

Tele-assistance in Chronic Respiratory Failure Patients: a Randomised Clinical Trial

M. Vitacca<sup>1</sup>, L. Bianchi<sup>1</sup>, A. Guerra<sup>1</sup>, C. Fracchia<sup>3</sup>, A. Spanevello<sup>4</sup>, B. Balbi<sup>5</sup>, S. Scalvini<sup>2</sup>

1 Divisione di Pneumologia, Fondazione S. Maugeri, IRCCS, Lumezzane (Bs) – Italy

2 Servizio di Telemedicina, Fondazione S. Maugeri, IRCCS, Lumezzane (Bs) – Italy

3 Divisione di Pneumologia, Fondazione S. Maugeri, IRCCS, Montescano (Pv) – Italy

4 Divisione di Pneumologia, Fondazione S. Maugeri, IRCCS, Cassano delle Murge (Ba) – Italy

5 Divisione di Pneumologia, Fondazione S. Maugeri, IRCCS, Veruno (No) – Italy

*Correspondence:*

*Michele Vitacca M.D.,*

*Pneumology Division*

*Fondazione Salvatore Maugeri,*

*Via Mazzini 129, 25066*

*Lumezzane (Bs), Italy.*

*e-mail: mvitacca@fsm.it.*

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## Abstract

Chronic respiratory patients requiring oxygen or home mechanical ventilation experience frequent exacerbations and hospitalisations with related costs. Strict monitoring and care have been recommended.

The primary aim was to evaluate reduction in hospitalisations and secondarily exacerbations, general practitioner (GP) calls and related cost-effectiveness of tele-assistance (TA) for these patients.

240 patients (101 COPD) were randomized to two groups: intervention group received one year TA program while controls received traditional care

No anthropometric and clinical differences were found between groups both in baseline and in mortality (18% for TA, 23% for controls). As compared with controls, TA group experienced less hospitalizations (- 36%  $p < 0.02$ ), less GP urgent calls (- 65%  $p < 0.002$ ), less acute exacerbations (- 71%  $p < 0.0001$ ). Only COPD patients, as a separate group had more subject free from hospitalizations ( $p = 0.012$ ), emergency room admissions ( $p = 0.0008$ ), urgent GP calls ( $p = 0.013$ ) or exacerbations ( $p < 0.0001$ ). Each patient referred to staff  $36 \pm 25$  times. After deduction of TA costs, the average overall cost per each patient was 33% less than that for usual care.

In chronic respiratory failure patients on oxygen or home mechanical ventilation, a nurse-centred Tele-assistance prevents hospitalizations while it is cost/effective. The COPD group seems to have the bigger advantage from tele-assistance.

*(clinical trials identifier N° NCT00563745)*

## Introduction

Home care for respiratory patients is a complex array of services delivered in an uncontrolled setting in which patients and families are integral members of the health care team (1). Complexity, lack of direct control, acute exacerbations on chronic conditions, all likely contribute to the difficulty in organizing home care assistance (1). Among home care programs, mechanical ventilation at home (HMV) shows a great prevalence in European countries (2).. Follow-ups have been strictly recommended to be structured and are to be integrated with technology for patients on HMV (3-5) since traditional, nurse-based home follow-up programs, if they exist, have limitations relating to the number of patients that can be included, costs and logistic problems such as distance and time needed to reach the patients at their homes. A recent ATS statement (1) has emphasized the need of a strict follow up of these frail patients. In particular home care should focus on a patient-centered perspective and patient and family satisfaction: reduction of complications resulting from hospitalization, maintaining an acceptable quality of life, and enabling a comfortable and dignified death have been proposed as major end points (1). Chronic obstructive pulmonary disease (COPD) seems to be the most problematic chronic disease for all the health systems, with frequent exacerbations, hospitalisations and related costs (6-9). Various follow-up models to prevent hospitalizations and exacerbations have been proposed: these include self management (10,11), home care (12), dedicated chronic care model supported by information technologies or not (13,14). The need to rationalize health care costs (15,16,17) has prompted the development of new technologies for home assistance (18). The model of telemedicine has recently been tested in different studies (13, 19-22) with the major end-points to assess program feasibility. However, controlled studies that evaluate the influence of this new technique on outcomes are lacking.

