



Safety and Effectiveness of ICD Follow-up using Remote Monitoring

ECOST Study

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On behalf of the ECOST Study Investigators



Disclosure

- Research grants, Advisory board, conferences fees from:
 - Biotronik, Boston Scientific, Medtronic, Saint Jude Medical, Sorin Group
 - Bayer, Boehringer-Ingelheim
Meda, Sanofi-Aventis
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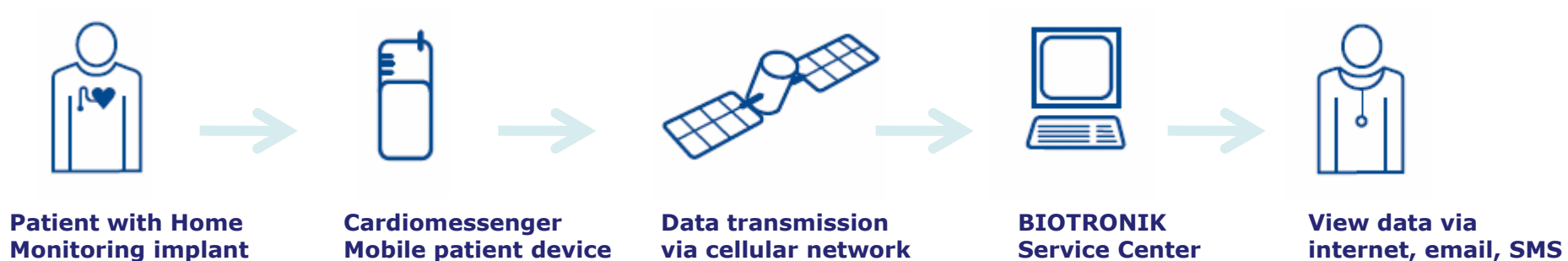


Background

- The implant rate for ICD in the prevention of Sudden Cardiac Death has reached in 2010 an average of
 - ~250 per million population in Europe
 - ~675 per million population in USA
- HRS/EHRA 2008 expert consensus on the monitoring of CIEDs points out
 - The potential of remote ICD follow-up to increase patient safety and convenience
 - The need of proofs with clinical studies
- Remote follow-up of ICDs (TRUST) has been demonstrated to reduce the number of in person device F.U. without increasing death, strokes and ICD related AE requiring surgical interventions
- Global cardiovascular safety of Remote follow-up remains uncertain

Home Monitoring system

- HM allows the **transmission of diagnostic data** from the ICD to the physician by:
 - Communication by a radiofrequency transmitter circuitry integrated in the ICD
 - Acceptance and transfert data from the ICD to a service center using a telephone landline via the Cardiomessenger®
 - Data reception by the service center and generation of a cardiologic report accessible online by the physician via a secure Internet access
 - Potential alerts to the physician of clinical or technical events





Primary Hypothesis

- We hypothesized that ICD follow-up with Home Monitoring would be **safe** and **cost-effective** when compared with standard ambulatory follow-up
- Safety was defined as **Major Adverse Events (MAE)** including
 - Death from any cause
 - Major cardiovascular adverse event
 - Major device-related adverse event
- **Adverse Event(AE)** was defined as major if:
 - Fatal or life-threatening
 - Prompts or prolongs a hospitalization
 - Causes major or permanent disability or injury
 - Requires an intervention to prevent permanent impairment or damage



Secondary Hypothesis

- Objective: **Evaluation of the effectiveness** of Home Monitoring on:
 - Inappropriate therapies
 - Number of ICD charges
- Objective: **Cost of Care** in ICD recipients
(not available)



Study Design

- Designed to detect the **non-inferiority** in the primary end point:
 - 80% power
 - 5% significance level
 - Sample size requirement of 400 patients

- **Randomized controlled trial**

Randomization on a 1:1 basis to:

Remote Monitoring Follow-up

Vs.

