

Supplementary Tables

	Randomised to SPVR (n=8)	Randomised to IPVR (n=11)	Overall (n=19)
Any protocol deviation	2/8 (25.0%)	6/11 (54.5%)	8/19 (42.1%)
Patient did not meet the trial eligibility criteria but was treated in the trial	0/8 (0.0%)	0/11 (0.0%)	0/19 (0.0%)
Patient received the alternative treatment to that allocated	0/8 (0.0%)	0/11 (0.0%)	0/19 (0.0%)
Patient did not receive cell saver set up	2/8 (25.0%)	2/11 (18.2%)	4/19 (21.1%)
Patient became unblinded	0/8 (0.0%)	5/11 (45.5%)	5/19 (26.3%)

Abbreviations: SPVR=Standard Pulmonary valve replacement; IPVR=Injectable Pulmonary valve replacement

Supplementary table 1 Protocol deviations

		Randomised to SPVR (n=8)	Randomised to IPVR (n=11)	Overall (n=19)
Duration of operation (mins)*		3.7 (0.7)	2.9 (1.0)	3.2 (0.9)
Lowest haematocrit (%)		33.4 (5.2)	31.2 (4.2)	32.1 (4.7)
Lowest core temperature (°C) ^a		34.7 (0.4)	35.0 (1.2)	34.9 (0.9)
Cell saver set up		6/8 (75.0%)	9/11 (81.8%)	15/19 (78.9%)
Volume infused (ml)		393.5 (0.0, 535.0)	483.0 (244.0, 607.0)	482.0 (100.0, 607.0)
Bypass data				
If blood: Temperature	Warm (≥35 °C)	1/5 (20.0%)	1/2 (50.0%)	2/7 (28.6%)
	Cold (<35 °C)	4/5 (80.0%)	1/2 (50.0%)	5/7 (71.4%)
Infusion mode	Antegrade	5/5 (100.0%)	2/2 (100.0%)	7/7 (100.0%)
Timing	Continuous	1/5 (20.0%)	0/2 (0.0%)	1/7 (14.3%)
	Intermittent	4/5 (80.0%)	2/2 (100.0%)	6/7 (85.7%)
Duration of bypass (mins)		71.8 (17.2)	42.7 (19.2)	59.3 (22.9)
Arrhythmias				
During procedure	AV block	0/8 (0.0%)	0/11 (0.0%)	0/19 (0.0%)
	Nodal	0/8 (0.0%)	1/11 (9.1%)	1/19 (5.3%)
	JET	0/8 (0.0%)	0/11 (0.0%)	0/19 (0.0%)
	Atrial fibrillation/flutter	3/8 (37.5%)	1/11 (9.1%)	4/19 (21.1%)
	Ventricular tachycardia	0/8 (0.0%)	0/11 (0.0%)	0/19 (0.0%)
	Ventricular fibrillation	1/8 (12.5%)	5/11 (45.5%)	6/19 (31.6%)
	None	4/8 (50.0%)	6/11 (54.5%)	10/19 (52.6%)
On chest closure	AV block	0/8 (0.0%)	0/11 (0.0%)	0/19 (0.0%)
	Nodal	0/8 (0.0%)	0/11 (0.0%)	0/19 (0.0%)
	JET	0/8 (0.0%)	0/11 (0.0%)	0/19 (0.0%)
	Atrial fibrillation/flutter	1/8 (12.5%)	0/11 (0.0%)	1/19 (5.3%)
	Ventricular tachycardia	0/8 (0.0%)	0/11 (0.0%)	0/19 (0.0%)
	Ventricular fibrillation	0/8 (0.0%)	0/11 (0.0%)	0/19 (0.0%)
	None	7/8 (87.5%)	11/11 (100.0%)	18/19 (94.7%)
Pacing	Single chamber	1/8 (12.5%)	0/11 (0.0%)	1/19 (5.3%)
	Dual chamber	1/8 (12.5%)	2/11 (18.2%)	3/19 (15.8%)
	None	6/8 (75.0%)	9/11 (81.8%)	15/19 (78.9%)
Products used intra-operatively				
Blood products used intra-operatively	RBC	0/8 (0.0%)	4/11 (36.4%)	4/19 (21.1%)
	FFP	1/8 (12.5%)	0/11 (0.0%)	1/19 (5.3%)
	Platelets	0/8 (0.0%)	0/11 (0.0%)	0/19 (0.0%)
	Cryoprecipitate	1/8 (12.5%)	0/11 (0.0%)	1/19 (5.3%)
Activated factor VIII		0/8 (0.0%)	0/11 (0.0%)	0/19 (0.0%)
Tranexamic acid		4/8 (50.0%)	7/11 (63.6%)	11/19 (57.9%)
Dose (g)		10.6 (1.1, 166.0)	1.1 (1.0, 2.3)	1.3 (1.0, 20.0)
Aprotinin		4/8 (50.0%)	1/11 (9.1%)	5/19 (26.3%)
Dose (million units)		6.0 (4.5, 6.5)	6.0 (6.0, 6.0)	6.0 (5.5, 6.5)
Protamine		8/8 (100.0%)	10/11 (90.9%)	18/19 (94.7%)

