

Cardiac pacemakers ...

- Have experienced a constant increase since the first device was implanted in 1958.
- Are indicated for people who have a slow hearbeat as the sinus node disease, atrioventricular block and other heart disorders.
- Must be monitored every 3-12 months intervals, depending on the pacemakers type and patient clinical circumstances.

Telemedicine in cardiology allows ...

- Register and evaluate of correct proper of device implanted.
- Detect early cardiovascular events.
- Know problems related with the device status.
- Increase the attention of older patients and more complexity.
- Improve the patient quality of life.
- Save time and effort both health professionals as patients and their caregivers.
- Reduce the costs associated with the patient monitoring.



Justification

- *Work overload in pacemaker consultations* due to an exponential increase in the number of implanted cardiac devices.
- Limited existing evidence on the effectiveness, safety and cost-effectiveness of tele-monitoring of conventional pacemakers, particularly based on patient-reported outcomes such as Health-Related Quality of Life (HRQoL).



Objective

The main purpose of the present study was to assess the effectiveness of tele-monitoring (TM) in patients with pacemakers regarding reliability, safety and health-related quality of life, compared to traditional follow-up in outpatient clinic.

Methods

- The NORDLAND study is a controlled, randomized, non-masked clinical trial in pacemaker patients, with data collection carried out during the pre-implant stage and after 6 months.
- Between August of 2014 and November of 2015, all patients over 18 years-old who were implanted a pacemakers (PM) during the study period were selected (n=50), and they were assigned to either a tele-monitoring group (n=25) or a conventional hospital monitoring (HM) group (n=25).
- The *EuroQol-5D* (EQ-5D) utilities and visual analogue scale (VAS) and the *Minnesota Living with Heart Failure Questionnaire* (MLHFQ) were used to measure Health-Related Quality of Life.
- Baseline characteristics and number of hospital visits were also analyzed.

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 and Wilcoxon signed ranks test for *Minnesota Living with Heart Failure (MLHF) Questionnaire*.
3. Results are presented, including the corresponding 95% confidence intervals (95% CI).
4. Analyses were carried out with SPSS (SPSS Institute, Inc., Chicago, IL, USA) statistical software.

Results

- The baseline characteristics of the two study groups were similar for EQ-5D utilities (TM:0.81; HM:0.76; $p=0.47$), EQ-5D VAS (TM: 64.00; HM:64.88; $p=0.86$) and the *MLHFQ* (TM:20.20; HM:28.96; $p=0.07$).
- At the 6 month follow-up, there were no significant differences between the groups in EQ-5D utilities (TM: 0.81; HM: 0.76; $p=0.54$) and EQ-5D VAS scores (TM: 72.71; HM: 59.79; $p=0.08$).
- The *MLHFQ* score was improved in relation to the baseline score (TM: 15.80; HM: 13.21; $p<0.001$).
- The number of in-office visits was similar in both groups (TM: 1.24 vs HM: 1.12; $P<0.30$).

Results

Differences in Health-Related Quality of Life at 6 months of follow-up.

	All			Tele-Monitoring			Hospital Monitoring		
Health Related Quality of Life - Specific									
	Month 0	Month 6	p	Month 0	Month 6	p	Month 0	Month 6	p
MLHFQ	24.58	14.53	<	20.20	15.80	0.04	28.96	13.21	0.001
[95CI]	[19.30-29.86]	[9.04-20.02]	0.001	[14.48-25.92]	[7.18-24.42]		[19.97-37.95]	[5.86-20.56]	
Health Related Quality of Life - General									
EQ5D	64.83	66.74	0.42	64.00	72.71	0.07	64.88	59.79	0.46
VAS	[56.74;70.14]	[60.46;73.01]		[55.77;72.23]	[65.58;79.83]		[51.69;74.07]	[49.44;70.14]	
[95CI]									
EQ5D	0.78	0.79	0.71	0.81	0.81	0.92	0.76	0.76	0.50
utilities	[0.72;0.85]	[0.71;0.86]		[0.74;0.87]	[0.69;0.93]		[0.64;0.88]	[0.65;0.87]	
[95CI]									

N (month 1) =49 (TM group: 25; HM group: 24). N (month 6) =49 (TM group: 25; HM group: 24). Values are expressed as means [95CI: 95% confidence interval of means]. EQ5D: EuroQoL-5D; VAS: Visual Analog Scale; MLHFQ: Minnesota Living with Heart Failure Questionnaire.

DISCUSSION

MAIN FINDINGS

1. Absence of significant differences in EQ-5D utilities and EQ-5D VAS as assessed at 1 and 6 months between patients included in the TM group and those undergoing conventional monitoring in the hospital.
2. Significant differences in MLHFQ were found in both groups between the enrolment and the end of follow-up period.
3. TM of the users with pacemakers was as safe as the scheduled in-office visits.
4. Early detection of cardiovascular events reduced the number of adverse events.
5. In-office follow-up visits number for both groups was similar and no significant differences were found.

LIMITATIONS

- First, it is an open trial in which both patients and physicians knew the type of follow-up for all patients, an aspect that may have potentially influenced their behavior.
- Second, the number of patients enrolled in this single-centered trial with a limited number of implants per year may have limited the ability to detect differences between groups.
- Finally, the generalization of results to other settings may be supported as participant characteristics were quite similar to those reported in previous studies in terms of age, gender, symptoms and indications.

Conclusions

The NORDLAND trial suggests that tele-monitoring of pacemakers in older adults is an equivalent option to hospital monitoring, in terms of health-related quality of life.



Perspectives

Future researches of tele-monitoring of users with pacemakers should focus on economic assessments of multicenter studies, involving a long term follow-up.





**TUSEN TAKK FOR OPPMERKSOMHETEN
MUCHAS GRACIAS – THANK YOU VERY MUCH**

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