

# Retrospective Study Determining Factors Leading to Paravalvular Leakage and Success Rate of Percutaneous Transcatheter Closure of Leakage— Royal Sussex County Hospital Brighton

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**Abstract:** this study aims to examine the risk of prosthetic valve leaks and the success rate of closure of paravalvular leakage (PVL) using percutaneous intervention. this is a retrospective study of patients that have undergone valve replacement surgery and subsequently later presented with PVL. In these patients a percutaneous intervention was favoured to remedy the leakage. Patient information was collected pre and post PVL closure surgery through looking at patient notes. Information was collected in a spreadsheet form with parameters including date of initial valve replacement, and dates of PVL, severity of leak, leakage pre and post PVL closure by information provided from transoesophageal echocardiogram.

**Keywords:** paravalvular leakage, percutaneous transcatheter approach, valve replacement surgery.

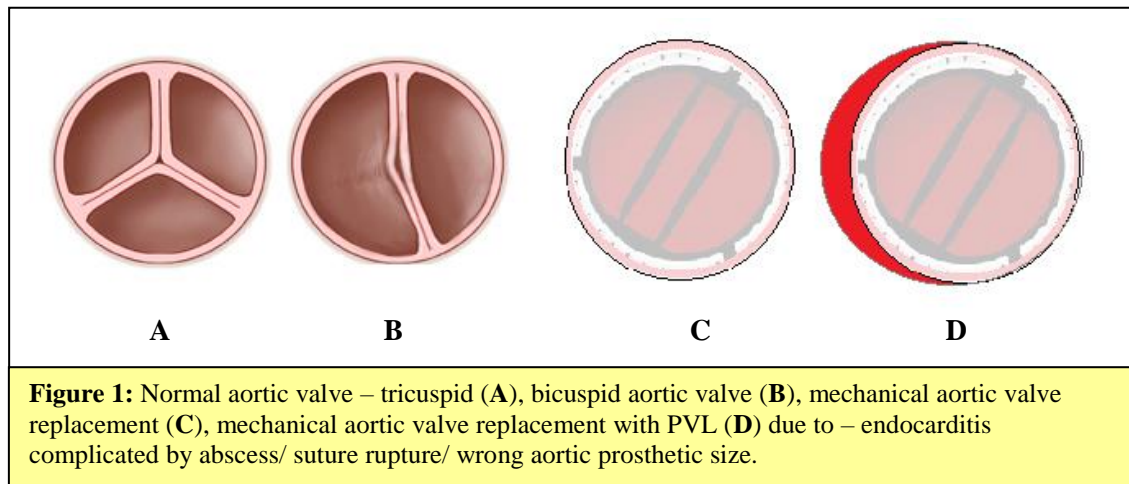
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## 1. INTRODUCTION

Valve replacement surgery is the second most common surgical procedure (second to Coronary Artery by-pass graft). On average eighteen thousand valve replacement/repair surgeries are performed in England each year (UCL). Valves replaced can be either bioprosthetic or mechanical. Approaches to valve replacement are surgical or transcatheter. Procedural complications include infections, clotting (due to mechanical valve replacement), stroke, primary valve failure (in cases of tissue valve replacement valve may wear out), arrhythmia and paravalvular leakage (PVL).

### *Aetiology and mechanism:*

Paravalvular leakage accounts for 2-12% in mitral valve replacement and 1-5% of aortic valve replacement (krishnaswamy 2013). PVL is regurgitation or reversal of the flow of blood from the implanted prosthesis, namely between the sewing ring of the prosthetic valve and the annulus (Ionescu 2003). Mechanism of PVL includes: 1) patient/prosthesis mismatch. 2) Incomplete valve adherence to the annulus. 3) Low or high positioning of prosthetic valve. (trantini 2011). Aetiology of these leaks are commonly disruption of suture around the sewing ring of the prosthesis and annulus, it can lead to single or multiple leaks, symptomatic or asymptomatic, old pre-existing or new. Asymptomatic leaks are usually minor jets of PVL regurgitation that occurs in 15-50% (Bhindi) of valve replacement surgeries and usually will remain, causing no symptoms or serious sequelae. Risk factors for PVL includes (see figure 1): 1) Incorrect prosthesis size 2) infectious factors such as active endocarditis complicated by abscess, 2) Annulus factors such as, calcification, bicuspid valve disease (causes severe dilation of aortic annulus) 3) technical factors dependant on surgeon skills and experience 4) previous valve surgery e.g. redo valvular surgeries, 5) patient factors, such as elderly, low body mass index (smolka G, noble)

