

Percutaneous or surgical treatment of post infarction VSD: The UK National Registry

**Dr Joel Giblett MD** Liverpool Heart and Chest Hospital

On behalf of the UK PIVSD investigators

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CRF<sup>\*</sup>

## **Disclosure Statement of Financial Interest**

I, Joel Giblett DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.



## Introduction

- Post infarction ventricular septal defect (PIVSD) is a rare but lifethreatening complication of acute myocardial infarction<sup>1</sup>
- Mortality following surgical repair remains high<sup>2</sup>
- Evidence for percutaneous treatment of PIVSD is confined to small case series<sup>3</sup>
- This registry sought to investigate current practice in the UK and characterize patients treated with either technique

2. Giblett *et al*. Heart. 2020;106:878–884

8. Calvert et al. Circulation 2014;129:2395–2402

# **Study Design**

#### Design

- **DESIGN:** Retrospective observational registry, with *detailed case note review* in each centre
- **PRIMARY OBJECTIVE:** To evaluate 5-year all-cause mortality in both surgical repair and percutaneous closure
- SECONDARY OBJECTIVE: To evaluate survival to hospital discharge, analyze contemporary trends in treatment of PIVSD, and assess predictors of survival





## **Centers and Investigators**

#### Freeman Hospital

- David S. Crossland
- Guy's and St. Thomas' Hospital
  - Brian R. Clapp
- Leeds General Infirmary
  - James R. Bentham
- Liverpool Heart and Chest Hospital
  - John P. O'Neill
  - Rod H. Stables
  - Suneil K. Aggarwal
  - Bilal H. Kirmani
  - D. Mark Pullan

#### Keele University

- Mamas A. Mamas
- Andrija Matecic
- Kings College Hospital
  - Ritesh Kanyal
  - Jonathan Byrne
  - Philip MacCarthy

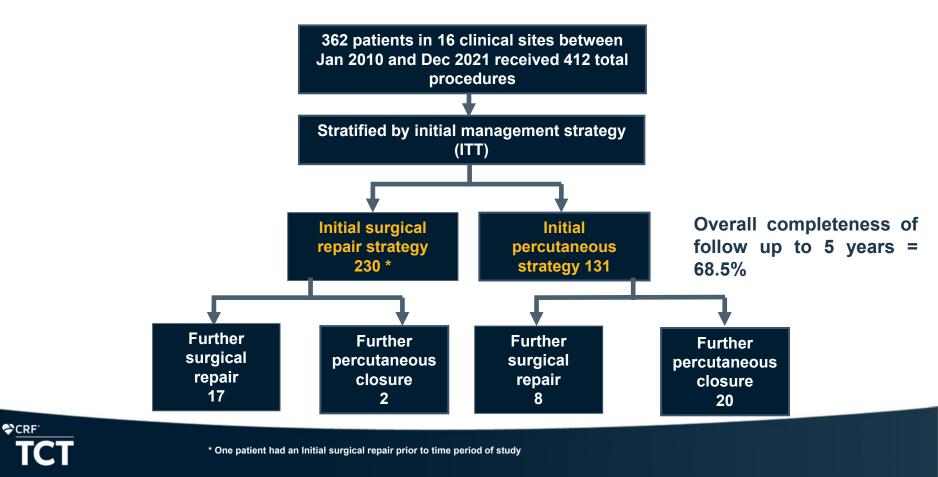
- Nottingham University Hospital
  - William H.T. Smith
  - Jakub Marczak
- Queen Elizabeth Hospital
  - Sudhakar George
  - Joe De Giovanni
- Royal Infirmary of Edinburgh
  - David B. Northridge
  - Jack Andrews
- Royal Papworth Hospital
  - Leonard M. Shapiro
  - David Jenkins
  - Choo Y. Ng
  - Shreenidhi Venuraju
  - Tobias MacCarthy
  - Jonathan Vibhishanan

