysis low, moderate and serious risk of bias; in the end, the studies and their characteristics were classified into mild, moderate and serious risk of bias. A plotted result of the bias assessment was performed with the Robvis online tool [11]. Two independent reviewers (R. I, Y.O.) assessed the risk for bias. When there was a disagreement, a third reviewer (F.D.A.) made the final decision.

2.4. Statistical analysis

Continuous variables are presented as median (first quartile-third quartile). Data inference was performed only if at least two studies reported data for every single outcome. A Mantel-Haenszel method for Odds Ratios with 95 % confidence intervals (CIs) and inverse variance for mean difference among lengths of stay and standard deviation (sd) were used for the analysis. Whenever continuous data were reported by median and interquartile range, mean and sd were derived using the method described by Hozo [12]. Statistical heterogeneity was assessed through the inconsistency index I2 and stratified into low (0–24 %), moderate (25–49 %) and high (major than or equal 50 %) heterogeneity. A random-effect model was used to pool data from the chosen studies. To assess the publication bias, a funnel plot was generated for the primary outcome and Egger's test was performed to evaluate the presence of bias. Forest plots were used to represent differences in clinical endpoints. A significant cut-off value of less than 0.05 was chosen to identify statistical relevance. All analyses were performed with Review Manager (RevMan) Version 5.4. The Cochrane Collaboration, 2020 and SPSS (v.29.0).

3. Results

3.1. Studies characteristics

Thirteen observational studies[13–25], globally encompassing 2003 patients underwent surgical valve replacement, were included in the final analysis. Two studies included only patients with mitral PVL and this patient subset was overall the most frequent. The median follow-up time was 2,1 years, interquartile range 1.75–3.75 years; the study with the shortest follow-up period considered only in-hospital events while the study with the longest follow-up was 6,3 years. Studies' characteristics are reported in Table 1. Publication bias for 30-day mortality was absent based on the funnel plot and Egger's test results (**Figure S1**). Qualitative assessment for bias of the studies with ROBINS-I is presented in **Figure S2**. The analysed population consisted of 940 patients who underwent transcatheter closure of PVL while 1.063 were treated with cardiac surgery for a total of 2003 patients. Patient characteristics from each study are listed in Table 2. The transcatheter and surgical cohorts slightly differed for age, with a median age 63.7 and 61.4 years respectively while mostly differed in STS score, 4,59 % and **3.31 %**, history of previous endocarditis, 16 % and 27 %, and haemolysis presentation, 43 % and 30 %. Procedural data are reported in **Table S2**. Preferred surgical access was sternotomy and the majority of cases underwent valve replacement; in the transcatheter group the most adopted device was Amplatzer Vascular Plug III while the access routes differed among centres. There was a negligible cross-over rate between treatment arms, most of them from transcatheter to surgical treatment as shown in **Table S3**. Endpoints definition along with inclusion and exclusion criteria are reported in **Table S3**.

3.2. Clinical outcomes

The definition of clinical outcomes varied between studies, especially for composite endpoints (**Table S3**).

3.2.1. Short-term outcomes

Forest Plots for 30-days outcomes between transcatheter and surgical PVL correction are represented in Fig. 2. A negative significant association was found between transcatheter treatment and 30-day mortality (OR 0.28, 95 % CI 0.18–0.42, $p < 0.001$) while technical and procedural success odds did not differ among the two approaches (OR 0.27, 95 % CI 0.06–1.17, $p = 0.08$ and OR 0.77, 95 % CI 0.36–1.64, $p = 0.50$ respectively) even if we could observe a trend favouring surgical correction. **In Figure S3 and S4**, other 30-day outcomes are plotted. Major bleeding, infections and acute kidney injury rates were higher in the surgical group (respectively OR 0.17, 95 % CI 0.03–0.85, $p = 0.03$, OR 0.20, 95 % CI 0.07–0.58, $p = 0.003$ and OR 0.32, 95 % CI 0.15–0.62, $p = 0.001$) while persistence of moderate or severe PVL was observed mainly in the transcatheter group (OR 3.56, 95 % CI 1.49–8.49, $p = 0.004$). No differences were found for short-term stroke (OR 0.49, 95 % CI 0.22–1.08, $p = 0.08$) and re-intervention (OR 1.07, 95 % CI 0.36–3.20, $p = 0.90$) among the two treatments. Length of hospital stay was significantly lower in the transcatheter group (Mean Difference −9.66 days, CI 95 % −12.37 to −6.94, $p < 0.001$) **Figure S5**.