**Presentation:**

Although PVL is an uncommon complication, it is an important one, requiring early treatment and management (safi). These PVLs, if severe (in 5% of the cases Bhindi) can cause haemodynamic instability leading to various presentations this can lead to significant mortality and morbidity; symptomatic sequela includes haemolytic anaemia, arrhythmia, infectious endocarditis and congestive heart failure (Hoffmayer, Smolka).

**Diagnosis:**

PVL is often suspected in physical examination via the presence of prosthetic murmur. The severity of these leaks and confirmation are determined usually through imaging modalities. Transoesophageal echocardiogram (TOE) has proved to be the most accurate method of initial detection and diagnosis of these regurgitations compared to transthoracic echocardiogram (TTE) (Smolka). TOE is often required in multiple projections to determine details of size, location and number of leaks. Traditional 2D echocardiography can be supported with new technologies such as multislice computed tomography and 3D echocardiography, thus a 3D reconstruction is generated providing crucial information for transcatheter procedures such as relationship of PVL to sewing ring.

**Treatment:**

Severe or significant PVLs can be treated via the following approaches: conservative approach (watch and wait for asymptomatic leaks and good ventricular function), medical treatment, surgical closure, or transcatheter closure or palliative care for patients with end-stage heart failure (aim is to resolve problem before reaching end-stage heart failure).

**1. Conservative (Watch and wait- for at risk patients):**

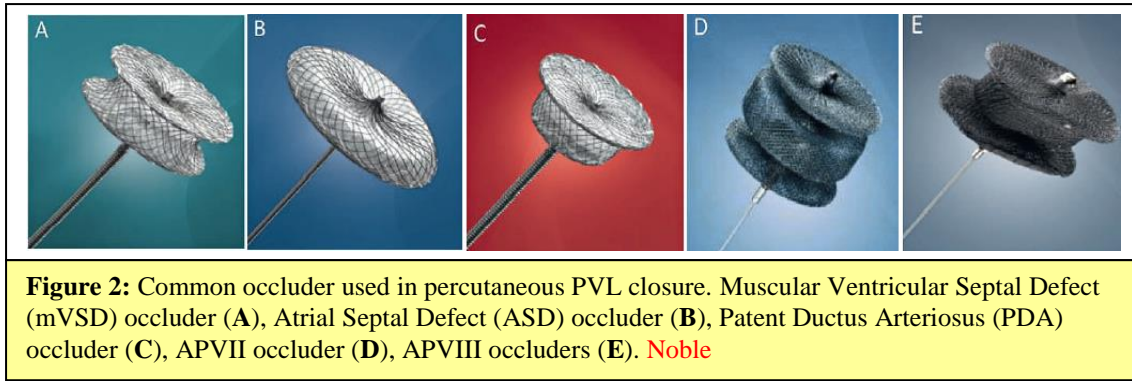
Regular follow up appointments and TOE's are arranged to ensure no worsening of ventricular function and symptoms. Patients are usually also treated via medical treatment.

**2. Surgical approach:**

Re-operation is the first choice of treatment when PVL exists with other dysfunctions such as mechanical or infectious (endocarditis) or comorbid conditions coronary artery disease requiring CABG. (smolka) Reoperative risks are higher and it also carries higher mortality but mortality rates are less than conservative treatment (for mitral valve Genoni).

