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VALVE REPLACEMENT SURGERY COMPLICATION : SYSTEMATIC REVIEW IN LITERATURE

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Abstract

This review is aiming to systematically summarize the literature on Valve replacement surgery complication. The present review was conducted by searching in Medline, Embase, Web of Science, Science Direct, BMJ journal and Google Scholar for, researches, review articles and reports, published over the past years. Books published on Valve replacement surgery complication. If several studies had similar findings, we randomly selected one or two to avoid repetitive.

***Results**. Based on findings and results this review found all included RCTs had some methodological flaws. Among patients with major VC, vascular dissection (62.8%), perforation (31.3%), and access-site hematoma (22.9%) were the most frequent modes of presentation. Major VC, but not minor VC, were associated with significantly higher 30-day rates of major bleeding, transfusions, and renal failure requiring dialysis, and with a significantly higher rate of 30-day and 1-year mortality [3] Five patients (10%, CL 5.7 to 13.9) in group A suffered late acute aortic dissection. Acute aortic dissection (5 vs 0, p = 0.0001) and sudden death (7 vs 0, p = 0.0001) occurred more frequently in patients with BAV. [4] We recorded no structural valve deterioration requiring surgical valve replacement in either group. Moderate or severe aortic regurgitation occurred in 40 (14%) of 280 patients in the TAVR group and two (1%) of 228 in the SAVR group (p<0·0001). [5].*

Keywords: *Valve, replacement, stenosis, surgery, vascular complication*

Vascular complications (VC) Trans femoral (TF) Trans catheter aortic valve replacement (TAVR) aortic valve replacement (AVR).

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INTRODUCTION:

The heart is a pump made of muscle tissue. It has 4 pumping chambers: 2 upper chambers, called atria, and 2 lower chambers, called ventricles. Valves between each of the heart's pumping chambers keep blood flowing forward through the heart.[1] When valves are damaged or diseased and do not work the way they should they may need to be repaired or replaced. Conditions that may cause heart valve dysfunction are valve stenosis (stiffness) and valve regurgitation (leaky valve). [1]

When one (or more) valve(s) becomes stenosis (stiff), the heart has to work harder to pump the blood through the valve. Valves can become narrow, stiff from infection (such as rheumatic fever or staph), and aging. If one or more valves become leaky, blood leaks backwards, which means less blood is pumped in the right direction. Based on your symptoms and the overall condition of your heart, your healthcare provider may decide that the diseased valve(s) needs to be surgically repaired or replaced. [2]

The diseased valve may be repaired using a ring to support the damaged valve, or the entire valve may be removed and replaced by an artificial valve. Artificial valves may be made of carbon coated plastic or tissue (made from animal valves or human valves taken from donors). You and your healthcare provider will talk about the pros and cons of each type and what might be best for you. [2]

METHODS:

The present review was conducted December 2018 in accordance with the preferred reporting items for systematic reviews and meta-analyses (PRISMA) declaration standards for systematic reviews. We reviewed all the topics on Valve replacement surgery complication. To achieve this goal, we searched Medline, Embase, Web of Science, Science Direct, and Google Scholar for, researches, review articles and reports, published over the past 15 years. Books published on iron deficiency management.

Our search was completed without language restrictions. Then we extracted data on study year, study design, and key outcome on Valve replacement surgery complication. The selected studies were summarized, and unreproducible studies were excluded. Selected data is shown in the Table 1.

Inclusion criteria

Only randomized clinical trials (RCTs) were considered for this systemic review and only studies that recruited patients with Valve replacement surgery were included in the review.

Exclusion criteria

Non-relating articles were discarded, while additional articles reporting on Valve repairing surgery were excluded.

Data extraction and analysis

Information relating to each of the systematic review elements was extracted from the studies and collated in qualitative tables. Direct analysis of the studies of Valve replacement surgery is made with extreme caution, as different sampling techniques can provide bias as overview of the assemblage

RESULTS:

All included RCTs had some methodological flaws. Sixty-four patients (15.3%) had major VC and 50 patients (11.9%) had minor VC within 30 days of the procedure. Among patients with major VC, vascular dissection (62.8%), perforation (31.3%), and access-site hematoma (22.9%) were the most frequent modes of presentation. Major VC, but not minor VC, were associated with significantly higher 30-day rates of major bleeding, transfusions, and renal failure requiring dialysis, and with a significantly higher rate of 30-day and 1-year mortality. The only identifiable independent predictor of major VC was female gender (hazard ratio [HR]: 2.31 [95% confidence interval (CI): 1.08 to 4.98], p = 0.03). Major VC (HR: 2.31 [95% CI: 1.20 to 4.43], p = 0.012), and renal disease at baseline (HR: 2.26 [95% CI: 1.34 to 3.81], p = 0.002) were identified as independent predictors of 1-year mortality. [3] Five patients (10%, CL 5.7 to 13.9) in group A suffered late acute aortic dissection. Acute aortic dissection (5 vs 0, p = 0.0001) and sudden death (7 vs 0, p = 0.0001) occurred more frequently in patients with BAV. All survivors were assessed by echocardiogram. The mean diameter of the ascending aorta was 48.4 mm in group A and 36.8 mm in group B. Three patients in group A were operated on because of ascending aorta aneurysm more than 6 cm in diameter. [4] We screened 3105 patients, of whom 699 were enrolled (348 assigned to TAVR, 351 assigned to SAVR). Overall mean Society of Thoracic Surgeons Predicted Risk of Mortality score was 11·7%. At 5 years, risk of death was 67·8% in the TAVR group compared with 62·4% in the SAVR group (hazard ratio 1·04, 95% CI 0·86–1·24; p=0·76). We recorded no structural valve deterioration requiring surgical valve replacement in either group. Moderate or severe