- Royal Stoke Hospital
  - Robert Butler
  - Megan A. Butler
- Royal Surrey County Hospital
  - Nicholas Buttinger
  - David Hildick Smith
- University Hospital Bristol
  - Wan Cheol Kim
  - Mark S. Turner
- University Hospital Southampton
  - Nicholas Hayes
- Morriston Hospital and University Hospital of Wales
  - Ayush Khurana
- Wythenshawe Hospital
  - Mamta Buch

#### **Co-Chief Investigators: Patrick A. Calvert and Joel P. Giblett**



## **Study Flow Chart**



#### **Patient Characteristics**

Characteristics	Initial percutaneous management (N=131; 36.2%)	Initial surgical management (N=231; 63.8%)	P-value
Age (years), median (IQR)	72 (64, 77)	67 (61, 73)	<0.001
Female sex, %	35.1	28.1	0.167
Body mass index (kg/m²), median (IQR)	28 (25, 31)	26 (24, 30)	0.010
Comorbidities, %			
Hypertension	46.6	55.0	0.124
Diabetes mellitus	19.8	16.0	0.356
Chronic lung disease	9.2	10.8	0.616
Prior or current smoking	42.0	61.0	<0.001
Hypercholesterolaemia	30.5	37.7	0.172
Prior cerebrovascular incident (thromboembolic or haemorrhagic)	3.1	3.5	0.834
Creatinine (mg/dL), median (IQR)	1.2 (0.9, 1.6)	1.3 (1.0, 1.8)	0.707



#### **AMI Characteristics**

Characteristics	Initial percutaneous management (N=131; 36.2%)	Initial surgical management (N=231; 63.8%)	P-value
Territory of myocardial infarction			0.023
Anterior	43.5	32.2	
Inferior	55.7	63.0	
Lateral	0.8	0.4	
Posterior	0.0	4.3	
Vessels with coronary artery disease			0.437
0	0.0	0.9	
1	47.1	39.0	
2	30.3	36.8	
3	21.0	22.5	
4	1.7	0.9	
Initial AMI treatment, %			0.413
None	56.2	58.8	
PCI	41.5	38.2	
CABG	0.8	0.0	
Thrombolysis	1.5	3.1	
PCI to infarct-related artery, %	41.5	38.7	0.596



## Hemodynamic State

Characteristics	Initial percutaneous management (N=131; 36.2%)	Initial surgical management (N=231; 63.8%)	P-value
NYHA class (worst prior to repair), %			0.457
1	3.1	4.8	
2	17.1	12.2	
3	32.6	30.1	
4	47.3	52.8	
Cardiogenic shock, %	51.9	62.8	0.044
Dialysis/filtration (prior to repair), %	6.1	10.8	0.134
Mechanical circulatory support (prior to repair), %			0.050
None	32.8	22.9	
Intra-aortic balloon pump	66.4	74.0	
Impella Device	0.8	0.0	
Extracorporeal membrane oxygenation	0.0	2.2	
IABP + ECMO	0.0	0.9	



#### **Defect Characteristics**

Characteristics	Initial percutaneous management (N=131; 36.2%)	Initial surgical management (N=231; 63.8%)	P-value
Defect size* (mm), median (IQR)	18 (14, 22)	20 (15, 27)	<0.001
Defect site, %			0.192
Anterior	21.1	18.8	
Inferior	53.9	64.2	
Apical	25.0	16.2	
Mid septum	0.0	0.4	
Other	0.0	0.4	
LV systolic function (on procedural TOE or last			0.165
echo before repair)			0.105
Normal (EF >50%)	33.8	26.6	
Moderate (EF 31-49%)	43.8	54.1	
Severe (EF <30%)	22.3	19.2	
RV function (on procedural TOE or last echo before			0.007
repair)			0.007
Normal (EF >50%)	32.8	18.1	
Dilated RV	16.4	21.2	
Dilated RV with impaired function	50.8	60.6	



\* Defect size recorded as "Large" in 6.1% percutaneous and 13.4% surgical patients



