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Clinical and Psycological Telemonitoring and Telecare of High Risk Patients with Chronic Heart Failure through Wireless Technologies: The Icaros Project

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Abstract

Background: Disease management is mandatory for the home care of most patients with chronic heart failure. We report the results of ICAROS (*Integrated care vs Conventional intervention in cArdiac failure patients: Randomized Open label Study*), an Italian trial of telemonitoring and telecare combining wireless and mobile technologies to obtain optimal therapeutic control, fast and effective interpretation of clinical data and improved patients' adherence.

Methods: Eighty patients were randomized before hospital discharge after an episode of acute heart failure, to a usual care group (UC) (n=40: follow-up at our Outpatients' clinic) or to an integrated management group (IM) (n=40: patients learned to use a PDA computer and kept in touch daily with our Centre to receive instructions, encouragement, clinical and psychological assistance.

Results: At enrolment, groups were similar for age (UC 73 ± 3 years; IM 71 ± 2 years); NYHA class (UC 2.90 ± 0.69; IM 3.08 ± 0.57), left ventricular function (EF%) (UC 32 ± 8%; IM 32 ± 7%), plasma levels of BNP (UC 361 ± 72 pg/ml; IM 314 ± 94 pg/ml). At one-year follow-up, IM patients showed better adherence, reduction of anxiety and depression and lower NYHA class and plasma levels of BNP with respect to UC patients (NYHA: 2.08 ± 0.38; BNP: 202 ± 127 pg/ml, $p<0.05$ vs UC patients). Mortality and hospital re-admissions for congestive heart failure were also reduced in IM patients ($p<0.05$).

Conclusions: In ICAROS, regular acquisition by wireless technologies of clinical and psychological data provided a good model for clinical decision-making, determining better quality of life and reducing mortality and hospitalizations.

Keywords: Chronic heart failure; Disease management; Telemonitoring; Telecare; Wireless technologies

Introduction

In western world, death and disability due to heart failure, especially in its terminal phase, are increasing and represent a growing economic burden on all National Health Systems [1,2]. The quest for a correct disease management of heart failure has involved a great number of research groups, but in the real world patients are still not treated as they should. At the beginning of this century, the Italian study TEMISTOCLE [3] showed that a structured follow-up for heart failure patients discharged from the hospital, as recommended at the time by *disease management* [4] did not exist. The same problem has been recently reported in other European countries and in the USA [5].

In recent years, the availability of Internet, portable phones and wireless technologies has created the possibility of an affordable processing of large amounts of data, to help the management of clinical information. Different approaches of *Telemonitoring* and *Telecare* have proven useful and possibly cost-effective [6-17]: their positive results, including improvement in the quality of life, have been emphasized by some meta-analyses [18,19]. However, in multicenter randomized studies the reduction in hospital admissions and mortality has been less convincing [20,21], so that current European Guidelines do not include telemonitoring and telecare for the management of chronic heart failure [22].

After TEMISTOCLE, a network for the integrated management of patients with chronic, stable heart failure has been developed in Italy, with favorable preliminary results [23-26]. To fill the gap between these models of home-based care for stable patients, and the hospital-based care for acute and sicker patients, we designed the ICAROS project (*Integrated care vs Conventional intervention in cArdiac failure patients: Randomized Open label Study*), in which the clinical approach of heart failure specialists was integrated with Internet and wireless technologies with the aim of developing a decision-making model that could fit the needs of fragile patients [27].

Methods

Preliminary phase

A dedicated software was developed to collect patients' data on a

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smartphone PDA, and allow their subsequent wireless transmission to the remote server for storage and analysis. The system was designed to communicate with each patient, asking simple questions about his/her symptoms and giving information and counselling through visual and acoustic reminders.

