

# DECLARATION OF CONFLICT OF INTEREST

# Euro Observational Research Programme:

## Atrial Fibrillation Ablation Pilot Registry

### Short-term results

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## Atrial Fibrillation Ablation Pilot Study: a new feature of the EURObservational Research Programme

### Primary endpoint

To describe the clinical epidemiology of patients undergoing an AFib ablation procedure, and the diagnostic / therapeutic processes applied in these patients across Europe.

#### Specific aims

- To describe the demographic, clinical, and biological characteristics of patients undergoing a first AFib ablation procedure.
- To describe the diagnostic and therapeutic approaches undertaken in the routine practice of cardiologists performing AFib ablation procedures.
- To assess the acute and chronic outcomes.
- To assess the short- and long-term safety/complications of the procedure.
- To assess how the participating centres evaluate the success of the procedure during the follow-up.
- To evaluate how the recommendations of the most recent European guidelines are adopted in clinical practice.

# Atrial Fibrillation Ablation Pilot Registry

## Methods

### Study design

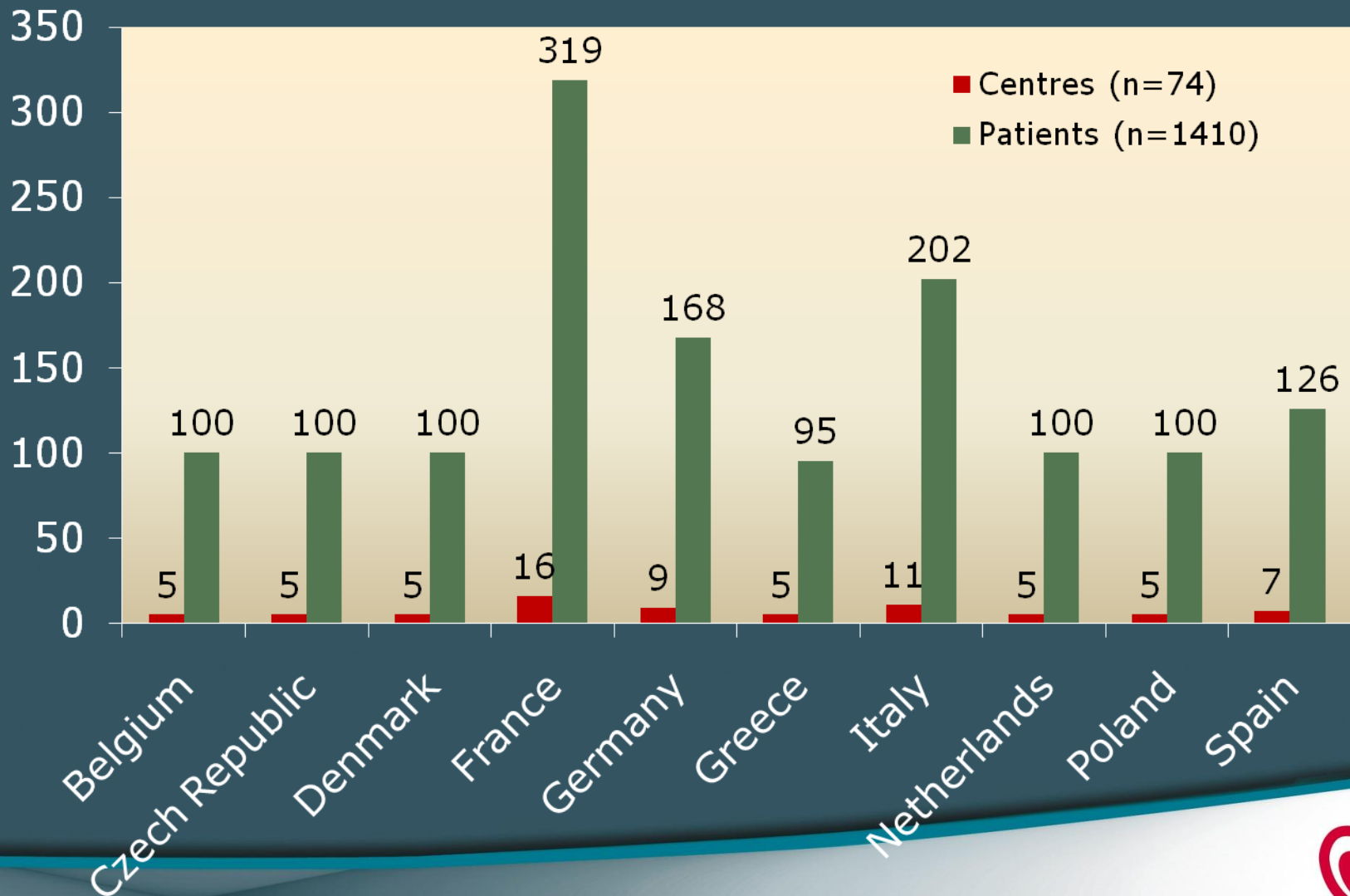
Prospective, multicentre, observational survey of consecutive patients (20 patients/centre) undergoing a first AFib ablation procedure, followed-up for 1 year.

