

Fig 1. Consort diagram

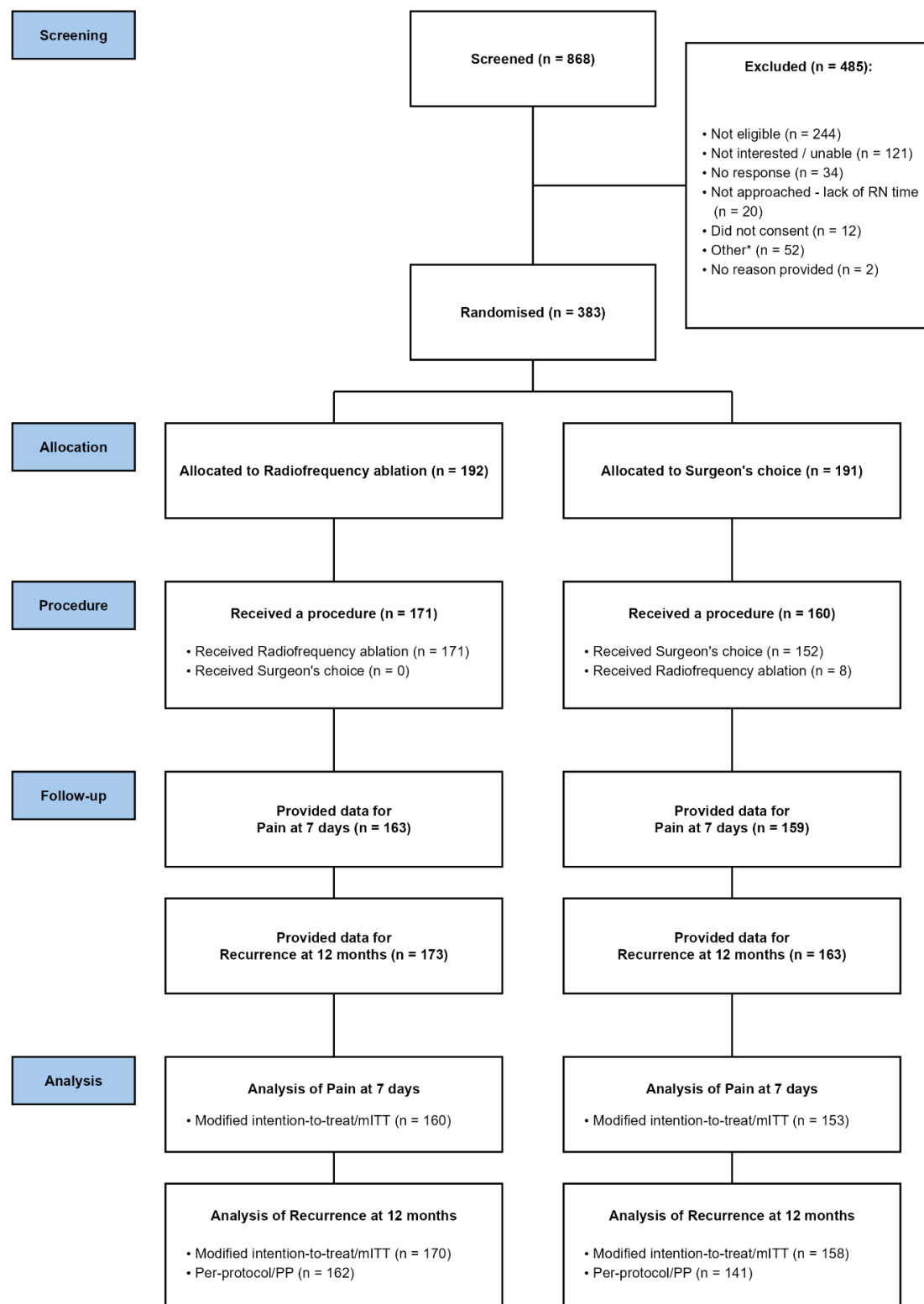


Table 1. Baseline characteristics

	RFA	Surgeon's choice	Overall
	(N = 170)	(N = 158)	(N = 328)
Age (years)	49.0 (38, 57)	49.0 (38, 60)	49.0 (38, 59)
Sex			
Male	103 (61%)	97 (61%)	200 (61%)
Female	67 (39%)	61 (39%)	128 (39%)
Ethnicity			
British or Irish	130 (76%)	125 (79%)	255 (78%)
Any other White background	10 (6%)	7 (4%)	17 (5%)
Asian	15 (9%)	12 (8%)	27 (8%)
Any Black, African, or Caribbean background	6 (4%)	8 (5%)	14 (4%)
Any mixed background	5 (3%)	4 (3%)	9 (3%)
Any other ethnic group	2 (1%)	1 (1%)	3 (1%)
Prefer not to say	2 (1%)	1 (1%)	3 (1%)

