

# NATURE-HF: NATional TUNisian REgistry of Heart Failure



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# DISCLOURE

I declare have no conflict of interest in this study.

This study was sponsored by the Tunisian Society of Cardiology and Cardiovascular Surgery

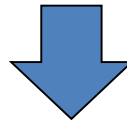
# Introduction

- ❑ HF is common and described as a true **pandemic** (prognostic improvement of heart diseases, aging of the population)
  
- ❑ HF is a serious pathology:
  - ❑ Annual mortality rate: 7 to 17%
  - ❑ 5-year-mortality rate: 50%
  
- ❑ Major economic impact:
  - ❑ Treatment
  - ❑ Hospitalization:
    - ❑ Early re-hospitalization at 30 days: 30%
    - ❑ 32 to 44% at 1 year



**Challenge**

Bias of Clinical Trials  
(Selected Patients)



Advantages of Clinical Registres  
(Real Life patients)



**STCCCV**  
Société Tunisienne de Cardiologie  
& de Chirurgie Cardio-Vasculaire

## National Tunisian Registry of Heart Failure



2017

NIH U.S. National Library of Medicine

ClinicalTrials.gov

<https://clinicaltrials.gov/show/NCT03085576>

# NAtional TUnisian Registry of Heart Failure

NCT03262675

## NATURE-HF



Tunisian Society of Cardiology and  
Cardiovascular Surgery



A non-interventional, national  
longitudinal study of heart failure  
performed with 200 cardiologists

START DATE  
October 2017

### Study Summary

The NATURE-HF is a national clinical non-interventional registry of heart failure, carried out in Tunisia at cardiology departments in hospitals and in liberal cardiology consultations. 100 cardiologists participate in the enrollment of the eligible patients as investigators. A Committee of Experts validates the protocol methodology and supervises the data-management. A Steering Committee helps investigators to monitor their patient inclusions, performs audit trails and prepares the statistical analysis plan for the study.

Collected data are managed by the DACIMA Clinical Suite®, the electronic data capture platform which complies with the FDA 21 CFR part 11 requirements (Food and Drug Administration 21 Code of Federal Regulations part 11), the HIPAA specifications (Health Insurance Portability and Accountability Act), and the ICH standards (International Conference on Harmonisation).

### Study Outcomes

- **Composite outcome** including incidence of cardiovascular death (sudden death, death from refractory heart failure and death from stroke), incidence of non-cardiovascular death and heart failure readmission. [Time Frame: At 1, 3 and 12 months from patient enrollment]
- Incidence of heart failure readmissions [Time Frame: At 1, 3 and 12 months from patient enrollment]
- Incidence of death of all causes (cardiovascular death and non-cardiovascular death). [Time Frame: At 1, 3 and 12 months from patient enrollment]
- Incidence of cardiovascular death including sudden death, death from refractory heart failure and death from stroke. [Time Frame: At 1, 3 and 12 months from patient enrollment]

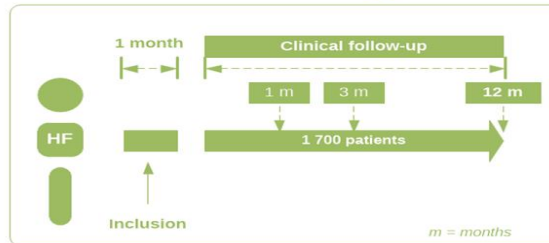
### Inclusion Criteria

- Patient with chronic heart failure
- Patient with acute heart failure (new onset or not)
- The diagnosis of heart failure is at the discretion of the investigator
- Informed and signed consent

Sexes Eligible for Study: All  
Ages: 20 Years and older (Adult, Senior)

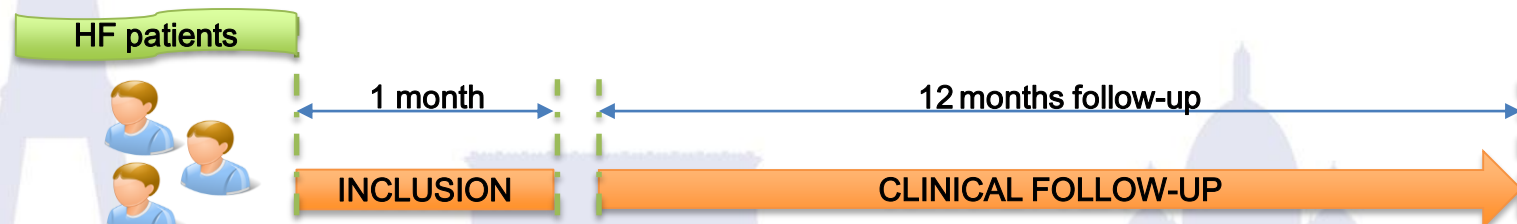
### Exclusion Criteria

- Life expectancy <12 months for extra cardiac disease
- Isolated Right Heart Failure
- Pregnant woman
- Renal failure with creatinine clearance < 15 ml / min
- Hemodialysis patients
- Cardiac surgery planned within 3 months
- Congenital heart disease



# Methodology

- National clinical non-interventional registry of heart failure, carried out in Tunisia at cardiology departments in hospitals and in liberal cardiology consultations.
- Longitudinal, observational, multicenter study including 2040 P suffering from acute or chronic Heart failure



2040 patients

October 16, 2017 to  
November 17, 2017



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## Inclusion Criteria

- Patient with chronic heart failure
- Patient with acute heart failure (new onset or not)
- The diagnosis of heart failure is at the discretion of the investigator
- Informed and signed consent

## Non Inclusion Criteria

- Life expectancy <12 months for extra cardiac disease
- Isolated Right Heart Failure
- Pregnant woman
- Renal failure with creatinine clearance < 15 ml / min
- Hemodialysis patients
- Cardiac surgery planned within 3 months
- Congenital heart disease

# Objectives

Describe the epidemiological profile of acute and chronic heart failure in Tunisia.

**Primary objective:** to assess the MORBI-MORTALITY of acute and chronic heart failure over one year of follow-up in Tunisia.

The morbidity and mortality of heart failure is defined by the occurrence of cardiovascular death (sudden death, ACS, refractory heart failure, stroke), death from any cause (cardiovascular and non-cardiovascular), rehospitalization for one year.





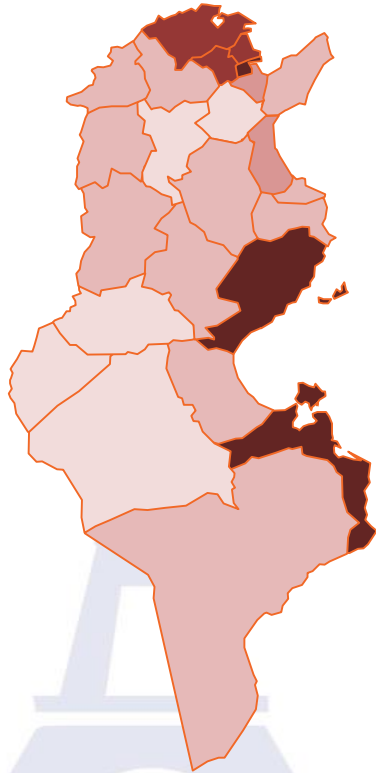
# Registry Objectives

## Secondary objectives:

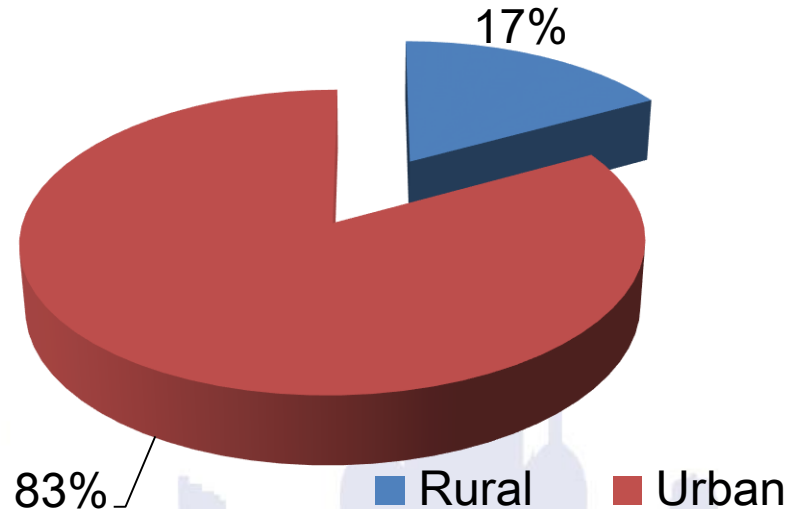
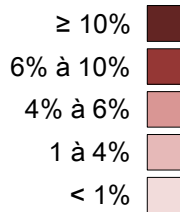
- Assess cardiovascular death incidence over one year of follow-up
- Assess the death rate of all causes on a follow-up of one year
- Describe the readmission rate for heart failure
- Identify the predictors of cardiovascular mortality
- Assess the adhesion to the European recommendations

# Baseline Characteristics

N = 2040

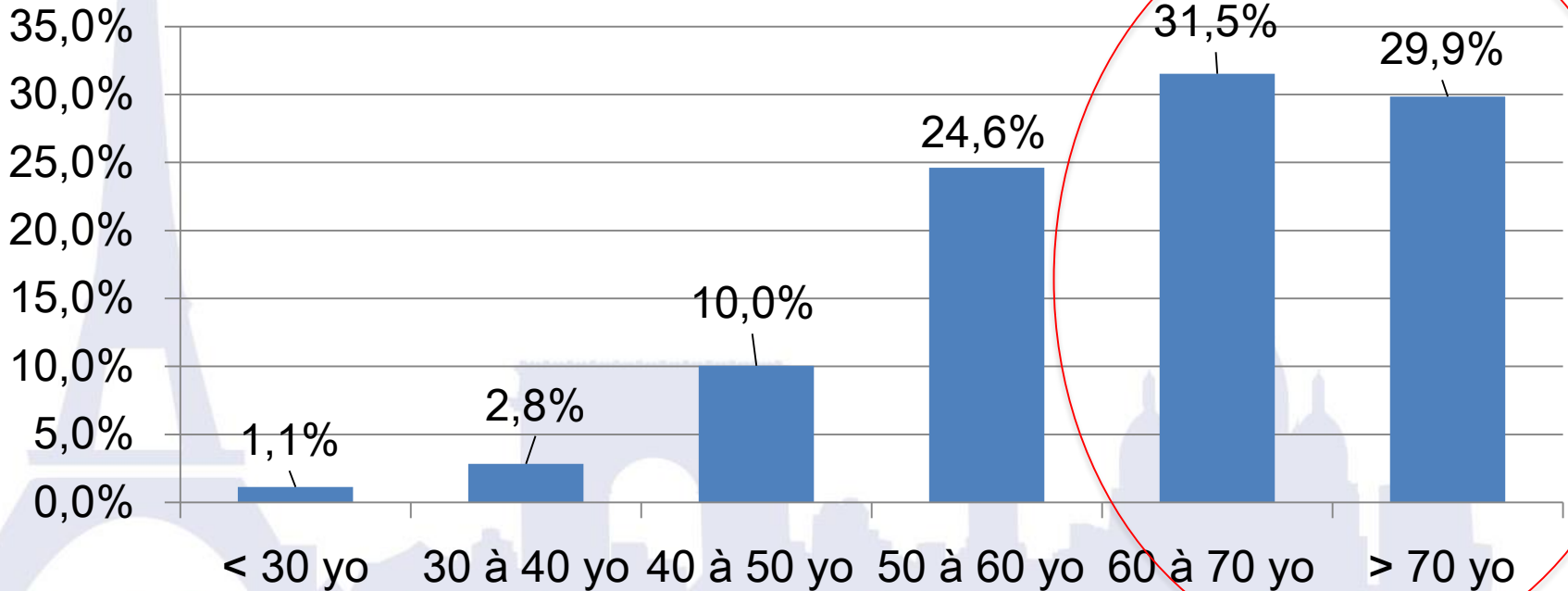


All tunisian regions included patients according to eligibility criteria



# Baseline Characteristics

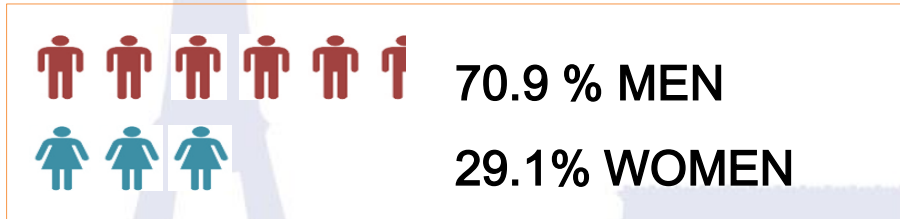
Population Age  
Mean age: 63.6 ans  $\pm$  12.6



