Early and intermediate survival after transcatheter aortic valve implantation: systematic review and meta-analysis of 14 studies

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ABSTRACT

Background: Transcatheter aortic valve implants (TAVIs) is indicated as an alternative to surgical valve replacement for patients unfit for surgery. No systematic review has studied survival after 2 years and limited information is available on between-study heterogeneity.

Objectives: A systematic review and meta-analysis on intermediate survival after TAVI.

Data sources: PubMed, EMBASE, Scopus and references of selected articles.

Study eligibility criteria: Clinical studies evaluating TAVI, published between 2010 and 2012, reporting survival at 2 or more years.

Participants: About 3500 patients from 14 studies.

Study appraisal and synthesis methods: Proportion meta-analysis with 95% CI and heterogeneity assessment (I^2 and Cochran's Q). Meta-regression analysis was performed as well.

Results: Pooled immediate postoperative death rate was 7.8% (95% CI 6.2% to 9.8%, I^2=40.8%; Cochran's Q=97.7 with 92.9 df, p<0.0001) and stroke rate was 3.8% (95% CI 2.8% to 5.0%, I^2=34.3%; Cochran's Q=96.5 with 92.9 df, p<0.0001). Pooled death rates at 1, 2 and 3 years were 23.2%, 31.0% and 38.6%, respectively. Among studies reporting on concomitant percutaneous coronary intervention, pooled death rates at 30 days, 1 year and 2 years were 6.3%, 17.8% and 25.8%, respectively.

Limitations: Although our analysis examined a total of about 3500 patients, only a minority of these were actually followed up after 2 years.

Conclusions: Pooled survival rates after TAVI (at 2 years: 69.0%; at 3 years: 61.4%) can be considered excellent, particularly in the light of the high-risk profile of this patient population.

Implications of key findings: The favourable intermediate outcome in patients subjected to TAVI seems to justify its use in patients unfit for surgery. Such pooled results indicate that TAVI is a valid alternative to surgical valve replacement, but lack of data on late durability after TAVI prevents its use in low-risk patients with long expectancy of life.

ARTICLE SUMMARY

Article focus

- Transcatheter aortic valves can be indicated for patients unfit for surgery or as an alternative to surgical valve replacement.
- No difference in mortality at 2 years was found in one randomised trial comparing transcatheter valve versus surgical replacement.
- No systematic review has studied survival after 2 years and limited information is available on between-study heterogeneity.

Key messages

- In our meta-analysis of 14 studies, pooled survival rates at 2 and 3 years were 69.0% and 61.4%, respectively.
- Survival rates up to 2 years were similar to those reported in the randomised trial.
- Immediate and intermediate death rates were worse than those reported in a recent meta-analysis of 48 studies examining patients aged >80 years who underwent conventional isolated aortic valve replacement.

Strengths and limitations of this study

- Our study conveys original information beyond 2 years in a quite large series of studies.
- Although our analysis examined a total of about 3500 patients, only a minority of these were actually followed up after 2 years.

INTRODUCTION

Although the results at 2 years of the randomised PARTNER trial have shown similar death rates between transcatheter aortic valve implant (TAVI) and conventional aortic valve replacement (AVR),[1] extending this comparison on the basis of other studies can be worthwhile.

With regard to surgery, a recent meta-analysis has examined survival in patients aged ≥80 years undergoing conventional

isolated AVR.[2] From the analysis of 48 studies summarising the experience of three decades, Vasques *et al*[2] reported a pooled death rate at 2 years of 16.4% (95% CI 14.4% to 18.4%), which is clearly a more favourable outcome than has commonly been thought so far.

The experience with TAVI is much more recent. One meta-analysis of 16 studies has systematically determined the rates of major outcomes up to 1 year,[3] but limited information is available on late results.[3 4] The presence of a learning curve has consistently affected the results produced by this device,[5] therefore, only the most recent studies are likely to reflect the outcomes expected with this technique.

For these reasons, we undertook the present meta-analysis of available studies to summarise the current data on the intermediate outcome after TAVI.