**3. Transcatheter approach:**

This approach is preferred for high risk patients where surgical approach to closure is deemed unfavourable. A catheter is percutaneously passed through the femoral artery under CT guidance and occluder devices are introduced (figure 2) to try and close the leakage. Intra-operative TOE and post-operative TOE are use to monitor any regurgitation. These devices are introduced through different approaches e.g. trans-septal puncture for mitral PVL or trans-apical approach. These devices come in a range of shapes and size and their use are often synonymous with occluders used for patent foreman ovale or patent ductus arteriosus or septal defects. Although percutaneous approach is minimally invasive there are complication associated with it, which includes: device embolisation, device prosthesis interference, haemolysis (new or transient), atrio-ventricular block (new or transient), pericardial bleeding, false aneurism, contrast anaphylaxis and infection or haematoma formation at femoral site. Nobel



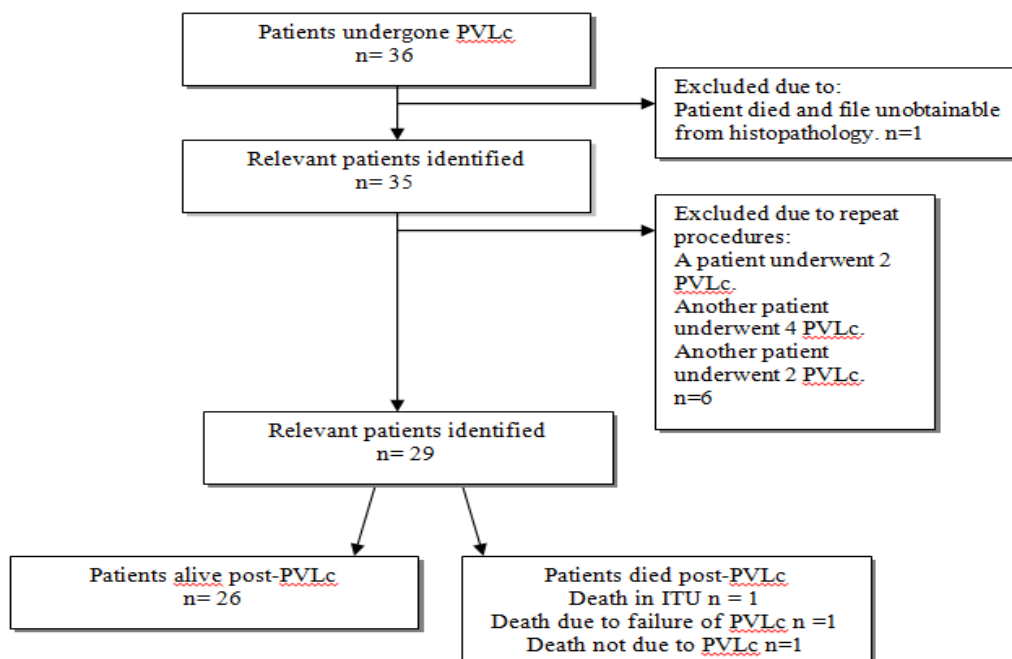
#### 4. Palliative approach:

Patients with end-stage heart failure, which have no curative treatment option, are palliatively treated using the Liverpool Care Pathway for the Dying Patient.

## 2. METHOD

A list of 36 patients who underwent paraprosthetic/valvular leakage closure (PVLc) through percutaneous transcatheter intervention was obtained. These patients underwent PVLc between 2006 to February 2013 by consultant Mr Hildick-Smith of Royal Sussex County Hospital (RSCH).

Data collection took place at the Central Library of RSCH where patient notes were kept. Each file were thoroughly examined and details of valve replacement surgery and circumstances leading to replacement was noted, such as prosthetic valve size, history of endocarditis, rheumatic fever, bicuspid valve disease, if valve was re-operated on, surgeon performing procedure and other predisposing factors obtained from literature search were included. Not all valve replacement data could be obtained from patient notes, as some patient were private patients/transferred patients/valve replacement surgery had been done long time ago and at different institutions. These data were collected in a spread sheet form. PVL data were also collected by looking at procedural reports and TOE reports pre and post procedure. New York Heart Association (NYHA) classes were used to identify patient shortness of breath, and Canadian Cardiovascular Society (CCS) Classification of chest pain was obtained using history from patient notes. Unfortunately post operative NYPA and CCS could not be obtained. Another spreadsheet was obtained from Mr Hildick-Smith was combined with our spreadsheet, his spreadsheet included patient presentation, outcome (pre/post-op and last follow up), position of PVL and devices used to occlude leak.