In-Person Follow-up



Inclusion / Exclusion Criteria

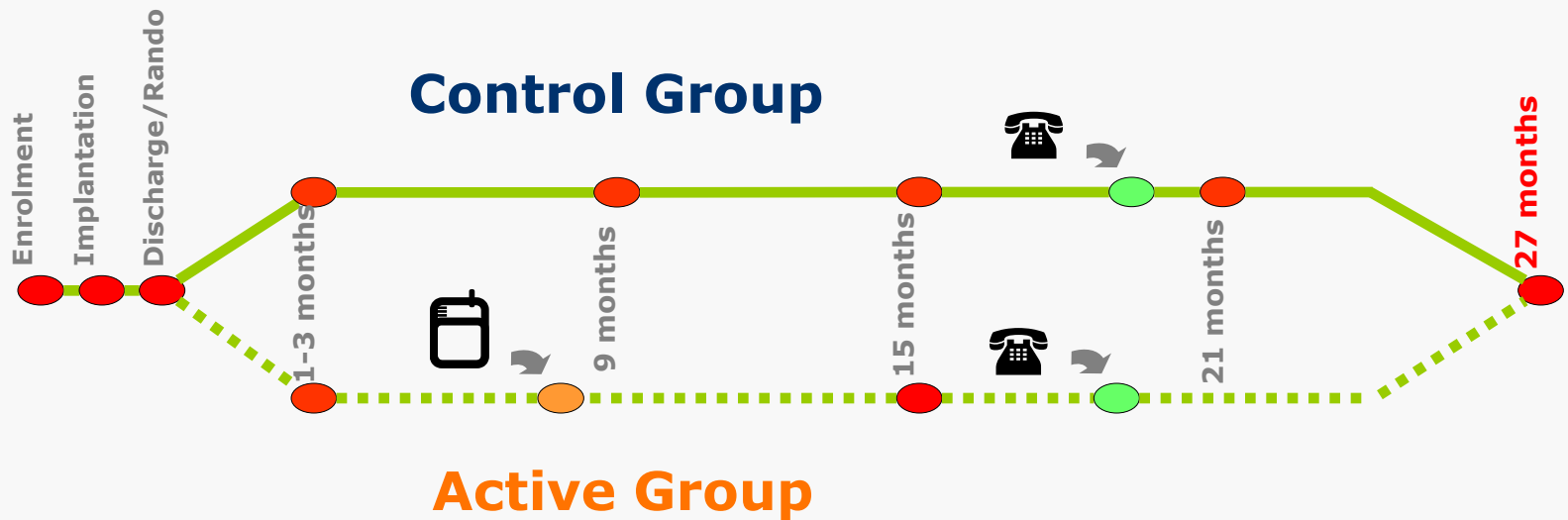
Key Inclusion criterias:




- **Indication or single or dual chamber ICD (without CRT)**

Key Exclusion criterias:

