GENERAL UNIVERSITY HOSPITAL IN PRAGUE

FIRST FACULTY OF MEDICINE
Charles University

Catheter Ablation of Atrial Fibrillation / Tachycardia in Patients with Pulmonary Hypertension. A Multicentre Randomized Trial

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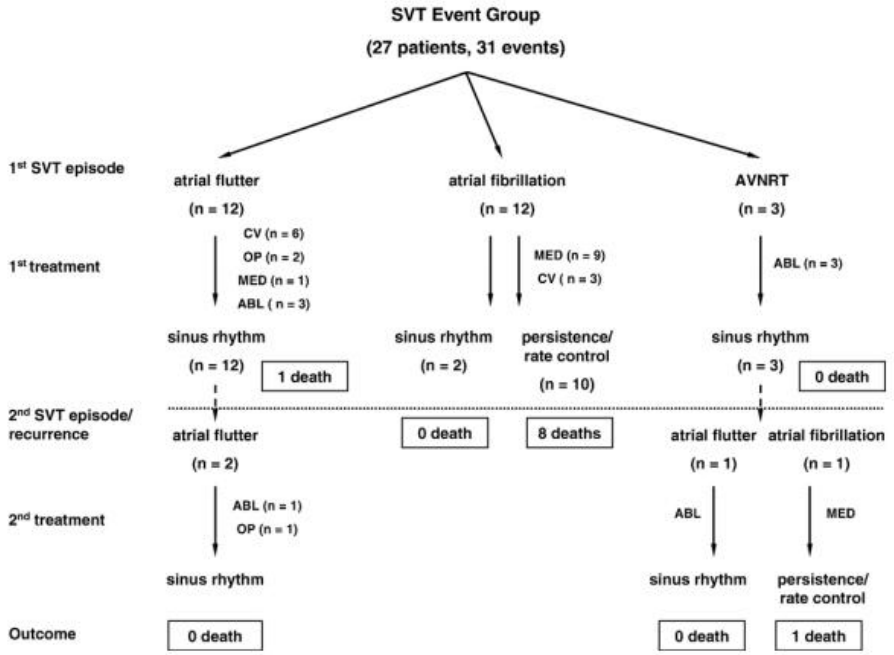
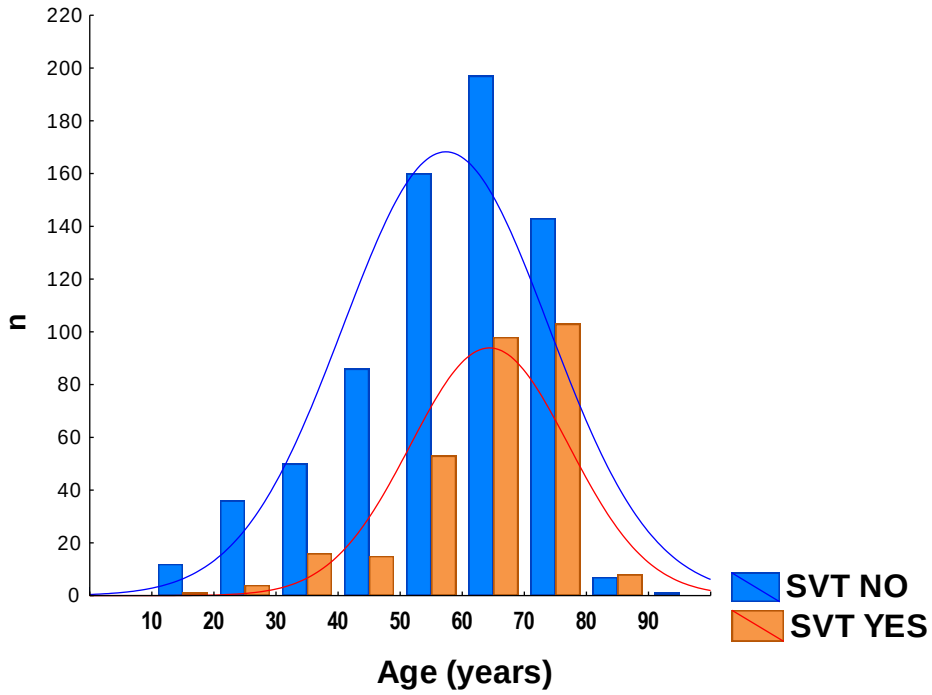
Pulmonary hypertension and cardiac arrhythmia

