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REVISTA ESPAÑOLA DE COMUNICACIÓN EN SALUD

II CONFERENCIA INTERNACIONAL DE COMUNICACIÓN EN SALUD

Investigación, bienestar y salud

EVIDENCE-BASED IN TELE-MONITORING OF PATIENTS WITH PACEMAKERS: THE PONIENTE STUDY

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NILS mobility project

eea grants

TOPICS

- Telemedicine
- Pacemakers
- Communication
- Health economics
- Music
- Daniel Catalán

https://www.youtube.com/watch?v=-oQO-kGU2lA

INTRODUCTION

TELEMEDICINE IN CARDIOLOGY ALLOWS…

1) To register and evaluate of correct proper of device implanted.

2) To detect early cardiovascular events.

3) To know problems related with the device status.

4) To increase the attention of older patients and more complexity.

5) To improve the patient quality of life.

6) To save time and effort both health professionals as patients and their caregivers.

7) To reduce the costs associated with the patient monitoring.

Introduction

USE OF PACEMAKERS

- ✓ Pacemakers have experienced a constant increase since the first device was implanted in 1958.
- ✓ Indicated for people who had a slow hearbeat as the sinus node disease and atrioventricular block.
- ✓ To be monitored every 3-12 months.

Introduction

Modalities of pacemakers follow-up

Hospital Monitoring	They are the visits that patients performing to the hospital and usually involves an evaluation of: 1) Device function. 2) Cardiac events. 3) Patient clinical status. 4) Pacemaker can be reprogrammed 5) Making changes in medication.
Remote Monitoring	Data transmitted are corresponding with : 1) Device function. 2) Cardiovascular events 3) It is possible to obtain the clinical status.

Objectives

To provide comprehensive data on cost-utility in follow-up of users with pacemakers in terms of cost per quality-adjusted life years (QALYs) gained.

Secondary objectives:

- To evaluate the health-related quality of life, functional capacity, proportion of adverse events (AE), and number of follow-up visits.
- To compare the costs related to the type of follow-up.

METHODS

DESIGN

Controlled, non-randomized, nonblinded single-center clinical trial

(with 12 months of follow-up as of the implant date).

Patients in tele-monitoring group had not to go to the hospital to be monitored.

Patients in hospital monitoring group had to attend to the hospital to be monitored.

DATA COLLECTION

The study was developed in Poniente Hospital (Almería, Spain):

1) It belongs to the Spanish National Health System.

2) Reference population of 256,000 inhabitants.

3) Every year between 90-100 pacemakers are implanted.

STUDY POPULATION

Inclusion criteria:

1) Be at least 18 years old.

2) Have a Carelink PM implanted.

3) Understand and be able to properly perform self-monitoring at home.

Exclusion criteria:

1) Be participating in another study.

2) Refuse to participate in this research.

DATA COLLECTION

→ Medical history assessment.

→ Patient interviews.

→ Accounting Unit of the hospital.

Interviews (effectiveness evaluation)

EuroQol-5D (EQ5D): mobility, self-care, usual activities, pain/discomfort and anxiety/depression.

Duke Activity Status Index (DASI): functional capacity in domestic, labor, sexual and recreational or leisure activities in cardiovascular patients.

Cost Analysis

National Health System Perspective

Patients Perspective

FOLLOW-UP

2 + 4

1) EQ-5D and DASI.

2) Pre-implant, and 1, 6 and 12 months after implant.

Statistical Analysis

1) Patient baseline characteristics and potential differences between groups were compared using a difference in means test for continuous variables and a difference in proportions test (binomial method) or Chi-Square test (replaced by the Fisher exact test for cells with n<5 cases) for qualitative variables.

2) Differences between groups in the pre-specified endpoints were also assessed using the difference in means or proportions tests.

3) Results are presented, including the corresponding 95% confidence intervals (95% CI).

** Analyses were carried out with SPSS (SPSS Institute, Inc., Chicago, IL, USA) and STATA (College Station, Texas) statistical software.