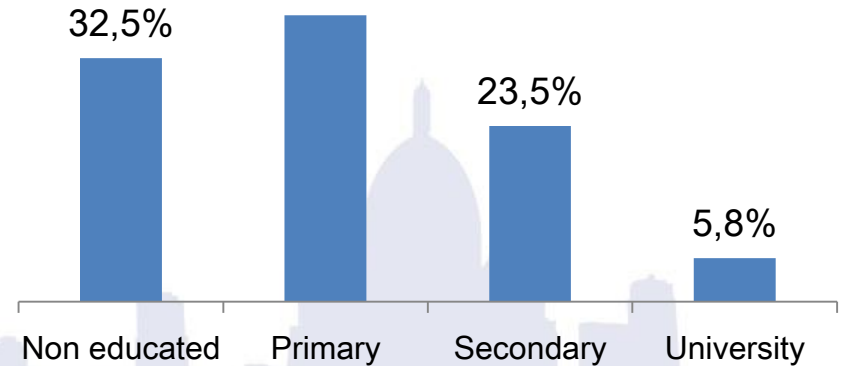
# Baseline Characteristics

Population demographics  
N = 2040

## Gender



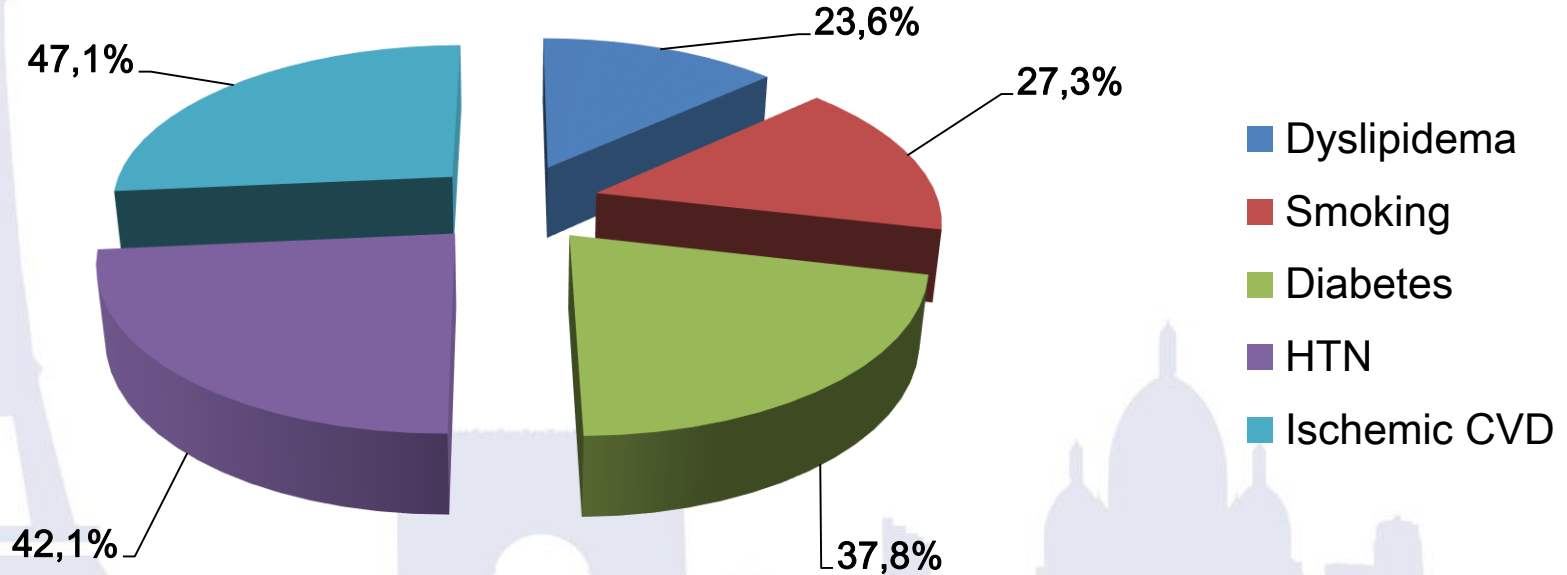
## Education



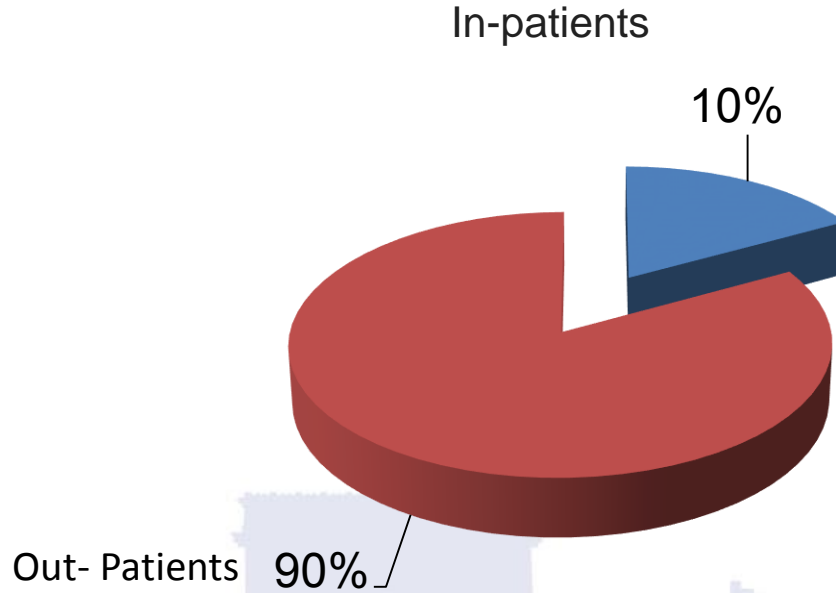
# Baseline Characteristics

## Patient History

N = 2040



## Baseline Characteristics

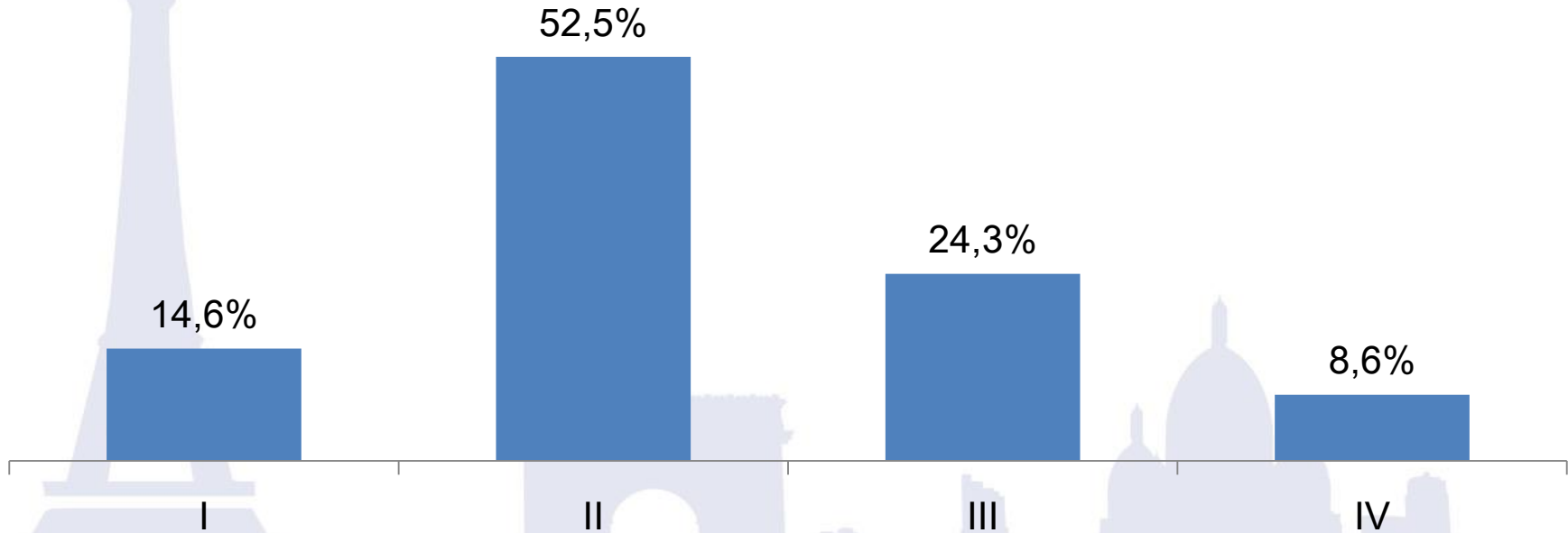


Chronic HF: 72,7%  
New onset HF: 27,3%

# Baseline Characteristics

## NYHA Classification

N = 2040

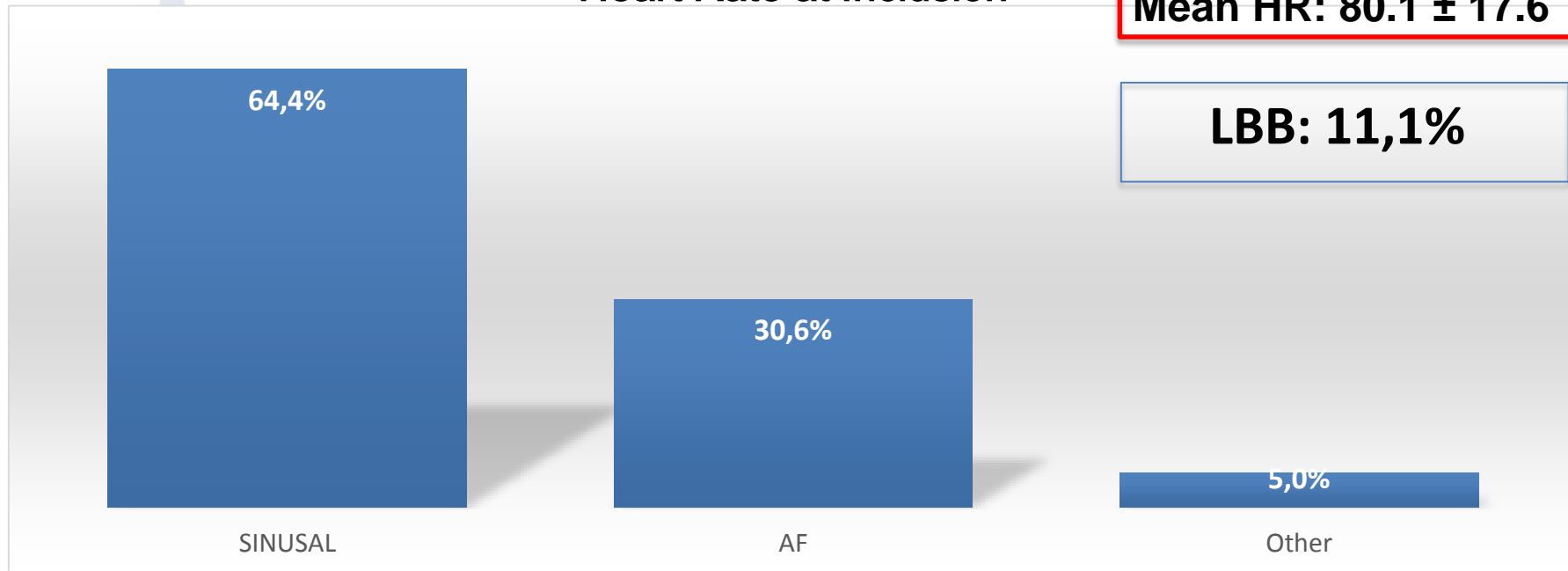


# Baseline Characteristics

## Heart Rate at Inclusion

**Mean HR: 80.1 ± 17.6**

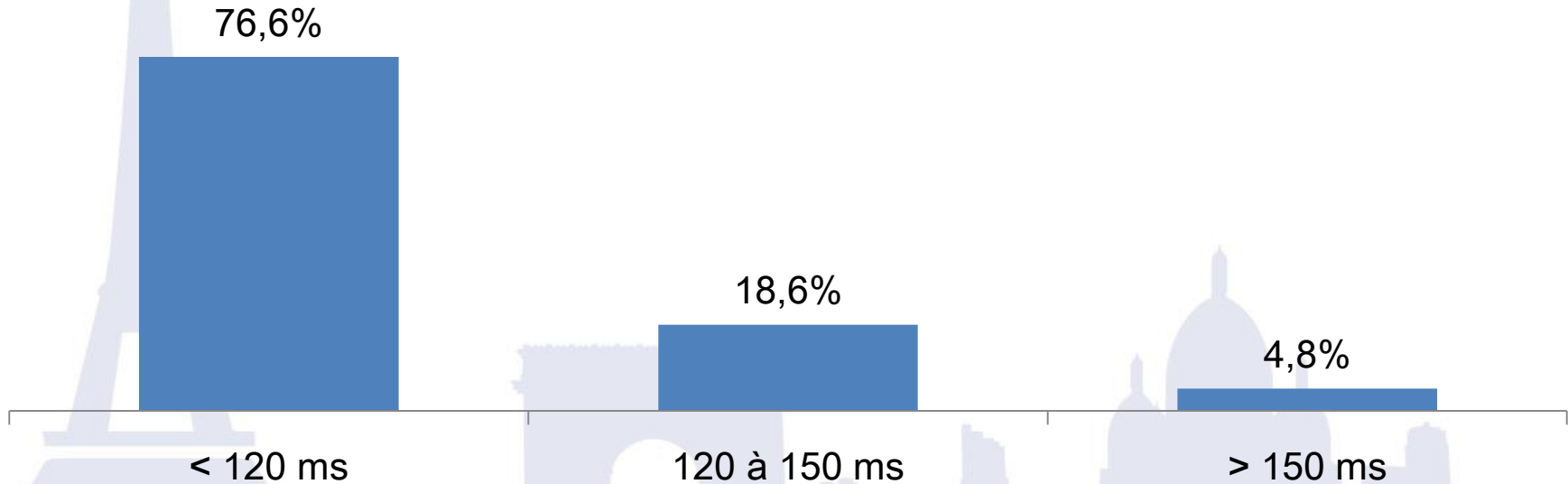
**LBB: 11,1%**



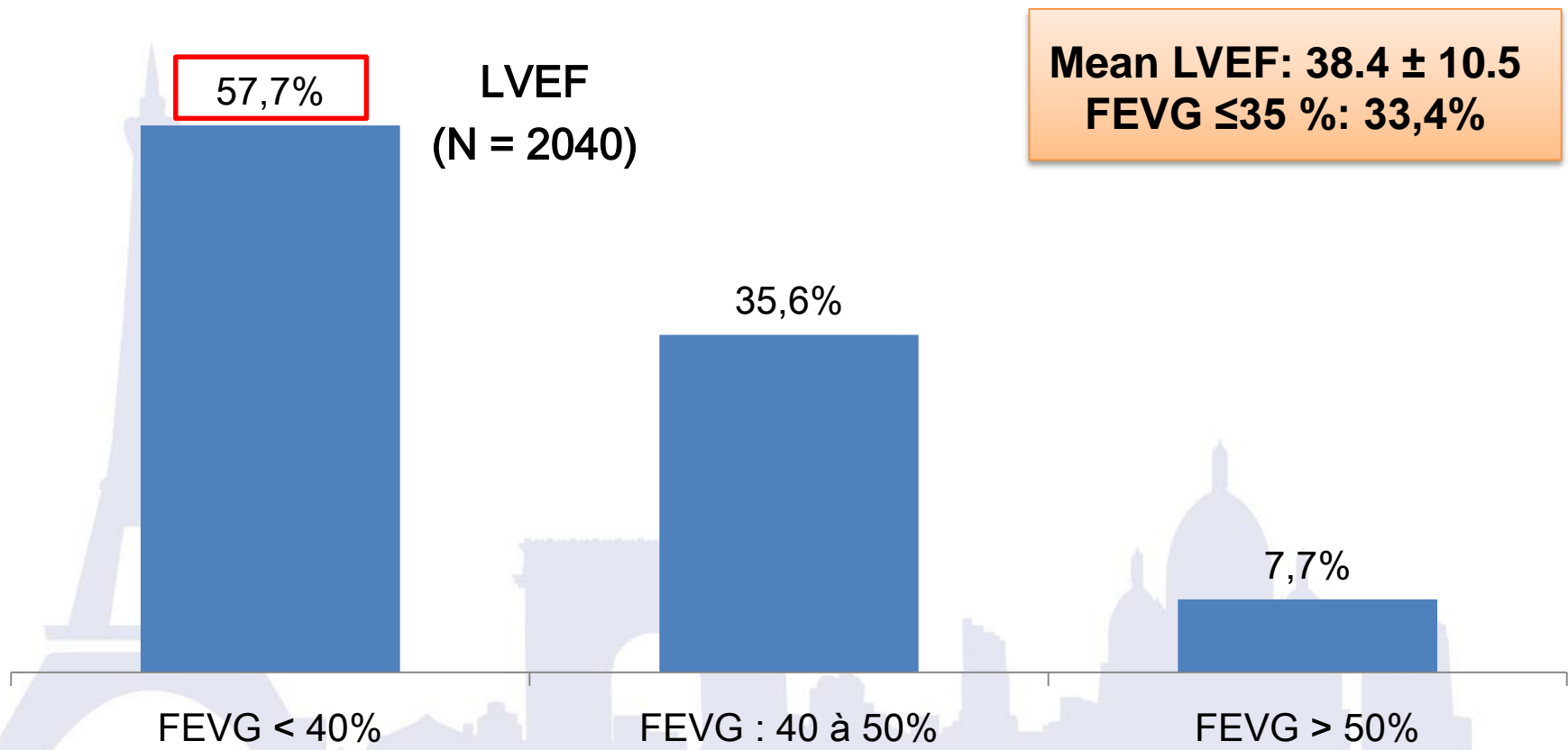


# Baseline Characteristics

QRS time  
N = 2040



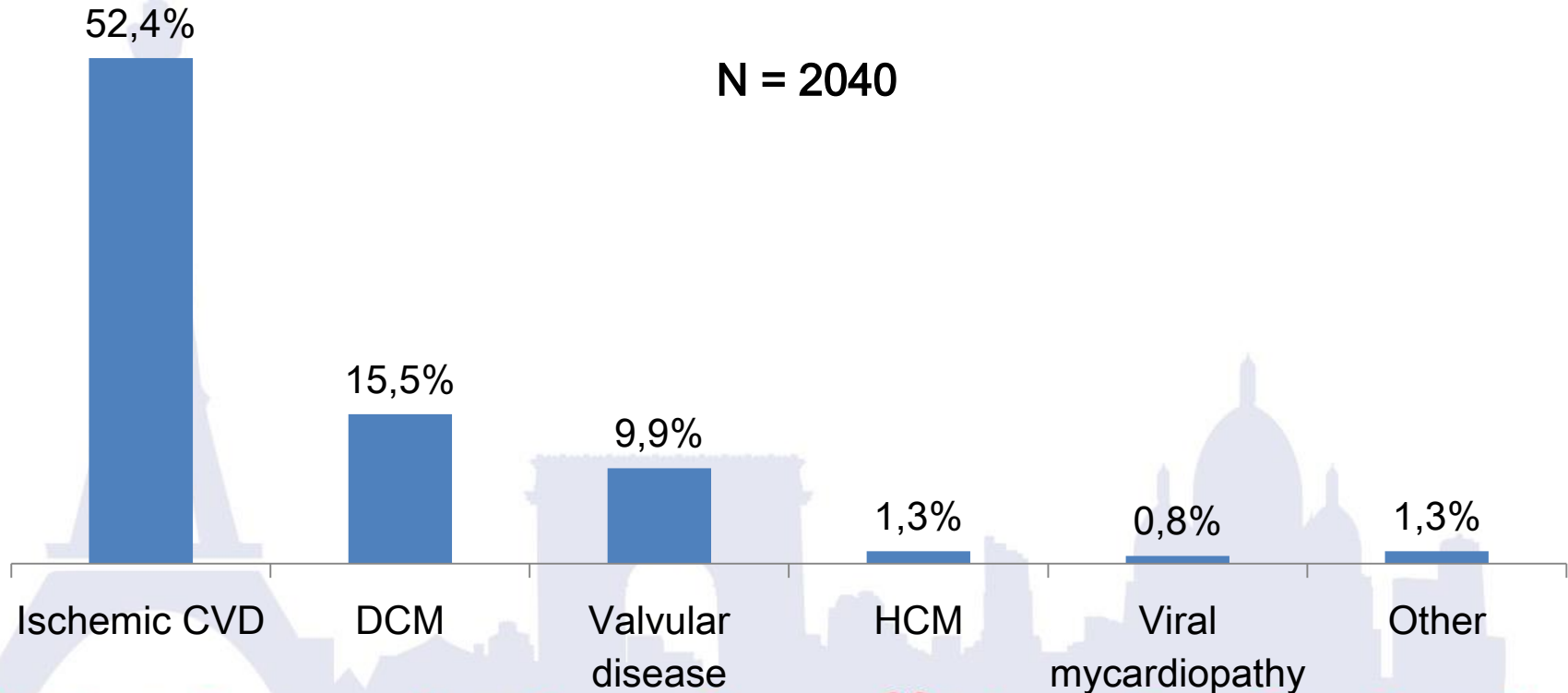
# Baseline Characteristics: left ventricular systolic function