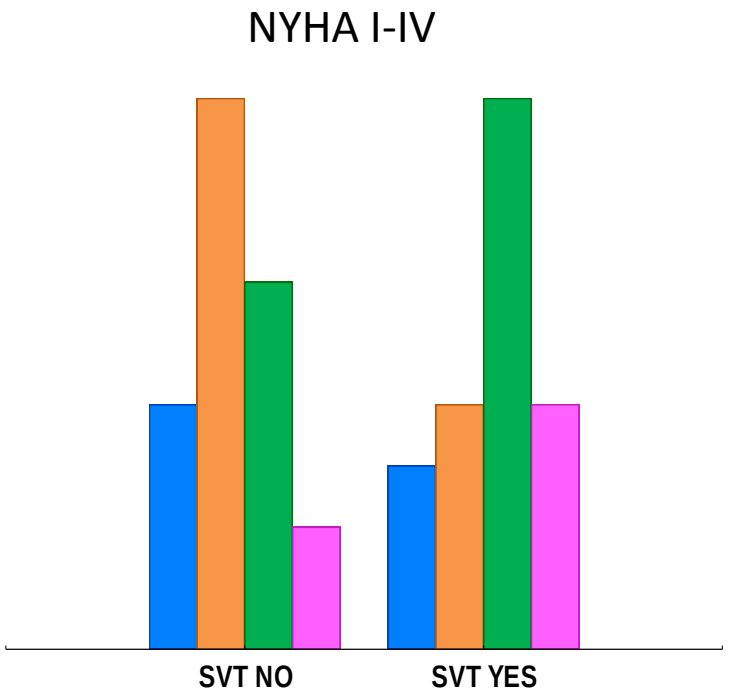
Author / year	Incidence	Significance of SVT
Ruiz-Cano / 2011	SVT 10%	SR ↑ clinical outcome
Tongers / 2007	SVT 12%	SR ↑ clinical outcome
Wen / 2014	AF + AFL 14%	Permanent AF ↑ mortality
Olsson / 2013	AF + AFL 25%	Absent SR ↑ mortalita
Rottlander / 2011	AF 31%	SR ↑ clinical outcome
		Mix pre- and post-capillary PH



Tongers et al., 2007.

Clinical profile of patients with pulmonary hypertension and arrhythmia

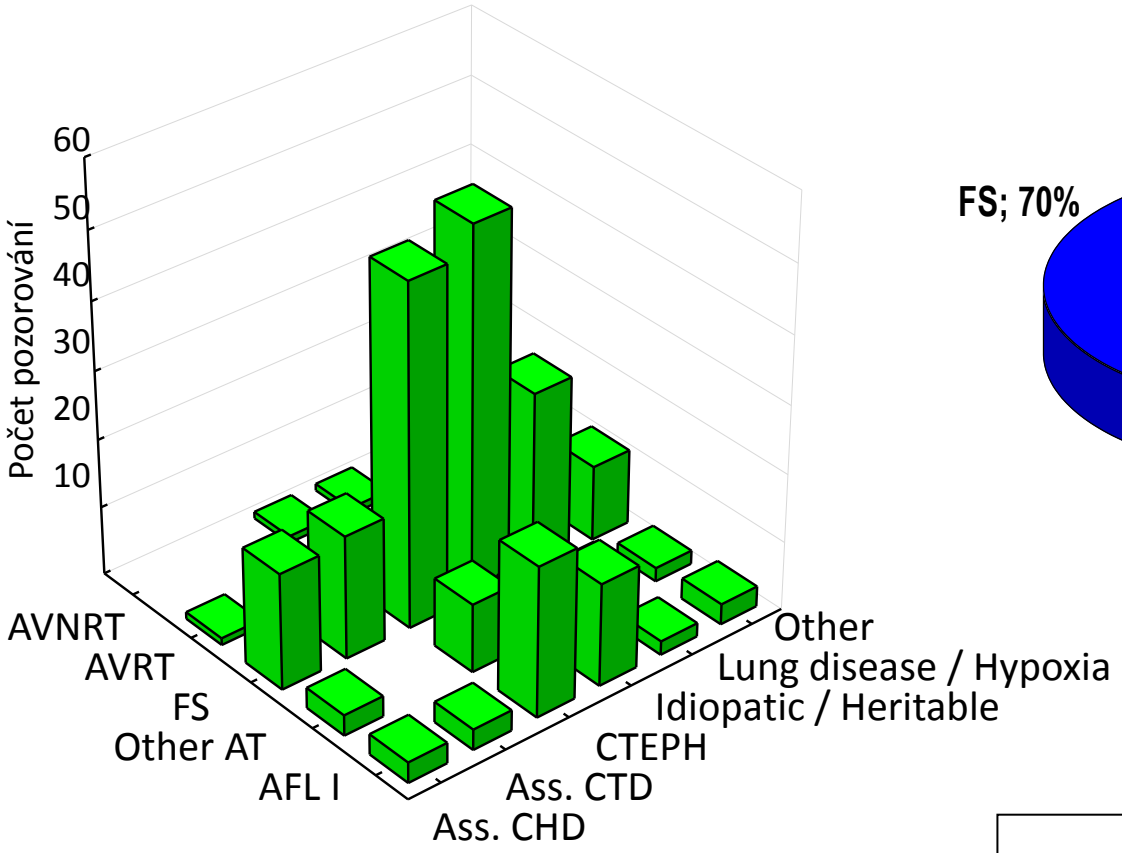


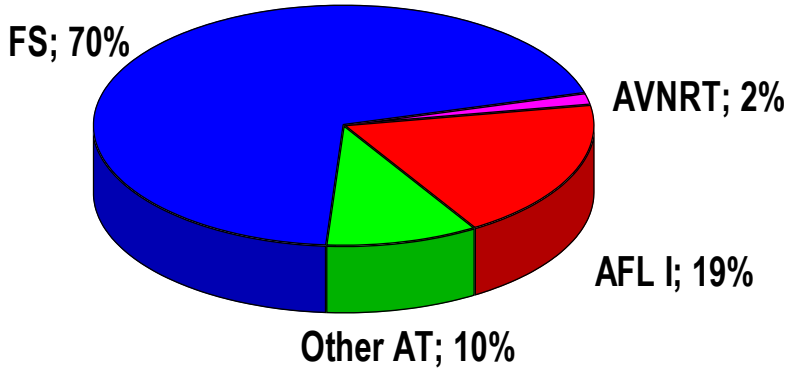


Parametr (Ø±SD)	SVT YES n = 291	SVT N0 n = 750	p
Age (years)	64 ± 13	57 ± 16	0.001
NYHA (I-IV)	2.9 ± 0.9	2.3 ± 0.8	0.02