Technology for remote control

The remote control included: (1) a patient front-end, (2) a medical front-end, (3) a software web-based system for assistance in the clinical decision. The *patient front-end* operated through a PDA that each patient received at discharge from the hospital. According to the clinical characteristics of the individual patient, the cardiologist decided both the variables to be followed up (i.e. heart rate, body weight, blood pressure, ECG transmission) and the frequency of monitoring (i.e. daily for blood pressure and body weight, weekly for the ECG). After the system initialization, patients were asked to transmit the requested information at a pre-scheduled time: their messages on the PDA could be either on a discrete digital or on a continuous analogic scale. Moreover, a pre-set acoustic alarm reminded the correct time for therapy. The PDA was also structured for the remote transmission of ECG and blood pressure collected with a commercial device [27]. Finally, the software included specifically designed questionnaires or visual scales for the monthly testing of anxiety and depression [28,29]. After each transmission, the system *back-end* stored the information sent by all patients, to be subsequently analyzed. The *medical front-end* collected and integrated all received data, so that at any time both clinical and psychological history could be evaluated. At a defined pre-scheduled time, the cardiologist analyzed the information received by each *patient's front-end*, evaluated their clinical priority and could call the patient or send an SMS to modify the therapy, ask more information or recommend a clinical control. The system created a graphic trend of the variables preliminarily chosen by the cardiologist, so that a more frequent control could be asked for those that were found more difficult to control (i.e. a patient could be asked to transmit his/her blood pressure twice a day if a great variability was observed, to tailor the timing of drugs' administration). The *administration/analysis terminal* was represented by the whole database and the application server software, where all data were stored for subsequent statistical analysis.

Study population

This prospective, randomized, parallel open study enrolled patients with chronic heart failure who were discharged from the hospital after an admission for a clinical instabilization. Table 1 summarizes inclusion and exclusion criteria. Therapy at enrolment followed 2008 European Guidelines [30]. Before discharge, all patients followed an educational session with a specialized Nurse regarding the everyday management of their disease (drugs, relevant signs and symptoms, lifestyle). Patients' General Practioners received a detailed clinical report and were informed on the study characteristics. Overall, 80 patients were randomized 1:1 either to an Integrated Management group (IM, n=40) or to a Usual Care group (UC, n=40), with a pre-defined follow-up of one year. Table 2 shows that the two groups did not differ regarding demographic, clinical, echocardiographic and neurohumoral characteristics.

Data collection

Figure 1 shows the outline of the study. Before discharge (time T0), all patients underwent (1) 12-leads electrocardiogram, (2) 2-D echocardiography with colorDoppler, (3) cardiopulmonary test if feasible; (3) plasma BNP levels assessment. In both groups, clinical evaluation was repeated 3, 6, 9 and 12 months afterwards (T_1, T_2, T_3 and T_4 respectively, (Figure 1); echocardiography was performed on visits T_2 and T_4. During clinical evaluations from T_0, to T_4, adherence to drugs' prescriptions was assessed formally using the validated Morisky Medications Adherence Scale [31].

Home-monitoring and home-care protocol

In the Usual Care group, patients were discharged with a pre-defined program of trimestral controls at our Heart Failure clinic, because referral to specialized outpatient clinics was, and still is, recommended by clinical guidelines for fragile patients [32,33]. In the Integrated Management group, patients and their care-givers undergo a specific training in the use of the dedicated PDA described above. Every day, the PDA acted as a reminder of the correct timing for the pills; moreover, at a fixed predefined time patients were asked to send via PDA their weight, blood pressure, heart rate and (in some cases) their diuresis. Monthly, a psychological assessment was performed through the PDA software about anxiety (STAI-6; Spielberger's State Trait Anxiety Inventory [29], depression (PHQ-9; Patient Health Questionnaire) [30] and perceived well being (PGWBI; Perception of General Well-Being Inventory) [34]. In addition, the psychologist was always available for patients' counseling during each follow-up visit. Through remote control, patients' clinical conditions and their compliance to medications was checked on a daily basis through a questionnaire. Moreover, the cardiologist could modify the treatment and suggest further evaluations or tests if needed.

Adverse events

A relevant goal of the study was to evaluate whether our rather complex and highly technological model of disease management could affect the clinical and psychological status of high-risk patients with chronic heart failure. Thus, we considered the impact of the Integrated Management on major and minor clinical adverse effects and on psychological variable, as described below. Cardiovascular

INCLUSION CRITERIA	*EXCLUSION CRITERIA*
1. NYHA class III/IV during hospital st ay 2. Left ventricular systolic dysfunction (EF ≤ 40%) 3. High risk of early re-hospitalization at discharge (at least 2): a. age >70 years b. >2 hospitalizations for heart failure in the last 6 months c. >1 co-pathologies (diabetes, COPD, cerebrovascular disease, renal failure).	1. Active waiting list for heart transplantation 2. No possibility of discharge at home 3. Hypertrophic cardiomyopathy 4. Surgically treatable valvular disease 5. Surgically treatable coronary disease 6. Myocardial infarction, *angina pectoris* or CABG in the previous two months 7. Psychiatric disease 8. Alcohol or drugs' abuse 9. Non-cardiac disease with frequent hospital admissions 10. Concomitant studies 11. Uncapability or refusal to learn the use of PDA 12. Life expectancy less than 12 months

Table 1: Enrolling Criteria.