# Baseline Characteristics

## HF Etiologies

N = 2040



# Baseline Characteristics

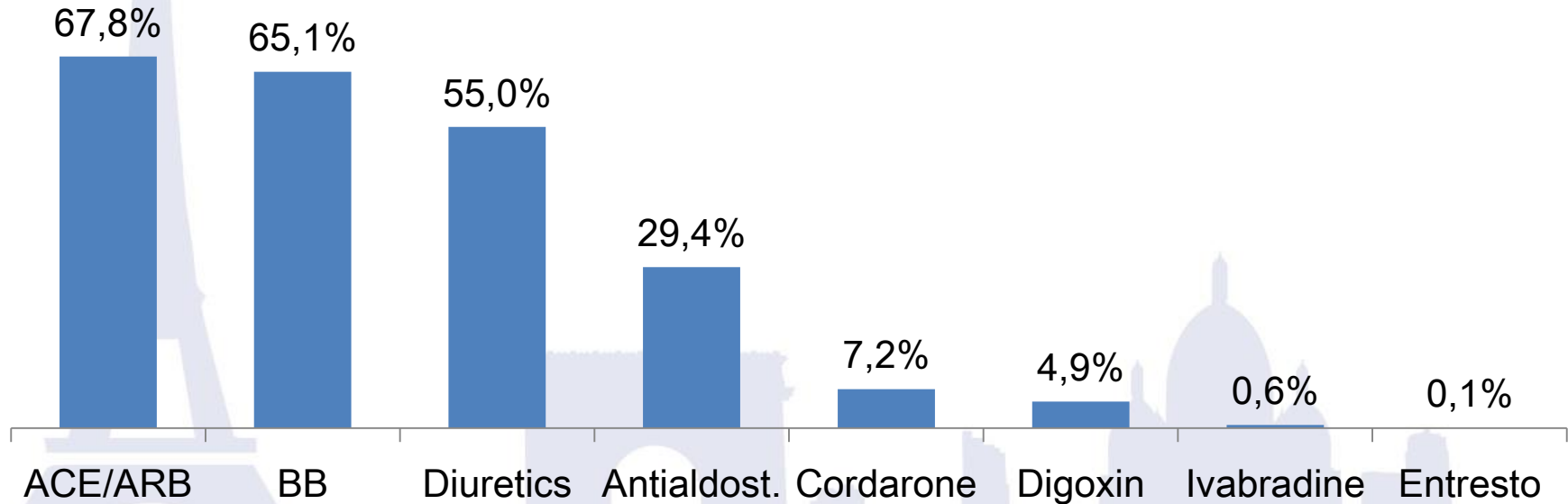
## Biological Characteristics

N = 2040

Endpoint	Statistics
Hb (g/dl)	12.7 ± 2.0
Anaemia	23.6%
Creatinine clearance (ml/min)	68.2 ± 26.0
> 60	87 %
30-60	11 %
15-30	2%
BNP (pg/ml)	332.9 ± 267.2
Rate of measured patients	2.7%