Fingrova. Z. 2021.
Havranek. S. 2020.

Pulmonary hypertension and cardiac arrhythmia



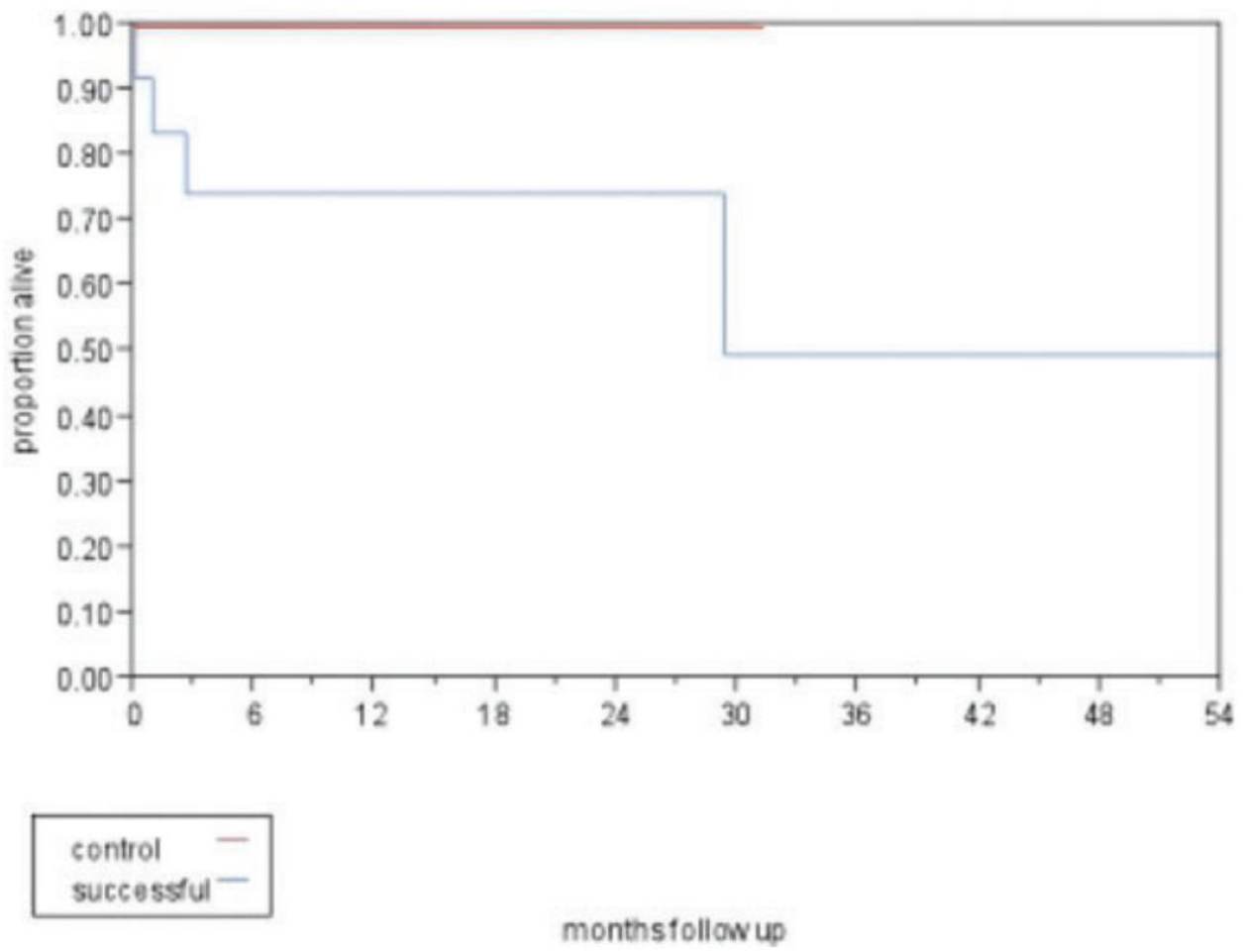


952 PH patients screened
Prevalence of SVT = 288 (30%)

Fingrova. Z. 2021.
Havranek. S. 2020.

Exact treatment strategy of AF / AT in PH has not been definitively established.

