PORTLink Study - Portuguese Research on Telemonitoring with CareLink®

Baseline and Preliminary Data of the Pilot Phase

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Abstract: The PORTLink study is a randomized controlled multicentre study that aims to assess whether the use of CareLink system (Medtronic Inc.) for remote monitoring of cardiac implantable electronic devices improves patient satisfaction and consumption of resources, when compared with conventional follow-up.

1 INTRODUCTION

Remote monitoring of implantable cardiac devices is a safe and effective alternative to conventional follow-up only with ambulatory clinical visits (Dubner, 2012). Previous studies have shown that remote monitoring is feasible in clinical practice, reducing the number of ambulatory scheduled visits, and contributing to higher patient safety and satisfaction, and better use of health resources (Dubner, 2012); (Burri, 2012). Nevertheless, patient satisfaction and impact at health resources should be confirmed at local level, since economic and cultural aspects may influence these outcomes (Burri, 2012).

The *Portuguese Research on Telemonitoring with CareLink* (PORTLink) study evaluates whether the use of Medtronic CareLink® system for remote monitoring of individuals with implantable cardioverter-defibrillators (ICD) or cardiac resynchronization therapy devices (CRT-D) improves the follow-up efficiency, in particular with regards to patient satisfaction and consumption of resources, when compared with conventional follow-up and independently of patient previous experience of conventional follow-up.

2 STUDY DESIGN

The PORTLink study is a prospective randomized, controlled, open-label, multicentre study conducted in Portuguese hospitals. The study was approved by the three participant centres in the pilot phase, and by the Portuguese Authority on Data Protection. All patients provided their consent to participate.

The sample of 240 patients is being recruited between 2012 and 2013 and will be followed-up for 12 months. Included patients should be ≥18 years-old, implanted with a Medtronic ICD or CRT-D, and eligible to use the CareLink service.

Participants are randomly assigned on a 1:1:1:1 basis: recently implanted starting follow-up on the remote monitoring protocol (group A) or starting conventional follow-up (group B); with previous experience on conventional follow-up changing to the remote monitoring protocol (group C) or without changing to the remote protocol (group D).

Clinical forms and patient questionnaires are filled during ambulatory visits and after each remote data transmission. The study primary endpoints are the proportion of patients satisfied with the monitoring protocol, the resources consumed and the clinicians' satisfaction with the CareLink service. The statistical analysis assumes a confidence level of 95%. For the baseline data of the pilot phase descriptive data are presented for the main clinical and socio-demographic variables.

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3 PRELIMINARY RESULTS

From April 2012 until May 2013, a total of 53 patients were included. Table 1 presents the baseline characteristics of the enrolled patients. No significant differences were observed between groups. The enrolment rate ranged from 1 to 12 participants per month (mean 4 participants/month). The patients had a mean time of follow-up of 7.7±4.3 months (mean±standard deviation).

The 36 (67.9%) initial consecutive patients with at least 6 months of study participation had a mean number of 0.7±0.9 in-office appointments and only 2 patients had one unscheduled appointment. The 21 (58.3%) patients in the CareLink groups had fewer appointments than the 15 (41.7%) patients in the control groups (0.3±0.7 vs. 1.2±0.9, $p<0.05$).

Patients in the CareLink groups had a total of 48 remote transmissions, from which 6 were unscheduled and due to patient decision. Regarding overall satisfaction of the centres with the use of the CareLink website during remote transmissions, all were satisfied (97.1%) or very satisfied (2.9%). The patient's use with the CareLink monitor was very easy for 14 (28%), and easy for 18 (38%) of the transmissions, while 16 (32%) were classified as wireless without any reported problems.

4 DISCUSSION

The enrolled participants are mainly man, older than 50 years-old and presenting ischaemic heart disease. Some information is being completed at the time, which explains the observed missing data.

Preliminary data seems to confirm a significant reduction of in-office appointments with remote monitoring, the patient ease of use of the CareLink monitor and the clinicians' satisfaction with the service.

It is still necessary to clarify the impact of remote monitoring regarding patient outcomes, including quality of life and long-term satisfaction. These will be evaluated in the PORTLink study in different groups of a population of patients and compared with conventional practice for the Portuguese reality.

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Table 1: Baseline characteristics of the enrolled patients.

	Total (n=57)	Group A (n=15)	Group B (n=10)	Group C (n=19)	Group D (n=13)
Age, years, mean±sd [1]	57.6±10.1	52.9±8.2	54.3±8.1	60.5±10.2	62.7±10.0
Men, n (%) [2]	42 (87.5)	8 (80.0)	8 (88.9)	16 (88.9)	10 (90.9)
Implant interval, months, mean±sd [3]	25.3±28.2	2.9±4.6	1.6±1.4	35.7±26.9	36.3±30.8
Education, years, mean±sd [2]	6.6±3.8	5.6±1.5	5.3±2.4	6.5±4.1	8.8±4.4
Professional status - retired, n (%) [4]	27 (55.1)	2 (22.2)	6 (60.0)	12 (63.2)	7 (63.6)
Accompanied patients, n (%) [5]	21 (44.7)	4 (44.4)	4 (40.0)	7 (38.9)	6 (60.0)
Device, n (%)					
ICD	40 (70.2)	10 (66.7)	7 (70.0)	13 (68.4)	10 (76.9)
CRT-D	17 (29.8)	5 (33.3)	3 (30.0)	6 (31.6)	3 (23.1)
NYHA functional class, n (%) [6]					
I	9 (20.0)	1 (12.5)	2 (22.2)	3 (16.7)	3 (30.0)
II	26 (57.8)	7 (87.5)	4 (44.4)	10 (55.6)	5 (50.0)
III/ IV	10 (22.2)	0 (0.0)	3 (33.3)	5 (27.8)	2 (20.0)
Underlying heart disease, n (%) [4*]					
Ischaemic cardiomyopathy	15 (30.6)	2 (20.0)	1 (11.1)	8 (40.1)	4 (36.4)
Myocardial infarction	14 (28.6)	1 (10.0)	3 (33.3)	3 (15.8)	7 (63.6)
Others	45 (91.8)	8 (80.0)	7 (77.7)	19 (100.0)	11 (100.0)
History of arrhythmia, n (%) [4]	35 (71.4)	6 (60.0)	7 (77.8)	14 (73.7)	8 (72.7)

Note: statistics are related to the available data, namely: [1]n =32, [2]n=48, [3]n=41, [4]n=49, [5]n=47, [6]n=45; [*]more than one option