## 3. RESULTS

Table 1: Baseline patient clinical characteristic

Clinical Characteristic	n(%) or Mean ( $\pm$ SD)
Age (yr)	67 (14)
<b>Gender</b>	
Male	24(83%)
Female	5(17%)
Body Surface Area (m <sup>2</sup> )*	2 (0.3)
Predicted aortic annulus diameter (mm)	22(1.5)
<b>No. of valve replacement surgeries on affected valve</b>	
One	
Two	25 (86%) 4 (14%)
<b>Risk Factors</b>	
None	
Smoking or Ex-Smoker	4(14%)
Diabetes Mellitus	9(31%)
Hypertension	6(21%)
Family History	20 (87%)
Dyslipidemia	4(14%) 16(55%)
<b>Other factors</b>	
Ischemic Heart Disease	
Chronic Kidney disease	12(41%)
Bicuspid aortic valve	3(10%)
Endocarditis	6(21%) 6(21%)
<b>Presentation</b>	
NYHA class	
Heart Failure	3 (0.8)
Haemolysis	19 (66%)
Atrial fibrillation	6 (21%)
Dyspnoea	3 (10%)
Syncope/dizziness	2 (7%) 2 (7%)
<b>Paravalvular leak grade (pre-closure)</b>	
Mild/Moderate	
Moderate/Severe	2(7%)
Severe	13(45%) 14(48%)
<b>Indication for surgery</b>	
Heart Failure	
Haemolysis	19(66%)
Both	3(10%) 5(17%)

\*The body surface area was calculated from the collected height and weight at presentation at replacement surgery and predicted aortic annulus size was calculated (Capps).

Table 2: Valve replacement characteristic

Prosthetic Valve	n (%) or Mean (±SD)
<b>Valve type</b>	
Bioprosthetic/tissue valve	5(17%)
Mechanical valve	22(76%)
CoreValve	2(7%)
<b>Size</b>	
Prosthetic aortic size (mm)	26 (3)
Prosthetic mitral size (mm)	30(2)
<b>Brand</b>	
Carbomedic Standard Mechanical	8(28%)
St Jude Mechanical	4(14%)
Starr Edwards Mechanical	2(7%)
Sorin	2(7%)
CoreValve	2(7%)
Others	5 (17%)
unknown	6(21%)

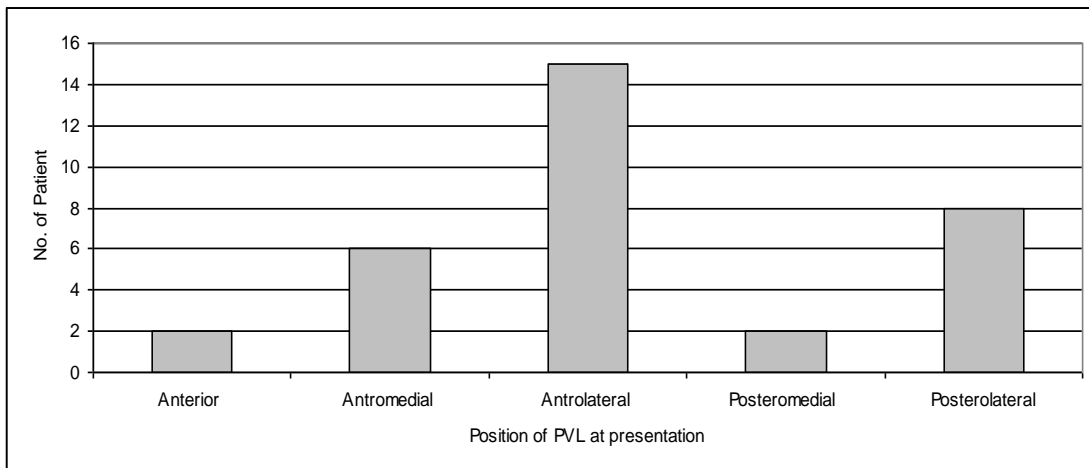


Figure 3: Common position of PVL.