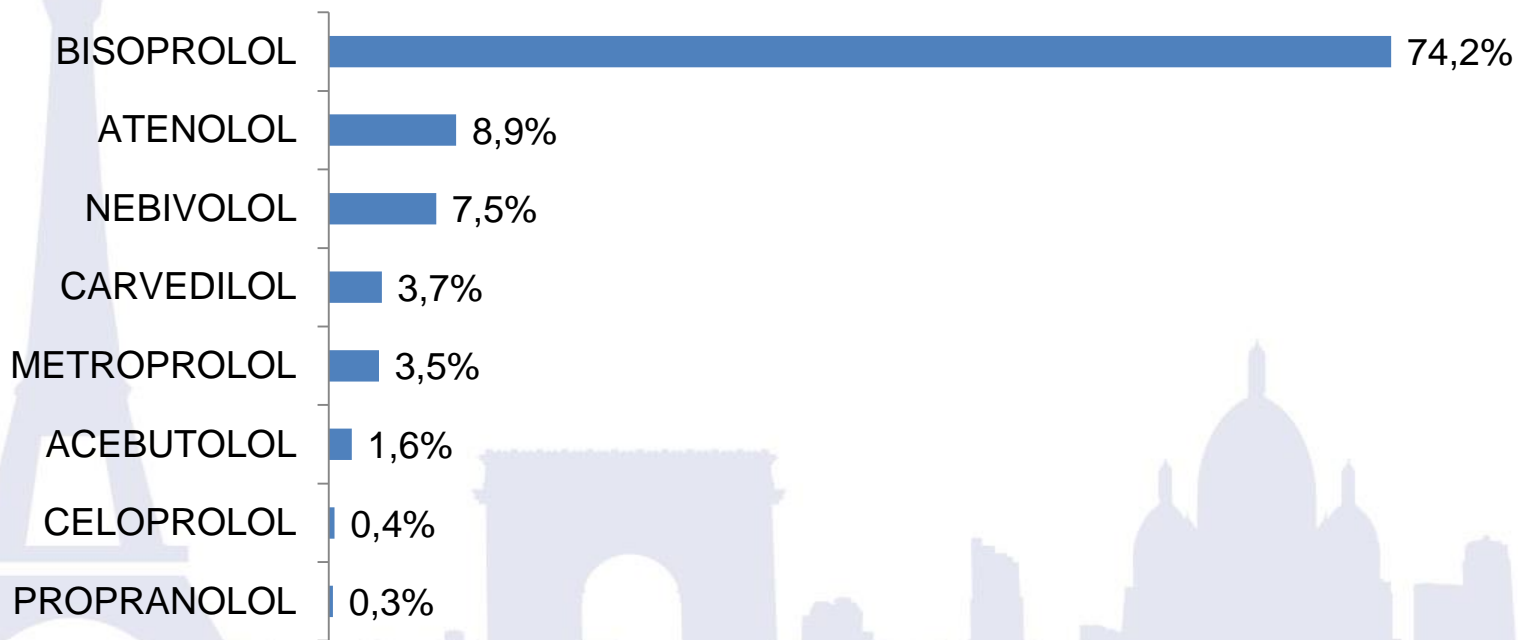
## HF Treatment

N = 2040



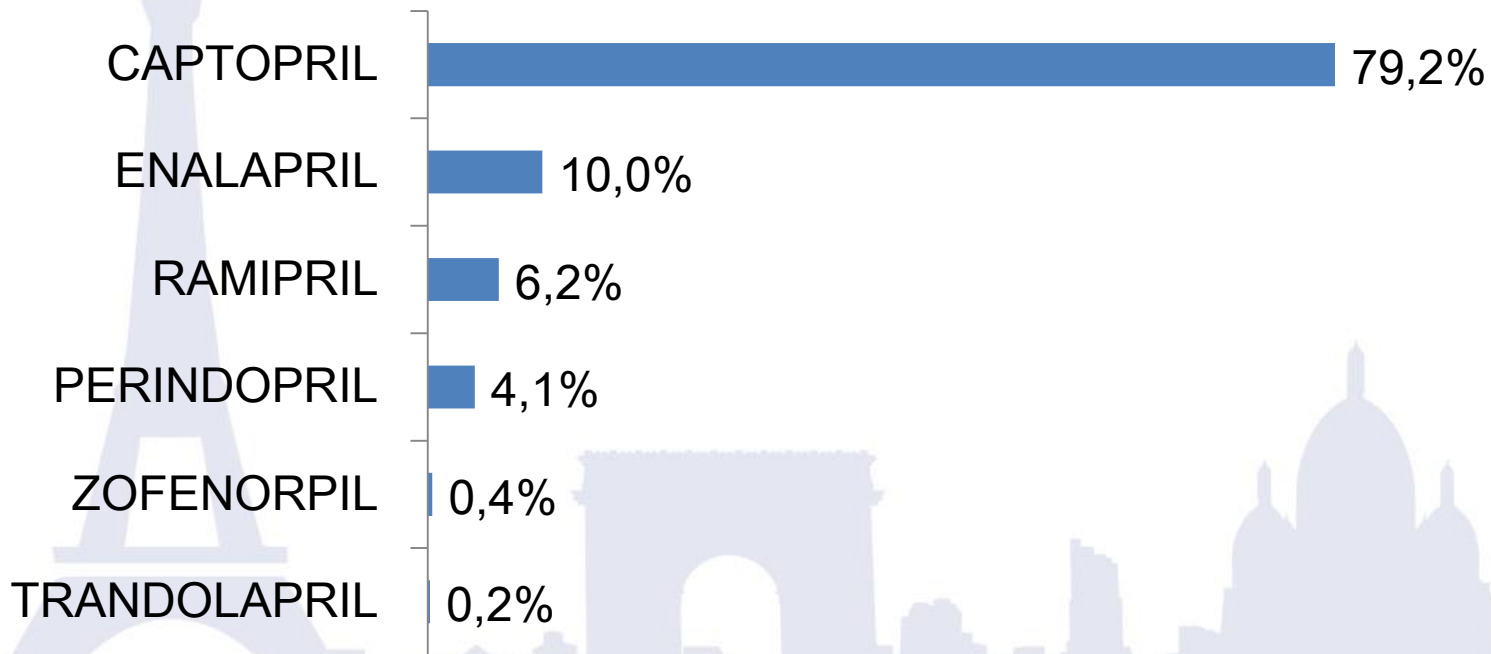
## HF Characteristics

### BETA BLOCKERS THERAPY



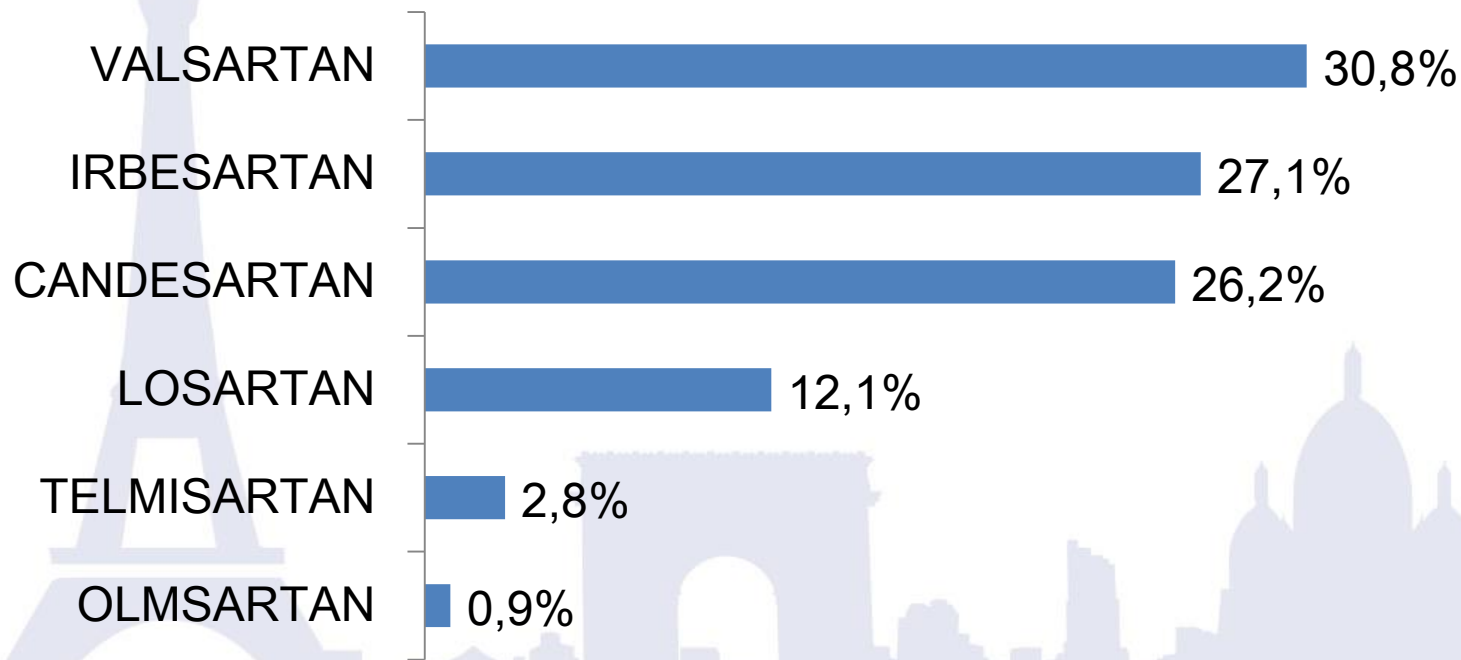
# HF Characteristics

## ACE THERAPY



# HF Characteristics

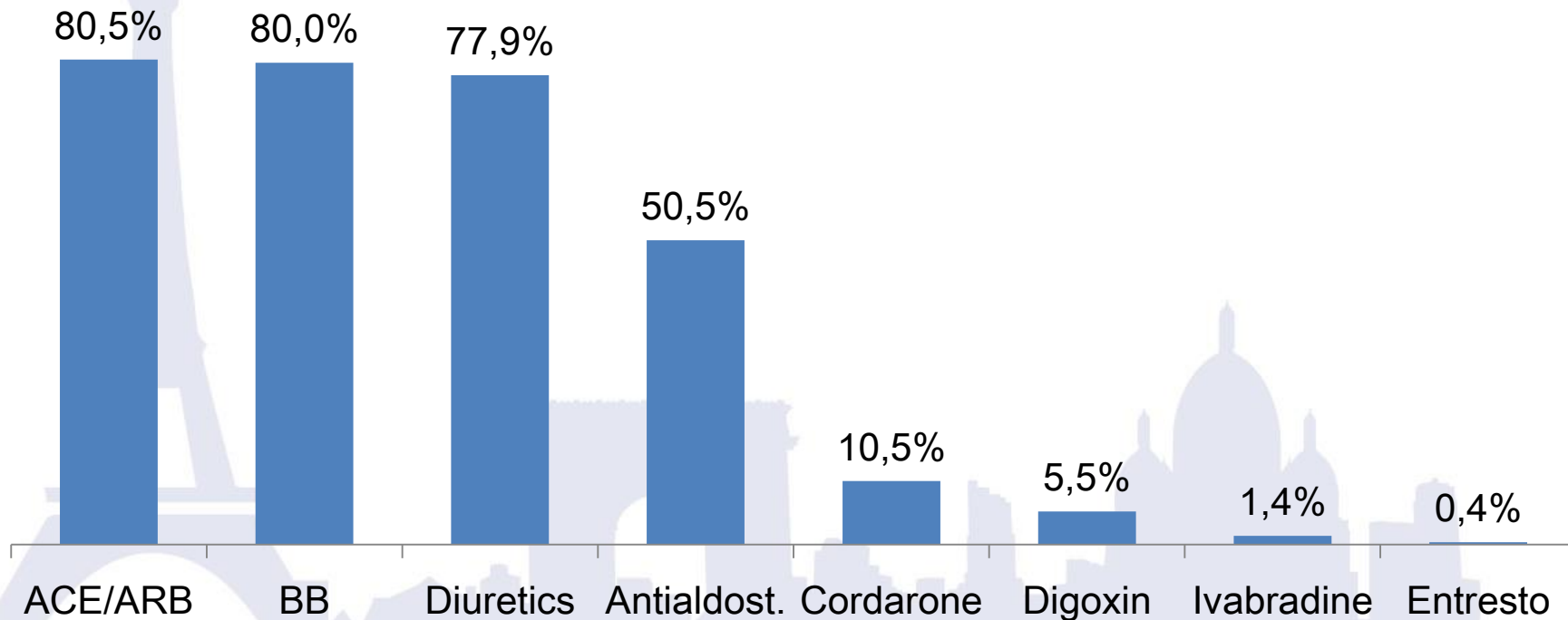
## ARB THERAPY





# HF Characteristics

## Treatment of patients with LVEF < 40%

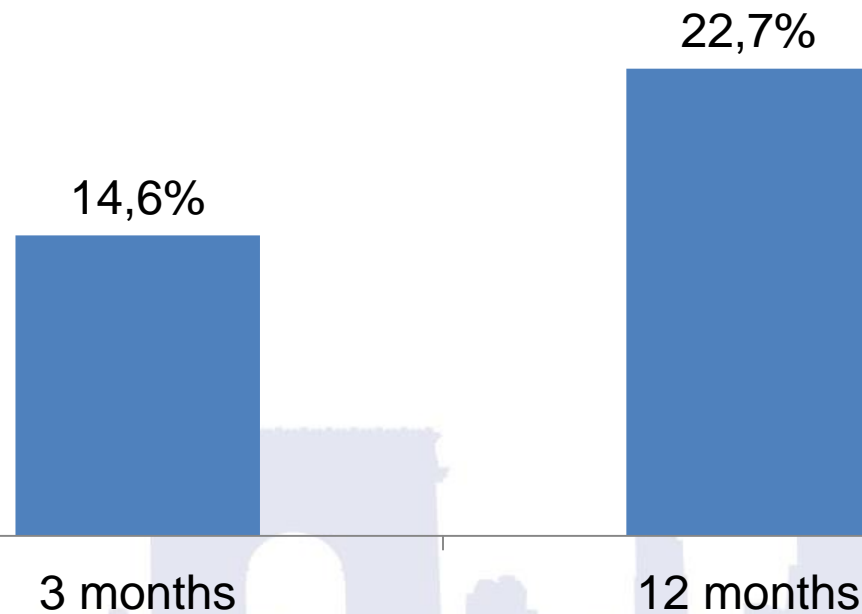


# HF Characteristics

## Predictive factors for therapeutic choice

	Endpoint	Yes	No	p
<b>B-Blockers</b>	Age (years)	63.1 ± 11.9	64.5 ± 13.8	0.014
	Gender (M)	72.8%	67.3%	0.009
	LVEF (%)	38.0 ± 9.8	40.1 ± 12.2	0.001
	Severe RV (Clear. < 30)	2.6%	2.1%	0.524
	COPD	2.8%	2.8%	0.976
<b>ACE/ARB</b>	Age (years)	63.3 ± 12.1	64.0 ± 13.7	0.241
	Gender (M)	71.2%	70.2%	0.659
	LVEF (%)	38.4 ± 10.0	38.6 ± 12.0	0.813
	Severe RF (Clear. < 30)	1.7%	3.9%	0.002
	COPD	3.0%	2.3%	0.316

