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# Low incidence and minimal impact of paravalvular leak after conventional aortic valve replacement.

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## ABSTRACT:

**OBJECTIVES:** To evaluate the incidence of paravalvular leaks (PVLs) after surgical aortic valve replacement (AVR) and assess its impact on postoperative outcomes.
**METHODS:** A retrospective review of 460 consecutive isolated AVR from January 2008 to December 2014. Postoperative transthoracic echocardiograms (TTE) and clinical notes were reviewed.
**RESULTS:** Thirty-five patients (7.6%) developed a PVL and formed the cohort of this report. TTE grading of PVL was trivial in 18 (51.4%), mild in 14 (40%), moderate in 2 (5.7%) and severe in 1 patient (2.9%), with an overall prevalence of developing moderate to severe PVL after AVR of 0.65%. Mean age was 63 years, 23 patients were males (65.7%) and mean logistic Euroscore was 8.35 $\pm$ 15.8%. Valve lesions were mainly stenosis (24 patients; 68.6%), regurgitation (7 patients; 20%) and mixed aortic lesions (4 patients; 11.4%). Implanted prostheses were 19 bioprosthesis (54.2%) and 16 mechanical valves (45.8%). We had one 30-days mortality (2.8%), 13 postoperative new onset atrial fibrillation (37%), permanent pacemaker 2.8%, cerebrovascular stroke 2.8%, re sternotomy for bleeding 2.8% and two patients needed hemodialysis (5.7%). Patients were followed up for 0.9 $\pm$ 1.2 years. When last seen, 27 patients were in NYHA class I (77.1%), six patients were in class II (17.1%) and two patients with moderate to severe PVL remained in NYHA class IV (5.7%). Peak aortic valve gradients ranged from 14 to 68 mmHg, with a mean gradient of 27.8 $\pm$ 13.3 mm Hg. Three patients with trivial PVL (8.5%) developed prosthetic valve endocarditis, with 2 patients among them requiring intervention for prosthetic valve failure (5.7%). Demographics, preoperative risk profiles and hospital outcomes were comparable to those recorded in the remaining 425 patients without PVL.
**CONCLUSION:** The incidence of PVL after conventional AVR is small and the development of moderate or greater leaks is negligible. Trivial to mild leaks had a benign course unless complicated by PVE. New percutaneous therapies for aortic valve disease must match these low rates.

**Key words:** Paravalvular leak, prosthetic valve dysfunction, aortic valve.

## INTRODUCTION

Paravalvular leak (PVL) is a well-recognized complication of conventional aortic valve replacement surgery (AVR) [1-3]. The incidence of PVL, including small non-significant jets, is estimated to be as high as 20% [4-5]. Most PVLs are hemodynamically non-significant; however moderate or severe PVL can lead to heart failure and increased risk of infective endocarditis. Smaller PVLs may cause intravascular haemolysis and anaemia. [6-8].

Increasingly, AVR is being performed by a variety of new techniques. These include insertion of conventional prosthesis via minimal access approaches for example; right lateral thoracotomy or hemisternotomy, the use of

sutureless prosthesis via conventional median sternotomy and minimal access routes and percutaneous valve insertion via transfemoral, transapical or trans-aortic routes (TAVI) [9-11]. In this study we set out evaluate the incident of PVL in our practice and to determine the prognosis and natural history of patients presenting with post-operative PVL

## MATERIAL AND METHODS

This was a retrospective study of prospectively collected data from our institutional database. The data is prospectively collected for the United Kingdom adult cardiac surgical database. From January 2008 to December 2014, 460 consecutive patients benefited from aortic valve replacement. They were 262 males (57%) and 198 females (43%) with a mean age 62.9 ± 15.6 years (range 17-84 years). The primary aetiology for valvular dysfunction was degenerative in 337 (73.3%), bicuspid aortic valve in 104 (22.6%), infective endocarditis in 16 (3.5%), and rheumatic valve disease in 4 (0.9%). The underlying valvular pathology was mainly stenosis in 351 (76.3%), regurgitation in 50 (10.8%) and mixed pathology in 56 patients (12.1%). There were 3 patients with annuloaortic ectasia (0.65 %).