	Randomised to SPVR (n=8)	Randomised to IPVR (n=11)	Overall (n=19)
Dose (mg)	275.0 (200.0, 350.0)	152.5 (100.0, 270.0)	225.0 (100.0, 300.0)
Heparin	8/8 (100.0%)	10/11 (90.9%)	18/19 (94.7%)
	26500.0 (19000.0, 30000.0)	15000.0 (10000.0, 25000.0)	20000.0 (15000.0, 27000.0)
Dose (IU)			
Hydroxyethyl starch	0/4 (0.0%)	1/5 (20.0%)	1/9 (11.1%)
Human Albumen Solution	0/8 (0.0%)	0/11 (0.0%)	0/19 (0.0%)
Plasma-Lyte	5/8 (62.5%)	7/11 (63.6%)	12/19 (63.2%)
Gelofusine	0/5 (0.0%)	0/4 (0.0%)	0/9 (0.0%)
Hartmann's solution	6/8 (75.0%)	5/11 (45.5%)	11/19 (57.9%)
Status at end of operation Alive	8/8 (100.0%)	11/11 (100.0%)	19/19 (100.0%)

Notes:

* Duration of operation defined as knife to skin to knife down time

Data are presented as mean (SD), median (IQR) or n (%)

Missing data (SPVR, IPVR):

^a Data missing for 1 patient (0, 1)

Abbreviations: SPVR=Standard Pulmonary valve replacement; IPVR=Injectable Pulmonary valve replacement; SD=Standard deviation; AV=Atrioventricular block; JET=Junctional ectopic tachycardia; RBC=Red blood cells; FFP=Fresh frozen plasma; GTN= Glyceryl Trinitrate; VF= Ventricular fibrillation; RVOT= right ventricular outflow tract; PA= Pulmonary Artery; CPB=Cardiopulmonary bypass

Supplementary table 2 Additional intra operative characteristics

		Randomised to SPVR (n=8)	Randomised to IPVR (n=11)	Overall (n=19)
On return from theatre				
Lactate (mmol/l)		0.9 (0.3)	1.2 (0.6)	1.1 (0.5)
Temperature (°C)		36.5 (0.7)	36.6 (0.9)	36.5 (0.8)
Fluid balance				
Fluid balance at 12 hours (ml)		329.5 (62.0, 687.0)	11.0 (-273.0, 289.0)	166.0 (-65.0, 556.0)
Blood results during first 24 hrs post op				
Lowest haemoglobin (g/dl)		55.5 (11.8, 110.5)	94.0 (10.3, 127.0)	94.0 (10.3, 124.0)
Lowest MABP (mm HG)		62.6 (9.1)	62.1 (10.5)	62.3 (9.7)
Lowest haematocrit (%)		33.9 (5.2)	31.1 (10.8)	32.3 (8.8)
Highest lactate (mmol/l)		1.3 (1.2, 1.5)	1.5 (0.8, 2.8)	1.4 (1.0, 2.0)
Activated factor VIII	During first 24hr	0/8 (0.0%)	0/11 (0.0%)	0/19 (0.0%)
	24hr to discharge	0/8 (0.0%)	0/11 (0.0%)	0/19 (0.0%)
Reoperations				
Reoperation		0/8 (0.0%)	2/11 (18.2%)	2/19 (10.5%)
Type	Chest reopened	-	2/2 (100.0%)	2/2 (100.0%)
If chest reopened, reason:	Tamponade	-	0/2 (0.0%)	0/2 (0.0%)
	Bleeding	-	0/2 (0.0%)	0/2 (0.0%)
	Mediastinitis	-	0/2 (0.0%)	0/2 (0.0%)
	Cardiac arrest	-	0/2 (0.0%)	0/2 (0.0%)
	Low cardiac output	-	0/2 (0.0%)	0/2 (0.0%)
	Other*	-	2/2 (100.0%)	2/2 (100.0%)

Notes:

Data are presented as mean (SD), median (IQR) or n (%)

* Other reasons for chest reopening:

Significant pulmonary regurgitation on TTE, reoperation for PVR on bypass (n=1).