- ✓ **4 Western European countries:** Belgium, France, Germany and the Netherlands.
  - ✓ **2 Eastern European countries:** Czech Republic and Poland.
  - ✓ **3 Southern European countries:** Greece, Italy and Spain.
  - ✓ **1 Northern European country:** Denmark.

**Site selection** hospitals with  $\geq 50$  AFib ablation procedures/year

# Atrial Fibrillation Ablation Pilot Registry

## Final Results



# Atrial Fibrillation Ablation Pilot Registry

## Final Results

**Number of locked patients**

1410



**Afib Ablation procedure**

1391

**Reasons why Ablation  
Procedure was not performed**

- Complications not related to procedure 3 pts
  - Complications related to procedure 16 pts
- ↓
- Cardiac tamponade following transeptal puncture 7 pts
  - Intracardiac thrombus 7 pts
  - Cerebrovascular event 1 pt
  - Other 1 pt

# Atrial Fibrillation Ablation Pilot Registry

## Baseline characteristics 1

	All (n. 1410 pts)
Age (years), •median (IQR) •> 65 years, %	60 (52 – 66) 31.0
Females, %	27.9
Body Mass Index (kg/m <sup>2</sup> ) •median (IQR) •> 30 kg/m <sup>2</sup> , %	27 (25 – 30) 25.8
SBP (mmHg), •median (IQR) •> 140 mmHg, %	130 (120 – 140) 20.1
Creatinine (mg/dL), median (IQR)	0.9 (0.8 – 1.1)

# Atrial Fibrillation Ablation Pilot Registry

## Baseline characteristics 2

CHADS2 score	All (n. 1391 pts)
0	587 (42.2%)
1	98 (7.0%)
2	501 (36.0%)
3	172 (12.4%)
4	28 (2.0%)
5	5 (0.4%)

CHA2DS2-VASc score	All (n. 1391 pts)
0	294 (21.1%)
1	398 (28.6%)
2	348 (25.0%)
3	215 (15.5%)
4	80 (5.8%)
5	39 (2.8%)
6	11 (0.8%)
7	6 (0.4%)