## Percentage of Patients with optimized treatment



# HF Characteristics: resynchronization and defibrillator

FEVG  $\leq$  35%: 1/3 des P

Ischemic Heart failure: 40,6%

Endpoint	Statistics
- Patients Eligible for resynchronisation <b>N patients with LBB, LVEF <math>\leq</math> 35% and QRS <math>\geq</math> 150 ms</b>	32 P
CRT/P	2 P (6.3%)
CRT-D	1 P (3.1%)
IAD	1 (3.1%)
TOTAL	4 (12%)

# Morbi-Mortality

## 3 months Follow-up

**4.5%**

Cumulated hospitalisation

**9.9%**

Global mortality

**14.8%**

Global Morbi-Mortality

## 12 months Follow-up

**7.3%**

Cumulated hospitalisation

**13.0%**

Global mortality

**24.0%**

Global Morbi-Mortality

**Sudden death: 2,6 %**

**Sudden death: 3,3 %**

12,0%

10,0%

8,0%

6,0%

4,0%

2,0%

0,0%

< 1

1

2

3

4

5

6

7

8

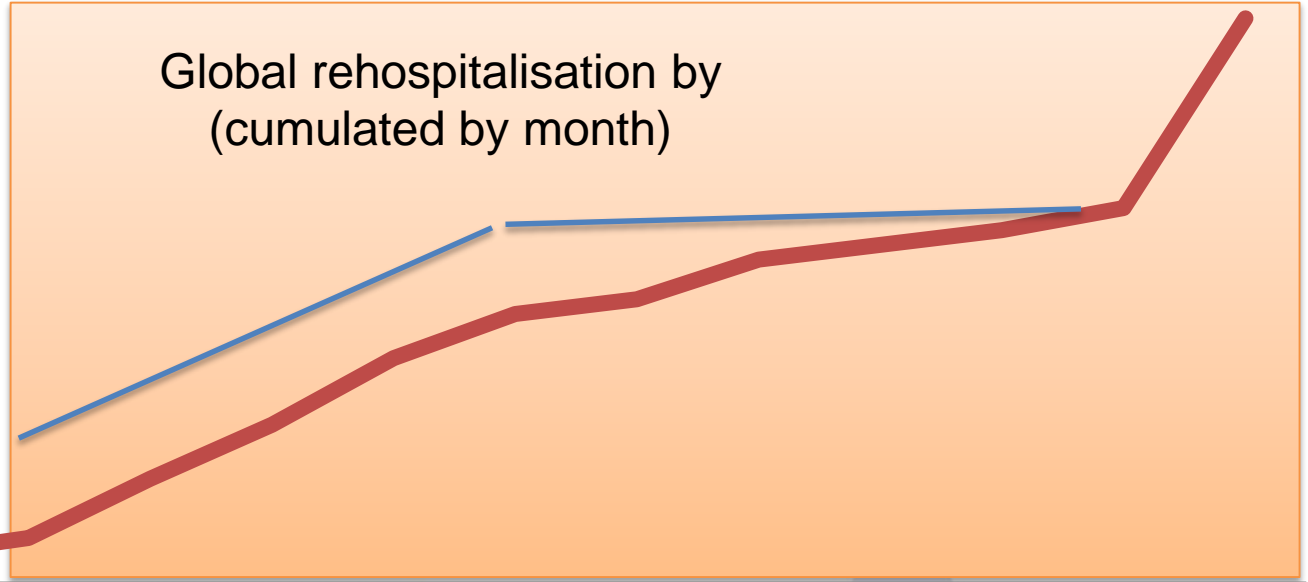
9

10

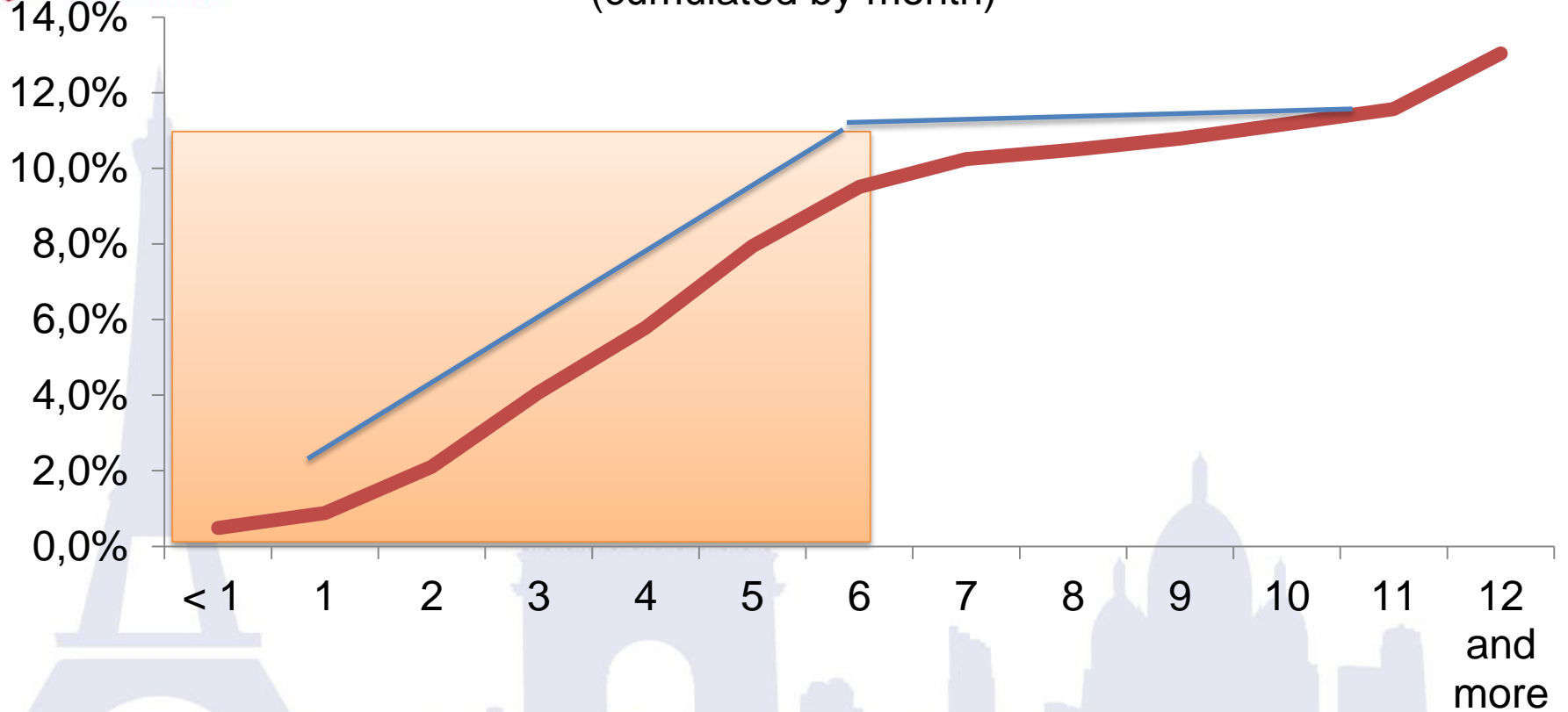
11

12  
and  
more

Global rehospitalisation by  
(cumulated by month)