Case	Flutter Cycle Length (ms)	Activation Pattern CW = Clockwise CCW-Counter-Clockwise	Catheter	Fluoro Time (min)	Total RF Lesions	Lesions for Initial Block	Acute Success
1	[illegible]	[illegible]	[illegible]	72	76	76	Yes
2				'3.1	30	7	Yes
3				:7.7	15	10	Yes
4				known	94	94	Yes
5				9.8	51	36	Yes
6				40	24	NA	No
7				known	Unknown	NA	No
8				35	32	12	Yes
9				1.8	10	8	Yes
1				known	45	29	Yes
1				41	9	7	Yes
1				4.8	19	14	Yes
1				14	26	14	Yes
1				37	17	8	Yes



Significant number of recurrence of novel – not targeted – arrhythmia.

Bradfield J, et al. J Cardiovasc Electrophysiol. 2012;23(11):1185-90.

Grant project AZV: NV18-02-00027

Definitive treatment strategy was not established.

Catheter ablation of atrial fibrillation has no data.

Aim of the study: To investigate the hypothesis of whether more extensive radiofrequency catheter ablation of the bi-atrial arrhythmogenic substrate instead of clinical arrhythmia ablation alone results in superior clinical outcomes in patients with PH and supraventricular arrhythmias.

Principal investigator: Štěpán Havránek – VFN, Prague

Co-investigator: Tomáš Skála – FN OL, Olomouc

Co-investigator: Adrian Reichenbach – IKEM, Prague

Study protocol

Two study arms:

A) Limited approach – catheter ablation of clinical arrhythmia only

B) Extensive approach – catheter ablation of clinical arrhythmia + substrate-based ablation

Study population

- **Pre-capillary PH** (PAMP ≥25 mmHg; PAWP ≤15 mmHg) or **combined post- a pre-capillary PH** (PAMP ≥25 mmHg; PAWP >15 mmHg; DPG ≥7 mmHg and/or PVR >3 W.U.).
- Age >18 years
- **Atrial fibrillation / atrial tachycardia scheduled for catheter ablation.**

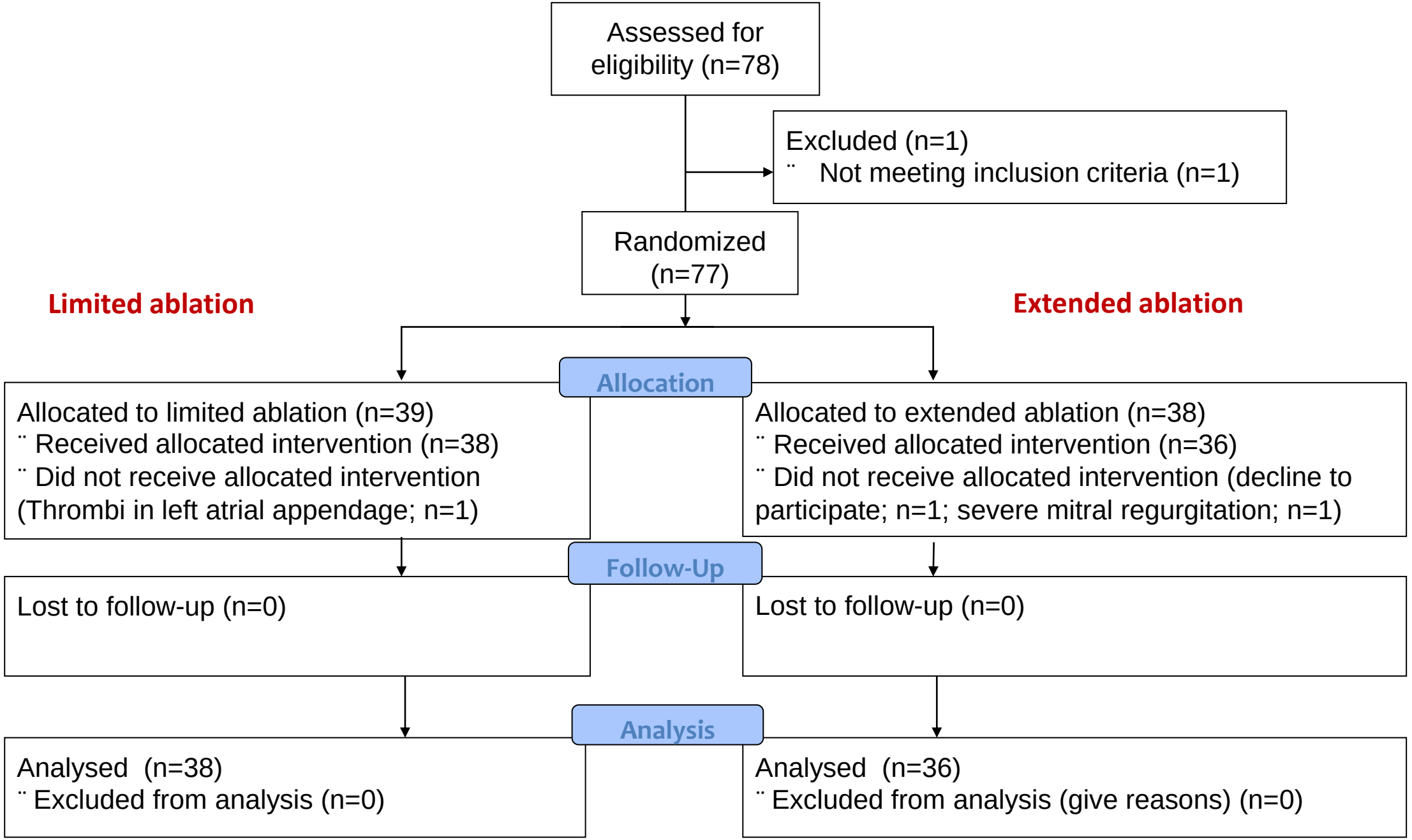
Study protocol

Primary endpoint

- Documented arrhythmia recurrence >30 seconds

Secondary endpoints

- On-drugs arrhythmia recurrence
- Symptoms of arrhythmia
- Number of emergency visits/hospitalizations
- Mortality
- Procedure-related major complication rate
- Antiarrhythmic drugs
- Re-ablation
- Pacemaker implantation
- Atrioventricular junction ablation.


