Discussant-ECOST

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Disclosure 2008-2011

	Speaker	Consultant	Trial committees
Medical devices			
EBR		+	+
Impulse Dynamics		+	
Medtronic	+	+	+
St Jude Medical	+	+	+
Sorin group	+	+	
Drug companies			
Boehringer-Ingelheim		+	
Novartis	+		
Pierre Fabre		+	+
Pfizer	+		
Sanofi-aventis	+	+	

Remote Monitoring of ICD Patients

Current clinical evidence from large scale RCT's:
based on surrogate endpoints

- **TRUST (N=1339 pts)**

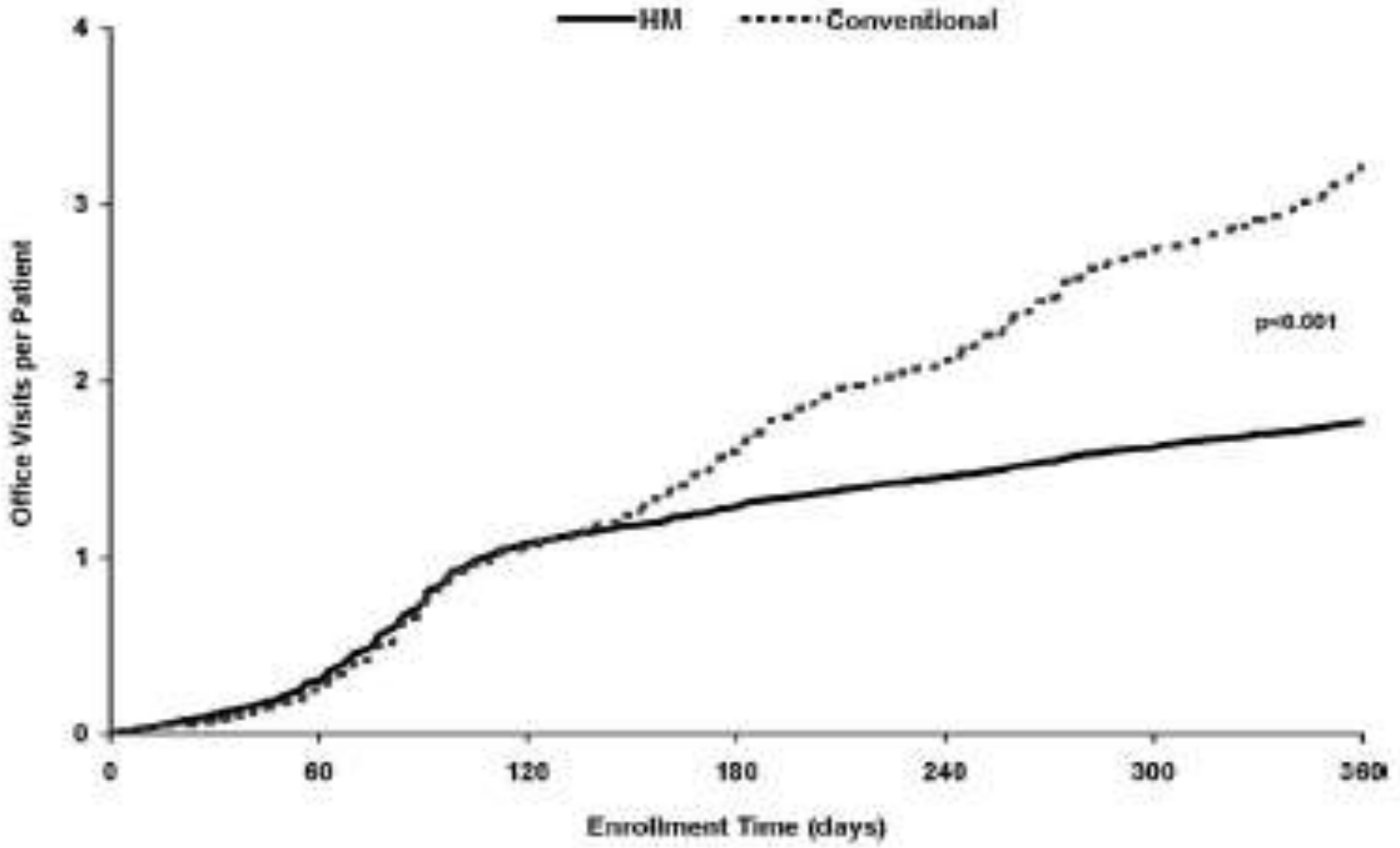
  Number of total in-office device evaluations
  Reduction by 45% without affecting safety
  Median time to evaluation: <2 vs 36d (P=0.002)

- **CONNECT (N=1997 pts)**

  Time from clinical event to clinical decision.
  Reduced from 22d to 4.6 d (P<0.001)
  Lenght of CV hospital stay: 3.3d vs 4.0d (P=0.002)

N Charma et Al Circulation 2010; 122: 325-332
GH Crossley et Al JACC 2011; 57: 1181-1189