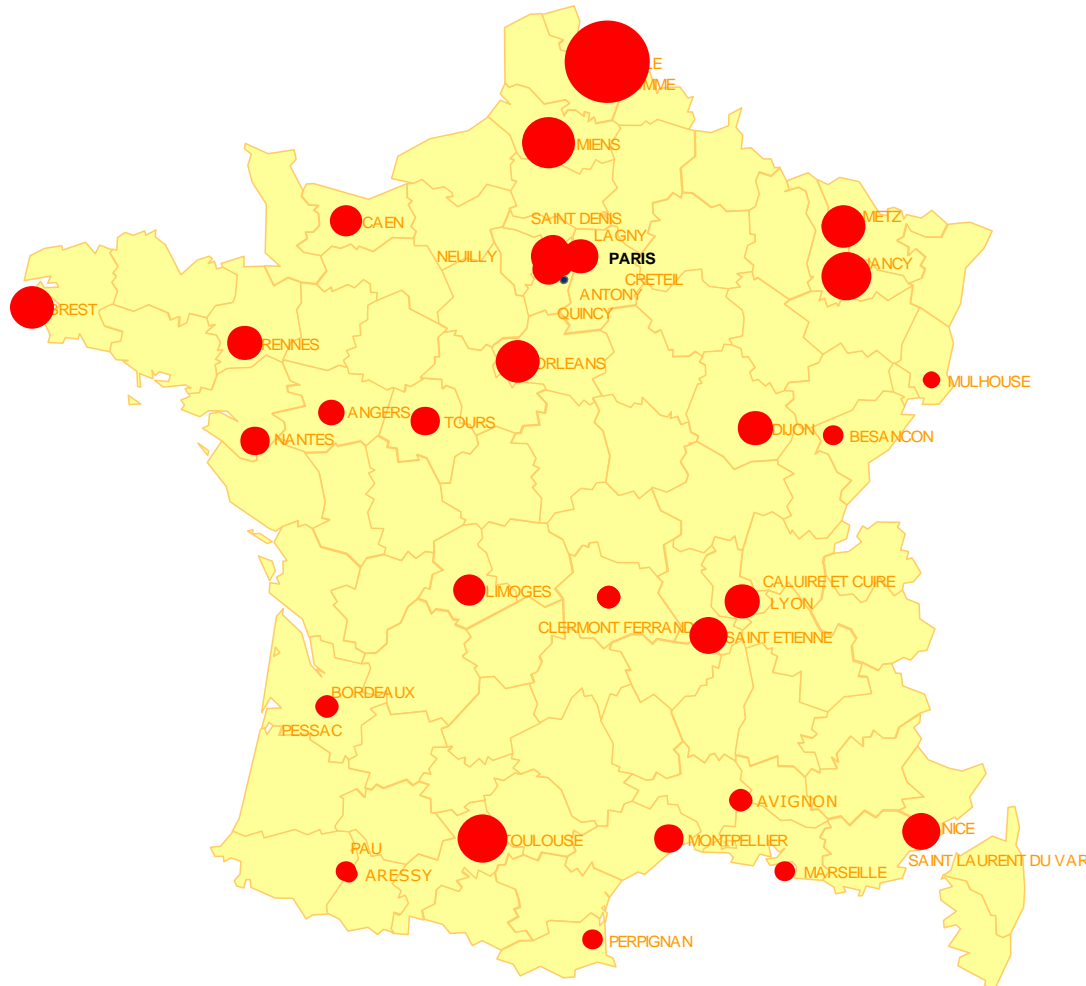
- **NYHA class IV**
- Pregnant woman or woman who plan to become pregnant during the trial
- Patient whose medical situation is not stable
- Presence of any disease, other than patient's cardiac disease, associated with reduced likelihood of survival for the duration of the trial, e.g. cancer, uraemia (urea $> 70\text{mg/dl}$ or creatinine $>3\text{mg/dl}$), liver failure, etc.
- Age < 18 years
- Patient unable to handle Home Monitoring system correctly
- The patient is not willing and able to comply with the protocol
- Change of residence expected during study
- Participation in another clinical study
- Patient unwilling to sign the consent for participation.

Study Flow



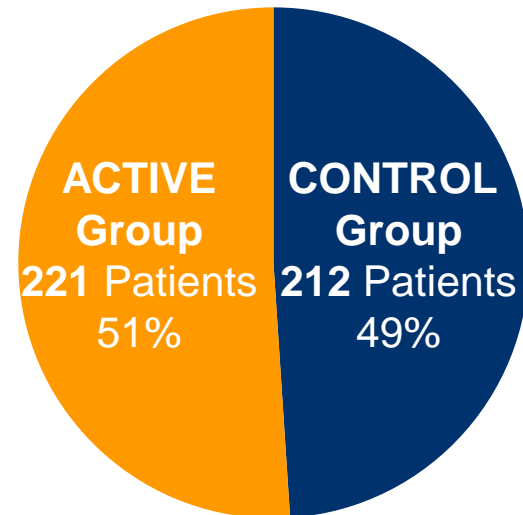
-  Mandatory follow-up (in-office visit)
-  Additional follow-up triggered by Home-Monitoring
-  Additional follow-up triggered by Patient and/or Physician