The primary aim of this study was to evaluate the reduction in hospitalisations resulting from a tele-assistance program (TA) based on a continuous 24 h on-call service and pulse oximetry

availability, as compared with the usual out-patient follow-up regimen in patients requiring oxygen therapy or HMV.

Secondary end points were to test reduction in home exacerbations, emergency room accesses, GP urgent calls and a possible cost-effectiveness.

## Methods

This prospective study was conducted in all patients with CRF discharged from the Respiratory Department of Fondazione S. Maugeri Gussago/Lumezzane (Italy) from 30<sup>th</sup> April 2004 to 31<sup>st</sup> March 2007.

The inclusion criteria were: 1) need of home mechanical ventilation, and/or 2) need of long term oxygen therapy (LTOT) and at least one hospitalization for respiratory illness in the previous year. Exclusion criteria were: 1) illiteracy or no telephone access at home 2) residence in a nursing home 3) no caregiver to facilitate telephone contacts 4) refusal. Of 351 CRF patients, 240 (68.3%) fulfilled the selection criteria and were enrolled in the study (fig.1). Using a set of computer-generated random numbers in 1:1 ratio patients were assigned to the treatment or control group. After informed consent was obtained all patients received a pulse oximetry device (Nonin 9500 oximeter Minneapolis Plymouth USA). In selected cases (severe clinical and pulse-oxymetric worsening in spite of drug therapy re-arrangement, long term oxygen or mechanical ventilation resetting, correct titration of oxygen supply during night and activities of daily living, and suspect of nocturnal hypoventilation) patients received a pulse oximeter with solid memory card (Nonin 2500 oximeter Minneapolis Plymouth USA) plus a modem system (30 EM model Medical Botticelli web, Digicom Cardano al Campo Varese Italy) able to transmit a pulse arterial saturation (pSat) trace through the home telephone line. When necessary the trace was sent to a receiving station where a TA nurse was available 40 h/week (8 am to 4 pm 5 days/week) to provide a real-time tele-consultation. TA nurse followed patients in study and other 80-100 patients inserted in the same TA program of our hospital. Unscheduled calls were transferred to

the on duty pulmonologist who provided a consultation. The call center was able to receive data 24 h/24 concerning patients' needs or questions and, when needed, the pulmonologist on duty was contacted. TA group patients had no scheduled out-patient visits with the pulmonologist. Scheduled appointments-telemonitoring and *ad hoc* appointments-teleassistance were conducted as described in detail elsewhere (22).

Patients in the usual care group were evaluated by the physician before discharge. Follow-up outpatient visits aimed at assessing compliance to therapy, HMO and/or LTOT were scheduled every 3 months according to the usual procedures of the study centre. The discharge plan did not include home nurse visits.

#### *Measurements and instruments*

At the first contact (baseline) the nurse tutor administered to TA patients a clinical scoring system, RESPICARD<sup>R</sup> (23); this was used during the follow-up telephone contacts to assess any clinical variation. The system is described in detail in Appendix 1. If there was a score variation of 3 points or more from baseline, the nurse was instructed to contact the pulmonologist for consultation. Baseline anthropometric and clinical data of all patients were recorded: premorbidity life style (of) score (ranging from 0= employed with maximal level of autonomy to 4= bedridden -PSL) (24), respiratory function, arterial blood gases and number of comorbidities. TA staff calls and number of pulseoxymetry recordings were registered in the electronic data base. During the study the following data were recorded: mortality, exacerbations requiring antibiotics and/or steroids, days free from the 1st exacerbation, hospitalizations, days free from the 1st hospitalization, ICU admissions, emergency room admissions, days free from the 1st emergency room access, urgent GP calls and days free from the 1st GP call. Details of the call centre are reported elsewhere (22). Fixed and variable call centre costs as well as nurse and medical 2<sup>o</sup> opinion costs are reported elsewhere (25). Pulseoxymetry devices costs (table 4) were calculated as the hire costs for the study duration or dividing the total costs by the number of patients enrolled in 3 years. The total TA costs were expressed as monthly cost and mean cost

per patient. Health System costs were calculated by multiplying the number of events (stay or performances) for the unit cost per event using Medicare Diagnosis-Related-Group reimbursement values. Costs for drugs and transportation were directly calculated using information about market prices.