Body mass index (Kg/m ²)	27·1 (24·0, 30·7)	27·8 (24·1, 32·0)	27·4 (24·0, 31·2)
Medical history			
Previously tried diet and lifestyle changes	170 (100%)	148 (100%)	328 (100%)
Failed one episode of RBL	101 (59%)	99 (63%)	200 (61%)
Grade III haemorrhoids inappropriate for RBL treatment	135 (79%)	122 (77%)	257 (78%)
Haemorrhoid grade			
II	79 (46%)	65 (41%)	144 (44%)
III	91 (54%)	93 (59%)	184 (56%)
Time from randomisation to surgery (days)	71·5 [25, 129]	60·5 [23,117]	63·5 [25,122]

Table 2. Outcome measures

Outcome <i>Timepoint</i>	RFA		Standard care		Difference (95% CI)	ICC*
	Number analysed	n (%) or mean [SD]	Number analysed	n (%) or mean [SD]	Adjusted difference in percentages or means	
Recurrence (co-primary endpoint)						
<i>12 months</i>	170	80 (47%)	158	62 (39%)	7.4% (-5.3%, 20.1%)	0.007
Patient-reported cure						
<i>12 months</i>	136	26 (19%)	129	23 (16%)	3.1% (-4.7%, 11.0%)	-0.019
Persistence**						
<i>6 weeks</i>	159	24 (15%)	148	8 (5%)	8.9% (-3.0%, 14.9%)	0.05
Pain (NPRS range 0 to 10; higher is worse pain)						
<i>1 day</i>	165	3.9 [2.9]	153	5.4 [2.9]	-1.53 (-2.04, -1.02)	0.19
<i>7 days (co-primary endpoint)</i>	160	4.1 [3.0]	153	3.9 [3.1]	0.17 (-0.67, 1.01)	0.011
<i>21 days</i>	153	2.0 [2.5]	146	1.5 [2.1]	0.56 (0.05, 1.07)	0.0094
<i>6 weeks</i>	157	1.2 [2.2]	149	1.0 [2.1]	0.18 (-0.25, 0.61)	0.070
<i>12 months</i>	135	1.2 [2.0]	130	1.3 [2.2]	-0.13 (-0.58, 0.32)	0.055
<i>Average over days 0 -7***</i>	159	3.8 [2.5]	151	4.6 [2.4]	-0.74 (-1.27, -0.20)	0.11
Symptoms (HSS range 0 to 15, higher is worse symptoms)						
<i>6 weeks</i>	155	3.1 [3.5]	146	2.3 [3.0]	0.67 (-0.00, 1.35)	0.27
<i>12 months</i>	133	2.7 [3.1]	127	2.5 [3.0]	0.22 (-0.58, 1.02)	-0.01
Incontinence (Vaizey, range 0 to 28, higher is worse incontinence)						
<i>6 weeks</i>	155	2.6 [4.4]	146	2.3 [4.2]	0.23 (-0.33, 0.79)	0.03
<i>12 months</i>	133	1.7 [3.0]	146	2.1 [3.9]	-0.37 (-1.23, 0.50)	0.01
Health utility (EQ-5D-5L, range -0.59 to 1: higher is better health)						
<i>1 day</i>	165	0.74 [0.20]	153	0.64 [0.27]	0.100 (0.047, 0.152)	0.12

<i>7 days</i>	160	0.70 [0.27]	153	0.72 [0.22]	-0.022 (-0.070, 0.026)	-0.006
<i>21 days</i>	153	0.83 [0.19]	146	0.88 [0.14]	-0.047 (-0.077, -0.016)	0.026
<i>6 weeks</i>	158	0.86 [0.19]	149	0.87 [0.18]	-0.013 (-0.047, 0.020)	0.075
<i>12 months</i>	135	0.89 [0.18]	129	0.87 [0.19]	0.013 (-0.028, 0.055)	0.026
Days taken off work (up to 6 weeks)						
<i>At least one or more</i>	158	78 (49%)	148	60 (41%)	8.7% (-2.8%, 20.1%)	-0.008
<i>Number of days</i>	158	7.4 [11.6]	148	4.9 [7.9]	2.5 (0.2, 4.8)	-0.013

Table 3. Adverse events

	Radiofrequency ablation		Standard care	
	Number of events [SAEs]	No (%) patients	Number of events [SAEs]	No (%) patients
Any adverse event	31[7]	25 (14.0%)	23[6]	21 (13.8%)
Anal fissure	3	3 (1.7%)	2	2 (1.3%)
Bleeding	5	5 (2.8%)	3[1]	3 (2.0%)
Faecal incontinence	1	1 (0.6%)	2	2 (1.3%)
Hospitalisation due to bleeding	4[4]	4 (2.2%)	2[2]	2 (1.3%)
Hospitalisation due to pain	1[1]	1 (0.6%)	2[2]	2 (1.3%)
Hospitalisation due to urinary retention	0	0	1[1]	1 (0.7%)
Hospitalisation for blood transfusion	1[1]	1 (0.6%)	0	0
Infection	0	0	3	3 (2.0%)
Pain	9[1]	7 (3.9%)	6	6 (3.9%)
Pelvic sepsis/abscess	1	1 (0.6%)	1	1 (0.7%)
Perianal haematoma	3	3 (1.7%)	0	0
Urinary retention	2	2 (1.1%)	0	0
Unknown	1	1 (0.6%)	1	1 (0.7%)