	ALL PATIENTS n=80	USUAL CARE n=40	INTEGRATED MANAGEMENT n=40	P χ^2/t test
Age	72 ± 3	73 ± 5	71 ± 4	
Males/Females	59/22	29 / 18	30 / 4	NS
Ischemic Heart Disease (%)	44 (54.3%)	26	17	NS
Diabetes (%)	38 (46.9%)	20	18	NS
Familiar history of IHD (%)	33 (40.0%)	18	15	NS
Smokers (%)	48 (59.3)	26	22	NS
Hypercholesterolemia (%)	22 (27.2%)	14	8	NS
NO RISK FACTORS (%)	9 (11%)	5 (12%)	4 (10%)	NS
1 risk factor (%)	12 (15%)	8 (20%)	4 (10%)	NS
2-3 risk factor (%)	26 (32%)	15 (38%)	11 (28%)	NS
>3 risk factor (%)	34 (43%)	19 (48%)	15 (38%)	NS
SAP mmHg	123 ± 11	127 ± 10	119 ± 12	NS
DAP mmHg	75 ± 9	79 ± 8	70 ± 11	NS
HR b/min	67 ± 5	67 ± 4	67 ± 6	NS
BMI Kg/m²	26.8 ± 1.0	27.3 ±1.1	26.2 ± 0.8	NS
NYHA class	3.01 ± 0.45	2.90 ± 0.69	3.08 ± 0.57	0.33
ECHOCARDIOGRAM				
EF (%)	32 ± 5	32 ± 8	31 ± 6	0.31
PAP (mmHg)	40 ± 8	39 ± 9	41 ± 13	0.48
Diastolic dysfunction (%)	35 (43%)	16 (40%)	19 (47%)	NS
Moderate/severe MR (%)	29 (36%)	15 (39%)	13 (33%)	NS
BLOOD TESTS				
K+ (mEq/l)	4.40 ± 0.5	4.34 ± 0.6	4.42 ± 0.7	NS
Na+ (mEq/l)	142 ± 2.3	142 ± 3.6	142 ± 4.1	NS
Glucose (mg/dl)	101 ± 6	102 ± 8	100 ± 7	NS
Hemoglobin (g/dl)	12.94 ± 1.3	12.46 ± 1.5	13.35 ± 1.3	NS
Serum creatinine (mg/dl)	1.32 ± 0.6	1.22 ± 0.5	1.37 ± 0.5	NS
BNP (pg/ml)	332 ± 93	361 ± 72	314 ± 94	p=0.59
PSYCHOLOGICAL TESTS				
STAI-6	41.8 ± 7.4	41.5 ± 6.6	42.2 ± 8.2	NS
PHQ-9	25.9 ± 3.4	25.0 ± 3.3	26.8 ± 3.3	NS
PGWBI	61.4 ± 8.3	62.1 ± 8.7	60.6 ± 7.8	NS
MMAS	2.7 ± 0.5	2.7 ± 0.9	2.8 ± 0.4	NS

SAP: systolic arterial pressure; **DAP:** diastolic arterial pressure; **HR:** heart rate; **EF:** ejection fraction; **PAP:** pulmonary artery pressure (estimated); **MR:** mitral regurgitation; **BNP:** Brain Natriuretic Peptide; **STAI-6:** Spielberger's State Trait Anxiety Inventory; **PHQ-9:** Patient Health Questionnaire for depression; **PGWBI:** Perceived General Well Being Index; **MMAS:** Morisky Medical Adherence scale

Table 2: Patients' Characteristics at Enrolment.