TRUST Trial: Primary Objective



N Charma et Al Circulation 2010; 122: 325-332

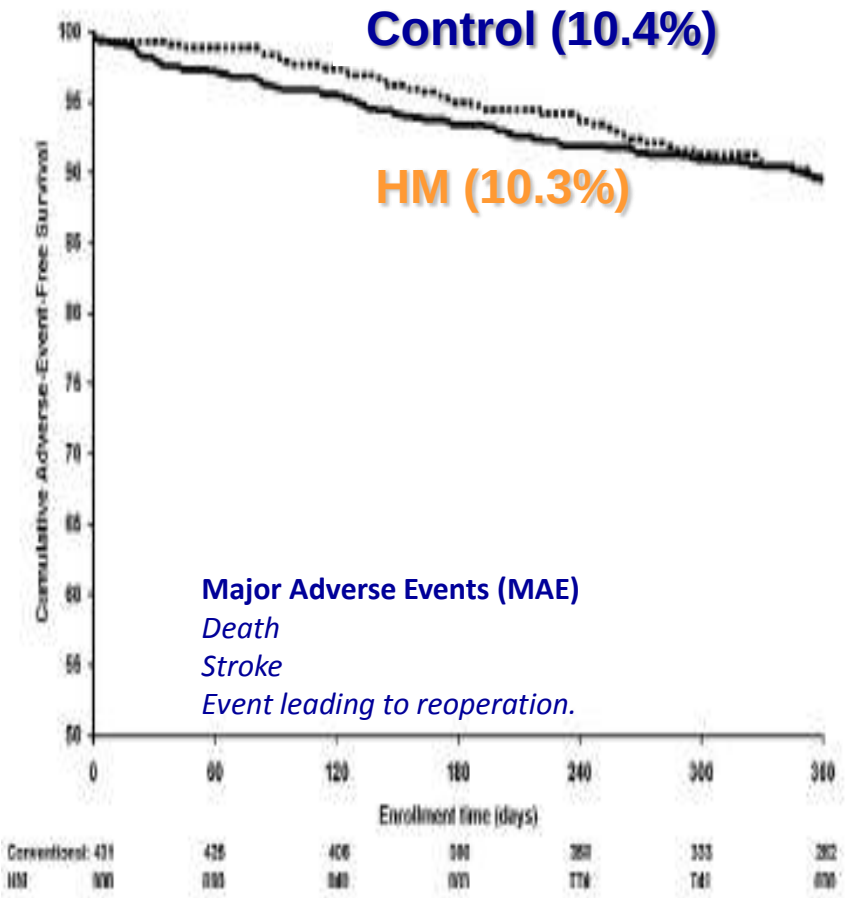
ECOST and EVATEL

First randomised trials with robust clinical EP

- Nearly similar design, inclusion criteria and endpoints
- But, different objective:
  - Safety (MAE) > Efficiency in ECOST
  - Safety and efficiency (MCE) in EVATEL

Clinical safety of Home Monitoring

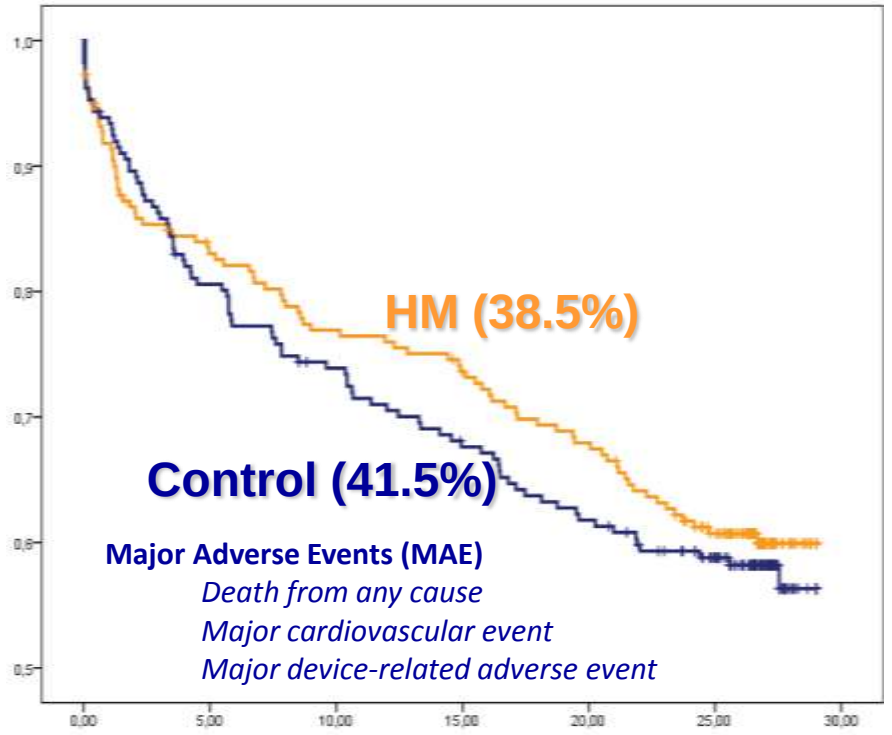
TRUST: Secondary endpoint



Major Adverse Events (MAE)

Death
Stroke
Event leading to reoperation.

ECOST: Primary endpoint



Major Adverse Events (MAE)

Death from any cause
Major cardiovascular event
Major device-related adverse event

Hypothesis of non-inferiority validated in ECOST

ECOST and EVATEL

Global results

- **ECOST:** Home monitoring non-inferior to Standard care (In-clinic visits)
- **EVATEL:** Non-inferiority non validated; No significant difference between Telemonitoring and Standard care

ECOST and EVATEL

Differences between studies?

	ECOST	EVATEL
Sponsor	**Industry**	**Institutional/Gov.**
Nb systems tested	**1 (HM)**	**All available**
Nb patients	**433**	**1501**
F/u duration (mo)	**Mean=27**	**12**
Baseline characteristics		
Secondary prevention	47%	35%
1-st implant	85%	100%

ECOST and EVATEL

Concordent results:

As compared with Standard care

- **Remote monitoring of ICD patients is clinically safe**
- **No clear evidence that RM can contribute to prevent major CV events** (even if favorable trend in ECOST)
- **Clear evidence that RM reduces the risk and number of inappropriate therapies: RRR=37-52%**
- **Significant reduction on charged shocks and total shocks with HM: possible impact on device longevity (ECOST)**
- **RM cost-effective? No clear response at that time**