Three swabs left inside patient found on post-operative chest x-ray, chest re-opened on PICU to retrieve swabs (n=1).

Abbreviations: SPVR=Standard Pulmonary valve replacement; IPVR=Injectable Pulmonary valve replacement; SD=Standard deviation; MABP=Mean arterial blood pressure

Supplementary table 3 Post-operative details

		Randomised to SPVR (n=8*)	Randomised to IPVR (n=9*)	Overall (n=17*)
Heart rate (bpm) ^a		79.5 (70.5, 85.0)	66.5 (59.0, 75.0)	75.0 (62.5, 82.5)
LV function				
LV function	Good	4/8 (50.0%)	6/9 (66.7%)	10/17 (58.8%)
	Mildly impaired	3/8 (37.5%)	3/9 (33.3%)	6/17 (35.3%)
	Moderately impaired	1/8 (12.5%)	0/9 (0.0%)	1/17 (5.9%)
Global longitudinal strain (%) ^b		-19.4 (-19.4, -19.4)	-19.0 (-21.0, -15.0)	-19.0 (-21.0, -15.0)
Biplane ejection fraction (%) ^c		56.0 (47.0, 69.0)	66.0 (51.0, 67.0)	61.0 (51.0, 67.0)
MAPSE lateral (cm) ^d		1.4 (1.3, 1.7)	1.7 (1.3, 2.1)	1.6 (1.3, 1.8)
MAPSE septal (cm) ^e		1.2 (1.0, 1.3)	1.2 (1.1, 1.4)	1.2 (1.0, 1.3)
Mitral Inflow Doppler				
E wave velocity (cm/s)		83.9 (76.0, 95.3)	77.0 (72.0, 90.0)	80.0 (73.3, 90.7)
A wave velocity (cm/s)		64.5 (51.0, 90.3)	63.0 (59.1, 80.0)	63.0 (55.0, 82.5)
E/A wave ratio		1.2 (1.1, 1.5)	1.3 (1.1, 1.8)	1.2 (1.1, 1.7)
E wave deceleration time (ms) ^f		220.0 (159.0, 239.0)	156.5 (130.5, 174.0)	159.0 (155.0, 220.0)
Tissue Doppler (pulse wave)				
LV E/E' (cm/s) ^g		8.0 (7.7, 12.0)	6.4 (6.0, 7.3)	7.5 (6.0, 8.6)
RV function				
RV function	Good	2/7 (28.6%)	3/8 (37.5%)	5/15 (33.3%)
	Mildly impaired	3/7 (42.9%)	2/8 (25.0%)	5/15 (33.3%)
	Moderately impaired	2/7 (28.6%)	3/8 (37.5%)	5/15 (33.3%)
TAPSE (mm) ^h		14.0 (12.0, 18.0)	16.0 (12.0, 18.0)	15.5 (12.0, 18.0)
Tricuspid valve				
E wave velocity (cm/s) ⁱ		65.0 (48.0, 82.0)	59.1 (52.0, 71.0)	63.5 (52.0, 75.0)
A wave velocity (cm/s) ^j		47.5 (34.0, 56.0)	45.0 (39.0, 51.4)	47.5 (37.0, 51.4)
E/A wave velocity (cm/s) ^k		1.3 (1.1, 1.8)	1.3 (1.1, 1.5)	1.3 (1.1, 1.6)
Tissue Doppler (pulse wave)				
RV S wave velocity (cm/s) ^l		6.7 (4.6, 8.0)	9.1 (7.6, 10.6)	8.0 (6.4, 10.0)
RV A wave velocity (cm/s) ^m		5.1 (4.0, 7.0)	4.2 (3.7, 12.3)	4.9 (4.0, 8.0)
RV E wave velocity (cm/s) ⁿ		7.0 (5.0, 8.4)	6.6 (6.0, 9.0)	6.8 (6.0, 8.4)
RV E/E' (cm/s) ^o		7.6 (2.9, 10.7)	7.3 (6.3, 7.9)	7.3 (4.0, 10.4)
RVOT velocity given		7/8 (87.5%)	7/9 (77.8%)	14/17 (82.4%)
RVOT velocity (m/s)		0.9 (0.7, 1.4)	1.0 (0.9, 1.4)	0.9 (0.8, 1.4)
TR velocity given		5/8 (62.5%)	5/9 (55.6%)	10/17 (58.8%)
TR velocity (m/s)		2.5 (2.3, 2.7)	2.9 (2.8, 3.2)	2.7 (2.5, 3.0)
Pulmonary valve function				
Peak velocity (m/s)		2.6 (2.3, 2.8)	2.4 (1.9, 2.8)	2.5 (2.2, 2.8)
Peak gradient (mmHg)		26.5 (17.1, 32.3)	23.0 (14.0, 30.0)	24.0 (14.0, 30.0)
Pulmonary regurgitation		3/8 (37.5%)	5/9 (55.6%)	8/17 (47.1%)
Severity	Mild	2/2 (100.0%)	4/4 (100.0%)	6/6 (100.0%)

