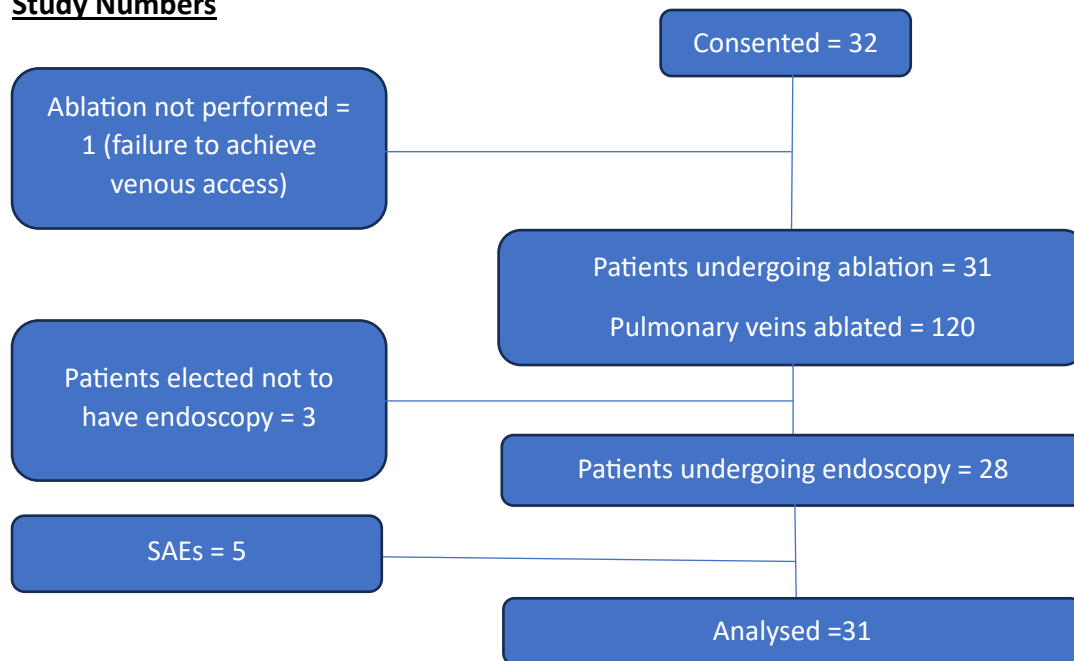


The safety and efficacy of using shorter ablation times during pulmonary vein isolation using a multielectrode radiofrequency balloon catheter.

Trial registration number: ISRCTN72715606

Participant flow

Study Numbers



Baseline characteristics

	N= 31
Male gender	23 (74.2)
Age at the time of procedure, years	66 [60-70]
Hypertension	20 (64.5)
Diabetes	4 (12.9)
Obstructive sleep apnea	4 (12.9)
CKD	1 (3.2)
Thyroid dysfunction	4 (12.9)
Smoker	3 (9.7%)
Ischaemic heart disease	5 16.1)

Paroxysmal atrial fibrillation	24 (77.4)
Persistent atrial fibrillation	7 (22.6)
LVEF, percentage	56 [55-60]

Outcome measures

	Per patient (N= 31)	Per PV (N= 120)
Successfully isolated veins at the end of the procedure	31 (100)	120 (100)
Successfully isolated with HelioStar catheter	30 (96.8)	119 (99.1)
Successful first pass isolation	-	100 (83.3)
Isolation requiring two applications	-	11 (9.2)
Isolation requiring three or more applications	-	9 (7.5)
Oesophageal temperature rise > 42°C	3 (9.7)	3 (2.5)
Endoscopically detected oesophageal lesions (EDEL)	1 (3.2)	-
EDEL Type 1	1 (3.2)	-
EDEL Type 2	0	-
Atrioesophageal fistula	0	-
Freedom of AF/AT at 12 months FU	25 (80.6)	

Adverse Events

	Number	Expected	Related	Resolved
Serious Adverse Events	3	1	1	2
SAE 1	Patient presented acute ST elevation during ablation, treated with nitrates. Coronary angiography during the procedure showed no abnormalities. Probable air embolism or coronary vasospasm, resolved during procedure. Echocardiogram post showing no effect on heart function. Patient recovered without any sequels.			
SAE 2	Patient taken to A&E due to taking an overdose of opioids to self-harm. Patient recovered and seen by the Mental health team. Unrelated to the study.			
SAE 3	Patient diagnosed with Diffuse Large B-cell non-Hodgkin lymphoma, undergoing chemotherapy. Unrelated to the study.			

	Number	Expected	Related	Resolved
Adverse Events	8	4	4	8
AE 1	Patient presented with chest pain within a week after the ablation and attended A&E. All investigations were normal and pain settled. Probably mild pericarditic pain post ablation.			

AE 2	Patient presented with chest pain within a week after the ablation and attended A&E. All investigations were normal and pain settled. Probably mild pericarditic pain post ablation.
AE 3	Patient presented with epigastric discomfort after his endoscopy. Reviewed in the Cardiology department, with unremarkable bloods, ECG and echocardiogram. Gastro team suggested that most likely the symptoms were related to the endoscopy probe manipulation in a patient with a previously known significant hiatus hernia. Symptoms did settle within 5 weeks.
AE 4	Patient presented a skin burn in vicinity of the return ablation patches. This was reviewed by the Dermatology team and treated conservatively until resolved without sequelae.
AE 5	Patient had an atrial septal defect that was known prior to his ablation and a plan has been made to percutaneously close it 2-3 months after ablation. The patient had this as scheduled, without complications.
AE 6	Patient presented with episodes of PR bleeding 45 days after the ablation, on a background of known haemorrhoids. No other cause was found and bleeding settled.
AE 7	Patient had been presenting with pain in one of his toes for weeks prior to his ablation. This continued to occur post ablation and eventually he was admitted 9 months after ablation and the vascular team thought the presentation was most likely related with a prior embolic event. A decision was made by them to change his anticoagulant agent. Symptoms resolved.
AE 8	Patient presented with right leg pain 9.5 months after ablation and was diagnosed with a right leg deep venous thrombosis. After discussion with the Haematology team, his anticoagulant agent was changed. No recurrences since.