The Fondazione S. Maugeri IRCCS Ethics Committee approved the study according to recommendations contained in the Declaration of Helsinki. (clinical trials identifier N° NCT00563745) and all patients gave their written informed consent to participate in the protocol.

### Data Analysis

We estimated a 80% power to detect a reduction of 9 points on the average value of the monthly hospitalization proportion between the two groups. The level of significance (alpha level or type I error level) is equal to 0.05. The estimated number of patients to be enrolled in each group was 100. Results are expressed as mean, SD, median and range or as percentages where appropriate. Statistical analysis was performed using SPSS software (release 12.0. SPSS, Chicago, IL). Descriptive data are shown as mean  $\pm$  SD. A two-sample t test was used to assess differences in baseline characteristics between the TA and control groups, and Mann-Whitney U test was employed for non-parametric data. Frequency distributions were analyzed with  $\chi^2$  test. In estimating resources, patients in the TA group were divided into two subgroups according to frequency of GP calls and the median was applied as a cut off value. Kaplan Meier survival analysis with log rank statistics adjusted for the use of home mechanical ventilation was employed to estimate time-to-event models. The same statistical model was applied after stratification according to diagnosis. Level of statistical significance was set at 0.05.

### Results

Among 351 patients with CRF (fig 1), 111 patients were excluded because of reduced cognitive status (n=43), insufficient family cultural requisites (n=32), lack of home prerequisite for TA (n=33), or refusing (n=34). The diagnosis of excluded patients was: COPD (56%), restrictive lung disease (15%), neuromuscular diseases (NM:10%), amyotrophic lateral sclerosis (ALS: 9%) and other (10 %). Baseline characteristics of TA patients and controls are shown in Table 1. No differences were found between groups for all the anthropometric, clinical and functional parameters at baseline both as a whole group and after stratification according to diagnosis. Among 57 COPD patients, 21 used NIV and 8 were tracheostomized under MV while in the group of 61 patients with other diagnosis, 29 used NIV and 18 the invasive mechanical ventilation. Out of 4227 TA calls, 2.42 calls/patient/month (median; range 12.0) were scheduled by the call centre staff while 0.5 calls/patient/month (median; range 10.5) were requested by the patients. The pulmonologist 2° opinion, the therapy modification and the pulse-oximetry request were 0.17 n/patient/month (median; range 4.5), 0.17 n/patient/month (median; range 2.7) and 0.33 n/patient/month (median; range 6), respectively. In 63% of cases patients' and caregivers' problems were resolved by nurses, in 37% of cases by nurse and pulmonologist together. The median value of telephone calls/month was 3.15 Telephone calls per month were on average 3.15. TA team received  $4.2 \pm 3.5$  reports/month of pulse-oximeter data (range 0 to 18): 36% of these were desaturation events ( $SpO_2 < 90\%$ ). Recording of a diurnal or nocturnal trend was prescribed  $0.78 \pm 1$  times/month; in 40% of these cases,  $SpO_2$  was  $< 90\%$  for more than 30% of the recording time. Desaturation events served as a main criterion for oxygen supply changing. During the TA follow-up, the oxygen supply was maintained in 79 patients, increased in 27 and reduced in 12. Fifty-five out of 76 ventilated patients (72%) have requested at least one call due to a trouble with the mechanical ventilation due to insufficient patient's compliance, ventilator damage, difficult interaction between patient and machine. The COPD patients when compared to others and tracheostomized patients when compared to NIV users were the groups who requested more assistance for ventilation (65.5% vs 42.5% and 65% vs 44% respectively). The