METHODS
Study design
Our study was designed to examine mortality at 2 years or more after TAVI, and so we excluded those studies based on follow-up less than 2 years. Furthermore, we limited our literature search to the period from January 2010 to June 2012 in order to restrict the analysis to the most recent studies, which are likely not affected by a learning curve. We retrieved many types of clinical studies (randomised trials, observational studies, single-centre study). All kind of prostheses so far implanted in humans were included in the present analysis. The keywords used for our search were: '*aortic valve' AND (percutaneous OR transcatheter)*, combined with the limitations '*only item with abstract*' and '*publication date from 2010 to 2012*'. Statistical analysis was carried out in the form of a proportion meta-analysis that generated study-specific rates of 1-year to 3-year mortality with their respective 95% CIs. Besides the data on survival at 2 years or more, additional information on baseline patient's and operative characteristics was extracted.

Management of survival information from Kaplan-Meier curves
Our study included a simplified analysis (in which the absolute event rates from the studies were determined on the basis of an approximate method[6]) and a more complex analysis (in which each Kaplan-Meier curve of the various studies was subjected to a complete reconstruction of the number of events along with their respective timings according to the recommendations of Tierney *et al*[7]). Since the simplified analysis gave the same results as those obtained from the more complex one, only the former is presented herein.

In the simplified analysis, the death rates at 2 years (death rates from any cause) were handled as follows. In those studies where all patients had been followed up until at least 2 years (with the obvious exception of deaths before 2 years), the percent death rate at 2 years was simply the ratio between the number of deaths

observed within this time interval and the total number of enrolled patients multiplied by 100. In the remaining cases (ie, in studies with censored patients), the death rate at 2 years was directly obtained from the Kaplan-Meier curve presented in the original study.

The study-specific input information for a proportion meta-analysis is represented by the ratio of number of deaths and number of patients entering the interval, and moreover, the denominator of this ratio acts as a study-specific statistical weight for the meta-analysis. In studies including censoring, to estimate numerators and denominators at specific time-points consistently with the purposes of our meta-analysis, we used the method of Stewart and Parmar.[6] Accordingly, assuming that the number of patients still at risk at the time-point concerned (eg, at 2 years) is known (eg, $N_{AR - 2\ years}$), this denominator (adjusted for the number of patient-years accumulated) is calculated from the following equation:

$$(\text{adjusted denominator}) = (N_{AR-2\ years})/(1 - RATE_{KM-2\ years})$$

where $RATE_{KM-2\ years}$ is the mortality Kaplan-Meier rate (expressed from 0 to 1).

Likewise, adjusted numerators at the time-point concerned were calculated as:

$$(\text{adjusted numerator}) = (\text{adjusted denominator}) \times (1 - RATE_{KM-2\ years}).$$

Finally, the adjusted study-specific crude event rate was determined as: (adjusted numerator)/(adjusted denominator).

According to these equations, if the number of enrolled patients at time zero is $N_{AR\text{-time}\ 0}$ and mortality at the time point concerned differs from 0, the 'adjusted denominator' is by definition less than $N_{AR\text{-time}\ 0}$. For obvious mathematical reasons, one exception takes place when no patients have been lost to follow-up over the initial 2 years (or, in other words, when all living patients have been followed up until at least 2 years) because in these cases the 'adjusted denominator' is equal to $N_{AR\text{-time}\ 0}$.

This method of downward readjustment of the denominator has the purpose to reduce (from the number of enrolled patients at time zero, or $N_{AR\text{-time}\ 0}$, to 'adjusted denominator') the statistical weight of the studies in which some of the patients initially at risk have not been followed up until the time-point concerned.

In our analyses at 1 and 3 years, similar equations were employed. In all of these three analyses, we planned to contact the investigators for cases where the raw data needed for our survival analysis could not be extracted as indicated above.