#### Time to presentation and repair; decision making

Characteristics	Initial percutaneous management (N=131; 36.2%)	Initial surgical management (N=231; 63.8%)	P-value
Time - AMI to presentation (days), median (IQR)	2 (0, 7)	2 (0, 7)	0.850
Time - AMI to VSD repair (days), median (IQR)	9 (6, 14)	9 (4, 22)	0.179
Multidisciplinary Team discussion, %			<0.001
None	15.3	51.9	
Documented informal discussion	38.2	25.5	
Formal Heart Team review	46.6	22.5	



#### **Percutaneous Procedures**

Characteristic		Characteristic	
General anaesthesia, %	93.1	Number of device placements attempts, %	
Imaging support, %		0	4.0
Fluoroscopy only	3.9	1	73.8
TTE	3.1	2	17.5
TOE	93.0	3	3.2
ICE	0.0	4	1.6
Arterial access, %		No. successful attempts, %	
None	1.6	0	13.7
Femoral	91.5	1	84.7
Radial	3.9	2	0.8
Axillary	1.6	3	0.0
Brachial	0.8	3	0.8
Radial and femoral	0.8	First successful attempt, device type, %	0.0
Venous access, %		Unsuccessful	9.2
None	5.5	Amplatzer™ P.I. Muscular VSD Occluder	64.1
Femoral	35.9	Amplatzer ™ Muscular VSD Occluder	12.2
Jugular	57.8	Amplatzer Muscular VSD Occluder Amplatzer™ Atrial Septal Occluder (ASO)	6.9
Both	0.8	Occlutech™ PmVSD Occluder	3.8
Inotropic support, %	45.0	Other	3.8
AV loop, %	84.7	Immediate shunt reduction, %	5.0
Balloon sizing, %	11.5	No reduction	11.2
Largest device size (mm), median (IQR)	24 (20, 24)	Partial reduction	69.6
Fluoroscopy time (minutes), median (IQR)	30 (19, 44)	Complete reduction	19.2

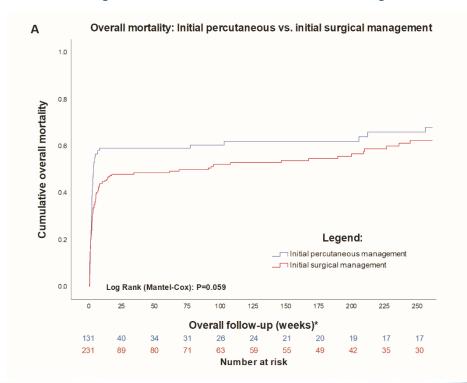


## **Surgical Procedures**

Characteristic	
Intraoperative transoesphageal echocardiography, %	100.0
Intraoperative intra-aortic balloon pump, %	77.1
Concomitant CABG, %	51.9
Concomitant valve procedure, %	
None	92.6
Mitral valve procedure	4.8
Tricuspid valve procedure	1.3
Aortic valve procedure	1.3
Concomitant VAD placement, %	1.7
Weaned to Extracorporeal membrane oxygenation	1.3
Surgical technique, %	
Patch	93.4
Oversewing/exclusion	4.8
Percutaneous device placed	0.4
Patch and Exclusion	1.3
Immediate shunt reduction, %	
No reduction	1.8
Partial reduction	31.7
Complete reduction	66.5
Cardiopulmonary bypass time (minutes), median (IQR)	155 (119, 213)



# **Results** *5-year cumulative mortality*



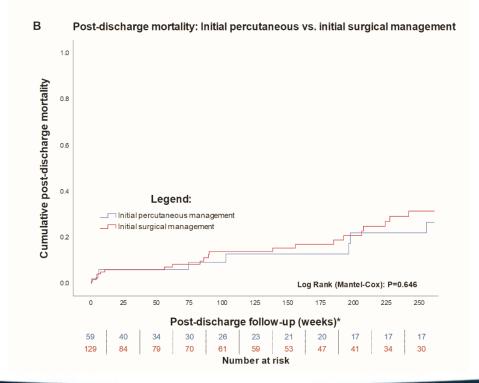
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#### Survival to hospital discharge and selected procedural complications