Respicard score was recorded during any nurse call contact. The average time spent by the nurse to administer it was  $4\pm 3$  minutes. In 57 out of 118 (48%) patients, the Respicard value worsened at least once during the study. Patients with a worsened clinical score compared with to patients with unchanged score had a higher number of hospitalizations ( $p < 0.04$ ), urgent GP visits ( $p < 0.04$ ) and home acute exacerbations ( $p < 0.0001$ ). The number of hospitalisations/month were significantly ( $p < 0.01$ ) fewer in the TA group ( $0.14\pm 0.21$ ) when compared to controls ( $0.22\pm 0.24$ ). In the control group more patients ( $p < 0.02$ ) had more than 2 hospital admissions during the study period whereas in TA more patients were free from hospitalization. The subgroup of COPD patients showed similar data to the whole group with fewer hospital admissions/month in the TA group ( $0.17\pm 0.23$ ) when compared to controls ( $0.30\pm 0.30$ ) ( $p < 0.019$ ). Figure 2A shows that the probability to remain free from hospitalization for the whole group ( $p = 0.004$ ) were significantly higher for TA than controls. Patients in the TA group ( $p < 0.0001$ ) were more likely to remain free from an acute exacerbations (figure 3A) than controls. Moreover the mean number of exacerbations per month was significantly ( $p < 0.0001$ ) higher in controls than TA ( $0.23\pm 0.38$  and  $0.78\pm 0.77$ , respectively). The total number/month of urgent GP calls was more frequent in controls than TA ( $0.22\pm 0.34$  vs  $0.07\pm 0.17$ , respectively) ( $p < 0.002$ ); patients in TA, compared with controls, showed a higher probability to avoid further GP urgent call, after the first ( $p = 0.0018$ ) (figure 3C). The number of patients who made more than 1 urgent call was higher in the control group than in TA ( $p < 0.002$ ) whereas the number of patients free from GP request was higher in TA than controls. The number of ER accesses/month was not significantly different between the two groups ( $0.07\pm 0.20$  and  $0.10\pm 0.17$  for TA and controls respectively) while the probability to avoid further ER access was higher in TA ( $p = 0.0012$ ) than in controls (figure 3E). Mortality was higher but not statistically different in controls (23 deaths = 23%) compared with TA (21 deaths = 18%) ( $p = 0.241$ ). Causes of death were acute respiratory failure (10 and 12 in TA and controls, respectively), multiple organ failure (5 and 7, respectively), pulmonary embolism (3 and 2, respectively), and heart

attack (3 and 2, respectively). 16 out of 21 TA patients and 11 out of 23 controls died in hospital. After stratification of patients according to diagnosis, only COPD patients (101 subjects) in the TA group experienced less hospitalisations ( $p=0.018$ ) (table 3) and had higher probability to avoid hospitalization ( $p=0.012$ ) than controls (figure 2B). Likewise, only COPD patients in the TA group ( $p< 0.0001$ ) showed a significantly higher probability to remain free from acute exacerbations (figure 3B), for further GP urgent call after the first ( $p=0.013$ ) (Figure 3D) and further ER access ( $p=0.003$ ) (figure 3F). Mortality rate did not differ between groups even after stratification according to diagnosis ( $p= 0.148$  in COPD subgroup). Table 2 shows detailed costs for TA activation and Health Care Services (HCS) during the whole study period for all patients and for the COPD subgroups. Tele-assistance costs consisted mainly of fixed costs based on the number of calls.. Savings in HCS costs were mainly due to the number of hospitalizations prevented in the TA group. It is noteworthy that a relatively small sample of 30 patients (14 in TA and 16 in the control group) needing ICU admission accounted for almost 50% of total costs of hospitalization in each group. Deducting costs for the TA program, the average overall cost per TA patient as a whole group was 33% less than that for controls and more than 50% for the COPD group .