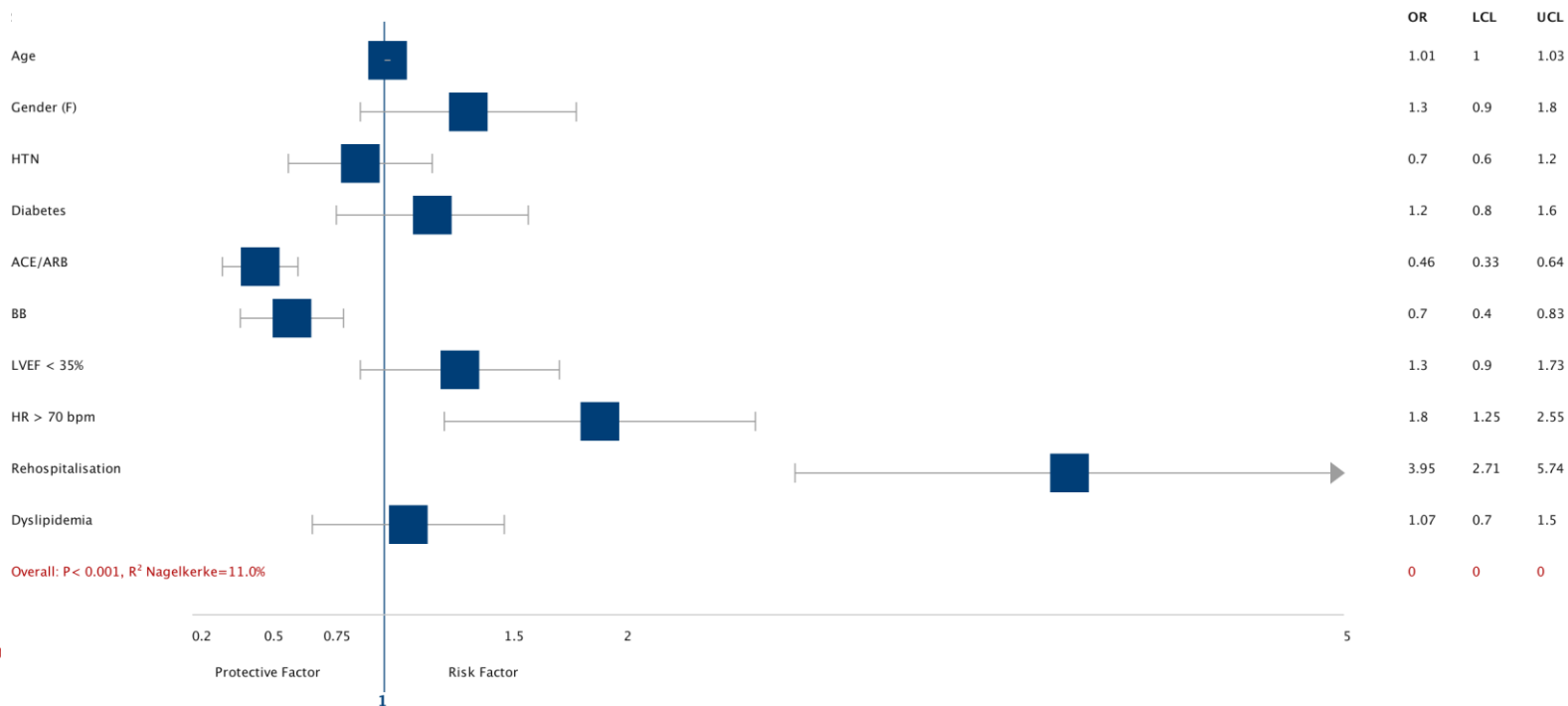


# Global mortality by (cumulated by month)



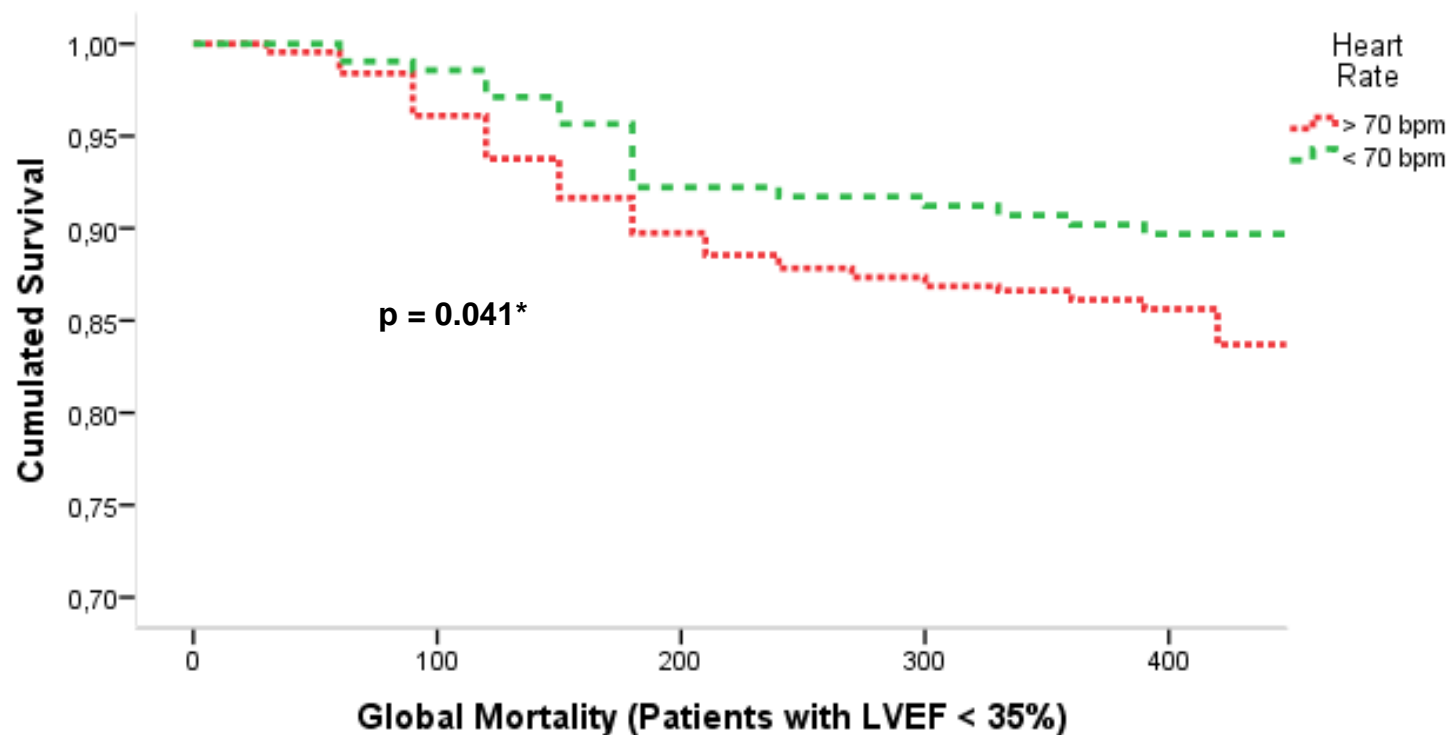
# Overall Mortality modelisation

Overall Mortality (12 months of follow-up)





## Survival Curve: HF, FEVG <35%



# Mortality vs Treatment optimization

Population	ACE or BB at optimal dose	ACE and BB at optimal dose	ACE and BB at suboptimal dose	P
Mortality Overall population	7.2%	13.4%	11.1%	0.133
Mortality patients within LVEF < 40%	9.8%	14.0%	0%	0.478
Sudden death	0%	1.7%	0%	0.308

## 12 months follow-up

### Independent factors of Morbi-Mortality

Endpoint	Yes	No	p
N	489 (24.0%)	1551 (76.0%)	-
Age (years)	66.3 ± 12.6	62.7 ± 12.5	< 0.001
Gender (M)	67.6%	71.9%	0.042
Diabetes	44.4%	33.1%	< 0.001
LVEF < 40%	83.4%	80.4%	0.188
HR (bpm)	82.4 ± 19.0	79.4 ± 17.2	0.002
VT/NSVT	2.9%	1.5%	0.4997
AF/Flutter	15.5%	17.3%	0.731
QRS > 120 ms	23.7%	17.1%	0.007
Creatinine Clearance	61.9 ± 27.5	70.5 ± 25.0	< 0.001

	EHFS II ( 2005)	OFICA ( 2009)	NATURE-HF (2017)
<b>Inclusions</b>	3580	1830	2040
<b>Age (mean yo)</b>	70	77	63
<b>Men</b>	61%	55%	70.9%
<b>AF</b>		27%	30.4%
<b>LVEF (%)</b>		42	38
<b>pEF (&gt;50%)/ rEF</b>	34% (>45%)	30% / 52%	43% / 57.7%
<b>In-patient mortality</b>	6.7%	8.8%	0.25%
<b>Rehospitalization at 12 M</b>	24%		7%
<b>Mortality at 12 M</b>	13,5%		13%
<b>ACE/ARB</b>	80%	78% (rEF)	80.5% (rEF)
<b>BB</b>	61%	53% (rEF)	80% (rEF)
<b>Antialdost.</b>		25% (rEF)	50% (rEF)
<b>Etiology</b>	Ischemic CVD /HTN	Ischemic CVD (75%)	Ischemic CVD (47%)/ HTN (42%)
<b>Co morbidities</b>		Diabetes (31%) Respiratory (21%) RF (CI<60): 62%	Diabetes (37%) RF (CI<50): 25% Anaemia (23.6%)