Characteristics	Initial percutaneous management (N=131; 36.2%)	Initial surgical management (N=231; 63.8%)	P-value
In Hospital Mortality, %	55.0	44.2	0.048
Stroke, %	0.8	5.6	0.021
Device embolization, %	7.6	n/a	/
Surgical patch dehiscence, %			/
No patch dehiscence	n/a	82.3	
Partial patch dehiscence	n/a	13.4	
Complete patch dehiscence	n/a	4.3	
Any repeat intervention, %			<0.001
None	78.6	90.9	
Percutaneous closure	5.4	6.5	
Surgical closure	15.3	0.9	
Both percutaneous and surgical closure	0.8	1.3	
Cardiac transplantation	0.0	0.4	
New pacemaker/ICD, %	1.5	6.9	0.023
Pneumonia, %	8.4	23.4	<0.001
Cardiac tamponade, %	5.3	6.1	0.779



#### Landmark analysis from hospital discharge



# Cox regression analysis for association with all cause 5-year mortality

Univariate Cox analysis **Multivariate Cox analysis** Variables Hazard Ratio (95% CI) **Adjusted Hazard Ratio P-value P-value** (95% CI) Percutaneous management<sup>1</sup> 1.31 (0.99, 1.73) 0.063 1.44 (1.01, 2.05) 0.042 Centre volume 1.00 (0.99, 1.01) 0.801 1.00 (0.99, 1.02) 0.759 Patients with multiple procedures 0.59 (0.38, 0.93) 0.023 0.61 (0.37, 1.03) 0.063 Time from AMI to VSD repair<sup>2</sup> 0.97 (0.96, 0.99) < 0.001 0.99(0.98, 0.99)0.037 1.02 (1.01, 1.04) 0.004 1.02 (1.00, 1.03) 0.075 Age Female sex 0.92 (0.68, 1.24) 0.587 0.79 (0.57, 1.11) 0.176 **Diabetes Mellitus** 1.10 (0.77, 1.57) 0.595 0.91 (0.61, 1.37) 0.665 **Hypertension** 1.31 (0.97, 1.78) 1.31 (0.99, 1.73) 0.056 0.077 PCI to IRA 1.20 (0.91, 1.59) 0.195 1.18 (0.88, 1.59) 0.270 Creatinine<sup>3</sup> 1.03 (1.02, 1.05) < 0.001 1.03 (1.01, 1.05) 0.002 Number of vessels with coronary artery disease 1.14 (0.96, 1.35) 0.146 1.22 (1.01, 1.47) 0.043 1.35 (1.13, 1.62) 1.13 (0.92, 1.37) NYHA class 0.001 0.241 **Cardiogenic shock** 1.97 (1.37, 2.84) 2.25 (1.67, 3.04) < 0.001 < 0.001 **RV dysfunction** 0.94 (0.68, 1.30) 0.694 0.88 (0.60, 1.29) 0.522

- 1) Versus Surgical management\
- 2) Per day
- 3) Per 10-unit increase

## Limitations

- Retrospective observational study
- Significant selection bias
- Some patients were only offered percutaneous treatment once surgical repair deemed unfeasible
- Involvement of heart team decision making was inconsistent
- Prospective studies are needed to evaluate optimal method and timing of treatment



## Discussion

- Largest registry of percutaneous cases with more than double the previous series and the first to offer comparison with surgical cases
- Mortality is high with any treatment option
- Signal of increased mortality with percutaneous treatment compared to surgical repair (but with the above strong caveats)
- Cardiogenic shock was the most powerful predictor of mortality in the analysis
- Timing of procedure remains contentious and needs further investigation



## Conclusion

- Both percutaneous and surgical management are complementary in real world clinical practice and offer significant survival advantage compared to historical data on medical therapy
- No difference between treatments in landmark analysis
- Shared decision making through the heart team is key for patients
- Further prospective studies are important in order to guide treatment decisions