3.2.2. Long-term outcomes

Long-term outcomes are reported in Fig. 3. There was no significant association between the interventions and long-term mortality (OR 0.65, 95 % CI 0.42–1.03, $p = 0.06$) even if a trend through lower death rates was observed for the transcatheter group. Persistence of moderate to severe PVL and NYHA class 3–4 were more frequent in the transcatheter group (OR 2.20, 95 % CI 1.27–3.81, $p = 0.005$ and OR 2.20, 95 % CI 1.27–3.81, $p = 0.005$ respectively). Rehospitalizations and

Table 1
Studies Characteristics. TC, Transcatheter Closure; SR, Surgical Redo; N,Number; PVL;paravalvular leak; NA Not Available.

Study	TC(n)	SR(n)	Publication Year	Enrollement Years	Mean/Median Follow-UP (years)	Mitral PVL(%)	Aortic PVL(%)
Taramasso er al.	17	122	2014	2000–2013	1.75	71	28
Angulo-Llanos et al.	51	36	2016	2008–2014	2.1	77	22
Pinheiro et al.	10	25	2016	2011–2013	1	60	37
Alkhouli et al.	195	186	2017	1995–2015	4	100	0
Millan et al.	80	151	2017	1994–2014	3.5	71	29
Wells et al.	56	58	2017	2007–2016	1	61	34
Zhang et al.	46	41	2017	2009–2015	4.1	61	35
Yang et al.	68	63	2018	2000–2016	2.7	41	42
Pu et al.	65	76	2020	2016–2019	1.75	60	38
Ramos et al.	39	46	2021	2004–2020	2	71	28
Giblett et al.	115	46	2022	2010–2021	In-hospital	NA	NA
Zorinas et al.	27	49	2022	2005–2019	TC 2.45 / SR 6.3	100	0

Table 2
Baseline Characteristics of the two cohorts. Data are presented with a median (interquartile range). STS, Society of Thoracic Surgeons Score; MV, Mechanical Prothesis; BV, Biological Prothesis; NYHA, New York Heart Association heart failure grading.

Arm	Age (years)	Men (%)	STSscore (%)	MV (%)	BV (%)	Previous Endocarditis (%)	Previous Sternotomies (n)	Haemolysis (%)	NYHA>=3 (%)
Transcatheter	63,7 (63–67)	63,6 (57–69)	4,59 (4,2–7,7)	82 (69–89)	18 (10–31)	16 (4–22)	1,96 (1,9–2,3)	43 (14–66)	78 (66–84)
Surgery	61,4 (52–64)	63 (55–67)	3,31 (2–5)	82 (70–92)	14 (8–30)	27 (13–33)	1,63 (1,5–1,7)	30 (10–35)	74 (64–83)
p- value	0.4	0.3	0.2	0.3	0.3	0.3	0.3	0.3	0.3