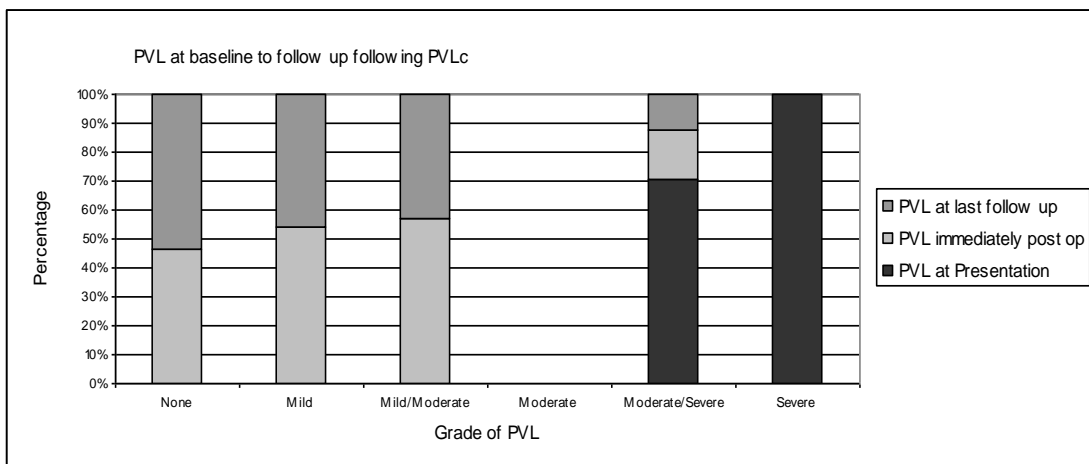


Figure 4: Grade of PVL at a) Presentation b) immediately after PVL closure c) following last follow up

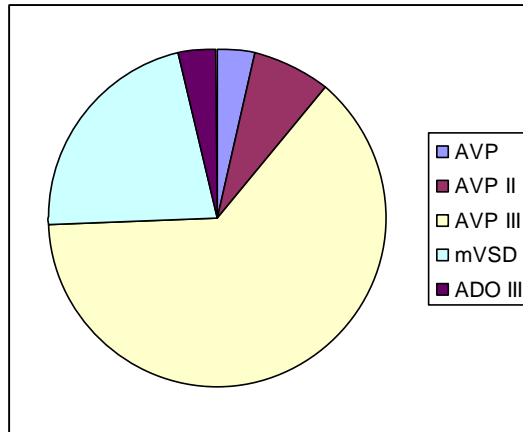
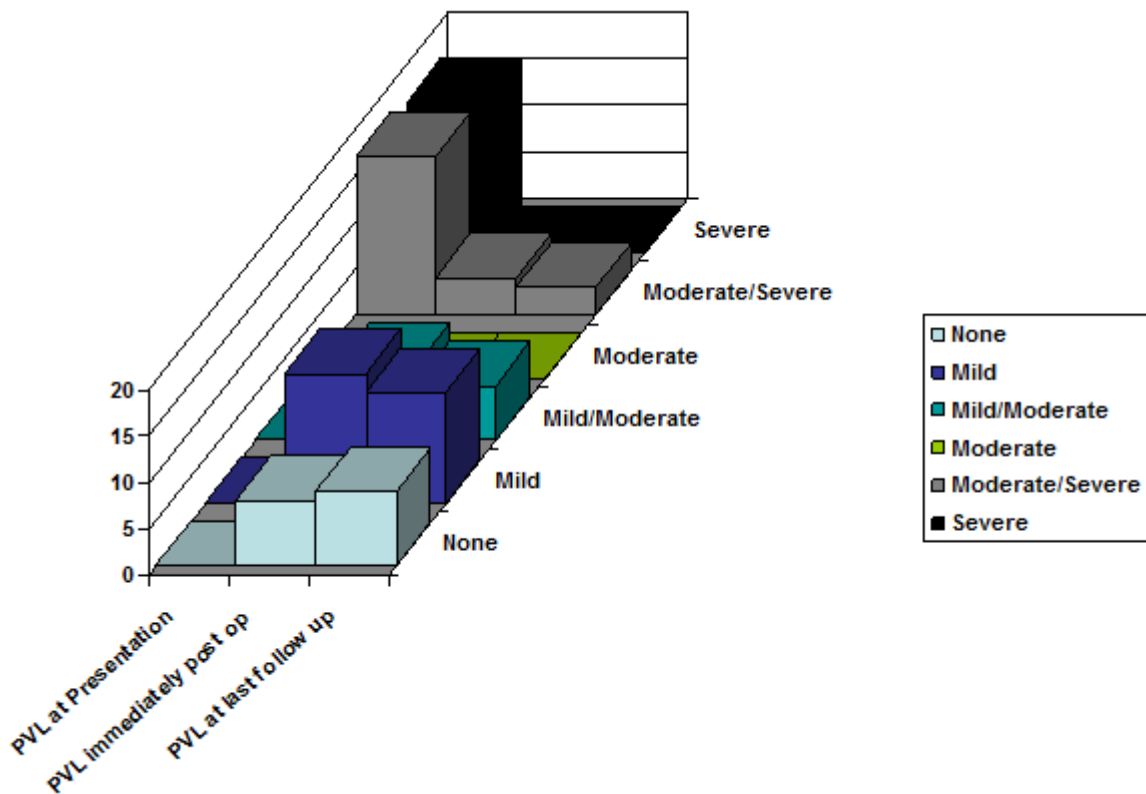