Results

PATIENTS' CHARACTERISTICS AT BASELINE

	All	Groups		P-value
		Tele-Monitoring (n = 30)	Hospital Monitoring (n = 52)	
Age, mean	**77.57** [76.00-79.15]	**76.77** [74.20-79.33]	**78.04** [75.99-80.08]	*0.44*
Women, %	**21.95** [12.99-30.91]	**30.00** [13.60-46.40]	**17.31** [7.02-27.59]	*0.18*
DASI, mean	**20.49** [19.22-21.76]	**21.42** [19.32-23.52]	**19.95** [18.32-21.58]	*0.27*
EQ5D utilities, mean	**0.70** [0.62-0.78]	**0.74** [0.62-0.81]	**0.67** [0.56-0.78]	*0.40*
Pacing indication n (%)				
Sinus node disease	15 (18.3)	4 (13.3)	11 (21.2)	*0.65*
Atrioventricular block	53 (64.6)	21 (70.0)	32 (61.5)	
Others	14 (17.1)	5 (16.7)	9 (17.3)	
Disease manifestations n (%)				
Syncope	46 (56.1)	19 (63.3)	27 (51.9)	*0.75*
Dizziness	24 (29.3)	7 (23.3)	17 (32.7)	
Dyspnoea	7 (8.5)	2 (6.7)	5 (9.6)	
Angina	5 (6.1)	2 (6.7)	3 (5.8)	
Stimulation n (%)				
VDD	18 (22.0)	9 (30.0)	9 (17.3)	*0.39*
DDD	44 (53.7)	13 (43.3)	31 (59.6)	
VVI	8 (9.8)	4 (13.3)	4 (7.7)	
VVIR	12 (14.6)	4 (13.3)	8 (15.4)	
Comorbilities n (%)				
Dyslipidemia	27 (32.9)	11 (36.7)	16 (30.8)	*0.76*
Tachyarrhythmias	34 (41.5)	12 (40.0)	22 (42.3)	*0.98*
Hypertension	64 (78.0)	24 (80.0)	40 (76.9)	*0.96*
Diabetes mellitus	31 (37.8)	6 (40.0)	19 (36.5)	*0.94*
Pharmaceutical treatment n (%)				
Antiplatelet drugs	34 (41.5)	12 (40.0)	22 (42.3)	*0.98*
Anticoagulants	25 (30.5)	9 (30.0)	16 (30.8)	*0.86*
Antiarrhythmics	20 (24.4)	10 (33.3)	10 (19.2)	*0.24*
Antihypertensives	56 (68.3)	20 (66.7)	36 (69.2)	*1.00*

Differences in functional capacity and HRQoL between baseline and 12 months follow-up

	All	p	Remote Monitoring	p	Hospital Monitoring	p
DASI [95CI]	**3.21** [1.52-4.91]	*<0.001*	**3.25** [0.96-5.53]	*0.007*	**3.19** [0.80-5.58]	*<0.001*
EQ5D-VAS [95CI]	**15.24** [9.64-20.85]	*<0.001*	**18.50** [11.09-25.91]	*<0.001*	**13.36** [5.50-21.23]	*<0.001*
EQ5D utilities [95CI]	**0.13** [0.04-0.22]	0.006	**0.15** [0.03-0.27]	*0.014*	**0.1194** [-0.01-0.25]	*0.072*

n=82 (Active group: 30; Control group: 52). 95CI: 95% confidence interval of mean differences;
EQ5D: EuroQoL-5D; VAS: Visual Analog Scale; DASI: Duke Activity Status Index.
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Functional capacity and HRQoL at 12 months

	All		Remote Monitoring		Hospital Monitoring		P-value
	mean	**95% CI**	**mean**	**95% CI**	**mean**	**95% CI**	**p**
Functional Capacity							
DASI	23.70	22.36-25.04	24.67	22.79-26.55	23.14	21.30-24.99	*0.279*
Health Related Quality of Life							
EQ5D VAS	73.66	70.78-76.54	77.50	73.55-81.44	71.44	67.55-75.33	*0.043*
EQ5D utilities	0.85	0.78-0.91	0.91	0.85-0.97	0.81	0.72-0.91	*0.154*
QALYs	0.80	0.75-0.84	0.84	0.77-0.91	0.77	0.71-0.83	*0.146*