## Discussion

This study shows that a Teleassistance program is effective in preventing hospitalizations, home acute exacerbations, and urgent GP calls and may be cost-effective in severe CRF patients needing home oxygen therapy and/or mechanical ventilation. The COPD group seems to take the greater advantage from tele-assistance.

A general consensus on which type of follow-up program can achieve optimal control in the management of chronic respiratory diseases is still lacking. A recent review (14) demonstrated that patients with COPD who received interventions with two or more chronic care model

(CCM) had fewer unscheduled/emergency centre visits, fewer hospitalizations, and minor hospital LOS compared with the control group. According to another recent survey, modern technologies of information and communication have been recommended for home mechanically ventilated patients (4) to improve information exchanging and monitoring among different people involved. In this perspective, we should first ask whether a TA program could be effective also in severe patients on LTOT and HMV. Surprisingly, few studies have been published on telemedicine in respiratory field and none of them reached a clear-cut demonstration of the advantages (if any) of telemedicine over other follow-up programs to improve management of these frail patients. Indeed, previous studies focused on COPD patients (13, 19-21), on LTOT (26,27), and addressed the potential impact and benefits of telemedicine in improving quality of life, patients' adherence to treatment, mortality rates and in reducing healthcare costs, home visits by nurses and costs for acute relapse and emergencies (13, 19-21,26,27).

In line with Casas (13) and Moiola (26), the present study confirms that an integrated multidisciplinary monitoring and care with the aid of information technologies can reduce hospitalizations by about 36%, GP urgent calls by 65%, home relapses by 71%, even in more severe patients. According to our primary end point (reduction of hospitalisations) this study also confirmed that patients affected with COPD seem to take a greater advantage from tele-assistance. Patients affected with other diseases (such as neuromuscular diseases or ALS) might benefit from Teleassistance as well, especially when linked to direct home care assistance; future goals should include patient and family satisfaction, maintenance of an acceptable quality of life and a dignified death at home. In these patients cost reduction could become a collateral benefit instead of a primary goal for teleassistance and home health care.

We confirmed the key role of nurses as a specialized figure able to educate patients and their families/caregivers before discharge, to screen all requests and to coordinate all actors involved in the follow-up. Interestingly, in spite of a great variability among patients, the median value of

calls per month was  $< 4$  and in 60% of cases the nurse-tutor alone was able to resolve clinical or logistic problems. Both urgent GP visits and outpatient visits in our specialized departments were fewer in the TA group than the control group. We should conclude to have reached a good economical result without affecting the quality of assistance.

Unlike the study by Casas (13) in which only 24% of patients were on LTOT, all patients enrolled in the present study were on LTOT and more than 70% were mechanically ventilated. Another important difference with the studies of Casas (13) and Moiola (26) was the round-the-clock availability of a TA call service through which a nurse tutor and/or a pulmonologist were available for consultation. Unlike other telemedicine programs in which periodic phone calls were scheduled every week (26) or every 3 months (13) as “*store-and-forward necessity*”, our service was an interactive on-line system as previously described (22). Moreover, to our knowledge, this is the first study, conducted on severe patients (which usually represent a great economic burden on HCS), in which a real cost/effectiveness analysis has been performed. The telephonic clinical score used by nurses in this study was demonstrated to be simple, repeatable and useful to detect sudden clinical worsening in such severe ventilated patients. A reduction in hospital admissions and indirect costs (28,29) had already been previously described when algorithms on computers were used by nurses to follow-patients after hospital discharge. Nonetheless, authors’ belief is that long-term management of chronic patients can be effective only with an interdisciplinary team. The reduction in hospital admissions observed in this study in the TA program, may have also been favoured by the prompt availability and use of the pSat device which has provided important data for staff decisions about diagnosis of hypoxemia and oxygen and/or MV prescription.