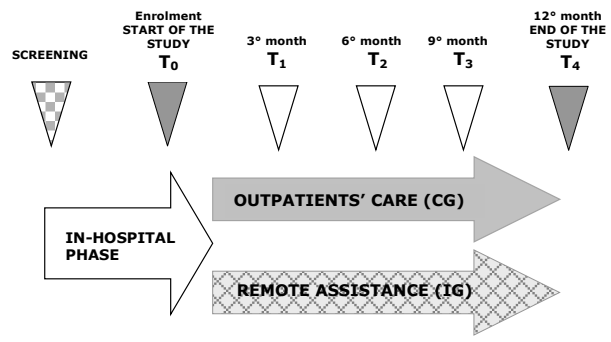

Figure 1: Flow-chart of the study protocol. See text for discussion.

death or hospitalization for heart failure lasting more than 3 days were considered *major adverse effects*, and represented the primary aim of the study. To quantify the use of healthcare resources, we also considered

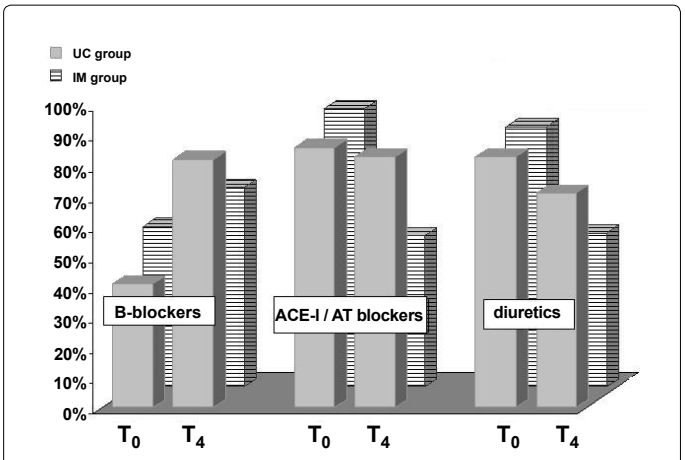

Figure 2: Difference in the percentage of patients in the two study groups who reached at least 70% of the target dose of each drug type at the beginning (T0) and at the end of the study (T4). In the figure, 100% is the ideal target dose recommended by Guidelines.

the following as *minor adverse effects* (1) any hospital stay of less than three days, included Emergency Department visits; (2) any unplanned instrumental investigation and/or blood testing; (3) any unplanned clinical visit.

Economical evaluation

To obtain a *global cost assessment*, at the end of the study we calculated the following variables [1] *intervention's cost*, as the sum of all costs for the start-up (electronic equipment, software, hourly cost of the instructing personnel) and for the medical and non-medical personnel (time used and its hourly cost) [2] events' cost (fees for visits, hospital admissions, blood tests, instrumental investigations etc.). The two types of cost were then attributed to each of the two study group as Euros/group of patients.

Statistics

Data were acquired and stored by ODBC technology. Analysis was performed on a Microsoft SPSS 11.5 package. In the Integrated Management group, we analyzed data from patients who could send by their PDA at least one set of data (intention to treat analysis, ITT). Continuous variables are expressed as mean ± 1 standard deviation (SD). We compared their values at baseline (T_0) and at one year follow-up (T_4) by t-test (within the same group) and by one-way analysis of variance (between groups). Categorical variables were compared using the χ^2 test with Yates' correction. A value of $P<0.05$ was considered significant.

Results

Feasibility of the study

The PDA was accepted by the patients and their care-givers: the system was easy to use, its instruction was straightforward and the telephone line was always available. Moreover, a toll-free number was available on weekdays, connecting the patients with their reference Centre, for any problem that could ensue. Overall, patients learned to use the system and only one dropped out after few days.