**Aortic valve insertion technique**

Valve insertion techniques were similar among the seven operating surgeons in our institution during the study period. In general, stented prosthesis were inserted using interrupted mattress sutures to place the valve in a supra aortic position. Braided non- absorbable suture were used. Felt pledgets were not routinely used but were employed where the operative surgeon felt they were required for patients with poor tissue quality. As shown in Table 1, the aortic valve was replaced with either mechanical (133 patients; 29.0%) or biological valve prosthesis (327 patients; 71.0%). Patient's age, preference and Surgeon choice were the main factors in deciding which prosthesis was employed.

**Echocardiograms**

It was our routine practice to perform a transthoracic echocardiogram prior to discharge for all AVR cases. PVL was defined as a regurgitant jet between the annulus of the valve and the valve sewing ring. Patients who were identified to have a PVL underwent transoesophageal echocardiograms to further assessment of the PVL. The latter was graded as trivial, mild, moderate or severe based on visual estimation and the diastolic slope of aortic regurgitation detected by continuous flow Doppler.

**TABLE 1:** Distribution of valve types implanted during the study period.

| | |
|---|---|
| St Jude mechanical valve | 83 (18%) |
| Sorin mechanical valve | 49 (10.7%) |
| Vascutek Aspire | 21 (4.6%) |
| 3F Aortic valve | 4 (0.08%) |
| Carpentier-Edwards Perimount | 125 (27.2%) |
| Medtronic Hancock II | 134 (291%) |
| Medtronic Mosaic | 14 (3%) |
| Sorin Solo valve | 15 (3.2%) |
| Sorin Soprano | 10 (2.2%) |
| St Jude Epic | 3 (0.07%) |
| St Jude Trifecta | 2 (0.04%) |
| Total | 460 |

## RESULTS

Figure 1 shows the prevalence PVL among the different types of prostheses. TTE grading of PVL was trivial in 18 (51.4%), mild in 14 (40%), moderate in 2 (5.7%) and severe in 1 patient (2.9%). The PVL group did not differ from the entire cohort of 460 patients in demographics or perioperative risk profile; 65.7% were male, and mean age was 62.9 ± 15.6 years. Mean logistic Euroscore was 8.35 ± 15.8%. Valve lesions were

stenosis (68.6%), regurgitation (20%), and mixed (11.4%). Aortic prostheses were bioprosthetic in 54% and mechanical in 46%. Other demographic and operative variables are shown in Table 2. There was no difference in incidence of PVL in AVR cases done by surgical trainees or consultants (7/113) (6.2%) versus 28/347 (8%).