ECOST Study Sites



433 patients were enrolled, randomised and followed for a mean of 24 ± 7 months

43 investigational centers in France





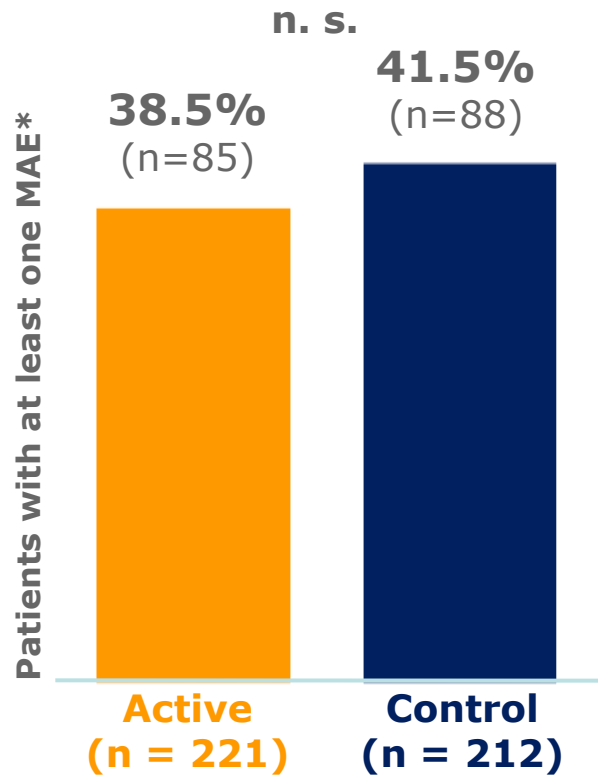
Population: Baseline Characteristics

Non significant difference

	ACTIVE	CONTROL
Number of patients	221	212
Age	62.0±13.0	61.2 ±12.0
Gender (male) (%)	87.3	89.2
LVEF (%)	34.7±13.0	35.1±13.6
NYHA (%) I / II / III	27 / 63 / 6	25 / 61 / 12
History of SVT (%)	17	14
Ischemic cardiop. /Non Ischemic cardiop. (%)	65 / 35	67 / 33
Primary prevention (%)	53.8	53.3
Dual chamber implants (%)	27.1	33.5
First implantation (%)	84.2	86.3