Assessed for eligibility (n=78)
Excluded (n=1)
¨ Not meeting inclusion criteria (n=1)
Randomized (n=77)
Limited ablation
Extended ablation
Allocation
Allocated to limited ablation (n=39)
¨ Received allocated intervention (n=38)
¨ Did not receive allocated intervention (Thrombi in left atrial appendage; n=1)
Allocated to extended ablation (n=38)
¨ Received allocated intervention (n=36)
¨ Did not receive allocated intervention (decline to participate; n=1; severe mitral regurgitation; n=1)
Follow-Up
Lost to follow-up (n=0)
Lost to follow-up (n=0)
Analysis
Analysed (n=38)
¨ Excluded from analysis (n=0)
Analysed (n=36)
¨ Excluded from analysis (give reasons) (n=0)

Baseline data

	Limited ablation N = 39	Extended ablation N = 38	p
Age (years)	69 (45-79)	72 (45-86)	NS
Males	24 (62 %)	18 (47 %)	NS
Pulmonary hypertension type			
- Pulmonary arterial hypertension	21 (54 %)	16 (42 %)	NS
- CTEPH	9 (26 %)	8 (29 %)	NS
- Lung disease / hypoxia	5 (15 %)	3 (11 %)	NS
- Other	4 (12 %)	1 (4 %)	NS
Arrhythmia type			
- AF total	20 (59 %)	20 (61 %)	NS
- Paroxysmal AF	8 (24 %)	5 (15 %)	NS
- Perzistent AF	9 (26 %)	12 (36 %)	NS
- Long-standing persistent AF	3 (9 %)	3 (9 %)	NS
- Atrial flutter type I	8 (24 %)	9 (27 %)	NS
- Other atrial tachycardia	5 (15 %)	4 (12 %)	NS
- Other arrhythmia	1 (3 %)	0 (0 %)	NS

Characteristics of ablations

	All patients N=74	Limited ablation N=38	Extended ablation N=36	p
Clinical arrhythmia present at baseline	28 (38%)	17 (45%)	11 (31%)	NS
SR present at baseline, clinical arrhythmia inducible	19 (26%)	11 (29%)	8 (22%)	NS
SR present at baseline SR, clinical arrhythmia non-inducible / not induced	14 (19%)	5 (13%)	9 (25%)	NS
Other than clinical arrhythmia present or induced at baseline	13 (18%)	5 (13%)	8 (22%)	NS
>1 arrhythmia in the history	10 (14%)	6 (16%)	4 (11%)	NS
>1 arrhythmia during the procedure	9 (12%)	5 (13%)	4 (11%)	NS