**Table 2:** Demographics and operative characteristics of 35 patients presenting with paravalvular leak

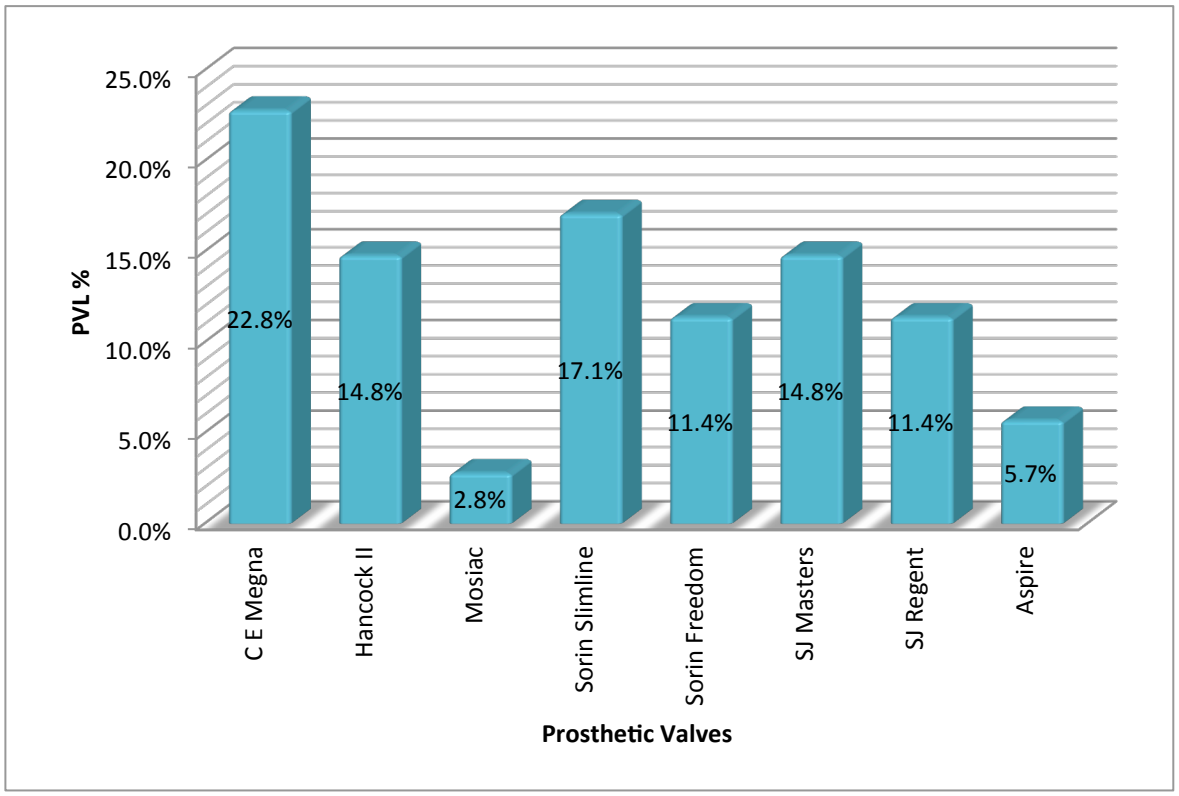
| | |
|---|---|
| Age (yrs.) | 62.9 ± 15.6 |
| Female sex | 12 (34.3%) |
| Main valve lesion: | |
| Aortic stenosis | 24 (68.6%) |
| Aortic regurgitation | 7 (20%) |
| Mixed lesion | 4 (11.4 %) |
| Main valve pathology | |
| Degenerative | 30 (85.7%) |
| Rheumatic | 1 (2.8%) |
| Endocarditis | 2 (5.6%) |
| Congenital | 2 (5.6%). |
| LV EF% | |
| Normal | 24 (68.6%) |
| 30-50% | 7 (20%) |
| <30% | 4 (11.4 %) |
| Creatinine >200 µmol/L | 1 (2.8%) |
| NYHA functional class: | |
| Class I | 6 (17.2%) |
| Class II | 9 (25.7%) |
| Class III | 16 (45.7%) |
| Class IV | 4 (11.4%) |
| Urgency: | |
| Elective | 29 (82.8 %) |
| Urgent | 5 (14.3%) |
| Emergency | 1 (2.9%) |
| Logistic Euroscore | 8.35 ± 15.8 |
| Type of prosthesis: | |
| Bioprosthesis | 19 (54 %) |
| Mechanical valve | 16 (46 %) |
| Bypass Time (min) | 82.2 ± 27.6 |
| Cross clamp time (min) | 63.4 + 17.8 |

In concordance, postoperative outcomes in the PVL patients were not significantly different to the entire cohort. As shown in Table 3, 30-days mortality was 2.8%. Morbidity was new onset atrial fibrillation in 37%, permanent pacemaker 2.8%, stroke 2.8%, haemodialysis 5.7% and re sternotomy for bleeding 2.8%. Postoperative peak aortic valve gradients ranged from 14 to 68 mmHg. At a mean follow-up of 0.9 ± 1.2 years for all patients, NYHA class was I, II and IV in 77.1%, 17.1% and 5.7% respectively. Two patients with moderate and severe PVL remained in NYHA IV. Three patients with trivial PVL developed prosthetic valve endocarditis (PVE) resulting worsening of their PVL requiring surgical re-intervention in 2 of them.