aortic regurgitation occurred in 40 (14%) of 280 patients in the TAVR group and two (1%) of 228 in the SAVR group (p<0·0001), and was associated with increased 5-year risk of mortality in the TAVR group (72·4% for moderate or severe aortic regurgitation vs 56·6% for those with mild aortic regurgitation or less; p=0·003). [5]

Table (1) Results from Sequencing Studies.

Risk factor	**Authors**	***Study design and sample***	**Result**	**Level of evidence**
major bleeding, renal failure requiring dialysis	**Philippe Généreux et a l** (2012)[3]	Randomized controlled PARTNER (Placement of AoRTic TraNscathetER Valve) trial, a total of 419 patients (177 from cohort B [inoperable] and 242 from cohort..	Sixty-four patients (15.3%) had major VC and 50 patients (11.9%) had minor VC within 30 days of the procedure. Among patients with major VC, vascular dissection (62.8%), perforation (31.3%), and access-site hematoma (22.9%) were the most frequent modes of presentation. Major VC, but not minor VC, were associated with significantly higher 30-day rates of major bleeding, transfusions, and renal failure requiring dialysis, and with a significantly higher rate of 30-day and 1-year mortality. The only identifiable independent predictor of major VC was female gender (hazard ratio [HR]: 2.31 [95% confidence interval (CI): 1.08 to 4.98], p = 0.03). Major VC (HR: 2.31 [95% CI: 1.20 to 4.43], p = 0.012), and renal disease at baseline (HR: 2.26 [95% CI: 1.34 to 3.81], p = 0.002) were identified as independent predictors of 1-year mortality.	**Level 3**
ascending aorta aneurysm	Claudio F Russo. Et al (2002)[4]	One hundred consecutive patients were allocated into two groups according to the presence of BAV (group A, 50 patients) or TAV (group B, 50 patients). Mean age was 51 ± 12 years in group A, and 50 ± years 12 in group B. No patients had hypertension or Marfan's syndrome. Until July 2001, mean follow-up was 234 ± 47 months in group A and 241 ± 43 months in group B.	Five patients (10%, CL 5.7 to 13.9) in group A suffered late acute aortic dissection. Acute aortic dissection (5 vs 0, p = 0.0001) and sudden death (7 vs 0, p = 0.0001) occurred more frequently in patients with BAV. All survivors were assessed by echocardiogram. The mean diameter of the ascending aorta was 48.4 mm in group A and 36.8 mm in group B. Three patients in group A were operated on because of ascending aorta aneurysm more than 6 cm in diameter.	**Level 2**

Moderate or severe aortic regurgitation	Michael J Mack(2015)[5]	Randomized controlled trial at 25 hospitals, in Canada (two), Germany (one), and the USA (23). We used a computer-generated randomisation sequence to randomly assign high-risk patients with severe aortic stenosis to either SAVR or TAVR with a balloon-expandable bovine pericardial tissue valve by either a trans femoral or trans apical approach. Patients and their treating physicians were not masked to treatment allocation. The primary outcome of the trial was all-cause mortality in the intention-to-treat population at 1 year, we present here predefined outcomes at 5 years.	We screened 3105 patients, of whom 699 were enrolled (348 assigned to TAVR, 351 assigned to SAVR). Overall mean Society of Thoracic Surgeons Predicted Risk of Mortality score was 11·7%. At 5 years, risk of death was 67·8% in the TAVR group compared with 62·4% in the SAVR group (hazard ratio 1·04, 95% CI 0·86–1·24; p=0·76). We recorded no structural valve deterioration requiring surgical valve replacement in either group. Moderate or severe aortic regurgitation occurred in 40 (14%) of 280 patients in the TAVR group and two (1%) of 228 in the SAVR group (p<0·0001), and was associated with increased 5-year risk of mortality in the TAVR group (72·4% for moderate or severe aortic regurgitation vs 56·6% for those with mild aortic regurgitation or less; p=0·003).	**Level 2**
major bleeding and new-onset atrial fibrillation	Craig R. Smith, etal (2011)[6]	Randomized controlled trial at 25 centers, we randomly assigned 699 high-risk patients with severe aortic stenosis to undergo either transcatheter aortic-valve replacement with a balloon-expandable bovine pericardial valve (either a transfemoral or a transapical approach) or surgical replacement. The primary end point was death from any cause at 1 year. The primary hypothesis was that transcatheter replacement is not inferior to surgical replacement	The rates of death from any cause were 3.4% in the transcatheter group and 6.5% in the surgical group at 30 days (P=0.07) and 24.2% and 26.8%, respectively, at 1 year (P=0.44), a reduction of 2.6 percentage points in the transcatheter group (upper limit of the 95% confidence interval, 3.0 percentage points; predefined margin, 7.5 percentage points; P=0.001 for noninferiority). The rates of major stroke were 3.8% in the transcatheter group and 2.1% in the surgical group at 30 days (P=0.20) and 5.1% and 2.4%, respectively, at 1 year (P=0.07). At 30 days, major vascular complications were significantly more frequent with transcatheter replacement (11.0% vs. 3.2%, P<0.001); adverse events that were more frequent after surgical replacement included major bleeding (9.3% vs. 19.5%, P<0.001) and new-onset atrial fibrillation (8.6% vs. 16.0%, P=0.006). More patients undergoing transcatheter replacement had an improvement in symptoms at 30 days, but by 1 year, there was not a significant between-group difference.	**Level 2**