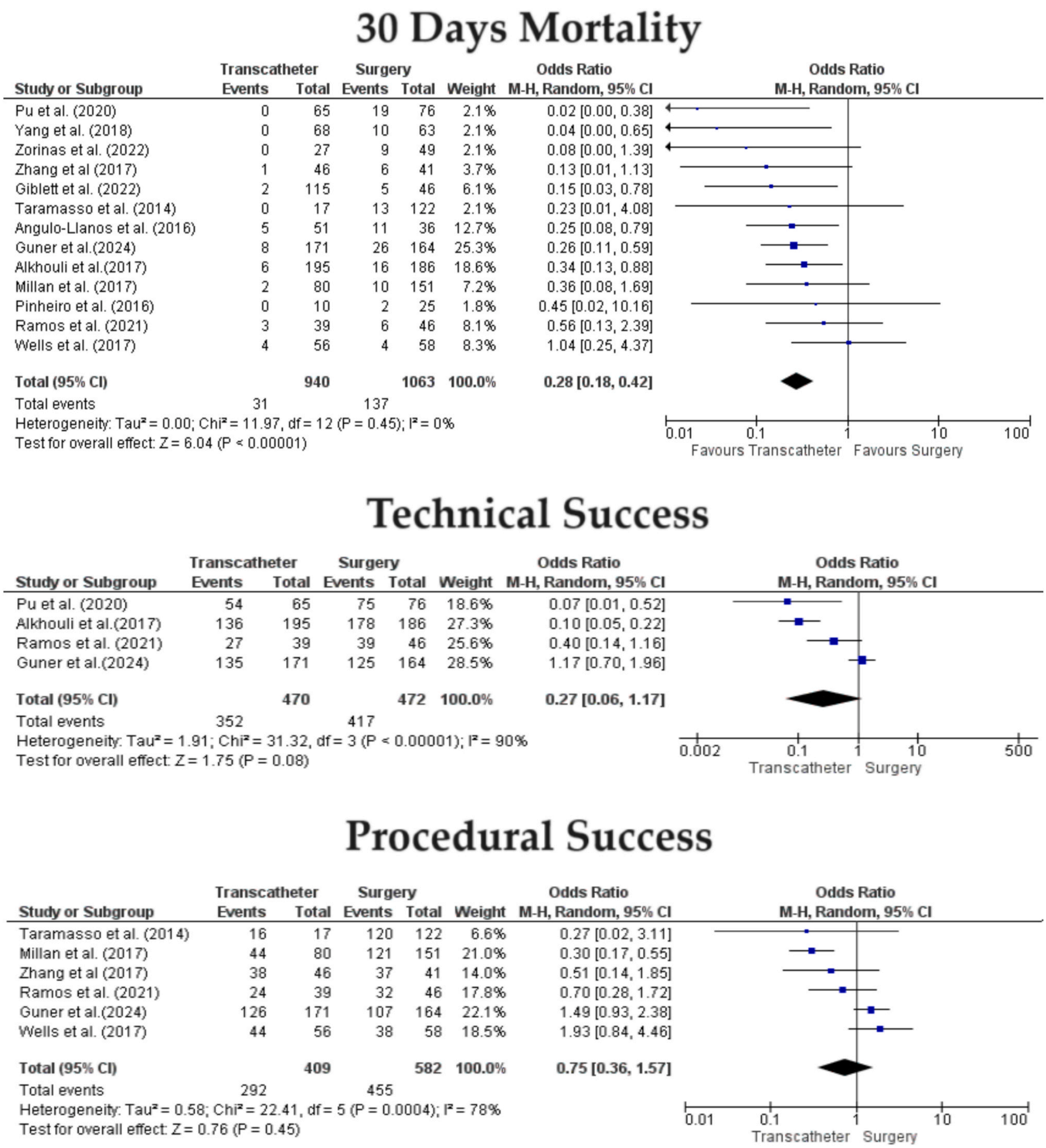

Fig. 2. Forest Plots for 30-days mortality, technical and procedural success.