# FRESH

FRENch Survey on Heart failure

## OBJECTIFS DE L'ETUDE

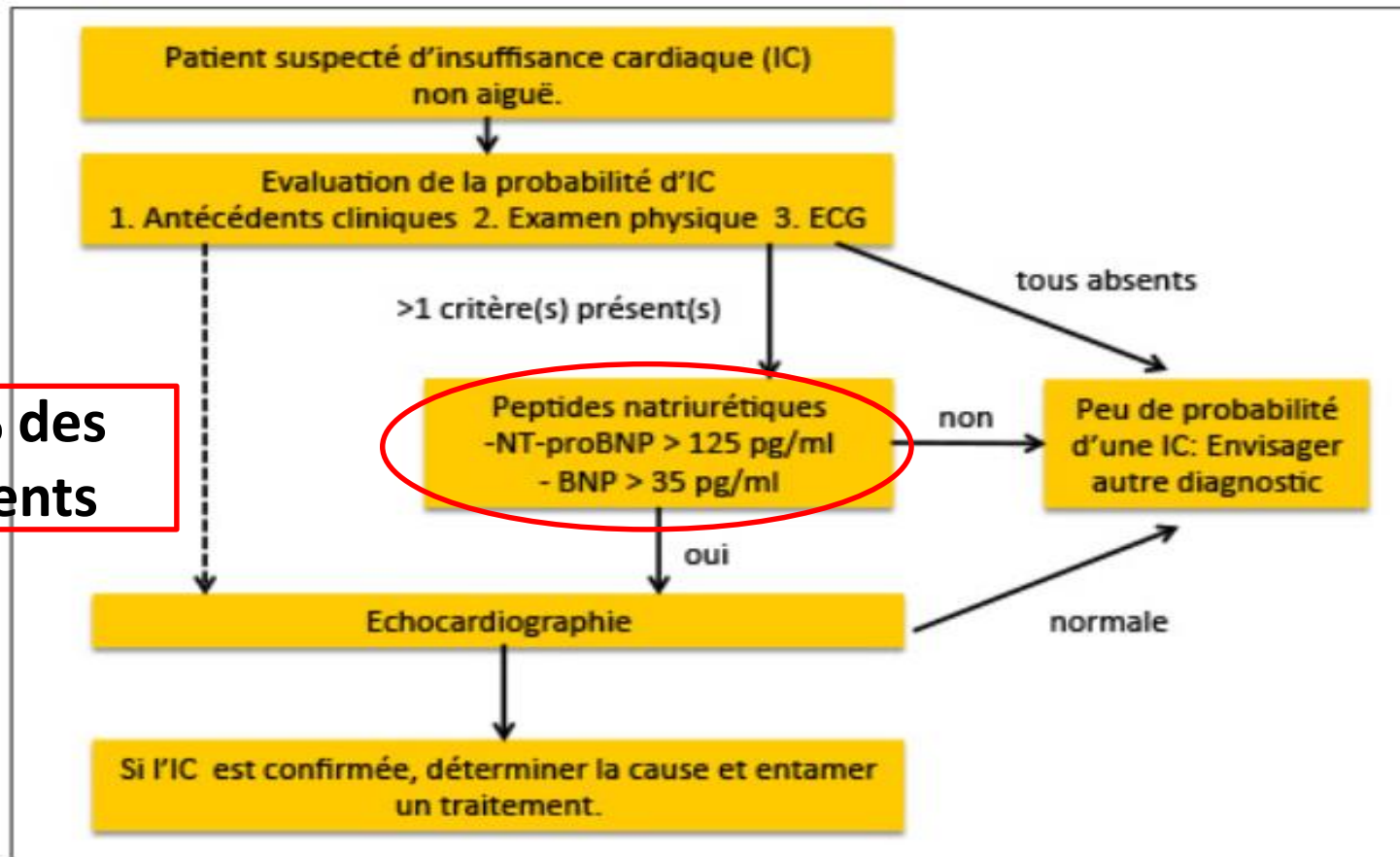
Objectif de l'observatoire : décrire la démographie, les caractéristiques cliniques et les pratiques concernant la prise en charge diagnostique et thérapeutique des patients admis pour insuffisance cardiaque aiguë et des patients insuffisants cardiaques chroniques ambulatoires, en France.

Nombre de patients attendus : 4000

Fin de la période d'inclusion : 31/12/2021

*La Société Française de Cardiologie a mis en place l'étude « FRESH »  
le 17 février 2014.*

**Bilan global** : Au 20 septembre 2018 : 2682 patients inclus par 32 centres actifs



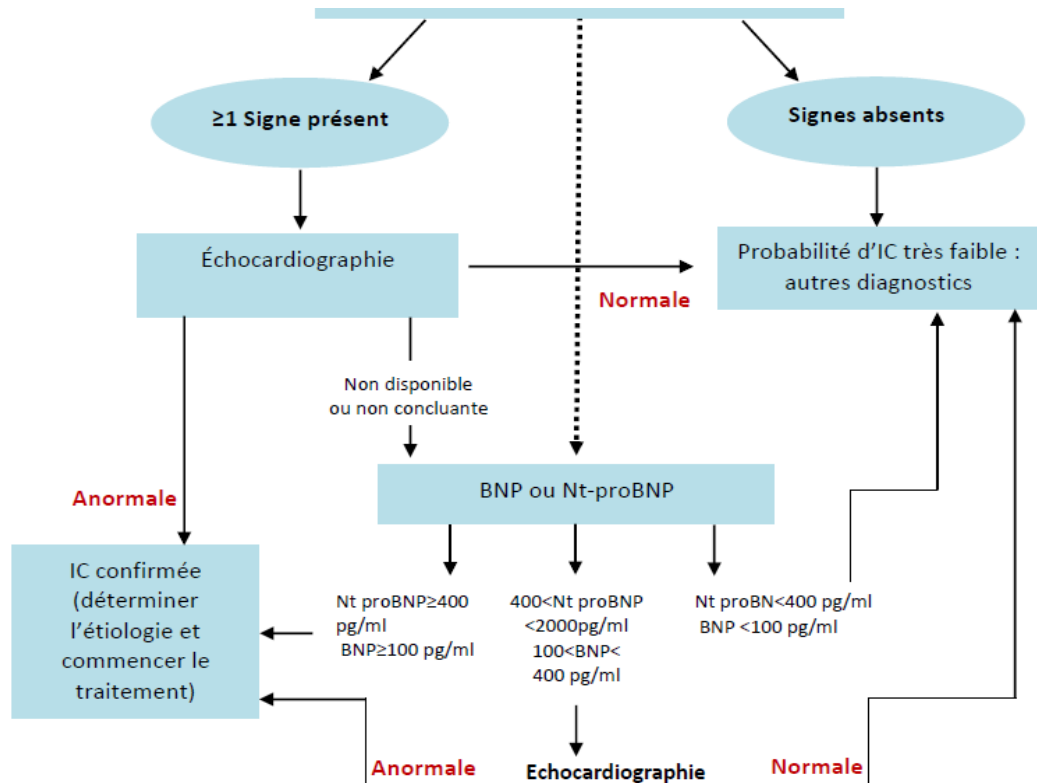
**2.7% des patients**

# L'Instance Nationale de l'Évaluation et de l'Accréditation en Santé (INEAS)

## Guide de pratique clinique

### LA PRISE EN CHARGE DE L'INSUFFISANCE CARDIAQUE CHRONIQUE CHEZ L'ADULTE

Juillet 2018



**Patient with symptomatic<sup>a</sup> HFrEF<sup>b</sup>**

**Therapy with ACE-I<sup>c</sup> and beta-blocker  
(Up-titrate to maximum tolerated evidence-based doses)**

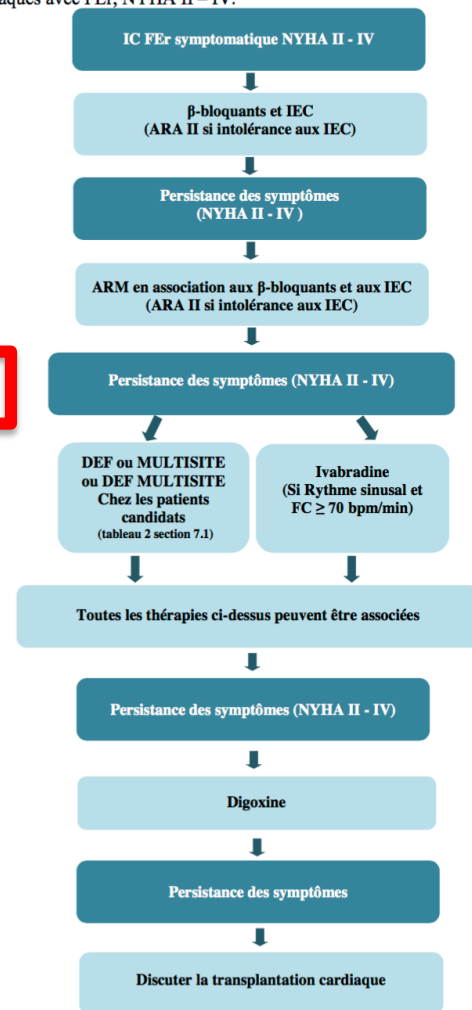
Still symptomatic and LVEF  $\leq 35\%$

No

Yes

**Add MR antagonist<sup>d,e</sup>  
(up-titrate to maximum tolerated evidence-based dose)**

**FIGURE 2** : Algorithme de traitement et conseil thérapeutique pour les insuffisants cardiaques avec FEr, NYHA II – IV.



Si signes de congestion

**Diurétiques de l'anse**



## prescriptions by private cardiologists

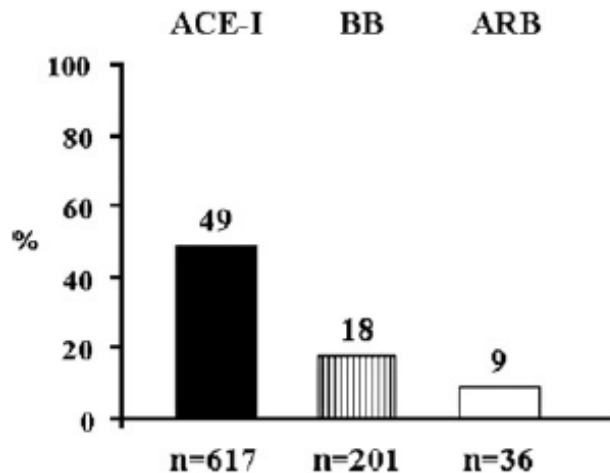
**ACE-I / ARB**

**91 %**

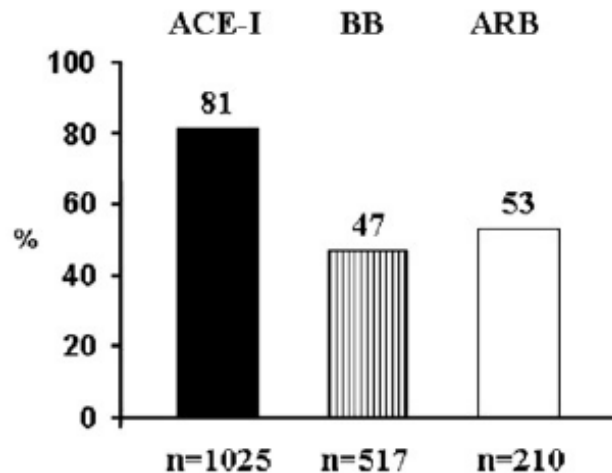
**Betablockers**

**65 %**

Use of the target doses \*



Use of at least 50% of the target doses\*



# Causes of therapeutic Inertia

Drugs	Parameters	Wald $\chi^2$	OR [95CI]	P
<b>ACEI/ARB</b>				
	Renal Failure	20.1	0.41 [0.28-0.61]	< 0.0001
	Age $\geq$ 75 years old	18	0.49 [0.35-0.68]	< 0.0001
<b>Beta-Blockers</b>				
	Asthma / COPD	82.1	0.31 [0.24-0.40]	< 0.0001
	Age $\geq$ 75 years old	31.3	0.54 [0.44-0.67]	< 0.0001
	NYHA III/IV	16	0.65 [0.52-0.80]	< 0.0001
	Coronary disease	8.3	1.37 [1.11-1.69]	0.004