Clinical results

Table 3 shows the main clinical and echographic variables at

	USUAL CARE n=40		INTEGRATED MANAGEMENT n=40		P ANOVA/χ^2
	T_0 baseline	T_4 followup	T_0 baseline	T_4 followup	UC-IM
NYHA class	2.90 ± 0.69	2.40 ± 0.45*	3.08 ± 0.57	2.08 ± 0.38*	<0.02
ECHOCARDIOGRAM					
EF (%)	32 ± 8	34 ± 10	31 ± 6	36 ± 9*	0.063
PAP (mmHg)	39 ± 9	38 ± 10	41 ± 13	33 ± 8*	<0.05
Diastolic dysfunction (%)	16 (40%)	14 (33%)	19 (47%)	10 (25%)*	0.081
Moderate/severe MR (%)	15 (39%)	15 (39%)	13 (33%)	12 (30%)	0.121
BLOOD TESTS					
BNP (pg/ml)	361 ± 72	263 ± 152	314 ± 94	202 ± 127*	0.058
PSYCHOLOGICAL TESTS					
STAI-6	41.5 ± 6.6	41.6 ± 6.0	42.2 ± 8.2	35.1± 6.3 §	<0.01
PHQ-9	25.03 ± 3.3	29.1 ± 3.3*	26.8 ± 3.3	24.0 ± 2.6 §	<0.01
PGWBI	62.1 ± 8.7	56.2± 8.7*	60.6 ± 7.8	68.3 ± 3.2 §	<0.01
MMAS	2.7 ± 0.9	3.0 ± 0.8	2.8 ± 0.4	3.8 ± 0.5*	<0.05

*=p<0.05 T_4 vs.T_0 (T-test); §=p<0.0001 T_4 vs.T^0 (T-test)

Table 3: Differences in Clinical Variables at Followup.

	USUAL CARE n=40	INTEGRATED MANAGEMENT n=40	P ANOVA/χ^2
MAJOR EVENTS			
Mortality	5	9	NS
Hospitalization for HF>3 days	12	23	<0.03
TOTAL MAJOR EVENTS	**17**	**32**	**<0.04**
MINOR EVENTS			
Unscheduled visits	35	9	<0.01
ER admissions			
Green/White code	6	10	n.a.
Yellow/Red code	0	7	n.a.
Total admissions	6	17	<0.02
TOTAL MINOR EVENTS	**41**	**26**	**<0.05**

Table 4: Adverse Events at Followup.

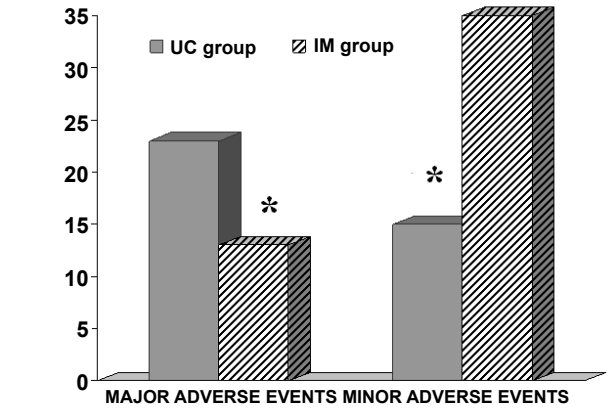

Figure 3: Different incidence of adverse events in the two study groups, grouped in Major and Minor according to the Study design.

baseline and at the end of follow-up (T_4) in the two groups of patients. We observed in both groups a significant improvement in NHYA class that was greater in the Integrated Management group. In these patients only, we observed a significant increase in left ventricular ejection fraction and a reduction in estimated pulmonary pressure at echocardiography. Moreover, BNP levels were lower at T_4 compared to T_0 in the Integrated Management group (-36%, p<0.05), while they did not change significantly in the usual Care group. Patients' compliance, evaluated by the Morisky Adherence Scale [31], was higher at T_4 than at T_0 in both groups, but highest in the Integrated Management group. Table 4 shows the impact of the two treatment strategies on major and minor adverse events: a significant reduction in major adverse events (the pre-defined goal of the study) was observed in the Integrated Management group.

Pharmacological treatment

Drugs were administered according to 2008 ESC guidelines [30]; to describe the process of titration, at each visit we expressed for each drug the dose being administered to the patient as a percentage of the target dose (defined as 100%). From (Figure 2), it appears that a gradual, significant drugs' titration was obtained only in patients of the Integrated Management group, while in the Usual Care group there was a gradual reduction of drugs' dosages, that at was significant in comparison with T0 when the use of beta-blockers and diuretics was considered.