If, on the one hand, the miscellaneous diagnosis of the study sample constitute a limitation of the study, on the other hand we are confident that the strength of this study lays in its radically different point of view, i.e. considering the burden of assistance as the primary requisite to include a patient in a TA program, independently of the underlying diagnosis. In this respect,

those included in this study were all frail patients suffering from CRF and home mechanically ventilated, thus with the common characteristic of a great burden of assistance. Another limitation of the study is the lack of any evaluation of patients' quality of life. This was mainly due to the difficulty of using standardised questionnaires for CRF patients on LTOT and/or MV. In spite of these limitations, we believe that these preliminary data confirm the feasibility and efficacy of a teleassistance project (29,30) for management of advanced stages of CRF patients. In conclusion the present study demonstrates that in severe and frail CRF patients needing home oxygen therapy and/or mechanical ventilation, a nurse-centred tele-assistance program (supported by the continuous availability of a 24-h call center and pulse oxygen device) is effective in preventing hospitalizations, home acute exacerbations, and urgent GP calls and may be cost-effective. The COPD group seems to take the greater advantage from such a program of tele-assistance.

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## Figure legends

Figure 1: trial profile of the enrolled patients

Figure 2: Comparison between studied groups (TA: dashed line and controls:continuous line) for probability to be free from exacerbations; A): all patients B): COPD patients

Figure 3 Comparison between studied groups (TA: dashed line and controls:continuous line) for probability to be free from exacerbations in the whole group (A) and COPD (B), from further urgent General Practitioner calls in the whole group (C) and COPD (D) and from further Emergency Room access in the whole group (E) and COPD (F)

**Table 1 Characteristics of patients**

	TA	Controls	P <
Patients, n°	118	102	
Age, y	61.2±17.6	61.1±17.4	NS
Sex, n° (%)	M= 75 (64%) / F= 43 (36%)	M= 74 (72%) / F= 28 (28%)	NS
Diagnosis:			
COPD, n° (%)	57 (48)	44 (43)	NS
Restrictive, n° (%)	14 (12)	14 (14)	
NM, n° (%)	24 (20)	26 (25.5)	
ALS, n° (%)	12 (10.2)	10 (9.8)	
Other, n° (%)	11(9.3)	8 (7.9)	
Ex smokers, n° (%)	55 (47%)	43 (42%)	NS
Current smokers, n° (%)	7 (6%)	9 (9%)	
Symptoms, y	9.5±9.3	10.3±8.9	NS
Patients under NMV, n° (%)	50 (42%)	52 (51%)	NS
Patients under IMV, n° (%)	26 (22%)	21 (21%)	NS
Patients under SB without MV , n° (%)	42 (36%)	29 (28%)	NS
HMV, years	2.1±1.8	1.9±2.0	NS
Patients on O2 LTOT, n° (%)	75 (64%)	63 (62%)	NS
LTOT, years	4.1±3.1	4±3.2	NS
FEV1, % prd §	39±23	34±16	NS
VC, % prd #	49±26	44±18	NS
PaO2, mmhg * @	65±14	63±14	NS
PaCO2, mmhg * @	46±8	47±9	NS
Ph* @	7.40±0.38	7.40±0.40	NS
MIP, % prd ^	42±30	38±15	NS
MEP, % prd °	39±24	41±19	NS
Comorbidities, n°	1.69±1.4	1.57±1.24	NS
PLS	2.50±0.94	2.45±0.86	NS

TA= Teleassistance program; COPD: chronic obstructive pulmonary disease; NM: neuromuscular diseases; ALS: amyotrophic lateral sclerosis; NMV: non invasive mechanical ventilation; IMV: invasive mechanical ventilation; SB: spontaneous breathing; HMV: home mechanical ventilation; LTOT: long-term oxygen therapy; FEV1: forced expiratory volume at first second;

§=available for 92 pts in TA group and 73 in controls; VC: vital capacity; # = available for 79 pts in TA group and 70 in controls; PaO<sub>2</sub>: arterial oxygen tension; PaCO<sub>2</sub>: carbon dioxide arterial tension; \*ABG measured in room air; @ = available for 85 pts in TA group and 78 in controls; MIP: maximal inspiratory pressure; ^ = available for 61 pts in TA group and in 59 controls; MEP: maximal expiratory pressure; ° = available for 59 pts in TA group and in 57 controls; PLS premorbidity life score (ref. 24)