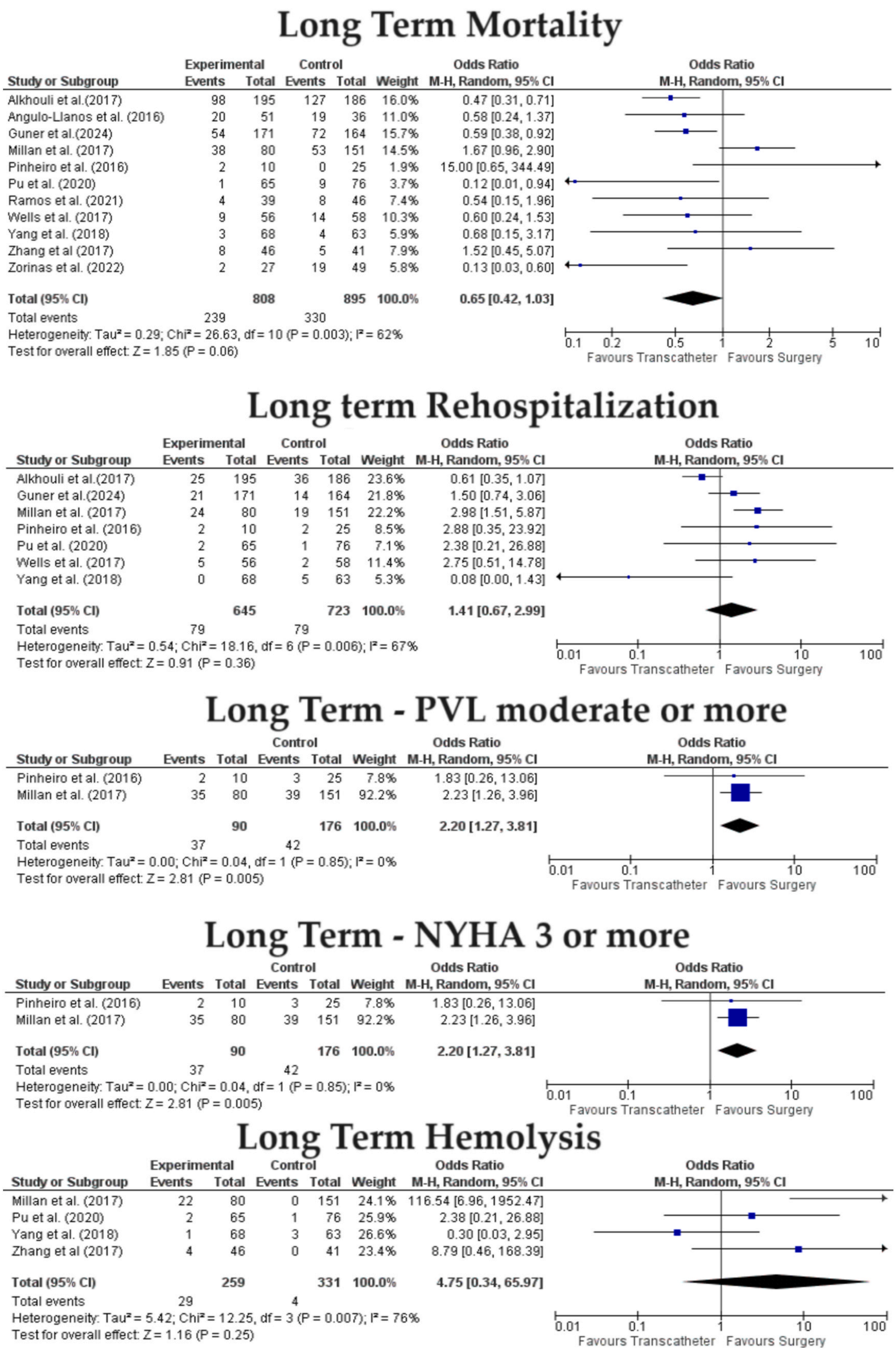

Fig. 3. Forest Plots for long-term outcomes.

haemolysis rates were not different between treatments (OR 1.41, 95 % CI 0.67–2.99, $p = 0.36$ and OR 4.75, 95 % CI 0.34–65.97, $p = 0.25$ respectively).