Notes:

Data are presented as median (IQR) or n (%)

* Two participants did not have 6-month Echo data available (n=0 SPVR, 2 IPVR)

Missing data (SPVR, IPVR):^a Data missing for 1 patient (0, 1);^b Data missing for 10 patients (7, 3);^c Data missing for 7 patients (5, 2);^d Data missing for 6 patients (3, 3);^e Data missing for 6 patients (3, 3);^f Data missing for 8 patients (3, 5);^g Data missing for 3 patients (1, 2);^h Data missing for 1 patient (1, 0);ⁱ Data

missing for 3 patients (1, 2);^j Data missing for 4 patients (1, 3);^k Data missing for 5 patients (1, 4);^l Data missing for 1 patient (1, 0);^m Data missing for 3 patients (1, 2);ⁿ Data missing for 3 patients (1, 2);^o Data missing for 5 patients (2, 3)

Abbreviations: SPVR=Standard Pulmonary valve replacement; IPVR=Injectable Pulmonary valve replacement; SD=Standard deviation; LV=Left ventricular; MAPSE= Mitral annular plane systolic excursion; RV= Right ventricular; TAPSE= Tricuspid annular plane systolic excursion; RVOT= right ventricular outflow tract; TR= Tricuspid regurgitation

Supplementary table 4 Post-Operative echocardiographic assessment at 6 months

		Randomised to SPVR (n=8*)	Randomised to IPVR (n=9*)	Overall (n=17*)
Heart rate (bpm)		73.3 (62.0, 78.1)	70.3 (60.1, 80.2)	72.9 (61.6, 80.0)
Cardiac MRI				
LV				
Ejection fraction (%)		63.7 (53.8, 73.2)	60.3 (55.5, 63.1)	62.3 (55.5, 67.0)
End diastolic volume	Absolute (ml)	146.6 (122.8, 172.4)	115.6 (110.1, 130.5)	128.6 (111.7, 153.8)
	Indexed (ml/m ²)	76.6 (58.2, 97.9)	64.8 (62.7, 74.7)	68.0 (59.9, 81.0)
End systolic volume	Absolute(ml)	53.3 (36.2, 79.8)	47.0 (42.6, 48.9)	47.0 (41.6, 61.6)
	Indexed (ml/m ²)	30.9 (16.7, 39.4)	28.8 (25.1, 30.5)	28.8 (22.7, 37.1)
Stroke volume	Absolute (ml)	89.8 (75.9, 107.0)	73.0 (61.1, 94.4)	83.7 (67.9, 100.6)
	Indexed (ml/m ²)	42.8 (38.4, 65.8)	42.9 (32.9, 46.1)	42.8 (35.2, 53.1)
Cardiac output	Absolute (l/min)	6.3 (5.6, 7.2)	4.5 (4.3, 5.7)	5.7 (4.5, 6.5)
Cardiac index	Indexed			
	(l/min/m ²)	3.3 (3.2, 4.0)	3.1 (2.6, 3.4)	3.3 (2.6, 3.7)
Mass	Absolute (g/m ²)	106.9 (95.7, 147.8)	79.9 (69.4, 92.6)	92.6 (74.7, 132.9)
	Indexed (g/m ²)	62.1 (51.1, 70.1)	51.1 (40.8, 56.3)	55.2 (45.3, 68.9)
GLS (%)		-14.9 (-18.4, -11.6)	-14.0 (-18.0, -12.0)	-14.0 (-18.0, -12.0)
RV				
Ejection fraction (%)		49.1 (43.3, 51.1)	45.2 (39.5, 48.4)	48.4 (39.9, 49.2)
End diastolic volume	Absolute (ml)	178.8 (169.5, 201.2)	159.8 (131.9, 205.0)	172.3 (133.5, 205.0)
	Indexed (ml/m ²)	105.6 (75.3, 113.5)	94.0 (78.5, 97.8)	94.0 (77.3, 111.3)
End systolic volume	Absolute(ml)	93.7 (76.4, 119.9)	87.1 (80.8, 107.8)	87.1 (80.8, 112.4)
	Indexed (ml/m ²)	47.6 (39.1, 65.1)	51.5 (47.5, 60.6)	51.5 (40.7, 61.7)
Stroke volume	Absolute (ml)	86.6 (73.2, 96.6)	72.9 (52.7, 92.6)	82.1 (63.8, 92.6)
	Indexed (ml/m ²)	42.2 (36.0, 59.2)	42.5 (31.0, 45.5)	42.5 (35.5, 56.7)
