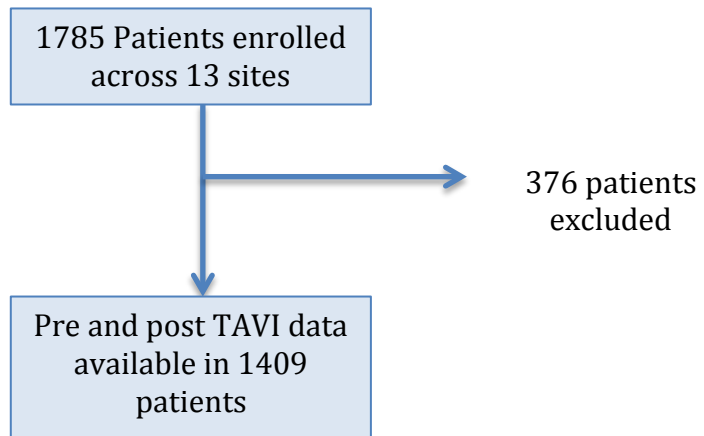# 3B Study Report

Participant Flow:

1785 patients were enrolled into the study

Of these 1785 patients
- Complete ECG data pre and post TAVI was available in 1409 patients
- 376 patients were excluded
-

1785 Patients enrolled across 13 sites

376 patients excluded

Pre and post TAVI data available in 1409 patients

Baseline Characteristics

	No LBBB	Pre-existing LBBB	New LBBB	All
Age	81.5 +/- 7.2	81.4 +/- 8.4	81.5 +/- 6.6	81.6 +/- 7.3
Male (%)	50.1	59.8	50.8	51.9
Diabetic (%)	28.4	21	31.4	28.0
PVD (%)	19.2	21.2	20.3	19.7
HTN (%)	56.5	60.2	61.3	57.6
CRD (%)	29.9	23.7	26.7	28.2
Pulmonary HTN	17.7	21.0	21.7	19.1
Current/Ex Smoker	56.1	54.8	57.2	56.2
CVA/TIA	17.7	15.1	15.2	16.7
Logistic Euroscore	20.1 +/- 12.5	21.9 +/- 12.9	18.8 +/- 12.2	20.3 +/- 12.6
Previous CABG	28.3	31.5	32.3	29.7
Previous BAV	13.7	17.2	10.3	13.4
Previous surgical AVR	4.3	7.7	3.8	4.7
Previous PCI	21.4	18.5	23.4	21.5
Pre TAVI CCS Class				
Class I	34.3	21.4	17.6	28.2
Class II	34.9	42.7	47.2	39.2
Class III	28.2	31.5	31.7	29.6
Class IV	2.6	4.5	3.5	3.2
Pre TAVI NYHA				
Class I	3.1	2.1	2.2	2.8
Class II	20.1	15.9	16.3	18.6
Class III	61.2	59.5	63.4	61.5
Class IV	15.5	22.6	18.1	17.1
Previous MI	23.7	27.8	28.2	25.5
Creatinine	112.3 +/- 66.0	124 +/- 67.6	116.5 +/- 54.9	116.7 +/- 68.2
LVEF pre TAVI				
-Preserved	43.9	26.4	26.7	37.4
-Mild impairment	36.6	38.1	50.2	39.9
-Mod impairment	11.2	21.3	14.9	13.6
-Severe impairment	8.3	14.2	8.3	9.1
AVA	0.7 +/- 0.2	0.7 +/- 0.2	0.7 +/- 0.2	0.7 +/- 0.2
Peak AV gradient	80 +/- 25.5	80.3 +/- 36.9	79.0 +/- 27.2	79.0 +/- 27.4
Mean AV gradient	47.2 +/- 16.0	46.2 +/- 16.9	46.5 +/- 16.4	46.4 +/- 16.2
Sinus Rhythm	75.5	77.6	79.2	76.6
PR interval (ms)	179.8 +/- 49.0	198.8 +/- 47.2	188.9 +/- 47.6	183.7 +/- 50.7
QRS duration (ms)	103. +/- 22.2	150.8 +/- 20.1	104.6 +/- 19.1	111.20 +/- 28.3