# Atrial Fibrillation Ablation Pilot Registry

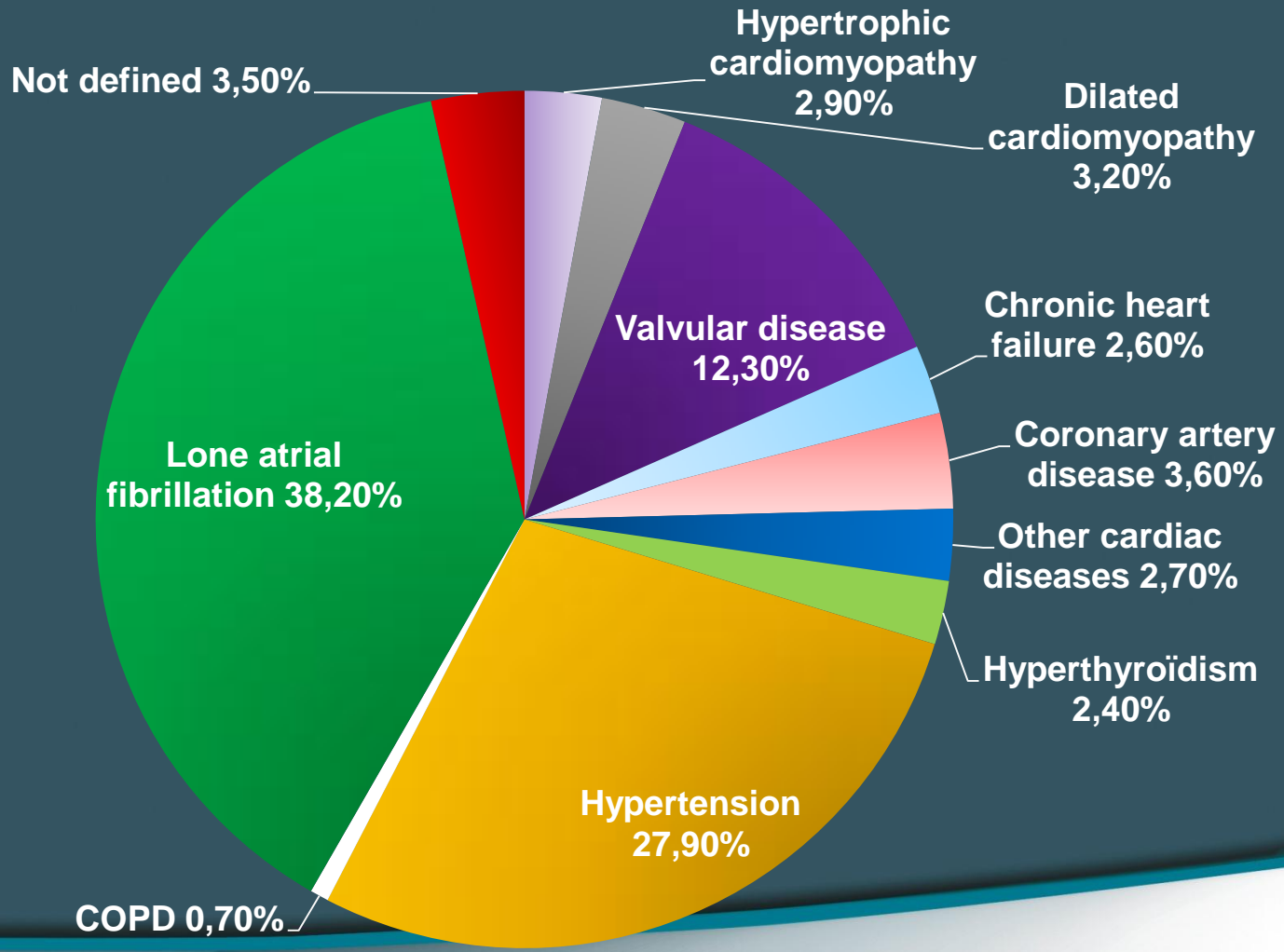
## Baseline characteristics 3

Risk factors	All (n. 1391 pts)
Diabetes mellitus, %	8.3
Hypertension, %	50.0
Active smokers, %	11.4
Hypercholesterolemia, %	31.6

