



## Telemonitoring in Cystic Fibrosis: Treatment's Adherence and Economical Evaluation in a Period of Three Years

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### ABSTRACT

*We examined data related to Adherence to telemonitoring in our Cystic Fibrosis patients followed at home for a period of 3 years. We tested the possible presence of a saving for Italian National Health Service. We kept electronic records of transmissions, in spreadsheet format. A summary of the activities was carried out automatically. A monthly average percentage of Adherence to prescribed frequency of transmissions is calculated. We performed an economic analysis of the costs for patients followed at home by telemonitoring, recalled under suspicion of acute pulmonary recurrence. We received, from February, 15 2010 to May, 31 2013, 2097 data transmissions overall. The average compliance in the reporting period was 28,86%, with increasing trend. We calculated a saving compared to traditional home care of €5.320,33 /year/patient. We conclude that the improvement of outcome in FC necessarily passes through an improvement of the Adherence to treatment. The presence of an economic advantage is once again, although not significant. More controlled psychological and behavioral studies are needed to establish the real long-term effectiveness of the use of Telehomecare in CF.*

**KEYWORDS : telemedicine ; telemonitoring ; cystic fibrosis ; economic evaluation**

### Introduction

In Cystic Fibrosis (CF), the natural history is characterized by recurrent episodes of respiratory infection that causes a progressive pulmonary damage, with decay of long-term lung function leading to death [1].

Spirometry shows over time in these subjects a reduction in forced expiratory volume in the first second (FEV1), and then also a reduction in Current Volume (FVC), which is around 2% of the expected value every year [2].

In case of pulmonary exacerbation, an early initiation of antibiotic treatment helps to prevent the development of more serious complications limiting consequently also the pulmonary damage in the long term. Early interventions also allow us to use advantageously less invasive antibiotic therapies, even using the oral route of administration [3].

### BACKGROUND

Since 2001, in the CF Centre of the Pediatric Hospital Bambino Gesù in Rome, we started to use Telehomecare (THC) in the follow-up of our patients at home. The first results of this work have been encouraging. We found a statistically significant reduction in hospital admissions and a tendency over time towards a better stability of the respiratory function [4].

It is known that, from a psychological point of view, telemedicine can help to improve the outcome through the acquisition of a better awareness of the disease and of the therapeutic program by the patient [5]. In our experience, the outcome improvement in the follow-up in CF necessarily passes through improving Adherence to treatment [6].

Regarding the economic aspect, to date definitive studies on a possible positive role of telemedicine in the rationalization of hospitalization related to long-term follow-up in CF are lacking.

We have attempted to quantify the costs of telemedicine in the fol-

low-up of our patients. In an initial feasibility study [7], we calculated a possible annual saving of € 5241 for each CF patient.

In a subsequent study, conducted "in the field" [8], we performed an economic analysis of the costs for 19 CF patients followed at home with remote monitoring for a period of 2 years. We analyzed the actual costs incurred by Italian National Health Service (INHS) every time they have been called to the hospital for suspicion of a respiratory exacerbation. We calculated a total saving, compared to the traditional method without telehomecare, of € 132,144.91 in 24 months, corresponding to € 3,303.62 / year / patient. The presence of an economic advantage for the INHS is then also confirmed, although the amount of the saving is not large, relatively to the total costs. Data from the study encourage a possible role of telemedicine in the organization of home care of patients with CF. In the present study we examined the clinical and economic data related to the activities of telemonitoring on behalf of our CF patients followed at home for a period of 3 years, in order to better understand the evolution of clinical trends and the evolution of the economic in time.

### Materials and Methods

This is a case feasibility study on using telehomecare for cystic fibrosis follow-up.

24 patients are currently included in the THC program.

A clinical diagnosis of CF was given in all subjects, confirmed by study of the CFTR gene and the sweat test. Patients included in THC program are still followed and treated with the usual protocols of follow-up, similar to those who do not practice [9].