Adverse events

These data are shown in (Table 4). The occurrence of *major adverse events* (mortality and hospitalizations for heart failure lasting more than 3 days) represented the primary goal of the study. In the whole population, at followup we had 14 deaths (14% one-year mortalità): 9 in the Usual Care and 5 in the Integrated Management group, without significant differences between groups. On the contrary, in the Integrated Management group there was a significantly lower incidence of hospitalizations (12 vs. 23; χ^2 with Yates' correction: p<0.03). Overall, in the Integrated Management group there was a significant reduction of the composite end-point of mortality and hospitalizations (32 vs. 17, χ^2 with Yates' correction: p<0.04). Both kinds of adverse events prevailed in the first 6 months of the study (χ^2 with Yates' correction: p<0.05) .

In the Usual care group, there was a lower incidence of *minor adverse effects* compared to patients in the Integrated Management group (26 vs. 41, χ^2 with Yates' correction: p<0.05). In the Integrated Management group, the most frequent minor adverse event was in fact a programmed visit, requested by the cardiologist after the analysis of the data transmitted by the PDA (35 vs. 15, χ^2 with Yates' correction:

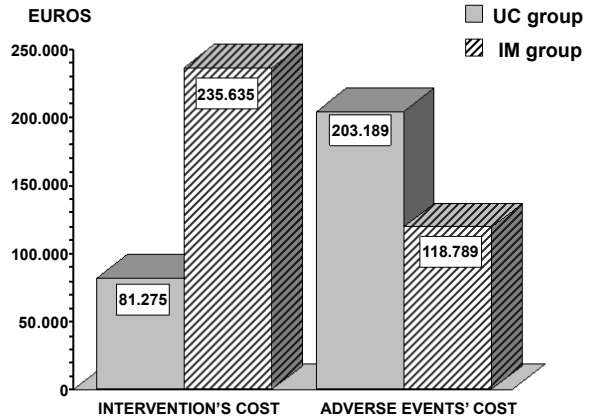

Figure 4: Differences among groups in the yearly cost for implementation of the study (i.e. the "intervention cost") and the management of the adverse events. Costs are expressed in Euros/patient.

p<0.01). On the other hand, Emergency Department admissions for worsening heart failure were more frequent in patients in the Usual Care group: 17 admissions, of which 7 in yellow code, with respect to 6 admissions, of which 4 in green code and 2 in white code (χ^2 with Yates' correction: p<0.02). No differences were found between groups regarding other end-points such as ICD implantation/revision, sincope, need for cardiac rehabilitation, need for cardiac surgery, hypertensive emergency (Figure 3).

Costs' analysis

Figure 4 shows that the Integrated Management was more expensive by 65% if the service provided was taken into account (Intervention's cost), but that a 42% costs' reduction was observed for aderse events cost (minor *plus* major events). We also run a sub-analysis taking into account separately minor from major events, considering a *cost/patient* at the end of follow up. In this case, the Integrated Mangement group allowed a 48% cut in the expenses for major adverse events compared to the Usual Care group (8.690 Euro/patient vs. 16.607 Euro/patient, P<0.05), while minor adverse events were 57% less costly in the Usual Care group (902 Euro/patient vs. 2105 Euro/patient in the Integrated Management group, P<0.05).

Psychological symptoms

At baseline, patients showed symptoms of psicological distress, such as anxiety, mild depression and a low perceived well being, as showed by the scores of the tests in (Table 1); no differences were observed between groups. Table 3 shows how these variables changed at followup. In the Integrated Management group, there was a significant reduction in depressive symptoms (-36%. P<0.0001), anxiety score (-38%, p<0.0001) and an increase in the perceived well-being score (PGWBI+23%, p<0.0001). In patients in the Usual Care group, on the contrary, we observed a slight worsening in depressive symptoms (-16%, p<0.01) and in the perceived well-being score (PGWBI-11%, p<0.01).

Disscussion

ICAROS characteristics

ICAROS showed that, in heart failure patients carrying a high risk of relapses, the regular acquisition of simple clinical information and the possibility for the patient of getting in touch easily with the staff helped to improve drugs' titration, to reach a better psychological status and quality of life, and moreover to reduce hospitalizations for heart failure. The participants to the projects enthusiastically brought in their different fields of expertise, and their teamwork represented key to the success. In our study, taking advantage of a well-organized call center and of our trained nurses' staff, who were all introduced to the patients and their caregivers, the use of PDA was illustrated already during the hospital stay. This helped the patients, who had more time for asking questions and familiarize with the device. Bearing in mind that we did not include patients with relevant social and cognitive problems, our coort of elderly patients used the PDA with ease and accepted the device; in fact only one of them refused to continue the study. In ICAROS, we used a nurse-based approach, similarly to what has been proposed by most studies [9,12,14,19,24]: the cardiologist was involved by the nurse when appropriate.