Table 2 Costs for TA activation and Health Care Service Costs

Telemedicine costs			All patients		COPD patients	
	Cost per unit	Factor to multiple	TA (€)	Control (€)	TA (€)	Control (€)
Call center costs *	20 €	N° calls/pz	716±504	0	821±537	0
Pulsed saturimetric device **	127€/pt	1 for pt	127	0	127	0
Trend pulsed saturimetric device ***	187€/pt	1 for pt (when requested)	187	0	187	0
<i>Total and monthly TA costs with pulsed saturimetric device</i>			<i>843±504</i> <i>86±56</i>	0	<i>948±537</i> <i>95±61</i>	0
<i>Total and monthly TA costs with trend pulsed saturimetric device</i>			<i>903±504</i> <i>94±61</i>	0	<i>1008±537</i> <i>104±66</i>	0
HCS costs						
Hospitalizations in RW	4000 € for admission	N° H	4610±5600	6588±7669	5754±6415	8727±9221
ER accesses	62 €	N° ER stay	38±84	57±87	39±63	80±105
Hospitalization in ICU (14 in TA group and 16 in control group)	According to DRG	N° of H	3998±15114	7509±22906	3842±15082	15365±31897
Outpatient visit	32€	N°	4±12	104±39	6±14	98±41
Urgent GP visit	30 €	N°	20±41	48±80	23±51	72±110
Antibiotics use (12 days)	55 €	N°	86±109	203±184	108±129	273±196
Steroids use (14 days)	6 €	N°	3±7	16±18	5±9	24±21
Home nurse visits	20€	N°	148±328	178±367	108±282	82±253
Private costs						
Transportation	0.23€/km	Km	0.8±3	27±25	1.2±3.2	21±7
<i>TOTAL HCS costs</i>			<i>8907±17580</i>	<i>14728±28694</i>	<i>9886±17534</i>	<i>24743±39484</i>

Legend: TA= Teleassistance program; HCS=Health care system; ICU=intensive care unit; RW=respiratory ward; ER=emergency room; GP= general practitioner. \* Fixed costs included equipment purchase and installation, installation of telecommunication lines, Variable costs included monthly line charges, maintenance costs, Nurse and Pulmonologist 2° opinion on duty calls; \*\*costs on hire; \*\*\*costs calculated dividing the total costs of the devices by the number of patients enrolled in 3 years; for details on costs see Ref 25.