In the more complex analysis not presented in this paper, the same readjustment of the study-specific

statistical weights was performed using the method described by Tierney et al.[7]

Meta-analysis

The death rates at 2 years for individual studies were then analysed according to a proportion meta-analysis using the random effect model. The pooling methods were the same as those reported in a previous study[2] and in numerous other studies[8] as well. Our meta-analytic results included: (1) the 95% CI for individual study-specific rates; (2) the meta-analytical pooled rate at 1, 2 and 3 years with 95% CI; (3) standard indexes assessing between-study heterogeneity including I^2 and Cochran's Q. Our meta-analysis was rerun under different conditions and particularly after excluding specific studies that were thought to be responsible for the large heterogeneity found in our primary analysis.

Meta-regression, in which we tested whether death rates were affected by specific covariates, was carried out as previously described.[2] Finally, because of the one-arm and observational nature of the included studies, our analysis did not include any adjustment aimed at evaluating publication bias.

RESULTS

Our literature search on PubMed yielded 963 eligible articles, which were scrutinised by two co-authors (AM and ST). Figure 1 illustrates the PRISMA diagram of our search. A total of 14 studies[1] [9–21] reporting on 3496 patients met our inclusion criteria and were included in our analysis. Tables 1 and 2 summarise the main characteristics of these studies.

The raw data extracted from the trials were adequate for our analysis, and so we did not have to contact any investigators. The pooled immediate postoperative death rate was 7.8% (95% CI 6.2% to 9.8%, I^2=40.8%; Cochran's Q=97.7 with 93 df, p<0.0001) and stroke rate was 3.8% (95% CI 2.8% to 5.0%, I^2=34.3%; Cochran's Q=96.5 with 93 df, p<0.0001).

Pooled death rates at 1, 2 and 3 years were 23.2%, 31.0% and 38.6%, respectively. Survival data are reported in figures 2 and 3. Only six studies reported data on 3-year mortality, and therefore we restricted further analysis at results at 2 years.

At 2 years, indexes of heterogeneity consistently were at levels of statistical significance (I^2=52.1%; Cochran's Q=27.2 with 13 df, p=0.012). Furthermore, 95% CI of the
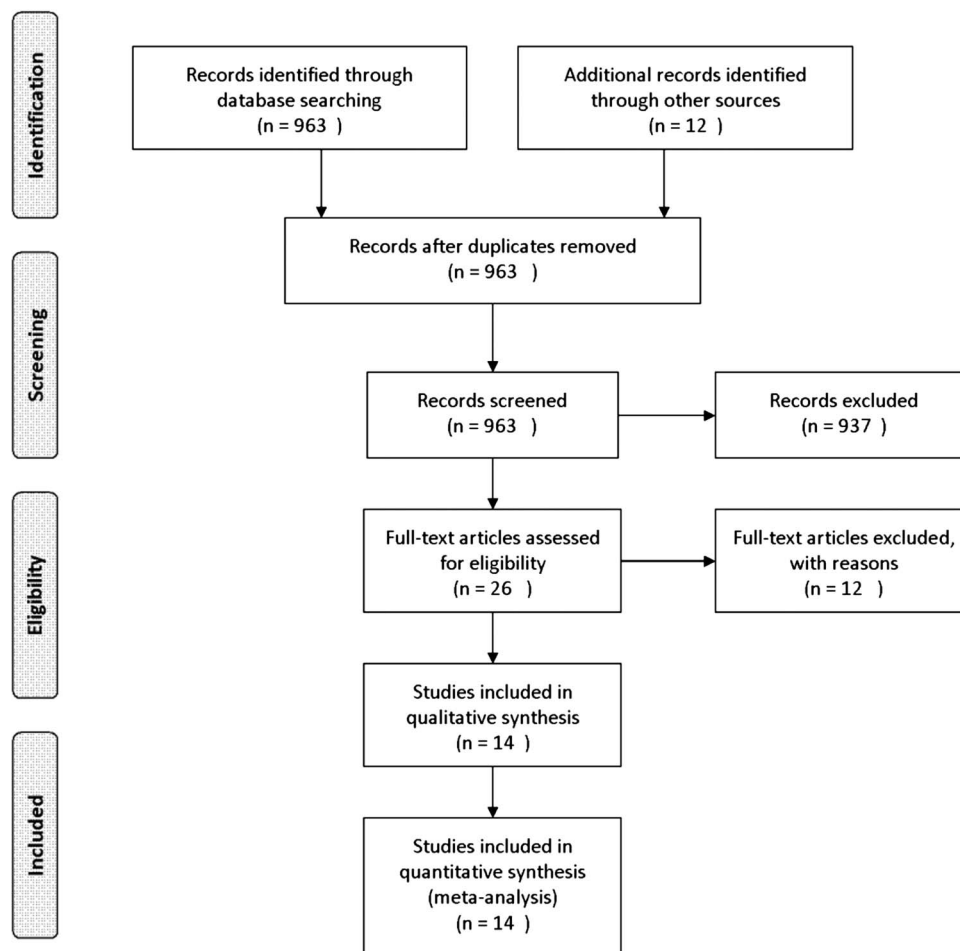