We used Spirotec™ instrumentation, which provides and transmits remotely data from spirometry and overnight pulse oximetry. The working method was described and discussed in a previous study [10].

Since February 2010, we started keeping an electronic register, in

spreadsheet format. For each transmission, the main parameters and the measures are recorded. A monthly statement of assets and the calculation of the average percentage of Adherence to the recommended frequency of transmissions (defined as the ratio transmissions / total patient days) is automatically done .

We also quantified the actual costs associated with the use of telehomecare in the follow-up of patients. We have considered as costs all the hospital admissions (Day and Ordinary), the cycles of therapy at home and the rent for the telemedicine equipments. We have considered as revenues the incomings from the use of the available beds and the working days retrieved.

We formulated the hypothesis that, without telehomecare, each recall would have resulted in hospitalization for the necessary clinical test and any treatment. To evaluate the possibility of an economic benefit from the use of THC, in order to rationalize hospital admissions, we compared the actual costs incurred by INHS with the costs that would be sustained if each recall had resulted in hospitalization.

**Results**

The data are related to the activity carried out in the period from February,15 2010 to May,31 2013.

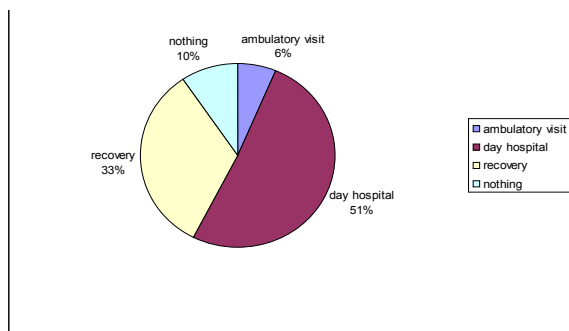
We enrolled in THC a total of 39 patients. 15 dropped out (38,46%), 9 for poor adherence (60%), 4 because they died (26,67%), 2 for other causes (13,33%) (Tab. 1).

**Balance of enrolment**

Patients	n.	%
enrolled	39	
active	24	61,54
drop-out	15	38,46
poor adherence	9	60,00
died	4	26,67
other	2	13,33

We followed in the period an average of 28 patients.

We received 2,097 transmissions containing 2766 spirometry and 706 pulse oximetry. Since April 2011 we received 1031 questionnaires regarding symptoms. We carried out all over 1803 phone calls, getting immediate response by the patient or family in about 85% of cases. The average adherence to treatment during the period was 28.86%, with increasing trend over time . We carried out, following the transmissions, 94 recalls in hospital which affected 24 patients (11 calls in 2010, 15 in 2011, 54 in 2012 and 14 in the first five months of 2013). Regarding the proceedings run, in 51% of cases the recall was followed by a Day Hospital and 33% by an hospitalization. In 6% of cases only a visit was performed (Fig.1).



**Fig.1. Measures that have followed the recalls.**

Regarding the economic aspect, the long-term follow-up with telehomecare resulted in a total calculated savings compared to the traditional method of € 414,985.87 in 39 months corresponding to € 5,320.33 per year per patient recalled (Tab.3).

**TABLE III. Cost analysis**

Unitary costs	
hospitalisation	€ 4.065,00
Day Hospital	€ 266,00
Ambulatory visit	€ 32,00
lv home cycle (21days)	€ 2.027,00
Oral home cycle (21 gg)	€ 283,00
SpiroteITM Monthly Loan	€ 210,00
Working day	€ 147,00
Observation period months	39
Patients involved n.	24
Retrievals n.	94
Telemedicine -	
Cost for 94 admissions (inpatient + outpatient therapy)	€ 580.638,93
Telemedicine +	
Cost of the services actually provided (INHS)	€ 235.304,06
Instrumentation rental for 24 patients	€ 187.530,00
Total costs	€ 422.834,06
Income for further utilization of beds	€ 239.835,00
Revenue for recovery of working days	€ 17.346,00
Total savings	€ 257.181,00
Effective cost of Telemedicine+ (cost - savings)	€ 165.653,06
Balance	
Tot. saving (Telemedicine- - Telemedicine+)	€ 414.985,87
Annual saving per patient (tot. saving/39 months/24patients) x12 months	€ 5.320,33

Obviously, the economic analysis refers to the parameters of remuneration of Italian National Health System (INHS), and therefore are only valid in this context.