3.2.3. Sensitivity analysis

A first sensitivity analysis was performed for technical and procedural success, including only studies that adopted the endpoint definition from the Journal of Americal College of Cardiology expert statement about clinical trials on PVL[26] (**Figure S6**). The heterogeneity remained high for both endpoints and still there was no significant difference between transcatheter and surgical approach for technical (OR 0.35, 95 % C.I. 0.03–3.96, $p = 0.40$) and procedural success (OR 0.63, 95 % C.I. 0.19–2.97, $p = 0.45$).

A second analysis was performed to try to address the high heterogeneity for technical and procedural success and long-term mortality pooled effect sizes. Funnel plot was drawn for each endpoint and outliers studies (out of the confidence interval) were removed; funnel plots were re-assessed to check the absence of more outliers and new forest plots were pooled (**Figure S7-9**). After outliers removal, heterogeneity tests and Egger's test for publication bias were all non-significant ($p > 0.05$). Technical success was significantly lower in the transcatheter group (OR 0.16, 95 % C.I. 0.05–0.46, $p < 0.001$) while procedural success did not significantly differ between PVL transcatheter and surgical closure (OR 1.09, 95 % C.I. 0.64–1.85, $p = 0.75$). Transcatheter PVL treatment resulted in lower rates of long-term mortality compared to the surgical approach (OR 0.53, 95 % C.I. 0.40–0.71, $p < 0.001$).

4. Discussions

This meta-analysis aimed to evaluate short and long-term outcomes of surgical and transcatheter treatment of patients with PVL after cardiac surgery. The main findings can be summarized as follows:

a) At 30-day follow-up, surgical correction of PVLs was associated with increased mortality, probably driven by higher rates of peri- and post-procedural complications; no differences were found for short-term stroke, although a numerically higher event rate occurred in surgical arm.
b) Technical, procedural success and reoperation rates were not significantly different between the two groups, but surgical correction was associated with lower rates of moderate or severe post-procedural PVL both at short and long-term follow-up;
c) A trend for increased long-term death rate in patients undergoing surgical correction of PVLs was observed, despite data documenting a significant reduction in symptoms burden (improving of NYHA class) and in post-procedural PVL grading.
d) After outlier studies removal as assessed by funnel plots, long term mortality and technical success rates were lower in the transcatheter group.

To our knowledge, this is the largest metanalysis including only double-arm studies: last to date metanalysis about this topic [27] gathered predominantly single-arm observational studies. Current international guidelines recommend to treat patients with PVL if experiencing significant haemolysis, endocarditis or severe heart failure symptoms and to choose the modality of treatment based on patient risk status, leak morphology and local expertise [28,29]. Indeed, for both transcatheter and cardiac surgery interventions, operator experience and centre volume have been demonstrated to be of prognostic value for both short and long term outcomes, and, even in absence of data on PVL closure, we may expect that these patients should be centralized in experienced centers in particular for the attentions and expertise needed for diagnostic assessment for location and severity of PVL and the fact that there are only very few centers with great number of this type of procedures performed [8,30–32]. Our results are in line with previous findings[27], with surgical treatment resulting in higher rates of technical success compared to transcatheter approach (96.7 % vs. 72.1 %) but also higher mortality at 30 days (8.6 % vs. 6.8 %), which, however, shifts toward a trend of higher mortality for percutaneous treatment at 1-year follow-up: this may be attributed to the higher prevalence of co-morbidities among patients selected for percutaneous intervention and the higher incidence of significant residual leak. Another explanation for these findings could be searched in the absence of landmark analysis in the considered long-term follow-up studies: the results could have been therefore biased by events that occurred in the first month of observation and this hypothesis is supported by visual inspection of Kaplan-Meyer curves of the included studies, as in the long-term period the survival curves switched in favor of reduced mortality for surgical correction, albeit not significantly. This could also explain previous conflictual results in long-term follow-up death rates of transcatheter and surgical correction [33–36]. The procedural success rate did not differ significantly between surgery and transcatheter group, even if it was numerically lower in the latter. Increasing expertise in dedicated centers and improvement in device technology could lead to higher rates of successful transcatheter closure of PVL and reduced cardiovascular events in this population as already demonstrated by Millan et al. in a previous meta analysis [37]. It is interesting to notice that no differences were found for short-term stroke; it could be expected that surgical reintervention would be associated with a higher stroke risk due to the use of cardiopulmonary bypass and greater invasiveness. We did not find more information about the use of cerebral protection devices in the trancatheter studies that could have significantly impact on the reduction of early-stroke.