# Atrial Fibrillation Ablation Pilot Registry

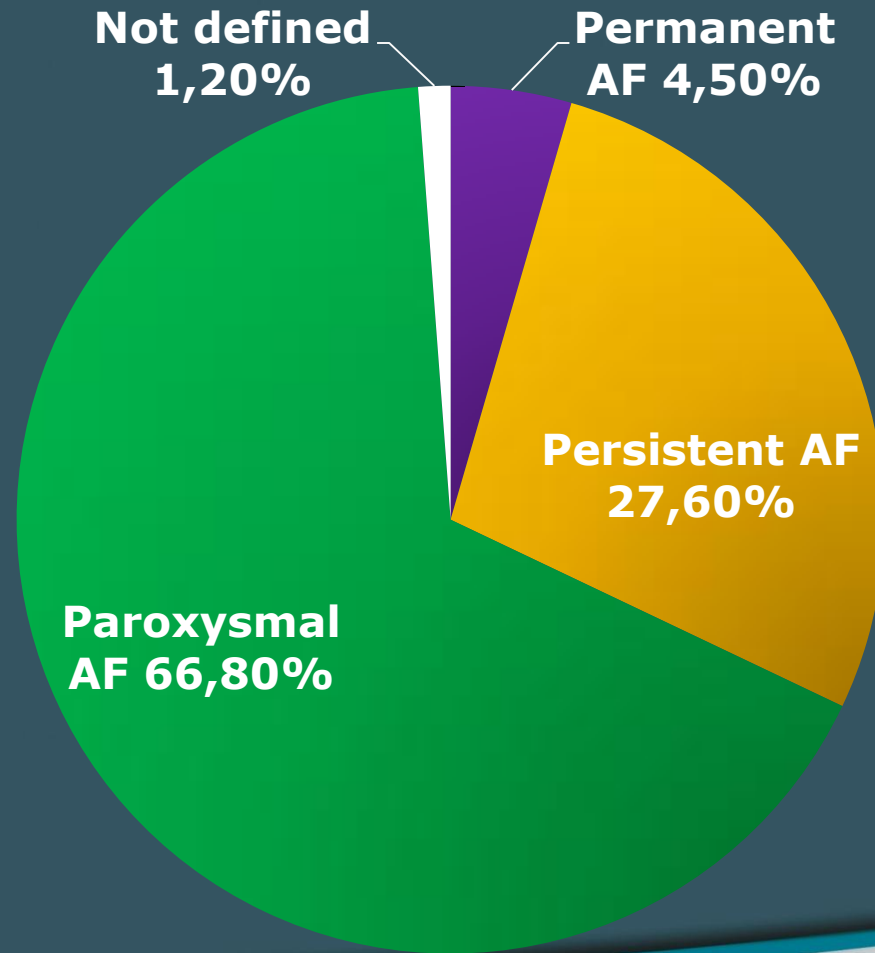
## Baseline characteristics 4

Underlying disease



# Atrial Fibrillation Ablation Pilot Registry

## Characteristics of AF 1



# Atrial Fibrillation Ablation Pilot Registry

## Characteristics of AF 2

	All (n. 1391 pts)
HR (bpm), median (IQR)	100 (81 – 120)
Number of episodes in the last month, median (IQR)	2 (1 – 7)
Associated symptoms, %	85.8
Prior electrical cardioversions, %	40.0
Prior pharmacological cardioversions, %	29.3

# Atrial Fibrillation Ablation Pilot Registry

## Characteristics of AF 3

Symptoms during AF	All (n. 1391 pts)
Palpitations, %	72.3
Syncope, %	3.8
Fatigue, %	41.8
Chest pain, %	10.4
Dizziness/Presyncope, %	13.7
Weakness, %	24.4
Dyspnea, %	37.6
No symptoms, %	13.1
Unknown, %	1.1

# Atrial Fibrillation Ablation Pilot Registry

## Procedures during hospital stay 1

	All (n. 1391 pts)
Electrocardiogram, %	98.4
Transthoracic echocardiogram, %	57.8
Coronary angiography, %	3.0
Holter, %	23.7
Exercise test, %	3.2
EP study, %	13.9
Transesophageal echocardiogram, %	67.2
CT scan	49.9
MRI scan	10.6

# Atrial Fibrillation Ablation Pilot Registry

## Ablation Procedure 1

Indications for ablation	All (n. 1391 pts)
Symptoms, %	89.7
Quality Of Life, %	73.4
Desire for drug-free lifestyle, %	34.9
Desire for sinus rhythm, %	39.6