**Discussion**

We observed an annual growth in the number of transmissions despite the decrease of the number of patients followed. This fact shows an increasing use of the system.

The progressive increase of Adherence to treatment means a better overall use of the method. Regarding the frequency of the transmissions, we have recommended to our patients a variable interval depending on the clinical condition, generally 2 times a week at least. In this sense, we expect the optimal adherence to treatment to be 100% for 2 transmissions per week / 5 working days. We got in clinical practice a constant and progressive increase of treatment's adherence to achieve in practice a doubling of the values during the period under review (Tab. 2).

**TABLE ii Summary of activity**

Activity from February,15 2010 to May,31 2013					Total
Years	2010	2011	2012	2013	3,25
patients n. (mean)	30	29,7	25,5	23,6	28,4
transmissions	536	730	831	357	2097
Adherence %	21,96	24,04	33,79	35,66	28,86%
Spyrometry	658	1048	1060	399	2766
Pulse oximetry	183	231	292	104	706
symptoms		322	709	318	1031
phone calls	466	592	745	333	1803
answers			618	285	618
% answers/calls			82,60%	85,62%	83,77%
inpatients	11	15	54	14	94

It is also to consider that CF patients are already burdened with a continuous load and considerable therapies, both medical and physiotherapy, and that this result has yet been obtained without requiring a precise timetable for recording. The method we have used in daily practice, described and discussed in a previous study, has remained unchanged. We report the objective fact that from 2011 we have started to call via cell phone always patients after a transmission, even under conditions of clinical stability. It is not possible to evaluate how much this has contributed to the increase in the values of adherence to treatment, at the current stage. The fact remains that this is the only change made in the protocol of follow-up. The possibility of a link between these data is interesting and certainly requires further studies to be defined.

The mobile phone was the medium we used to establish the contact. The percentage of the successful calls appears to have improved over time, but the mobile phone, in our opinion, continues to be valuable but not always completely reliable.

From the economic point of view, the presence of an economic advantage for the INHS is confirmed, even if not important. The increase in the calculated savings compared to our previous study indicates in our opinion a better efficiency of follow-up.

Some of our patients in telemedicine have never been recalled. For them it is impossible to carry out an assessment of the cost-effectiveness of telemonitoring that, in this case, has resulted only in costs.

There are currently no universally accepted criteria for inclusion of pa-

tients with CF in a telemonitoring program [11]. In Italy, in particular, telemonitoring is not within the Essential Levels of Assistance (LEA) provided by our National Health System (INHS). The viability of telemonitoring still depends, in individual cases, on voluntarily resources made available by the local health authorities.

From the perspective of economic and organizational constraints, it seems necessary to arrive to uniquely define as soon as possible the criteria for inclusion, both in relation to the individual clinical situation both at the lowest adherence to the method that is compatible with a clinical benefit, as well as economic. In our opinion the advantage in terms of quality of life for these patients remains in any case, resulting from the fact of having at home a tool that allows them to remain in contact with the CF centre more easily, which is certainly important, however, and could also be measured in terms of economy.

### Conclusions

The trend of both quantitative and qualitative parameters of our work is positive. The data are encouraging with regard to the possible role of telemedicine in the organization of homecare of chronic diseases. In the current state, however, reliable data on the long-term effectiveness of the use of Telehomecare in CF are lacking.

Data on the real long-term effectiveness of the use of Telehomecare in CF can only be obtained through a study of controlled type, for which appear the time to be ripe to format.

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