Two large multicenter studies about percutaneous corrections of PVL by Garcia and Calvert [31,38] showed a technical success rate of up to 91 percent. According to these studies, the AVP III device was used in the overwhelming majority of patients thanks to its advantageous characteristics of improved surface contact and faster occlusion with relatively low rates of complications in a population at high risk for surgery [39]; moreover, a recent study demonstrated high device success rate and no peri-procedural complications even with more than one device deployed during the same procedure (40). A recent multicentric study in Europe [40] showed a high midterm procedural and success rate of PVL closure with a different device: a comparison among devices has, to date, not been performed yet. On the other side, among studies considering only surgical treatment results, it was observed that efficacy of both repair and replacement techniques is as high as 98 % even with 20 years of follow-up [41,42]. Because the current literature does not allow direct comparison among types of surgical technique [33], the decision still relies on leak's characteristics and center or operator expertise. Different predictors on unsuccessful transcatheter repair have been identified [31,43], and careful evaluation of leak and prothesis anatomy is crucial in decision-making and in guiding both percutaneous and surgical procedures.

Two out of thirteen considered studies took into consideration patients with active endocarditis for a total of 22 patients (16,25), all of them having surgical paravalvular leaks closure. Endocarditis is associated with worse prognosis and periprocedural complications but, due to the paucity of data, it was not possible to perform sub-analysis for this subset of patients although it would be interesting to perform further analysis.

5. Limitations

The current study has several limitations. Firstly, the difference in surgical risk between the two study groups may have influenced the results of this meta-analysis, but it does reflect the approach of reserving percutaneous treatment for patients with a higher surgical risk. Secondly, heterogeneity was high for the majority of considered endpoints and this further hinders a definite interpretation of our results. Thirdly, only a few studies reported adjusted or matched effects size so that an analysis based only on multivariate results could not be performed and confounding bias can not be excluded. Fourthly, the absence of landmark analysis hinders to draw definite conclusion about long-term follow-up because of the impact of short-term outcomes on the total event number. Fiftly, there were different definitions of endpoints, especially for technical and procedural success even if some of the studies adopted the ARC definitions[26].

6. Conclusions

Transcatheter closure of paravalvular leaks is associated with lower short-term mortality rates. Persistance of moderate-severe PVL at short and long-term follow-up was observed more frequently in the transcatheter group compared to surgical treatment. Long-term rehospitalizations and all-cause mortality did not differ between the two strategies.

7. Main findings

Transcatheter correction of paravalvular leak is associated with lower 30-day mortality rates but lower rates of moderate-severe PVL resolution at short and longer-term follow-up. (**Central Illustration).**

8. Ethics approval.

No ethics approval nor patient consent was requested, because this is a study-level meta-analysis.

9. Submission declaration

The work described has not been published, it is not under consideration for publication elsewhere, its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and, if accepted, it will not be published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder.

10. Authorship

All authors have made substantial contributions to all of the following: (1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content, (3) final approval of the version to be submitted.

CRediT authorship contribution statement

Riccardo Improta: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Gianluca Di Pietro:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Yasser Odeh:** Data curation, Investigation, Methodology, Validation, Visualization, Writing – original draft, Writing – review & editing. **Arianna Morena:** Data curation, Formal analysis, Investigation, Validation, Visualization, Writing – original draft, Writing – review & editing. **Wael Saade:** Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Fabrizio D'Ascenzo:** Data curation, Formal analysis, Methodology, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Massimo Mancone:** Conceptualization, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – review & editing. **Fabio Miraldi:** Conceptualization, Funding acquisition, Investigation, Methodology, Resources, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcha.2024.101583.

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