Cardiac output	Absolute (l/min)	6.0 (5.1, 7.2)	4.6 (4.5, 5.5)	5.2 (4.6, 6.6)
Cardiac index	Indexed			
	(l/min/m ²)	3.0 (2.3, 3.6)	2.4 (2.2, 2.9)	2.7 (2.2, 3.1)
GLS (%)		-18.1 (-19.9, -9.8)	-20.0 (-22.5, -18.1)	-19.0 (-21.0, -12.6)
LA biplane				
End diastolic volume (ml)		36.6 (29.0, 44.0)	18.1 (16.8, 36.3)	33.0 (17.5, 39.8)
End systolic volume (ml)		70.8 (58.1, 79.8)	45.7 (41.1, 48.6)	56.0 (42.6, 71.8)
Pulmonary valve function **				
Peak velocity (cm/s)	MPA	243.1 (155.1, 279.2)	190.9 (171.4, 236.4)	199.3 (163.0, 253.8)
	LPA ^a	142.4 (124.7, 149.9)	117.7 (100.4, 134.6)	128.1 (111.6, 147.2)
	RPA ^b	137.5 (114.9, 148.4)	105.6 (88.5, 111.1)	112.2 (97.6, 142.8)
Antegrade (ml)	MPA	111.4 (83.8, 114.8)	88.4 (65.8, 96.6)	94.2 (71.9, 111.5)
	LPA ^c	41.4 (24.8, 42.8)	40.9 (28.3, 42.8)	41.2 (28.3, 42.8)
	RPA ^d	47.3 (39.1, 66.5)	43.3 (25.6, 49.1)	46.1 (35.8, 51.4)
Retrograde (ml)	MPA	0.0 (0.0, 0.6)	1.9 (0.4, 3.4)	0.4 (0.0, 1.9)
	LPA ^e	3.5 (2.2, 6.0)	2.1 (1.6, 5.6)	2.9 (2.0, 5.6)
	RPA ^f	0.2 (0.1, 0.4)	1.2 (0.4, 2.2)	0.4 (0.1, 1.7)
Net stroke volume (ml)	MPA	111.3 (83.5, 114.1)	88.4 (64.8, 94.2)	89.0 (68.6, 111.4)
	LPA ^g	36.8 (15.4, 39.8)	35.3 (23.0, 40.9)	36.3 (23.0, 39.8)
	RPA ^h	47.1 (38.7, 66.4)	42.1 (24.2, 47.8)	45.2 (34.6, 51.2)
Net flow (l/min)	MPA	7.3 (6.9, 7.7)	5.0 (4.7, 6.7)	6.7 (4.8, 7.5)
	LPA ⁱ	2.7 (1.5, 3.0)	2.9 (2.3, 3.0)	2.8 (2.3, 3.0)
	RPA ^j	3.4 (2.8, 5.0)	2.7 (2.1, 3.7)	3.1 (2.6, 4.0)

	Randomised to SPVR (n=8*)	Randomised to IPVR (n=9*)	Overall (n=17*)
End diastolic A wave	0/8 (0.0%)	0/9 (0.0%)	0/17 (0.0%)
If yes, volume (ml)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
MPA regurgitation fraction (%)	0.0 (0.0, 0.8)	2.0 (0.3, 4.7)	0.7 (0.0, 2.0)
MPA regurgitation fraction – A wave corrected (%)	0.0 (0.0, 0.8)	2.0 (0.3, 4.7)	0.7 (0.0, 2.0)

Notes:

Data are presented as median (IQR), mean (SD) or n (%)

* Two participants did not have 6-month MRI data available (n=0 SPVR, 2 IPVR)

** MRI assessment technique: Free breathing for n=17 (8 SPVR, 9 IPVR)

Missing data (SPVR, IPVR): ^a Data missing for 3 patients (1, 2); ^b Data missing for 1 patient (0, 1); ^c Data missing for 3 patients (1, 2); ^d Data missing for 1 patient (0, 1); ^e Data missing for 3 patients (1, 2); ^f Data missing for 1 patient (0, 1); ^g Data missing for 3 patients (1, 2); ^h Data missing for 1 patient (0, 1); ⁱ Data missing for 3 patients (1, 2); ^j Data missing for 1 patient (0, 1)

Abbreviations: SPVR=Standard Pulmonary valve replacement; IPVR=Injectable Pulmonary valve replacement; SD=Standard deviation; LV=Left ventricular; RV= Right ventricular; MPA=Main pulmonary artery; LPA= Left pulmonary artery; RPA= Right pulmonary artery; GLS=Global longitudinal strain; LA=Left atrial; MRI=magnetic resonance imaging

Supplementary table 5 – Post-operative MRI assessment at 6 months.