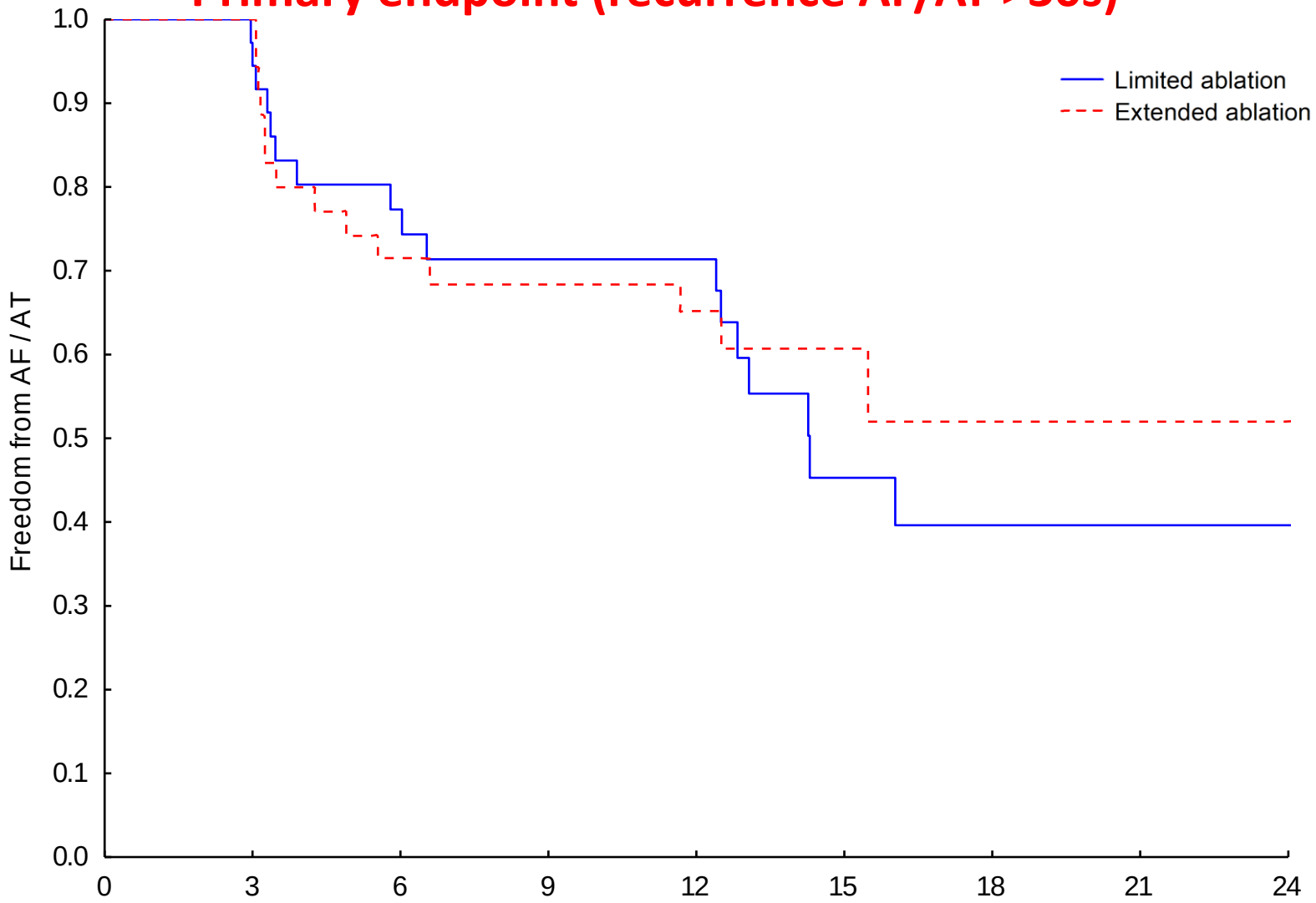
Characteristics of ablations

	All patients N=74	Limited ablation N=38	Extended ablation N=36	p
LA ablation	48 (65%)	21 (55%)	27 (75%)	0.15
- PVI alone	24 (32%)	10 (26%)	14 (39%)	NS
- PVI + additional lesions	22 (30%)	9 (24%)	13 (36%)	NS
- LA ablation without PVI	2 (3%)	2 (5%)	0 (0%)	NS
RA ablation	55 (74%)	22 (58%)	33 (92%)	0.0009
- CTI alone	17 (23%)	14 (37%)	3 (8%)	0.0036
- CTI + additional lesions	31 (42%)	2 (5%)	29 (81%)	<0.0001
- RA ablation without CTI	7 (9%)	6 (16%)	1 (3%)	NS
- SVC isolation	27 (36%)	1 (3%)	26 (72%)	<0.0001
- CFAE / LVA	14 (19%)	1 (3%)	13 (36%)	0.0002
- Intercaval line	26 (35%)	1 (3%)	25 (69%)	<0.0001
- RA/CS focal activity	4 (5%)	2 (5%)	2 (6%)	NS
- AVN slow pathway	3 (4%)	3 (8%)	0 (0%)	0.09

Characteristics of ablations

	Limited ablation N = 39	Extended ablation N = 38	p
Acute success	37 (94%)	36 (94 %)	NS
RA mapping	34 (88 %)	36 (94 %)	NS
- RA volume (CARTO)	214 (160-272)	207 (169-254)	NS
- RA surface (CARTO)	202 (174-235)	198 (174-216)	NS
- Area with reduced voltages (%)	7 (0-13)	8 (0-21)	NS
LA mapping	23 (68 %)	30 (91 %)	NS
- LA volume (CARTO)	122 (102-142)	114 (95-138)	NS
- LA surface (CARTO)	137 (124-157)	131 (111-153)	NS
- Area with reduced voltages (%)	4 (0-40)	6 (0-29)	NS
Procedure duration (min)	160 (131-180)	211 (160-243)	0.003
Fluoro time (min)	2.2 (1.4-6.0)	3.9 (2.1-8.5)	NS
RF time (min)	27 (18-42)	57 (39-70)	<0.001
No of ablation	36 (14-60)	74 (41-93)	<0.001
Serious complications	2 (5 %)	3 (8 %)	NS