# Atrial Fibrillation Ablation Pilot Registry

## Ablation Procedure 2

General information	All (n. 1391 pts)
Use of 3D mapping system, %	77.4
Use of remote navigation and ablation system, %	7.4
Use of rotational angiography for 3D reconstruction, %	4.0
General anesthetic during procedure, %	21.2
Intracardiac echocardiogram during procedure, %	17.9
Transesophageal echocardiogram during procedure, %	10.5
Procedure duration (min), median (IQR)	180 (130 – 220)
Fluoroscopy total time (min), median (IQR)	26 (15 – 45)



# Atrial Fibrillation Ablation Pilot Registry

## Ablation Procedure 3

Ablation modality	All (n. 1391 pts)
Non-irrigated radiofrequency, %	4.0
Radiofrequency with closed irrigation, %	2.2
Radiofrequency with open irrigation, %	77.8
Cryo, %	13.4
Duty-cycled radiofrequency energy, %	4.4
Laser balloon (endoscopic ablation system), %	0.8

# Atrial Fibrillation Ablation Pilot Registry

## Ablation Procedure

### Acute success

Yes	No	Unknown
978/1391 (70.3%)	182/1391 (13.1%)	231/1391 (16.6%)



- AF → SR during ablation, %: 31.1
- Non-inducibility of AF, %: 27.7

# Atrial Fibrillation Ablation Pilot Registry

## Adverse Events 1

No

1282/1391 (92.2%)

Yes

107/1391 (7.7%)

Unknown

2/1391 (0.1%)



	Yes (n. 107 pts)
CV, %	43.0
Peripheral/vascular, %	16.8
GI, %	0.9
Neuro, %	8.4
Pulmonary, %	7.5
General, %	5.6
Other, %	28.0

# Atrial Fibrillation Ablation Pilot Registry

## Adverse Events 2

Cardiovascular	N = 46 pts
Cardiac Arrest	1
Bradycardia requiring PM	3
Endocarditis	1
Myocardial infarction	1
Pericarditis	17
Cardiac perforation	11
No AF, atypical atrial flutter	4
Other	12

Peripheral / Vascular	N = 18 pts
A-V Fistula	6
Bleeding requiring transfusion	1
Hematoma requiring evacuation or transfusion	4
Peripheral thromboembolic event	1
Pseudo aneurysm	6