Figure 1 PRISMA diagram of our literature search. Other sources for identification of further articles included EMBASE and Scopus. The lack of survival information at 2 years was the only reason for the final exclusion of 12 studies. Last search was run on 1 July 2012.

Table 1 Characteristics of studies and baseline variables of patients who underwent transcatheter aortic valve implantation included in this analysis

First author	Year	Type of study	Type of prosthesis	Study period	Number of patients	Age	Mean STS score	Mean Logistic EuroSCORE	Coronary artery disease (%)	Prior CABG/ cardiac surgery (%)	Prior PCI (%)	Peripheral vascular disease (%)	Cerebro-vascular disease (%)	Pulmonary disease (%)	LVEF (%)
Abdel-Wahab[9]	2012	R, SC	CoreValve	09.2007–03.2011	125	81.0±6.4	–	24.3±13.8	72.8	19.2	30.4	16.8	10.4	–	47.7±14.5
Attias[10]	2010	P, SC	SAPIEN /CoreValve	10.2006–06.2009	83	81±9	15±8	26±14	50.6	21.7	19.3	27.7	–	32.5	52±15
Bleiziffer[11]	2012	P, SC	SAPIEN /CoreValve	06.2007–03.2009	227	81±7	7±5	21±14	52.0	18.5	–	26.9	18.1	22.9	–
Buellesfeld[12]	2011	P, MC	CoreValve	2006–2009	126	81.9±6.4	–	23.4±13.8	65.9	26.2	23.8	19.1	22.2	23.0	–
D'Onofrio[13]	2011	P, MC	SAPIEN	04.2008–09.2010	504	81.2±6.5	11.0±4.0	26.3±13.8	50.4	16.5	22.0	45.4	–	34.3	52.4±13.6
Gasparetto[14]	2012	P, SC	SAPIEN /CoreValve	06.2007–04.2011	191	80.5±56.0	–	21.4±13.4	59.2	15.2	14.1	–	31.9	27.8	54.3±12.9
Kalavrouziotis[15]	2011	P, SC	SAPIEN	04.2007–07.2010	35	79.2±9.4	7.5±3.6	18.8±14.1	60.0	31.4	34.3	–	28.6	17.1	59±13
Kodali[1]	2012	RCT	SAPIEN	05.2007–08.2009	348	83.6±6.8	11.8±3.3	29.3±16.5	74.7	42.5	33.3	42.8	27.6	43.7	52.5±13.5
Makkar[16]	2012	RCT	SAPIEN	05.2007–03.2009	179	83.1±8.6	11.2±5.8	26.4±16.2	67.6	32.4	26.3	30.2	26.8	41.3	53.9±13.1
Moat[17]	2011	P, SC	SAPIEN /CoreValve	01.2007–12.2009	870	81.9±7.1	–	–	47.1	–	–	29.0	–	28.7	–
Ussia[18]	2012	P, MC	CoreValve	06.2007–08.2008	181	80.9±6.1	11.4±9.9	24.0±13.5	53.0	18.8	28.2	14.9	–	18.8	–
Walther[19]	2012	P, SC	SAPIEN	02.2006–01.2010	299	82.1±6.4	12.0±7.7	31±15.8	–	28.1	–	47.2	18.7	43.1	55±14
Wenaweser[20]	2011	P, SC	SAPIEN /CoreValve	07.2007–09.2010	257	82.1±6.2	6.4±5.0	24.7±24.9	65.0	21.0	22.6	24.9	9.0	–	51±14
Ye[21]	2010	P, SC	Cribier–Edwards/ SAPIEN	10.2005–02.2009	71	80.0±8.1	12.1±7.7	34.5±20.4	74.7	43.7	43.7	85.9	31.0	28.2	–