**Table 3**: Hospital and postoperative outcomes in patients with paravalvular leak

| | |
|---|---|
| 30-Days Mortality | 1(2.8%) |
| Postoperative stay (days) | 12.9 ± 25.2 |
| Postoperative AF | 13 (37%) |
| Permanent Pacemaker insertion | 1 (2.8%) |
| Postoperative CVA | 1 (2.8%) |
| Need for haemodialysis | 2 (5.7%) |
| Re sternotomy for Bleeding | 1 (2.8%) |
| Peak Pressure Gradient across prosthesis (mmHg) | 27.8 ± 13.3 |
| Duration of Follow up (yrs.) | 0.9 ± 1.2 |
| NYHA functional class: | |
| Class I: | 27 (77.1%) |
| Class II | 6 (17.1%) |
| Class III | 0 |
| Class IV | 2 (5.7%) |
| Readmission related to valve problems | 3 (8.5%) |
| Re intervention for valve failure | 2 (5.7%) |

**Figure 1.** Prevalence of paravalvular aortic regurgitation among different types of valve prostheses




**DISCUSSION**

PVL is the most common form of non-structural prosthetic valve dysfunction [12, 13]. There are several hypotheses for the pathogenesis of early onset PLV in absence of infection. Technical factors including knot disruption, inadequate suture placement or extensive annular de-calcification impeding adequate apposition of the valve against the uneven annulus. Annulus tissue retraction from the sewing ring between sutures during healing has been proposed as a cause of late onset PVL [14]. Interestingly, the St. Jude Medical bileaflet tilting disk valve with a silver coating (Silzone) initially introduced to prevent prosthetic bacterial colonization yielded a higher- than-expected rate of PVL. This was thought to be due to inhibition of normal fibroblast response and incorporation of the sewing cuff fabric into the annular tissue in some patients [15, 16].

Our series confirms that the incidence of moderate or greater PVL after conventional AVR is low, 0.65% in our series. Trivial or mild PVL is more common, approximately 6.9%. However, these patients with trivial or mild PVL have a mostly benign post-operative course during the follow period.

The two main advances in aortic valve replacement surgery in the last decade have been percutaneous aortic valve replacement via trans-femoral, trans-apical or trans-aortic routes (TAVI) and sutureless aortic valve replacements. TAVI has been associated with significantly higher incidence of PVL compared with conventional surgery. In the 5 years data for the PARTNER A trial, the incidence of moderate or greater PVL was around 40%. These patients had a higher risk of death compared with patients with no PVL. Interestingly even mild PVL was associated with an increased risk of mortality [17, 18].

Sutureless aortic valve prosthesis implanted via conventional median sternotomy or minimally invasive approaches may also potentially decrease the complications of AVR particularly in high-risk patients [18]. Because the native valve is removed and the annulus

decalcified it is likely that PVL rates after sutureless valve insertion will be less that after TAVI. Indeed, although experience with these valves have been currently limited to few centers, reported PVL rates after sutureless AVR is around 5% with rates of moderate or greater PVL reported as 2-3% [19, 20]. There has been no data as yet to determine the prognosis of the patients with PVL after sutureless AVR.

Conventional AVR carries low mortality, low morbidity, low PVL rates, and has excellent long term results. However, this treatment has traditionally only been available to relatively 'fit' patients. TAVI and sutureless AVR have significantly increased the spectrum of patients who can have intervention for aortic valve disease. These techniques are in the early phase of clinical use and it is likely that there will be significant improvements in the technology and design of these new valves going forward. Reducing the risk of PVL must be one of the key areas for improvement in the future.

**Study Limitations**

The main limitation of our study is that it is a retrospective review of echo data. However, each TTE was re-examined to ensure accuracy of the data. Although valve insertion techniques were relatively standard during the study period, variations in these techniques dictated by patients or pathology are not accounted for in our analysis.

**CONCLUSION**

Mild PVL after conventional surgery has a benign course. Moderate and severe PVL is rare. In terms of PVL, conventional AVR remains the benchmark against which all emerging techniques and technologies should be measured.