majority of bleeding	Detlef Hering, et al (2005)[7]	Comparison of three different intensities of oral anticoagulation in a prospective, randomized multicenter design. Three months after valve replacement, patients were randomly assigned to stratum A, international normalized ratio (INR) 3.0 to 4.5; stratum B, INR 2.5 to 4.0; or stratum C, INR 2.0 to 3.5.	Fifty-one thromboembolic events (TEs) were documented, resulting in a linearized incidence of 0.75 TEs per 100 patient-years, 22 of which were minor (0.32% per patient-year), 10 were moderate (0.15% per patient-year), and 19 were severe (0.28% per patient-year). Thromboembolism following AVR was significantly lower than after MVR (0.53% per patient-year vs 1.64% per patient-year). Patients reported 1,687 bleeding complications (24.8% per patient-year). The vast majority of bleeding complications (n = 1,509; 22.2% per patient-year) were classified as minor, 140 were classified as moderate (2.06% per patient-year), and 38 were classified as severe (0.56% per patient-year). The clinically relevant incidences of moderate and severe TEs and bleeding complications were not significantly different between the three prespecified INR strata.	**Level 3**
death or major stroke	Michael J. Reardon etal (2015)	A total of 797 patients underwent randomization at 45 centers in the United States. Eligible patients were randomly assigned in a 1:1 ratio to transcatheter aortic valve replacement with the self-expanding transcatheter valve (transcatheter aortic valve replacement [TAVR] group) or to aortic valve replacement with a surgical bioprosthesis (surgical group). The 2-year clinical and echocardiographic outcomes were evaluated in these patients.	The rate of 2-year all-cause mortality was significantly lower in the TAVR group (22.2%) than in the surgical group (28.6%; log-rank test $p < 0.05$) in the as-treated cohort, with an absolute reduction in risk of 6.5 percentage points. Similar results were found in the intention-to-treat cohort (log-rank test $p < 0.05$). The rate of 2-year death or major stroke was significantly lower in the TAVR group (24.2%) than in the surgical group (32.5%; log-rank test $p = 0.01$).	**Level 4**

DISCUSSION:

The current report, drawn from a cohort of 419 patients with severe symptomatic aortic stenosis who underwent TF-TAVR, is the largest study to specifically evaluate the incidence, predictors of, and impact of major VC on long-term prognosis. The main results of the present study are as follows: 1) major VC after TF-TAVR using the first generation of large devices were frequent; 2) the occurrence of major VC after TAVR was associated with bleeding events, transfusions, and increased mortality; 3) the incidence and impact of major VC seems to decrease in a lower-risk population. The current study demonstrated the prognostic impact of major VC after TAVR on short- and long-term mortality. Indeed, major VC were associated with a more than 4-fold increase in 30-day mortality. Several other investigators have reported similar results.

Similar to previous reports, AVAs and aortic valve mean gradients remained stable over 2 years with TAVR and were superior to surgical replacement. We also found no evidence of early structural valve deterioration at 2 years.9 The rate of moderate or severe paravalvular regurgitation was higher in patients treated with a transcatheter valve, although the overall frequency was low at 2 years (6.1%). Longer term follow-up will provide more insight into the late term durability of transcatheter bioprostheses. The small number of patients with moderate to severe paravalvular regurgitation prevents a detailed analysis of the association of paravalvular regurgitation and 2-year mortality.1 Also, Clinical benefits of trans catheter replacement included significantly shorter stays in the intensive care unit and in the hospital. In addition, the functional class and 6-minute walk distance were strikingly improved at 1 year in the two study groups, although at 30 days, the benefits were greater with transcatheter replacement than with surgical replacement.

CONCLUSIONS:

In conclusion, we have shown that in patients with aortic stenosis who are at high risk for operative complications and death, surgical aortic-valve replacement and balloon-expandable transcatheter replacement were associated with similar mortality at 30 days and 1 year and produced similar improvements in cardiac symptoms.

In high-risk patients with severe aortic stenosis, transcatheter and surgical procedures for aortic-valve replacement were associated with similar rates of survival at 1 year, although there were important differences in per procedural risks

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