CABG, coronary artery bypass grafting; EuroSCORE, European System for Cardiac Operative Risk Evaluation; LVEF, left ventricular ejection fraction; MC, multicenter; P, prospective; PCI, percutaneous coronary intervention; R, retrospective; RCT, randomised controlled trial; SC, single center; STS, Society of Thoracic Surgeons.

Table 2 Operative data and immediate outcome in patients who underwent transcatheter aortic valve implantation included in this analysis

First author	Year	Transapical approach (%)	Associated PCI (%)	Implantation success (%)	In-hospital/30-days stroke (%)	30-days mortality (%)
Abdel-Wahab [9]	2012	0	44.0	100	6.0	4.0
Attias [10]	2010	100	0	94.0	4.8	7.2
Bleiziffer [11]	2012	23.8	–	–	2.6	11.5
Buellesfeld [12]	2011	0	–	83.3	9.6	15.1
D'Onofrio [13]	2011	100	–	99.2	3.0	8.3
Gasparetto [14]	2012	30.4	20.4	95.3	1.6	4.2
Kalavrouziotis [15]	2011	68.6	–	97.1	0	2.9
Kodali [1]	2012	30.0	0	94.3	4.6	3.5
Makkar [16]	2012	0	0	96.7	6.7	5.0
Moat [17]	2011	26.4	6.3	97.3	4.1	7.1
Ussia [18]	2012	0	–	91.7	2.8	11.0
Walther [19]	2012	100	–	–	0.7	8.7
Wenaweser [20]	2011	21.4	23.4	99.6	3.9	6.6
Ye [21]	2010	100	–	100	1.4	16.9

PCI, Percutaneous coronary intervention.

death rate ranged from 25.7% to 36.6% indicating considerable variability in this outcome end-point. Reasons that can explain this heterogeneity likely reside in the criteria for patient selection. Figure 3 clearly shows that patients classified as inoperable in the studies by Makkar et al[16] and Kodali et al[1] showed an increased mortality at 2 years. However, the between-study heterogeneity remained significant even after exclusion of these two trials (data of this sensitivity analysis not shown).

Sensitivity analysis for logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) showed that at 2 years, studies reporting on patients with a logistic EuroSCORE <25% had a pooled death rate of 31.4% (95% CI 26.4% to 36.5%), whereas it was 32.5% (95% CI 24.7% to 41.3%) among patients with a logistic EuroSCORE>25%.

Similarly, sensitivity analysis for Society of Thoracic Surgeons (STS) score showed that at 2 years studies

reporting on patients with a STS score <10% had a pooled death rate of 33.8% (95% CI 28.6% to 39.4%), whereas it was 32.0% (95% CI 26.1% to 38.6%), among patients with a STS score >10%. These findings were confirmed at meta-regression (p=0.802).

Interestingly, data from four studies[9 14 17 20] reporting on concomitant percutaneous coronary intervention (PCI) showed a somewhat lower death rate at 2 years (25.8%, 95% CI 22.0% to 30.1%, I^2=0%; Cochran's Q=59.9 with 75 df, p<0.0001). These improved results were consistent with somewhat lower mortality at 30 days (6.3%, 95% CI 5.0% to 8.0%, I^2=12.0%; Cochran's Q=77.6 with 75 df, p<0.0001) and 1 year (17.8%, 95% CI 13.5% to 23.0%, I^2=39.3%; Cochran's Q=89.5 with 75 df, p<0.0001). Scarce data on the extent of coronary artery disease and revascularisation policy prevented further comparative analysis. However, assuming that no concomitant PCI was performed in the other studies, meta-regression showed that a policy of coronary revascularisation was associated with significantly better 2-year survival (coefficient −0.004, p=0.024).