Outcome	Randomised to SPVR (n=8)	Randomised to IPVR (n=11)	Mean difference (95% CI)*	p-value
Chest drain volume in first 24hrs post-op hours (ml)	633.8 (249.8)	340.0 (167.3)	-277.6 (-484.0, -71.2)	0.005
Post-hoc sensitivity analysis: primary analysis adjusted for age and sex	-	-	-286.6 (-512.6, -60.7)	0.005

Notes:

Data are presented as mean (SD) or MD (95% CI) *Mean difference adjusted for centre.

Abbreviations: SPVR=Standard Pulmonary valve replacement; IPVR=Injectable Pulmonary valve replacement; CI=Confidence interval; MD=Mean difference

Supplementary table 6 – Primary outcome: Chest drain volume

Outcome	Randomised to SPVR (n=8)	Randomised to IPVR (n=11)	HR (95% CI)	p-value
Time to readiness for extubation (hours) *	6.8 (4.8, 7.7)	7.5 (5.6, 16.1)	0.69 (0.26, 1.88)	0.476
Time to first ICU discharge (hours)	17.0 (8.6, 32.2)	23.0 (16.5, 62.1)	0.50 (0.17, 1.48)	0.209
Total length of ICU stay (hours) **	18.6 (9.0, 33.1)	23.0 (16.5, 62.1)		
Time to fitness for discharge (days) *** x	8.0 (5.0, -)	7.0 (4.0, -)	1.48 (0.36, 6.02)	0.577

Notes:

Data are presented as median (IQR) or HR (95% CI)

* Date/time extubation performed used if date/time ready for extubation is missing (n=2: 2 SPVR, 0 IPVR)

** Includes duration of any re-admissions to ICU prior to hospital discharge

*** Fitness for discharge defined as all:

- Temperature: 36-38°C
- Heart rate: 60-100 beats/min for paediatrics, <90 beats/min for adults
- Oxygen saturation on air: ≥ 95%
- Respiration: 12-30 for paediatrics, 10-30 for adults
- White blood count: <12 x 10⁹/L
- C-reactive protein (CRP): Showing downward trend
- Bowel function: bowel has opened after surgery
- Physically mobile: physical ability has reached pre-surgery level

Abbreviations: SPVR=Standard Pulmonary valve replacement; IPVR=Injectable Pulmonary valve replacement; ICU= intensive care unit; IQR=Interquartile Range; HR=Hazard ratio; CI=Confidence interval

Supplementary table 7— Treatment estimates – secondary outcomes

Questionnaire domain *		Randomised to SPVR (n=8)	Randomised to IPVR (n=11)
EQ-5D **			
Summary index score	<i>6 weeks post-operative</i>	0.7 (0.6, 0.8)	0.8 (0.7, 0.8)
	<i>6 months post-operative</i>	0.8 (0.7, 1.0)	0.8 (0.7, 1.0)
Visual analogue scale	<i>6 weeks post-operative</i>	82.5 (67.5, 87.5)	67.5 (50.0, 86.0)
	<i>6 months post-operative ^a</i>	91.0 (70.0, 95.0)	83.5 (70.0, 95.0)
SF-36 ***			
Physical component summary	<i>6 weeks post-operative</i>	39.9 (36.9, 48.2)	36.3 (33.3, 46.3)
	<i>6 months post-operative</i>	48.9 (45.0, 56.2)	51.8 (45.4, 58.7)
Mental component summary	<i>6 weeks post-operative</i>	52.3 (33.9, 58.2)	47.4 (46.8, 57.5)
	<i>6 months post-operative</i>	51.8 (27.2, 57.6)	53.1 (38.9, 58.9)
Physical functioning	<i>6 weeks post-operative</i>	47.0 (42.2, 50.8)	40.3 (38.4, 44.2)
	<i>6 months post-operative</i>	49.9 (46.1, 57.5)	53.7 (46.1, 57.5)
Role – physical	<i>6 weeks post-operative</i>	34.7 (28.0, 44.8)	30.2 (28.0, 39.2)
	<i>6 months post-operative</i>	48.2 (43.7, 57.2)	48.2 (39.2, 57.2)
Bodily pain	<i>6 weeks post-operative</i>	38.6 (28.3, 49.1)	38.2 (34.6, 51.5)
	<i>6 months post-operative</i>	51.5 (42.2, 62.0)	51.5 (50.7, 55.5)
General health	<i>6 weeks post-operative</i>	49.6 (37.3, 59.8)	46.0 (45.1, 55.6)
	<i>6 months post-operative</i>	47.5 (30.8, 61.7)	55.6 (43.7, 66.5)
Vitality	<i>6 weeks post-operative</i>	46.7 (37.7, 58.5)	49.6 (31.8, 52.6)
	<i>6 months post-operative</i>	46.7 (28.8, 61.5)	52.6 (43.7, 64.5)
Social functioning	<i>6 weeks post-operative</i>	49.8 (39.8, 54.8)	47.3 (37.3, 57.3)
	<i>6 months post-operative</i>	52.3 (37.3, 57.3)	57.3 (42.3, 57.3)
Role - emotional	<i>6 weeks post-operative</i>	35.3 (28.3, 54.4)	42.2 (24.8, 56.2)
	<i>6 months post-operative</i>	49.2 (42.2, 56.2)	52.7 (45.7, 56.2)
Mental health	<i>6 weeks post-operative</i>	54.8 (35.2, 60.0)	48.3 (45.6, 58.7)
	<i>6 months post-operative</i>	53.5 (29.9, 58.7)	53.5 (40.4, 58.7)
CHQ-CF87 ****			