Clinical and Psycological results: ICAROS in the real world

Clinical management of patients with heart failure in everyday clinical practice often differs from what is recommended by International Guidelines. For patients bearing high risk of relapse and those in NYHA class III and IV, current opinions suggest a referral to heart failure outpatients' clinics managed by dedicated cardiologists [22], where a stricter adherence to recommendend treatments seems to improve patients' prognosis [35,36]. This is the reason why for patients in the Usuak Care group we choose the best care recommended by Guidelines, i.e. the referral to our Heart Failure Clinic, where they were regularly followed. To confirm the rightness of our choice, at one-year followup the clinical status of these patients was stable and their mortality, in fact lower than that reported in the literature [36,37], was similar to that of patients in the Integrated Management group.

At one-year follow-up, patients in the Integrated Management group showed higher adherence, improved clinical and psycological status, recovery in some parameters of prognostic relevance such as ventricular function and BNP levels, and reduction in hospitalizations for heart failure. We attribute these favourable results to the daily monitoring of vital paramenters and treatments' compliance, the weekly check of psychological well-being, and the possibility of performing unscheduled cardiological and psychological evalutions. Unscheduled controls are the reason of a higher number of minor adverse events in our study: not surprisingly however, the greater number of minor events, leading to therapy changes, compliance enforcement and psychologic counselling, could have contributed to the significant reduction of major adverse events. We can conclude that patients in the Integrated Management followed a management system of *even-better-care*, where the possibility of everyday monitoring and unscheduled, "open access" controls integrated the reguar routine provided by the best care of the Heart failure Clinic.

Cost/effectiveness

Some of the available studies claim that Telemonitoring reduces the cost of patients management by 20 to 30% [18,38,39]; however, these figures often do not include the extra expenses due to technical supplies, personnel, unscheduled visits and clinical tests. Albeit very crude, the analysis we present here shows that the clinical cost of the patients in the Integrated Care arm of the ICAROS was significantly lower (reduction of serious events), but that the cost of the service was significantly increased compared to that of standard care. This was not unespected, due to the need to develop and implement the whole system and train the personnel, and of the small number of patients treated.

Had ICAROS continued including a greater number of patients, the increased saving due to the reduction in hospitalization would surpass the cost of the service. Indeed, in patients with more severe disease like those we studied with the ICAROS project, Telemonitoring is more cost-effective in the long run [17,18,40].

ICAROS and other Telemonitoring/Telecare models

The goal of *Disease management* in a world of scarse financial availability is to reduce the operating cost without cutting effectivness and efficacy, by creating disease-specific pathways of diagnosis and care. Regarding heart failure care, a key issue is the definition of the figures that must be involved, of their level of expertise and of the kind of patients who should and could be treated [20,21]. Thus, it is mandatory to build a a completely new standard of assistance, involving a strict cooperation and information exchange among heart failure specialists, dedicated nurses and general practitioners: indeed, a patient should be followed, according to his/her clinical status, by anyone of these caregivers in different times [39]. A network of *telenursing* for patients with hert failure could help the General Practioner, allowing his/her regular exchange of clinical information and consulting with the Heart Failure Center [25,26]: an experience of this kind is currently ongoing in many Italian regions, and among them is Lombardia. We have already suggested that a Telemonitoring similar to the ICAROS model could take place in a first phase, soon after hospital discharge when patients are more fragile [27]. Indeed, after a decade and in a different population treated more aggressively in a Cardiology department, we confirmed the data of the TEMISTOCLE study [3], showing that the majoirity of events after discharge took place in the first six months.

A final consideration is that telemonitoring does not imply telecare: this may explain the failure of some ambitious, multicenter studies [20,21] and the better results coming from local experiences, where patients were most likely to benefit from an individually tailored interaction with dedicated, well-trained and highly specialized care providers [19,23,24]. In other words, without a spoonful of human touch, plain telemonitoring and telecare, although homogeneously provided following predetermined flow-charts, is probably costly an poorly effective [23,24,39].

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