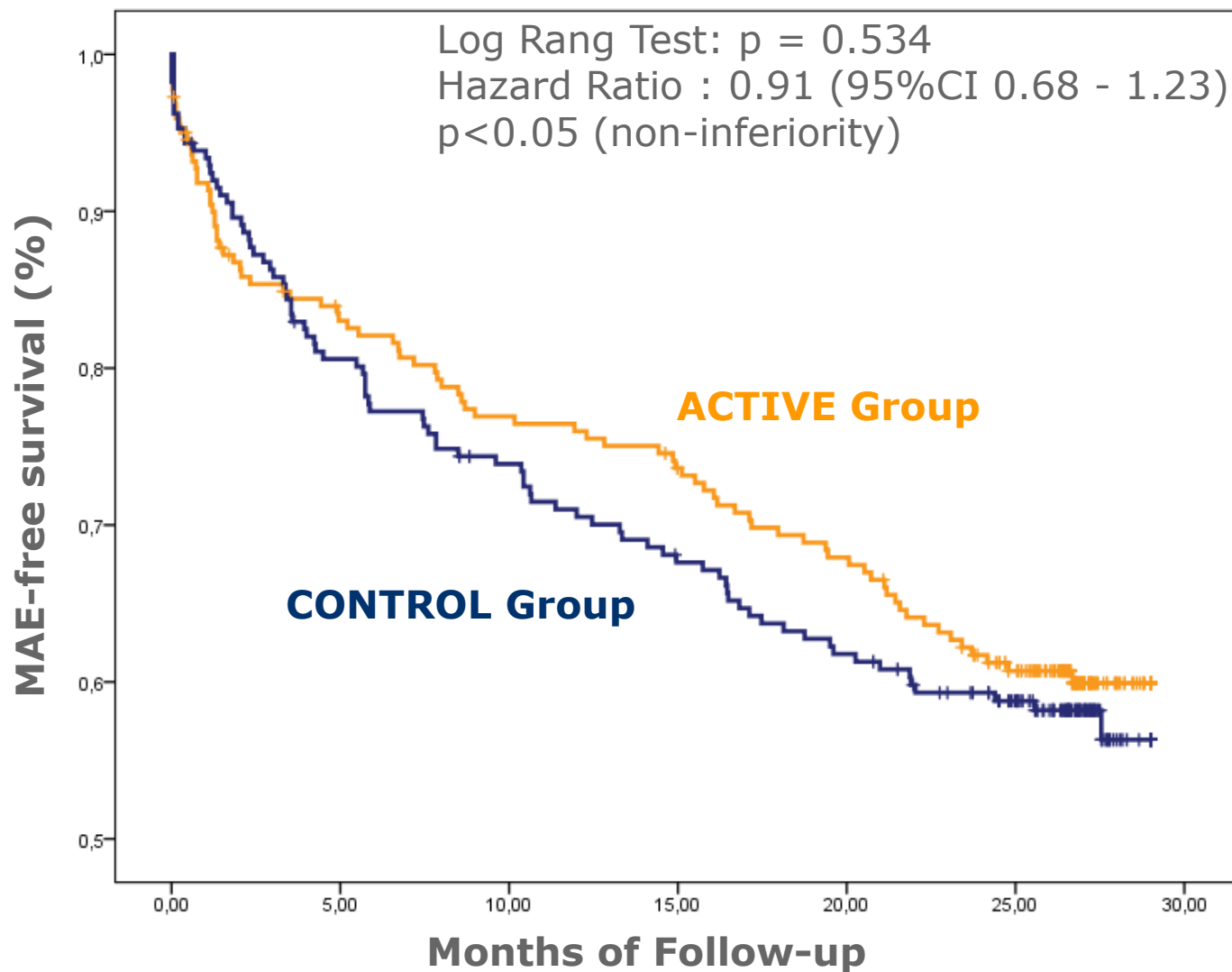
Primary End Point: Safety



- Home Monitoring follow-up associated with a non inferior safety

* MAE = Major Adverse Event

Cumulative Survival free of MAE





Primary End Point by Component

Procedure implant related MAE

Non significant difference

	ACTIVE (n=221)	CONTROL (n=212)
Hematoma	2	1
Infection	4	2
Venous thrombosis	0	2
Pneumothorax	3	0
Lead dislodgment (< 1 month)	5	1
VF Induction: test failure	1	3
Other	0	2
TOTAL	15 MAE (14 pt: 6.3%)	11 MAE (11 pts: 5.2%)



Primary End Point by Component

Cardiovascular MAE

Non significant difference

	ACTIVE (n=221)		CONTROL (n=212)	
	Events	Patients	Events	Patients
Ventricular arrhythmia without shock	10	8	4	4
Ventricular arrhythmia with shock	10	9	5	5
Electrical storm	15	11	17	12
Myocardial infarction	0	0	1	1
Supra ventricular arrhythmia	6	5	1	1
Stroke	7	4	0	0
Heart failure	40	25	61	32
Acute coronary syndrom	6	6	12	10
Other	1	1	6	6
TOTAL	95 MAE (59 pts: 26.7%)		107 MAE (63 pts: 29.7%)	



Primary End Point by Component

Device related MAE

Non significant difference

	ACTIVE (n=221)		CONTROL (n=212)	
	Events	Patients	Events	Patients
Inappropriate shock				
- related to SVT	3	2	6	6
- related to T-wave oversensing	1	1	1	1
- related to lead dysfunction	1	1	5	4
Lead dysfunction without shock	5	5	1	1
Other	3	3	4	4
TOTAL	13 MAE (12 pt: 5.4%)		17 MAE (14 pts: 6.6%)	



Primary End Point by Component

- Death occurred in 20 (9.0%) patients in the active group and 20 (9.4%) patients in the control group.
- No significant difference between groups

Deaths	ACTIVE (n=221)	CONTROL (n=212)
Stroke	1	0
Heart failure	7	8
Infarction	0	1
Arrhythmia	3	1
Non cardiac	7	8
Unknown	2	2
TOTAL	20 (9.0%)	20 (9.4%)



Secondary End Point: Effectiveness

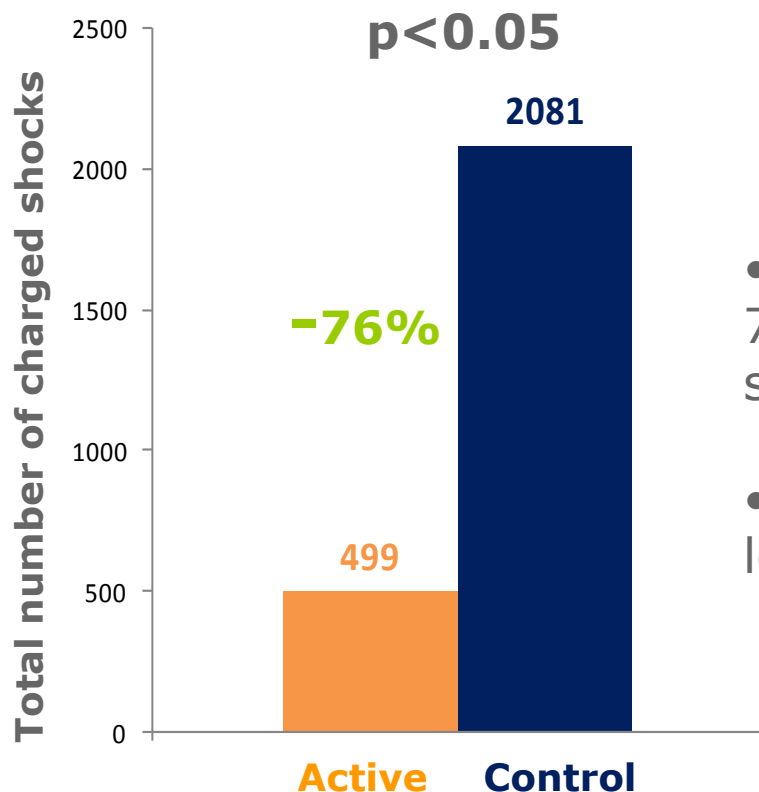
Inappropriate Shocks (IS)