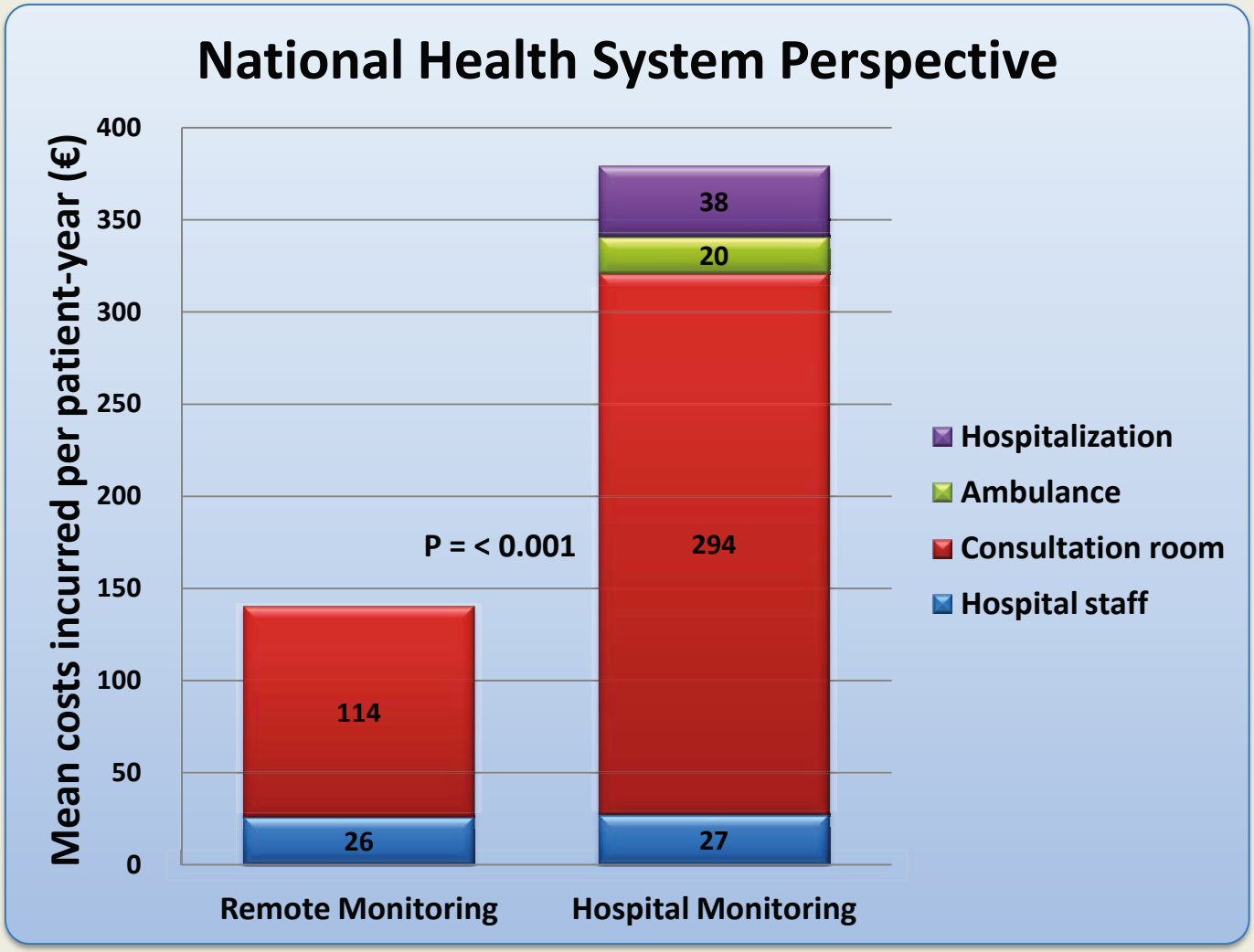
n=82 (Active group: 30; Control group: 52). 95CI: 95% confidence interval of means or proportions;
EQ5D: EuroQoL-5D; VAS: Visual Analog Scale; DASI: Duke Activity Status Index; QALYs: Quality Adjusted Life Years.