**Conflicts of interest:** none declared

**REFERENCES**

1. Lawrence H. Cohn. Cardiac surgery in the adult (Fourth Edition). New York: McGraw-Hill, 2011. 151.
2. Safi AM, Kwan T. Paravalvular regurgitation: a rare complication following valve replacement surgery. Angiology 2000; 51: 479-487.
3. Rallidis LS; Moyssakis IE; Ikonomidis I; Nihoyannopoulos P. Natural History of early paraprosthetic regurgitation: A five-year follow up. *Am Heart J* 1999; 138(2): 351-357.
4. Nair S, Bhatnagar G, Valencia O, Chandrasekaran V**:** Effect of valve suture technique on incidence of paraprosthetic regurgitation and 10-Year survival**.** *Ann Thorac Surg* 2010, **89:**1171-1179.
5. O-Rourke DJ, Palac RT. Outcome of mild periprostetic regurgitation detected by intraoperative transesophadeal echocardiography. J Am Coll Cardiol 2001; 38: 163-166.
6. Pate GE, Al Zubaidi A. Percutaneous closure of prosthetic paravalvular leaks: case series and review. Catheter Cardiovasc Interv 2006;68: 528-533
7. Lund O, Emmertsen K, Nielsen T, Jensen F, Christian F, Pilegaard H, Rasmussen B, et al. Impact of Size Mismatch and Left Ventricular Function on Performance of the St. Jude Disc Valve After Aortic Valve Replacement. Ann. Thorac. Surg 1997; 63: 1227-1234.
8. Genoni M, Franzen D, Vogt P, Seifert B, Jenni R, Künzli A, et al. Paravalvular leakage after mitral valve replacement: improved long-term survival with aggressive surgery? Eur J Cardiothorac Surg. 2000;17(1): 14-19.
9. Murtuza B, Pepper J, Stanbridge R, Jones C, Rao C, Darzi A, et al. Minimal Access Aortic Valve Replacement: Is It Worth It? *Ann Thorac Surg* 2008;85:1121-1131.
10. Umakanthan R, Petracek MR, Leacche M, Solenkova NV, Eagle SS, Thompson A, et al. Minimally invasive right lateral thoracotomy without aortic cross-clamping: an attractive alternative to repeat sternotomy for reoperative mitral valve surgery. J Heart Valve Dis. 2010;19(2):236-243.
11. Chu M, Borger M, Mohr F, Walther T. Transcatheter heart-valve replacement: update. CMAJ. 2010; 182(8): 791–795.
12. Akins CW, Bitondo JM, Hilgenberg AD, Vlahakes GJ, Madsen JC, MacGillivray TE. Early

and late results of the surgical correction of cardiac prosthetic paravalvular leaks. J Heart Valve Dis 2005;14(6):792–799.
13. Ionescu A, Fraser AG, Butchart EG. Prevalence and clinical significance of incidental paraprosthetic valvar regurgitation: a prospective study using transoesophageal echocardiography**.** *Heart* 2003, 89**:**1316-1321.
14. Davila-Roman VG and Waggoner AD. Prevalence and severity of paravalvular regurgitation in the Artificial Valve Endocarditis Reduction Trial (AVERT) echocardiographic study. J Am Coll Cardiol 2004; 44: 1467-1472.
15. Schaff H, Carrel T, Jamieson W, Jones k, Rufilanchas J, Cooley D, et al. Paravalvular leak and other events in silzone-coated mechanical heart valves: a report from AVERT. *Ann Thorac Surg* 2002; 73:785.
16. De Cicco G, Lorusso R, Colli A, Nicolini F, Fragnito C, Grimaldi T, et al. Aortic valve periprosthetic leakage, anatomic observations and surgical results. *Ann Thorac Surg* 2005; 79:1480.
17. Mack M, Leon M, Smith C, Miller D, Moses J, Tuzcu E, et al. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. The Lancet 2015; 385, 9986: 2477–2484.
18. Watanabe Y, Lefèvre T, Arai T, Hayashida K, Bouvier E, Hovasse T, et al. Can we predict postprocedural paravalvular leak after Edwards SAPIEN transcatheter aortic valve implantation? Catheter cardiovasc interv 2015 Jul;86(1):144-51.
19. Shrestha M, Folliguet T, Meuris B, Dibie A, Bara C, Herregods MC, et al. Sutureless Perceval S aortic valve replacement: a multicenter, prospective pilot trial. J Heart Valve Dis 2009;18 (6):698-702.
20. Sepehripour AH, Harling L, Athanasiou T. What are the current results of sutureless valves in high-risk aortic valve disease patients? Interact Cardiovasc Thorac Surg 2012; 14 (5):615-621.