- Remote Monitoring associated with a 52% reduction in the number of patients with inappropriate shocks and with a 72% reduction in the risk of IS related hospitalizations

	ACTIVE (n=221)	CONTROL (n=212)	P value
Number of patients with ≥ 1 IS	11 (5.0%)	22 (10.4%)	0.03
Number of IS delivered	28	283	0.05
Mean per patient	2.5 \pm 2.2	12.9 \pm 25.2	
Range	[1-8]	[1-87]	
Number of patients hospitalized	3	11	0.02

Secondary End Point: Effectiveness

Charged shocks



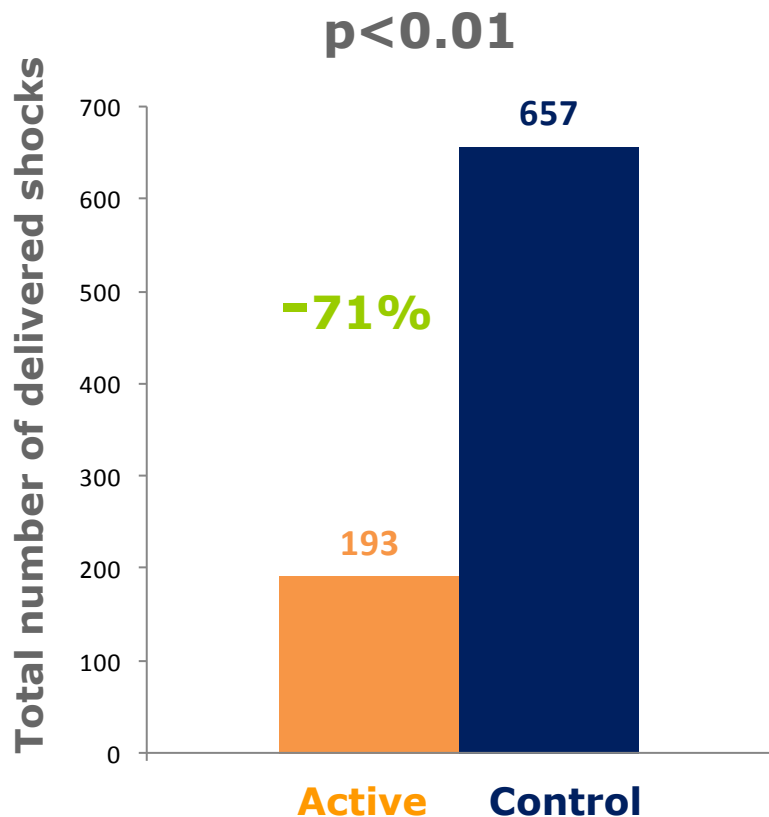
- Remote Monitoring associated with a 76% reduction in the risk of charged shocks
- With a significant impact on battery longevity (60% gain $p = 0.02$)

Mean per patient:	2.3±6.3	9.8±61.5
Number of patients:	69	72
Range [Nb shocks]:	[0-58]	[0-760]

Secondary End Point: Effectiveness

Delivered shocks

(appropriate and inappropriate)



- Remote Monitoring associated with a 71% reduction in the risk of delivered shocks

	Active	Control
Mean per patient:	0.9±3.3	3.1±12.9
Number of patients:	47	56
Range [Nb shocks]:	[0-33]	[0-116]



Conclusions

- Device management of patients with ICD using Home Monitoring[®] system with daily telemetry is safe
- It is not inferior to conventional In-person follow-up
- Remote follow-up is significantly associated with:
 - Reduction of 52% in the number of patients with inappropriate shocks
- Remote Monitoring might soon set a new gold standard of care for the FU of ICD recipients

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