Global Health	6 weeks post-operative		85.0 (60.0, 100.0)
	6 months post-operative		92.5 (57.5, 100.0)
Global behaviour item	6 weeks post-operative		100.0 (85.0, 100.0)
	6 months post-operative		85.0 (42.5, 92.5)
Physical functioning	6 weeks post-operative		81.5 (55.6, 100.0)
	6 months post-operative		96.3 (90.7, 100.0)
Role/Social limitations - Emotional	6 weeks post-operative		100.0 (100.0, 100.0)
	6 months post-operative		100.0 (61.1, 100.0)
Role/Social limitations - Behavioural	6 weeks post-operative		100.0 (100.0, 100.0)
	6 months post-operative		100.0 (50.0, 100.0)
Role/Social limitations - Physical	6 weeks post-operative		100.0 (33.3, 100.0)
	6 months post-operative		100.0 (100.0, 100.0)
Bodily Pain/Discomfort	6 weeks post-operative		70.0 (50.0, 100.0)
	6 months post-operative		80.0 (50.0, 90.0)
Behaviour	6 weeks post-operative		96.2 (92.6, 100.0)
	6 months post-operative		87.4 (53.2, 94.4)
Mental Health	6 weeks post-operative		82.8 (81.3, 90.6)
	6 months post-operative		82.8 (49.9, 89.8)
Self Esteem	6 weeks post-operative		91.1 (76.9, 96.2)
	6 months post-operative		86.6 (52.7, 95.5)
General Health perceptions	6 weeks post-operative		73.8 (73.8, 81.3)
	6 months post-operative		65.8 (46.9, 79.2)
Change in Health	6 weeks post-operative	About the same now as 1 year ago	1/3 (33.3%)
		Somewhat better now than 1 year ago	2/3 (66.7%)
	6 months post-operative	Somewhat better now than 1 year ago	1/4 (25.0%)
		Much better now than 1 year ago	3/4 (75.0%)
Family Activities	6 weeks post-operative ^b		66.7 (62.5, 70.8)
	6 months post-operative		100.0 (62.5, 100.0)
Family Cohesion	6 weeks post-operative		85.0 (85.0, 85.0)

6 months post-operative

85.0 (72.5, 92.5)

Notes:
Data are presented as median (IQR) or n (%)
* For all questionnaire domains, higher scores indicate better health.
** EQ-5D completed by n=18 (8 SPVR, 10 IPVR) at 6 weeks and n=19 (8 SPVR, 11 IPVR) at 6 months
*** SF-36 completed by adults only: n=15 (8 SPVR, 7 IPVR) at 6 weeks; n=14[#] (7 SPVR, 7 IPVR) at 6 months
**** CHQ-CF87 completed by paediatrics’ only: n=3 (0 SPVR, 3 IPVR) at 6 weeks; n=4 (0 SPVR, 4 IPVR) at 6 months
[#] One adult patient (randomised to SPVR) was inadvertently sent the child health questionnaire pack at 6 months.