# Atrial Fibrillation Ablation Pilot Registry

## Adverse Events 3

Neuro	N = 9 pts
Phrenic Nerve Damage	2
Stroke	4
TIA	4

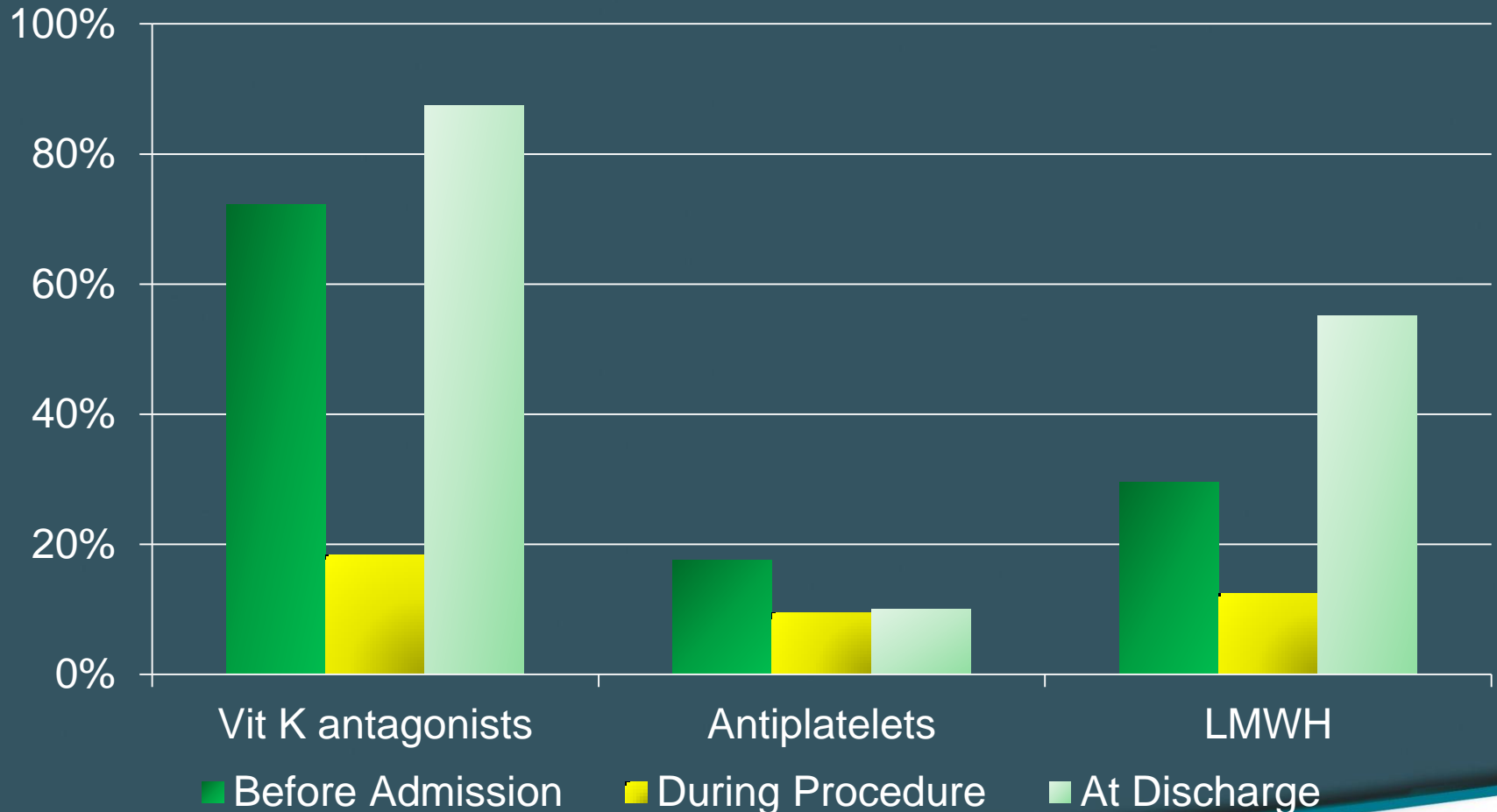
Pulmonary	N = 8 pts
Hemothorax	3
Pleural Effusion	2
Pneumothorax	1