Finally, transapical approach did not affect 2-year survival according to meta-regression (p=0.736).
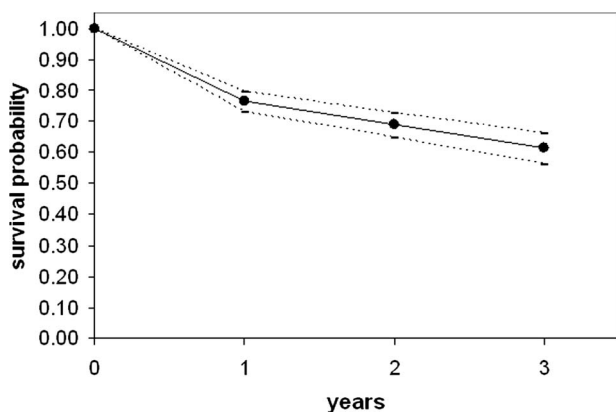

Figure 2 Survival after transcatheter aortic valve implant: the solid line (with circles) indicates the pooled results of our analysis while the dashed lines represent 95% CIs.

DISCUSSION

Our article raises a number of issues particularly if our findings are interpreted in the framework of other recent reports. First, the recent publication of the survival results from the SOURCE registry[22] allow us to compare the death rates at 1 year between the population included in our meta-analysis (3496 patients; 1-year mortality=23.2%) and the large patient series included in this registry (3195 patients; 1-year mortality=24.0%). While it should be stressed that the population enrolled in the SOURCE registry could not be included in our
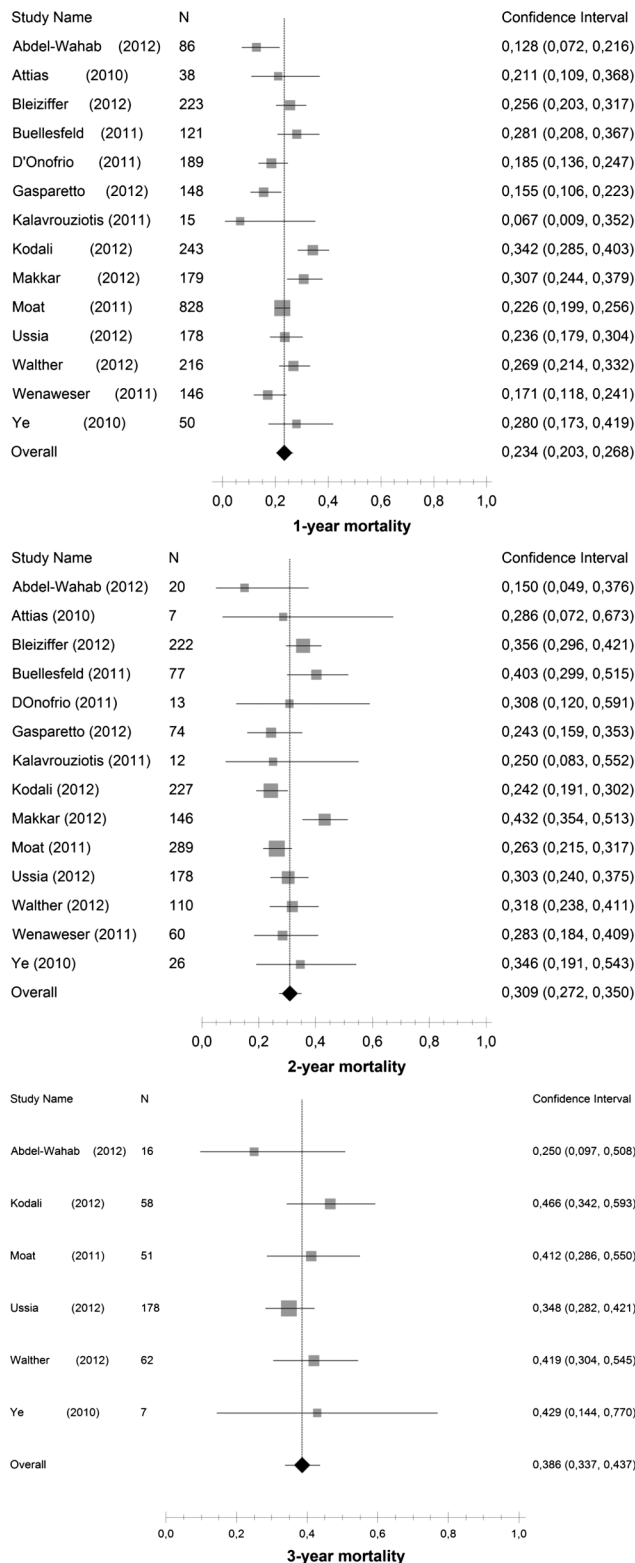
Figure 3 Study-specific death rates and pooled meta-analytic rates at 1 (upper panel), 2 (intermediate panel) and 3 years (lower panel) after transcatheter aortic valve implant; for each study, N indicates the adjusted denominator at the time-point concerned; CIs are at 95%.