Missing data (SPVR, IPVR):
^a Data missing for 1 patient (0, 1)
^b Data missing for 1 patient (-, 1)

Abbreviations: SPVR=Standard Pulmonary valve replacement; IPVR=Injectable Pulmonary valve replacement; IQR=Interquartile Range; SF-36=36-item Short-Form Health Survey

Supplementary table 8 Secondary outcome: Quality of life questionnaires

Event	Received SPVR (n=8)				Received IPVR (n=11)			
	All events		SAEs		All events		SAEs	
	Events/ patients	%	Events/ patients	%	Events/ patients	%	Events/ patients	%
Any event	12/5	62.5%	4/4	50.0%	20/8	72.7%	8/5	45.5%
EXPECTED EVENTS								
Any expected event	12/5	62.5%	4/4	50.0%	17/8	72.7%	5/3	27.3%
Cardiopulmonary bypass								
Displaced valve	0/0	0.0%	0/0	0.0%	3/3	27.3%	1/1	9.1%
Arrhythmias								
SVT/AF requiring treatment	1/1	12.5%	1/1	12.5%	0/0	0.0%	0/0	0.0%
New pacing ^a	0/0	0.0%	0/0	0.0%	1/1	9.1%	0/0	0.0%
Haemodynamic support								
Any inotropes used	4/4	50.0%	1/1	12.5%	6/6	54.5%	1/1	9.1%
Vasodilator used	3/3	37.5%	0/0	0.0%	2/2	18.2%	0/0	0.0%
Pericardial effusion								
Pericardial effusion ^b	1/1	12.5%	0/0	0.0%	0/0	0.0%	0/0	0.0%
Pulmonary complications								
CPAP	0/0	0.0%	0/0	0.0%	1/1	9.1%	0/0	0.0%
Re-operation								
Re-operation for valve related issues	0/0	0.0%	0/0	0.0%	1/1	9.1%	1/1	9.1%
Infective complications during hospital stay								
Valve related sepsis	0/0	0.0%	0/0	0.0%	1/1	9.1%	1/1	9.1%
Respiratory infection	1/1	12.5%	1/1	12.5%	1/1	9.1%	0/0	0.0%
Superficial wound infection	1/1	12.5%	0/0	0.0%	0/0	0.0%	0/0	0.0%
Infective complications post discharge								
Groin (Rt)	1/1	12.5%	1/1	12.5%	0/0	0.0%	0/0	0.0%
Pulmonary valve and septic embolism in lung	0/0	0.0%	0/0	0.0%	1/1	9.1%	1/1	9.1%
UNEXPECTED EVENTS								
Any unexpected event ^c			0/0	0.0%			3/2	10.5%

Event	Received SPVR (n=8)				Received IPVR (n=11)			
	All events		SAEs		All events		SAEs	
	Events/ patients	%	Events/ patients	%	Events/ patients	%	Events/ patients	%
Surgical and medical procedures								
Removal of foreign body			0/0	0.0%			1/1	9.1%
Pulmonary valve replacement			0/0	0.0%			1/1	9.1%
Infections and infestations								
Endocarditis			0/0	0.0%			1/1	9.1%

Notes:
SAEs are a subset of AEs.
^a The pacing was single. Temporary pacing did not become permanent.
^b The pericardial effusion was not drained
^c Further details of unexpected events will be given in Supplementary Table 10

Abbreviations: SPVR=Standard Pulmonary valve replacement; IPVR=Injectable Pulmonary valve replacement; SAE=Serious adverse event; MI=Myocardial infarction; SVT=Supraventricular tachycardia; AF=Atrial fibrillation; VF=Ventricular fibrillation; VT=Ventricular tachycardia; LVAD=Left ventricular assist device; ECMO=Extracorporeal membrane oxygenation; CPAP=Continuous positive airway pressure; ARDS=Acute respiratory distress syndrome; GI=Gastrointestinal; TIA=Transient ischemic attack

Supplementary table 9– Expected and unexpected adverse events and serious adverse events both in-hospital and during trial follow-up

Event	Full description	Timing	Maximum intensity	Relatedness	Group
Removal of foreign body	x3 swabs left inside patient - found on post-operative chest x-ray. Chest re-opened on PICU to retrieve swabs.	Post-surgery but pre-discharge	Mild	Not related	IPVR
Endocarditis	Was admitted with 10-day history of fever, shortness of breath, abdominal pain, cough, loss of appetite, intermittent nausea and vomiting and loose stools.	Post-discharge	Moderate	Unlikely to be related	IPVR
Pulmonary valve replacement					

Abbreviations: SAE=Serious adverse event; IPVR=Injectable Pulmonary valve; PICU=Paediatric intensive care unit

Supplementary table 10– Details of unexpected serious adverse events