Figure 5: Devices used for closure of PVL.



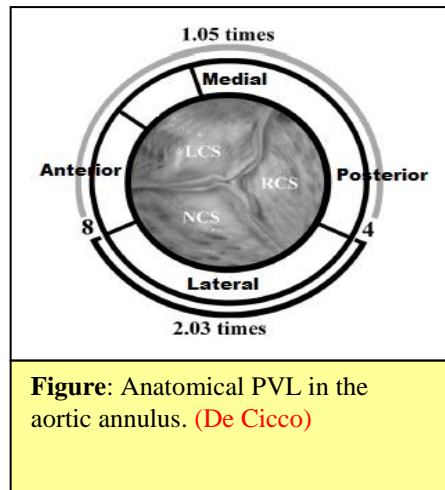
#### 4. DISCUSSION

##### Common signs and symptoms:

One patient required a complete valve replacement due to failure of closure via transcatheter approach.

Our study shows that PVL is more common in the aortic valve position, which is in agreement with another study performed; however larger studies (Hammermeister, Ionescu) showed prevalence of PVL was more common at mitral valve position after replacement with mechanical valve (17%, 33% vs. our data of 45%).

In total four patients were lost during this study. One patient died due to reasons other than PVL closure. Other patient notes were not retrievable (thus excluded from the study) and one patient died of end-stage heart failure due to PVL, palliative therapy was commenced and patient died shortly after failed PVL closure. The last patient died of cerebral haemorrhage in intensive care unit following successful closure of PVL. Complication of PVL was reported in two cases, one patient had contrast anaphylaxis and the other patient's device embolised to the pulmonary artery. Thus risk of complications is 10%, whereas the mortality rate from procedure 14%.



### Limitations:

Due to the constraint in sample size no statistical significance was proved between size of aortic valve prosthesis and predicted aortic annulus size. Also write about patient weight not being constant – weightloss during heart surgery.

This study is not large enough to determine significance. However it aims to contribute to current research available.

## 5. CONCLUSION

PVL is an important complication, it can present acutely or chronically. Thus patient follow up by surgeons is imperative not avoid the consequences of delayed treatment.

This study is not large enough to determine significance. However it aims to contribute to current research available.

## ACKNOWLEDGEMENTS

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