Cardiovascular events and workload during the follow-up

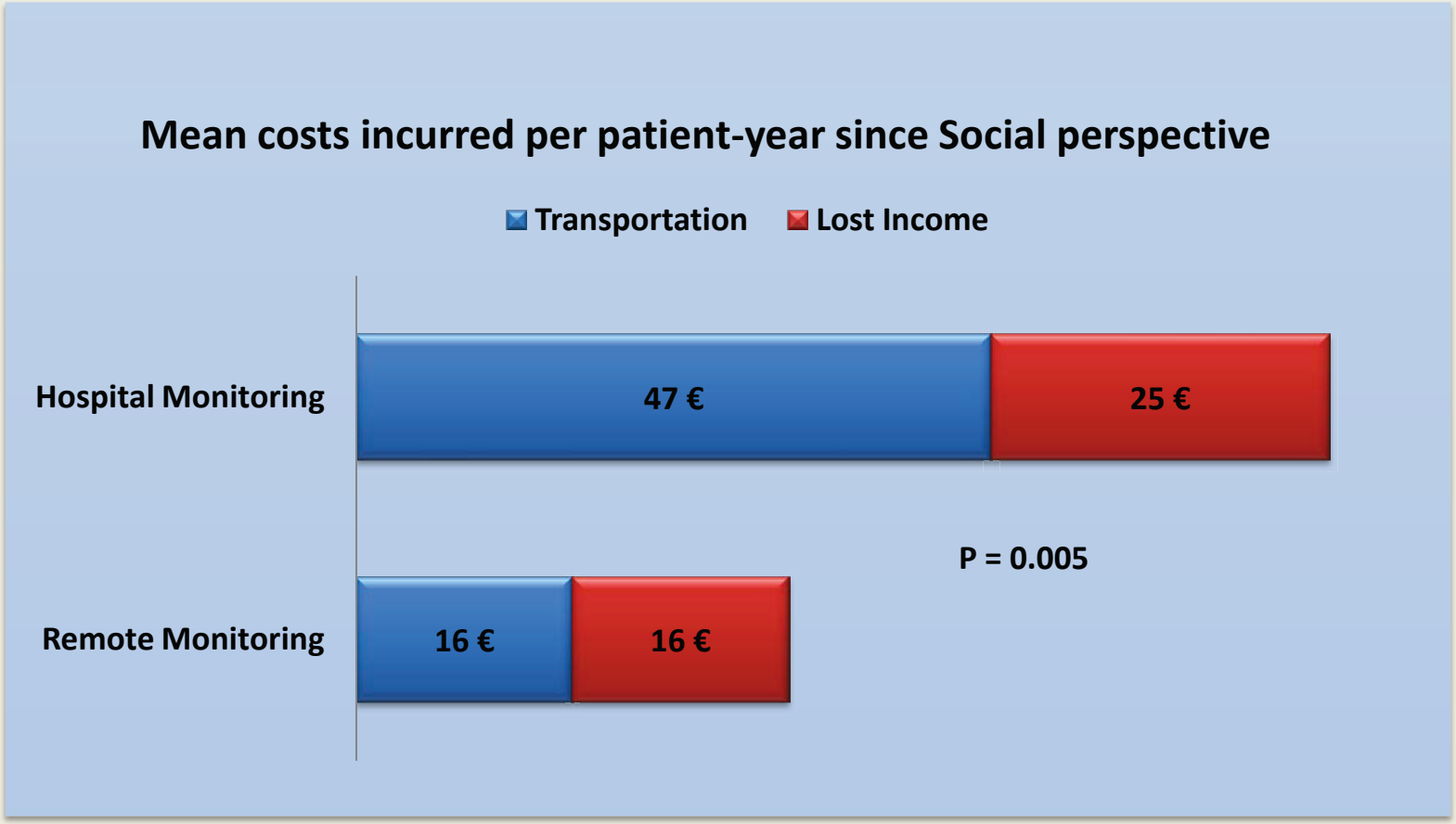
	All		Remote Monitoring		Hospital Monitoring		p
	mean	95% CI	mean	95% CI	mean	95% CI	
People with at least one cardiovascular event							
>4h in AT/AF	15.85	7.78-23.93	16.67	3.33-30.00	15.38	5.58-25.19	*0.878*
<4h in AT/AF	47.56	36.52-58.60	50.00	32.10-67.89	46.15	32.60-59.70	*0.737*
AF high	12.20	4.96-19.43	10.00	0.00-20.73	13.46	0.00-10.73	*0.644*
All	70.73	60.67-80.79	66.67	49.80-83.53	73.08	61.02-85.13	*0.539*
Mean cardiovascular events per person							
>4h in AT/AF	19.77	0.00-55.80	4.20	0.00-8.54	29.5	0.00-93.21	*0.481*
<4h in AT/AF	13.46	0.00-30.73	31.13	0.00-77.93	2.42	1.01-3.82	*0.102*
AF high	1.30	0.00-1.13	1.00	1.00-1.00	1.42	0.38-2.48	*0.545*
All	9.69	0.06-19.32	16.37	0.00-39.07	5.85	0.00-14.23	*0.297*
Transmissions/visits (workload)							
In hospital visits	3.54	3.28-3.79	2.87	2.40-3.33	3.92	3.66-4.19	*<0.001*
From home	0.71	0.46-0.97	1.97	1.56-2.37	0.00	0.00-0.00	*<0.001*
Total	4.29	0.00-5.80	4.83	4.34-5.32	3.92	3.66-4.19	*<0.001*