General	N = 6 pts
Allergic Reaction	4
Sepsis	2

Gastrointestinal	N = 1 pt
Esophageal Ulceration	1

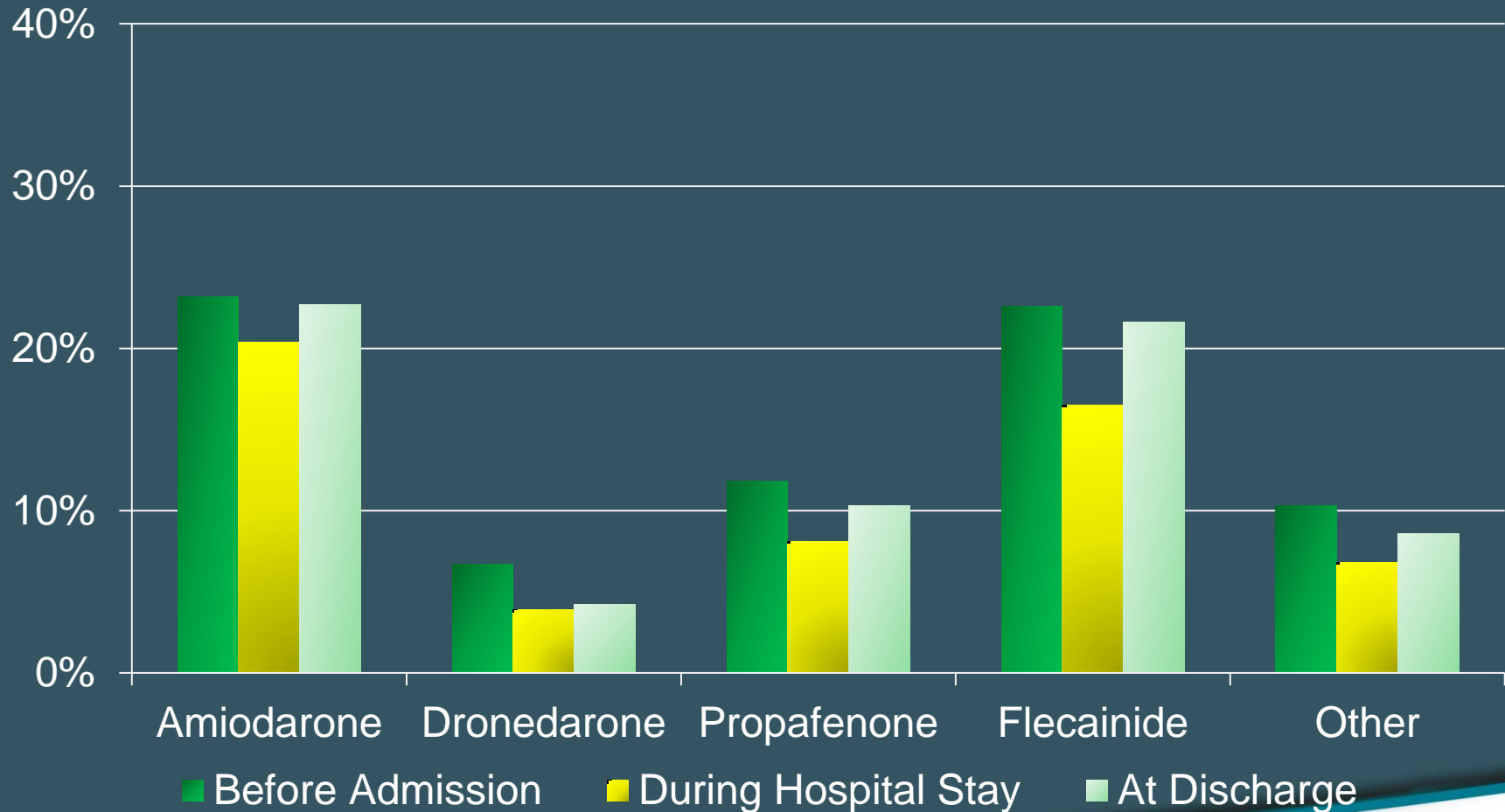
# Atrial Fibrillation Ablation Pilot Registry

## Medications: antithrombotics (n. 1391)



# Atrial Fibrillation Ablation Pilot Registry

## Medications: antiarrhythmics (n. 1391)



# Atrial Fibrillation Ablation Pilot Registry

## Discharge

	All (n. 1391 pts)
Length of stay (days), median (IQR)	3 (2 – 4)
Cardiac death not procedure related	1
Events not related to AF, %	2.9
CV, %	36.6
Non CV, %	63.4



# Atrial Fibrillation Ablation Pilot Registry

## Description of death

- Woman born on 02/08/1940
- Hypertrophic cardiomyopathy
- PM
- Hypertension
- Lung cancer radical operation in 1996
- Paroxysmal AF
- Ablation procedure on 01/04/2011
- Procedure duration = 95 min
- Acute success YES
- Cardiovascular AEs (cardiac arrest & endocarditis)

# Atrial Fibrillation Ablation Pilot Registry

## Conclusions

- ✓ The **Atrial Fibrillation Ablation Pilot Study** provides relevant information with regards to the current clinical practice across Europe.
- ✓ These data may prove useful when designing management strategies of patients suffering from atrial fibrillation.
- ✓ The Pilot experience has also provided invaluable information for the refinement of the data-set for its implementation in a long-term Atrial Fibrillation Ablation pan-European Registry.
- ✓ Evaluation of the results at the 12-month follow-up will give us more insight of real-life outcomes of the ablation of atrial fibrillation. Finally, further analyses by geographical areas may contribute by identifying local or more generalized needs in relation to this procedure.