analysis due to the lack of survival data after 1 year, these nearly identical results at 1 year suggest a good representativeness of the patients of our meta-analysis.

Since TAVI still is a rather novel procedure, data on the longer term outcome can be important and the 2-year results of the PARTNER trial (33.9% mortality) are particularly relevant from this point of view, also because they agree with those found in our meta-analysis (31.0% mortality at 2 years). The purpose of our analysis to study outcomes from other studies is worthwhile not only because information up to 3 years was estimated but also because information was obtained about the between-study variability of these outcomes.

Although a difference in 2-year mortality favouring AVR over TAVI could be suggested by indirectly comparing the present findings (31.0% with 95% CI of 25.7% to 36.6%) with pooled data of conventional surgery in octogenarians (16.4%, 95% CI 4.4% to 18.4%),[2] the PARTNER trial showed no such a difference. While the reasons underlying this discrepancy cannot be easily identified, one explanation can be that a variety of known and possibly unknown factors still tend to generate less reliable results with TAVI than those, more reproducible, reported with conventional surgery. This hypothesis is in keeping with the significant heterogeneity found across the TAVI studies included in our meta-analysis.

In patients fit for surgery, mortality risk after isolated AVR has significantly decreased during the last decade presumably because of improvements in anaesthesiological and peri-operative care as well as the introduction of mini-sternotomy AVR.[23] This may explain why patients aged >80 years undergoing AVR nowadays show unexpectedly good survival rates.[2] In light of this evidence, TAVI can be seen as a valid alternative in the very elderly only if the operative risk is prohibitive. Indeed, when operative risk of very elderly patients is not prohibitive their immediate and late survival after AVR are excellent.[2]

The impact of coronary artery disease and the benefits and risks associated with its concomitant treatment cannot be addressed in this meta-analysis. Even if coronary artery disease requiring revascularisation was an exclusion criteria in a few studies, the prevalence of coronary artery disease may have a significant impact on the early and late outcome of these patients[18] as suggested by better immediate and intermediate survival rates reported in a few series.[9 14 17 20] However, at this stage, scrutiny of the value of hybrid approach is not possible because of lack of specific data on the prevalence of coronary artery disease requiring revascularisation and timing of PCI.

A major limitation of our study is the fact that in studies with a follow-up beyond 2 years, the patients who reached this follow-up length were only 10% of the population initially enrolled. Another weakness of this analysis is the lack of information at individual patient level which prevented us from assessing the prognostic value of important clinical covariates and concomitant PCI.

The debate on the role that TAVI can have in the present therapeutic scenario is very lively, and

conflicting opinions have recently been published.[24 25] At the same time, although further studies on outcomes have been made available,[3 26] no additional information on the results beyond 2 years has been published.

In conclusion, despite the high level of heterogeneity, our pooled analysis of available survival data supports the effectiveness of TAVI at 2 or 3 years. TAVI can offer rather durable intermediate results and can therefore be considered a valid treatment in high-risk patients. However, lack of data on structural durability at this stage prevents its use in patients with low operative risk and long expectancy of life.

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