n=82 (Active group: 30; Control group: 52). 95CI: 95% confidence interval of means or proportions;
AF: atrial fibrillation; AT: atrial tachyarrhythmia.

Cost Analysis



Cost Analysis



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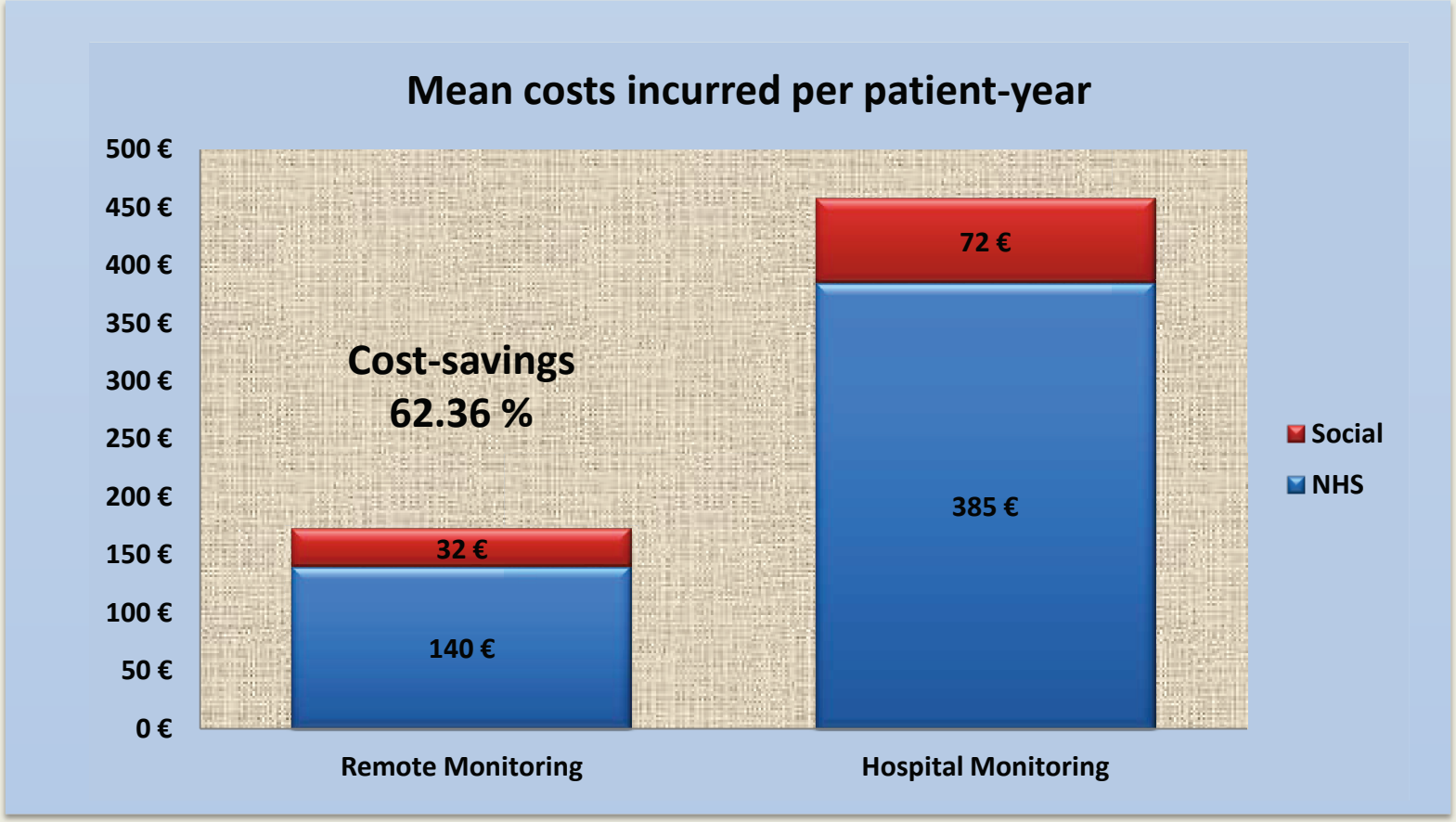

DISCUSSION

MAIN FINDINGS

→ Absence of significant differences in EQ-5D utilities and DASI.

→ Significant differences in EQ-5D VAS and number of in-hospital visits.

→ Early detection of cardiovascular events found in TM group reduced the number of Major Adverse Events.

→ Patients in TM group gained 0.07 QALYs more than those in the HM group at last of study period, with a cost savings of 62.36% per patient.

DISCUSSION

COMPAS and OEDIPE studies did not find any significant improvement in HRQoL for both groups **between the enrolment and the end of follow-up period**, unlike the PONIENTE study where were found considerable improvements in the EQ-5D utilities and VAS at the end of the study period.

After 12-months of follow-up, results for HRQoL showed in PONIENTE study are similar to those obtained in the COMPAS and OEDIPE trials. In these clinical studies were used the SF-36 questionnaire. Results revealed no differences in either the effectiveness or the safety of TM and HM.

The PONIENTE study has been **the first trial where the EQ-5D questionnaire has been used to assess the HRQoL in TM of users of pacemakers.**

Also has been **the first trial where the quality-adjusted life-years gained (*QALYs*) have been obtained** in patients with TM of pacemakers.

LIMITATIONS

First, it is a nonrandomized study where patients together the cardiologist decided which was the type of monitoring that was better suited to the patients characteristics.

In second place, it is an open trial in which both patients and physicians knew the type of follow-up where every patient was included.

Third, the final size obtained - derived from the single-center study and with a limited number of implants per year- and the size differences between groups, have reduced more the real statistical power.

Finally, and regarding the generalization of the results to other settings, the basal characteristics studied were very similar to those reported in the Spanish Pacemaker Registry, aspect that supports this generalization.

CONCLUSSION

The results provided by the PONIENTE study show that tele-monitoring of users with pacemakers **appears to be a cost-effective alternative** compared to the conventional follow-up in hospital.

TUSEN TAKK FOR OPPMERKSOMHETEN

ALMERIA – SPAIN

https://www.youtube.com/watch?v=fOTf1Ci_oUE