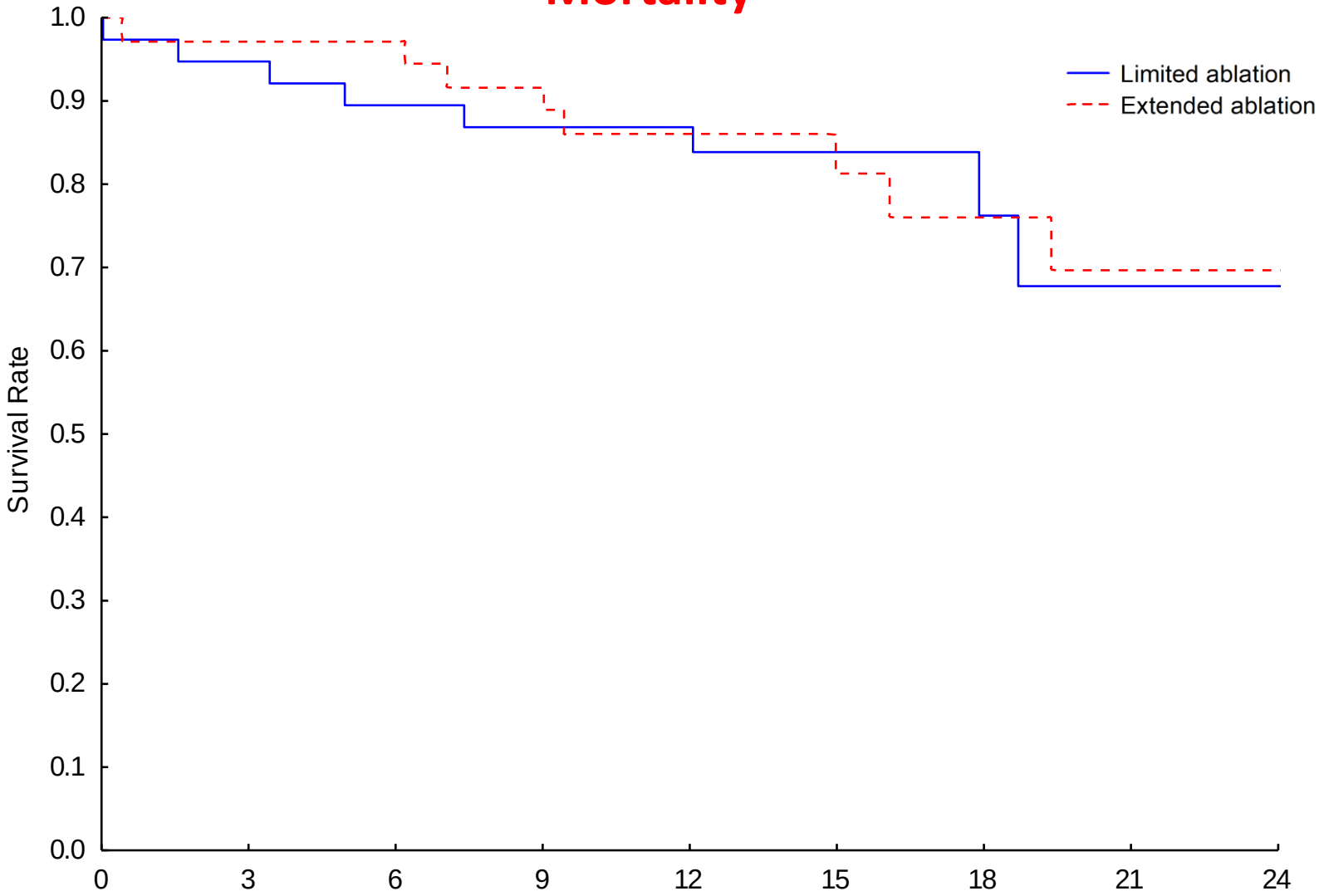
Primary endpoint (recurrence AF/AT >30s)



