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COMPARATIVE EFFECTIVENESS OF TELE-MONITORING OF PACEMAKER VERSUS CONVENTIONAL MODALITY: QUALITY OF LIFE AT THE 6 MONTHS OF FOLLOW-UP

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BACKGROUND

The use of remote monitoring (RM) of pacemakers is limited, and very few studies have focused on their comparative effectiveness.

OBJECTIVES

Evaluate the effectiveness of RM of pacemakers in comparison with the monitoring performed in hospital (HM).

PATIENT SELECTION

Patients were included in the study if they had been implanted with a single [VVI-VVIR] or double chamber [VDD-DDD] Medtronic Carelink® pacemakers within the past 18 years, if they were capable of understanding and correctly performing the home auto-monitoring or had a caregiver who could carry out this function, and is they agreed to participate in the study by signing the informed consent. Patients were excluded if they had been enrolled in another study, if they had any other cardiac device or if they refused to participate.

METHODS

Controlled, not randomized nor masked clinical trial, with collecting data pre and post-implantation and a follow-up of 6 months. All patients over 18 who were implanted a pacemakers in the study period were selected (n=83), being assigned either to RM (n=30) or to HM (n=53) group. Baseline characteristics and number of visits to the hospital were analysed, and the questionnaires administrated were EuroQol-5D (EQ5D) to evaluate the health-related quality of life and Duke Activity Status Index (DASI) to assess the functional capacity.

ETHICAL CONSIDERATION

The Almeria Health Research Ethical Committee approved the trial protocol and the study was developed in accordance with the precepts of the Declaration of Helsinki and Spanish laws on data protection and patient rights. All patients signed the corresponding informed consent prior to their enrolment, and appropriate measures were taken to ensure data privacy.

The trial protocol was registered in **ClinicalTrials.gov (Identifier: NCT02234245).**

RESULTS

Groups were similar in baseline characteristics, including EQ5D (RM:0,7299; HM:0,6769) and DASI (RM:21,41; HM:19,99). At 6 months, EQ5D was improved in both groups (EQ5D RM:0,8613; HM:0,8175; p=0,439) still without significant differences between them. DASI score was similar to baseline. Significant differences were found in number of follow-up transmissions/visits per patient, being lower for RM group (1.57 vs. 1.96; relative reduction 31%; p=0.015).

HEALTH-RELATED QUALITY OF LIFE AND FUNCTIONAL CAPACITY AT 6 MONTHS

	Mean	95% CI	Mean	95% CI	P
EQ5D (Utilities)	**0.86**	**0.77 – 0.95**	**0,82**	**0,75 – 0,89**	***0,44***
EQ5D (VAS)	**69,50**	**64,89 - 74,10**	**68,30**	**64,78 - 71,81**	***0,68***
DASI	**23,10**	**21,20 - 25,10**	**21,07**	**19,50 - 22,60**	***0,10***

EQ5D: EuroQoL-5D; VAS: VISUAL ANALOGUE SCALE; DASI: Duke Activity Status Index

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CONCLUSIONS

Although remote monitoring of pacemakers shows a similar effectiveness and safety, it significantly reduces the number of follow-up visits regarding hospital monitoring.

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