**Outcome Measures:**

Primary Outcome – 1 year Mortality
Mortality data was available for 1367 of the 1409 patients. The total 1-year mortality was 272 patients. New LBBB was associated with a trend towards increased 1-year mortality compared to patients not having LBBB, although this failed to reach statistical significance (p=0.416)

Predictors of Mortality	
Age	0.271
Female	0.812
Diabetes	0.033
Peripheral Vascular Disease	0.227
Hypertension	0.581
Chronic Respiratory Disease	0.985
Pulmonary hypertension	0.294
Current Smoker	0.128
Ex smoker	0.104
Previous CVA or TIA	0.083
Logistic Euroscore	0.005
Previous CABG	0.238
Previous BAV	0.001
Previous PCI	0.625
Pre TAVI NYHA Score	0.501
Previous MI	0.921
Previous MI with pre-existing LBBB	0.028
CKD (Creatinine)	0.003
Pre TAVI LVEF	0.464
Aortic Valve Area	0.806
Peak AV Gradient	0.000
Mean AV Gradient	0.001
Aortic Regurgitation	0.528
Atrial Fibrillation	0.039
PR Interval	0.677
QRS duration	0.069
RBBB pre –TAVI	0.694
New LBBB	0.416

Secondary Outcomes

Predictors of Permanent Pacemaker	
Variable	p-value
New LBBB	<0.001
Pre-TAVI LBBB	0.469
Age	0.738
Hypertension	0.027
Previous CABG	0.193
Previous BAV	0.421
Previous Surgical AVR	0.331
Pre-TAVI LVEF	0.037
Pre-TAVI AVA	0.177
Pre-TAVI Peak AV gradient	0.526
Pre-TAVI Mean AV gradient	0.400
Pre-TAVI Aortic Regurgitation	0.491
Pre-TAVI Atrial Fibrillation	0.308
Pre-TAVI PR Interval	0.108
Pre-TAVI QRS duration	<0.001
Pre-TAVI RBBB	<0.001

Change in LV systolic function
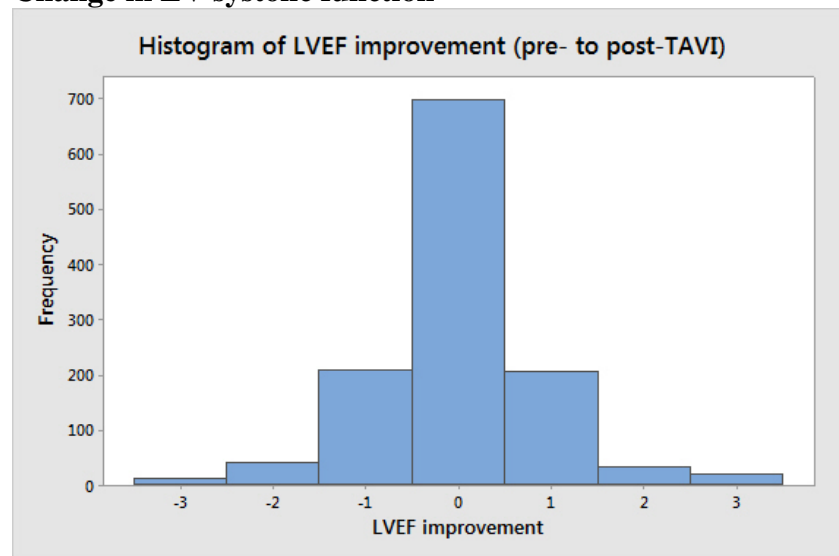
In the majority of patients, the LVEF remained unchanged following TAVI

1-year Mortality and Post TAVI LVEF

LVEF	1-year Mortality (%)
>55%	14.3
45-55%	6.9
35-45%	11.4
<35%	27.2

There is a trend towards higher 1-year mortality with lower ejection fraction post TAVI (p=0.086).

Adverse Events: This was a retrospective UK wide multicenter registry. There were no adverse events associated with this trial.