Patients at risk

Group A	38	35	26	23	21	8	6	4	4
Group B	36	34	24	21	19	7	6	5	3

Mortality

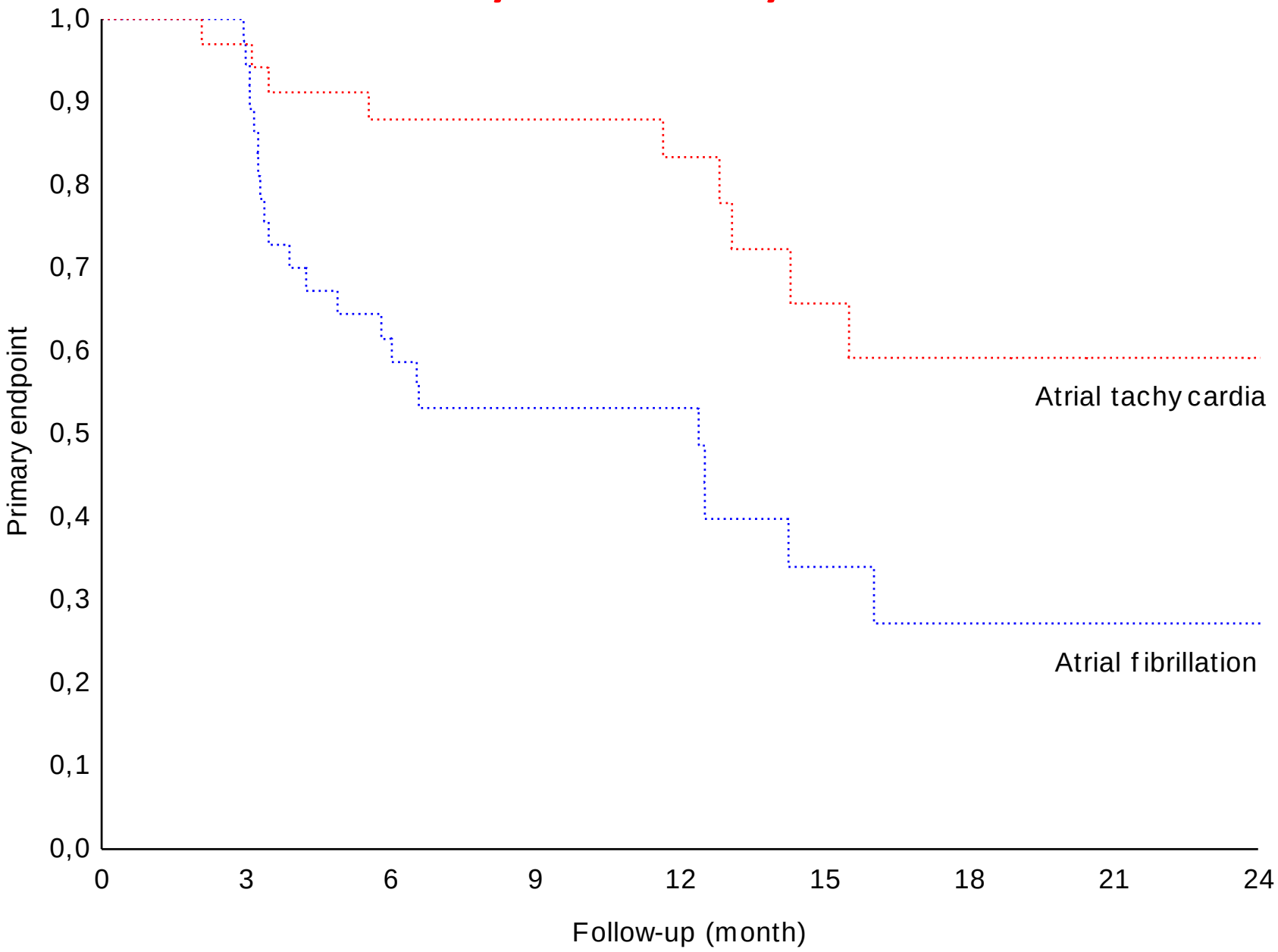


Patients at risk

Group A	38	36	34	33	29	14	10	6	6
Group B	36	35	35	32	30	16	14	10	8

	Limited ablation N=38	Extended ablation N=36	p
Primary endpoint	17 (45%)	15 (42%)	NS
Secondary endpoints			
- Documented on-drugs arrhythmia recurrence	10 (26%)	7 (19%)	NS
- Symptoms of arrhythmia	13 (34%)	10 (28%)	NS
- Patients with emergency visits / Number of emergency visits per patient	11 (29%) / 2 (1; 3)	9 (25%) / 2 (1; 2)	NS/NS
- Patients with hospitalization / Number of hospitalizations per patient	14 (37%) / 1 (1; 2)	13 (36%) / 2 (1; 2)	NS/NS
- Patients with cardiovascular emergency visits or hospitalization / Number of events per patient	13 (24%) / 1 (1; 3)	11 (31%) / 1 (1; 2)	NS/NS
- Mortality	9 (24%)	10 (28%)	NS
- Antiarrhythmic drugs (post-blanking period)	16 (42%)	7 (19%)	0.046
- Antiarrhythmic drugs (at the end of follow-up)	11 (29%)	7 (19%)	NS
- Reablation rate	5 (13%)	3 (8%)	NS
- Pacemaker implantation	3 (8%)	1 (3%)	NS
- AV junction ablation	0	1 (3%)	NS
Major procedural complications	5 (13%)	4 (11%)	NS

Rhythm subanalysis



Arrhythmia recurrences

	Limited ablation Total recurrences = 16		Extended ablation Total recurrences = 15	
Targeted arrhythmia	Recurrence of targeted arrhythmia, n	New* arrhythmia manifestation, n (type)	Recurrence of targeted arrhythmia, n	New* arrhythmia manifestation, n (type)
Atrial fibrillation	12	2 (AT)	7	2 (AT)
Typical AFL	0	1 (AF)	0	3 (1x AF + 2x AT)
AT	1	0	2	1 (AF)

Complications and SAE

	All patients N=74	Limited ablation N=38	Extended ablation N=36
Major procedural complication	9	5	4
- Vagal reaction with short cardiopulmonary resuscitation	1	1	0
- Arteriovenous fistula with surgical intervention	1	0	1
- Low cardiac output syndrome with prolonged hospitalization	1	0	1
- Progression of heart failure and death within 30 days	1	0	1
- Progression of chronic pericardial effusion treated conservatively	1	1	0
- Severe sinus bradycardia and permanent cardiac pacing after the procedure	3	2	1
- Sudden pulseless electrical activity 24 h after ablation	1	1	0
1-year death (>30 days after the procedure)	9	5	4
- PH and/or heart failure progression	4	3	1
- Intracranial bleeding	1	0	1
- Malignancy	1	1	0
- Unexplained	3	1	2

Conclusion

Extensive catheter ablation, compared with a limited approach, was not beneficial in terms of arrhythmia recurrence in patients with AF / AT and PH.

The absence of clear advance in the context of the prolonged procedural time in the PH population warrants the conclusion that performing additional, and perhaps unnecessary, ablation lesions should be generally avoided.

Patients with ATs manifested better outcome than AF patients.

No typical AFL recurrence was documented.

Thank you!