

## Evidence-Based in Telemonitoring of Users with Pacemakers at Five Years after Implant: The Poniente Study

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**Abstract :** Objectives: The purpose of this study was to analyze clinical data, health-related quality of life (HRQoL) and functional capacity of patients using a telemonitoring follow-up system (TM) compared to patients followed-up through standard outpatient visits (HM) 5 years after the implantation of a pacemaker. Methods: This is a controlled, non-randomised, nonblinded clinical trial, with data collection carried out at 5 years after the pacemakers implant. The study was developed at Hospital de Poniente (Almeria, Spain), between October 2012 and November 2013. The same clinical outcomes were analyzed in both follow-up groups. Health-Related Quality of Life and Functional Capacity was assessed through EuroQol-5D (EQ-5D) questionnaire and Duke Activity Status Index (DASI) respectively. Sociodemographic characteristics and clinical data were also analyzed. Results: 5 years after pacemaker implant, 55 of 82 initial patients finished the study. Users with pacemakers were assigned to either a conventional follow-up group at hospital (HM=34, 50 initials) or a telemonitoring system group (TM=21, 32 initials). No significant differences were found between both groups according to sociodemographic characteristics, clinical data, Health-Related Quality of Life and Functional Capacity according to medical record and EQ5D and DASI questionnaires. In addition, conventional follow-up visits to hospital were reduced in 44,84% ( $p < 0,001$ ) in the telemonitoring group in relation to hospital monitoring group. Conclusion: Results obtained in this study suggest that the telemonitoring of users with pacemakers is an equivalent option to conventional follow-up at hospital, in terms of Health-Related Quality of Life and Functional Capacity. Furthermore, it allows for the early detection of cardiovascular and pacemakers-related problem events and significantly reduces the number of in-hospital visits. Trial registration: ClinicalTrials.gov NCT02234245. The PONIENTE study has been funded by the General Secretariat for Research, Development and Innovation, Regional Government of Andalusia (Spain), project reference number PI/0256/2017, under the research call 'Development and Innovation Projects in the Field of Biomedicine and Health Sciences', 2017.

**Keywords :** cardiovascular diseases, health-related quality of life, pacemakers follow-up, remote monitoring, telemedicine

**Conference Title :** ICPHMT 2019 : International Conference on Public Health and Medical Technology

**Conference Location :** Paris, France

**Conference Dates :** March 28-29, 2019