## ACEI/ARB and Beta-Blockers

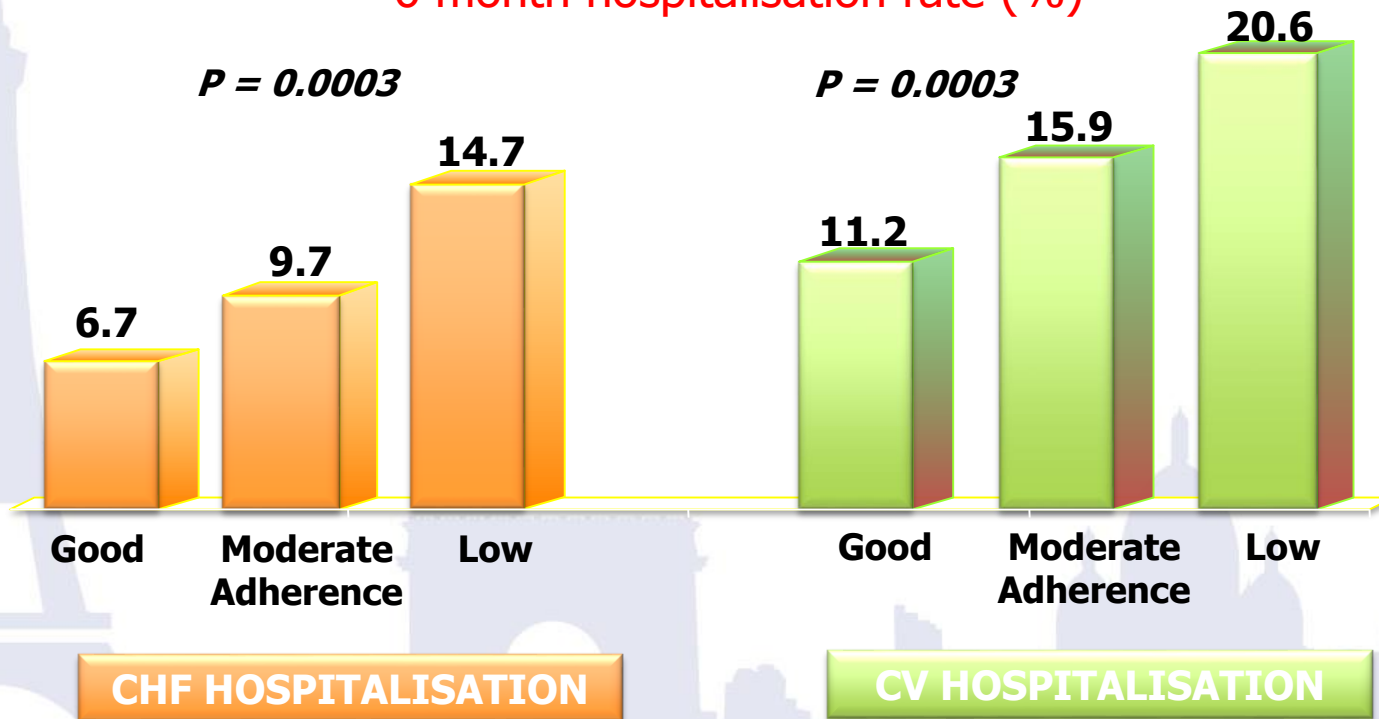
	Asthma / COPD	65.6	0.35 [0.27-0.45]	< 0.0001
	Age $\geq$ 75 years old	45.5	0.48 [0.39-0.59]	< 0.0001
	NYHA III/IV	10.1	0.71 [0.58-0.88]	0.001
	Coronary disease	6.3	1.31 [1.06-1.61]	0.01
	Renal Failure	5.4	0.69 [0.51-0.94]	0.02

## Spironolactone

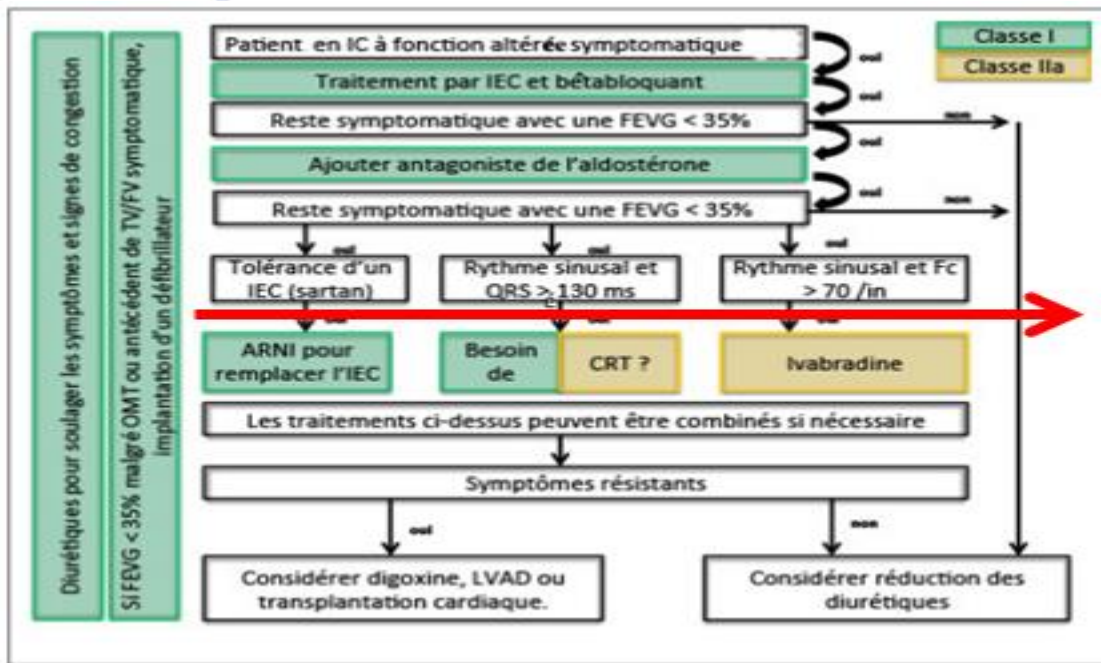
	Age $\geq$ 75 years old	25.1	0.57 [0.46-0.71]	< 0.0001
	Renal Failure	11.9	0.54 [0.38-0.77]	0.0005
	LVEF (%)	9	0.98 [0.96-0.99]	0.003
	Coronary disease	7.3	0.75 [0.61-0.93]	0.007

# ADHERENCE OF PHYSICIANS TO GUIDELINES THE MAHLER SURVEY (N=1400)

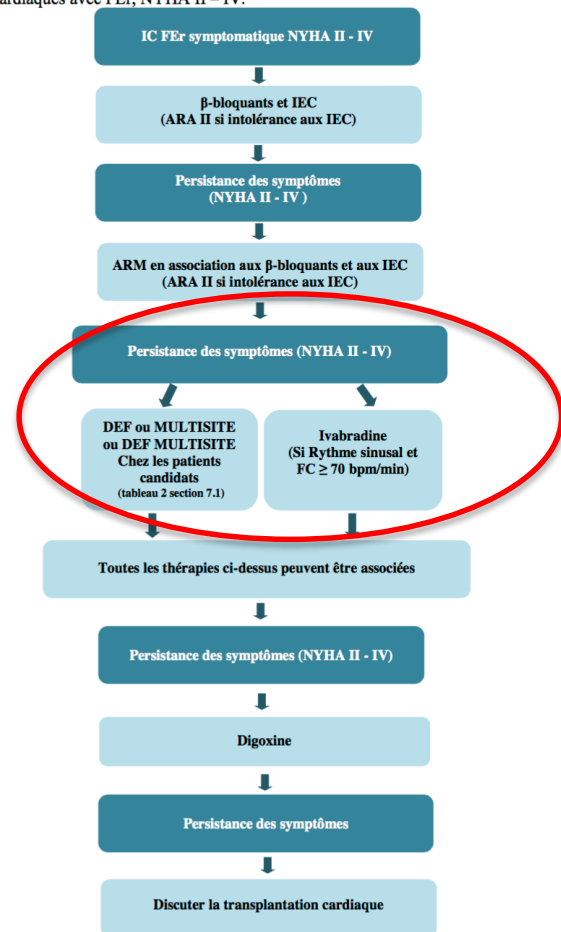
6 month hospitalisation rate (%)



Komajda. Eur. Heart J 2005



**FIGURE 2** : Algorithme de traitement et conseil thérapeutique pour les insuffisants cardiaques avec FEr, NYHA II – IV.



Si signes de congestion  
**Diurétiques de l'anse**

# Thanks to investigators

# Investigators List

Mehdi, Mechri 245  
Chedi, Yousfi 234  
Ali, Khorchani 222  
Kais, Sammoud 203  
Omar, Abid 177  
Oueies, Labidi 177  
Khaled, Ezzaouia 115  
Haithem, Radoui 93  
Sofien, Zayed 69  
Marwa, Chebbi 65  
Mouna, Hentati 40  
Ikram, Kammoun 34  
Dorra, Mbarek 27  
Selma, Charfeddine 27  
Amani, Farah 26  
Khaled, Sayahi 26  
Habib, Triki 25  
Imen, Gtif 25  
Fadoua, Omri 22  
Fares, Azaiez 21

Akram, Zouari 19  
Zine, Benali 15  
Rami, Tlili 14  
Wided, Nasraoui 14  
Lilia, Zakhama 12  
Aymen, Najjar 8  
Mouna, Chaker 8  
heb, Chahbani 7  
Afef, Benhalima 6  
Housseem, Thabet 6  
Faouzi, Addad 4  
Hela, Naanea 4  
Sana, Ouali 4  
Ahmed 3  
Ali, Benkhalfallah 3  
Leila, Abid 3  
Leila, Riahi 3  
Marwa, Chouaieb 3  
Samar, Mohamed 3  
Abdelhamid, Benjmaa 2

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Imen, Hamdi 2  
Rawdha, Othmani 2  
Saoussen, Antit 2  
Seifeddine, Azaiez 2  
Yasmin, Kammoun 2  
Aymen, Elamri 1  
Emna, Allouche 1  
Faten, Triki 1  
Haythem, Tangour 1  
Houcine, Zargouni 1  
Ines, Benameur 1  
Manel, Benhalima 1  
Meriem, Drissa 1  
Mokdad, Ayari 1  
Rym, Hentati 1  
Salah, Maskhi 1  
Sami, Milouchi 1  
Syrine, Abid 1  
Wejdene, Wachtati 1



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Abdeddayem Haggui  
Abdelhamid Ben Jmaa  
Abdelkader Selmi  
Abir Bouassida  
Abir Bouslim  
Achraf Alqodwa  
Adel Hdiji  
Ben Halima Afef  
Afef Lagrane  
Ahmed Sghaer  
Ahmed Bouakez  
Ahmed Elleuch  
Ahmed Fetoui  
Aida Khouaja  
Akram Zouari  
Alexandre Mebazaa  
Ali Belhani  
Ali Ben Khalfallah  
Ali Guesmi  
Ali Khorchani  
Ali Neji  
Amani Farah  
Amel Ouerghi  
Ameur Ben Youssef  
Amina Radoui  
Amine Boussofara  
Anas Sebri  
Anis Khouaja  
Anissa Gharbi

Anissa Joulak  
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Riadh Garbaa  
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Rim Ben Rejeb  
Rim Chrigui  
Rim Letaief  
Rym Ben Romdhane

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Samar Mohamed  
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Sami Bouraoui  
Sami Bouziri  
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Sami Gharbi  
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Samia Ernez Hajri  
Samia Fazaa  
Samir Kammoun  
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# Thanks to Steering committee



- Faouzi Addad
  - Leila Abid
- Ikram Kammoun
- Mohamed Sami Mourali
  - Wissem Sdiri
  - Leila Bezdah
  - Nadia Baraket
- Manel Ben Halima
- Khadija Mzoukhi
- Houssine Zargouni



# Thanks to Operational Staff

Rabie Razgallah  
Elifa Kanoun  
Karima Hezbri  
Sihem Guizani  
Amina Radoui



# Conclusion

- Acceptable outcome results
- A lot of inadequacy regarding treatment
- Prescribing is not just administering drugs: setting up and optimizing
- Few implantable devices
- Register a way to evaluate and evolve


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**Inclusion  
1<sup>er</sup> Mars  
à 19 Juin 2017**

**915  
INCLUSIONS**

**SUIVI 1 AN**

**NATURE-AF**

**NATIONAL TUNISIAN REGISTRY OF ATRIAL FIBRILLATION** 


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**Inclusion  
16 Octobre à  
21 Novembre  
2017**

**2 959  
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**SUIVI 1 AN**


**NATURE-HF**

**NATIONAL TUNISIAN REGISTRY OF HEART FAILURE** 

## National Tunisian Registries

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**NATURE-PCI**

# Thank You for your attention



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Joint au

7<sup>e</sup>  
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24,25 & 26  
OCTOBRE 2019  
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