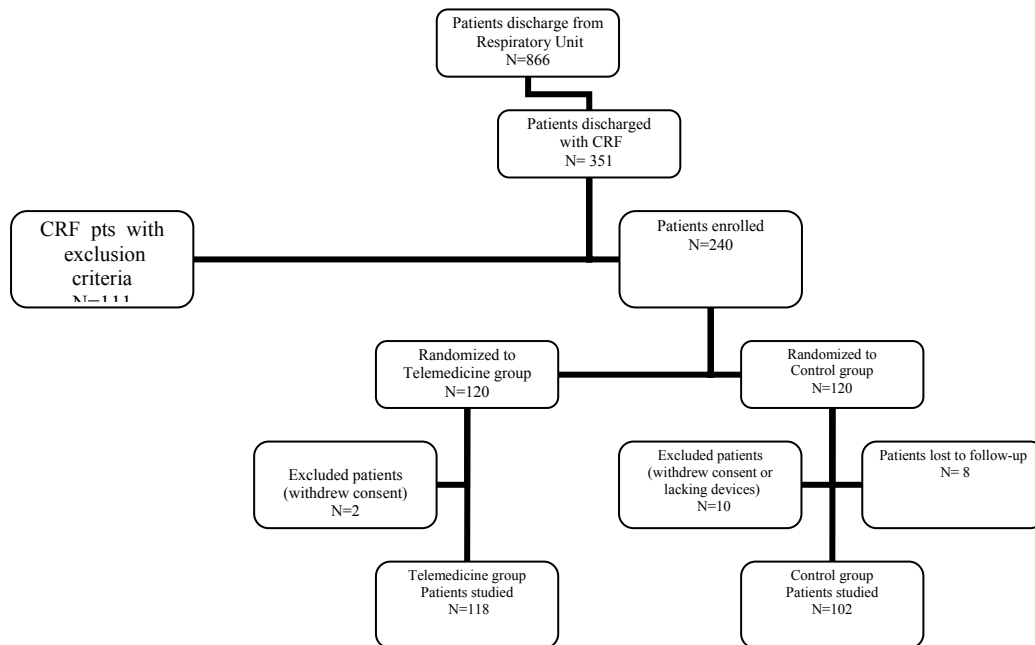
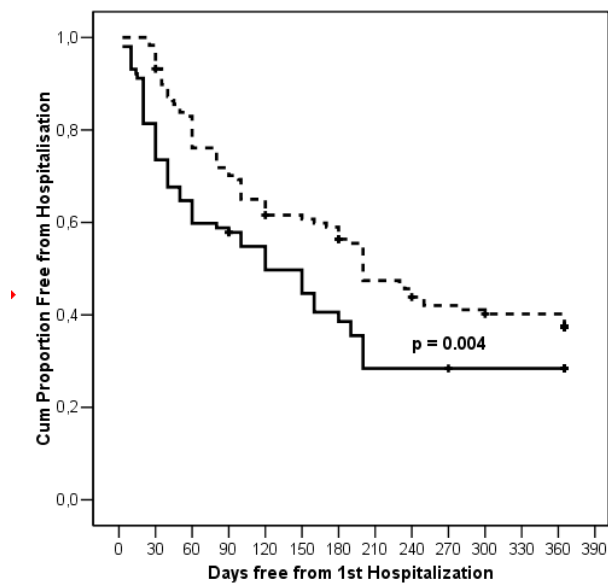
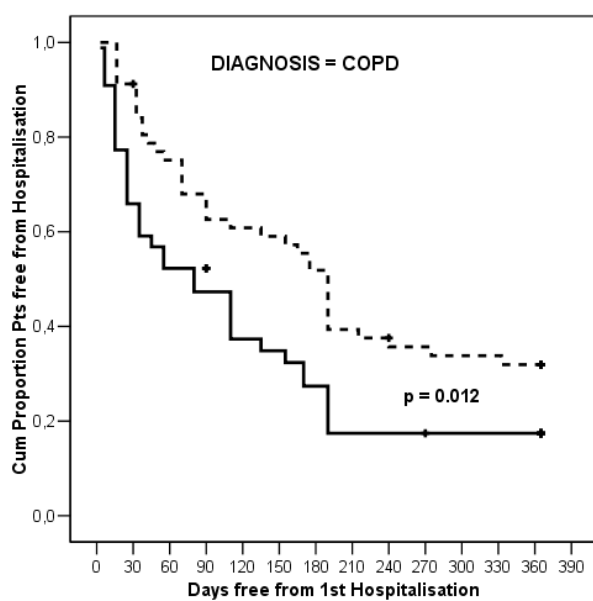


Figure 1: Trial profile of the enrolled patients

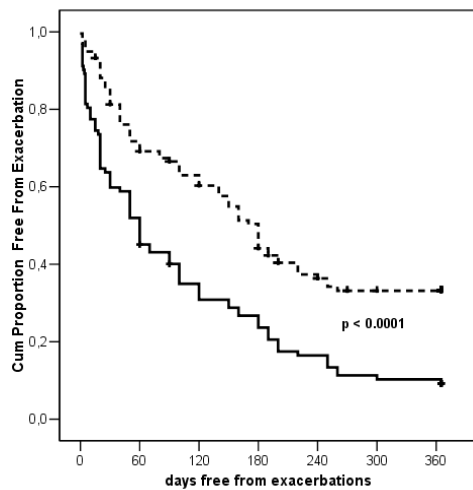


A: all patients

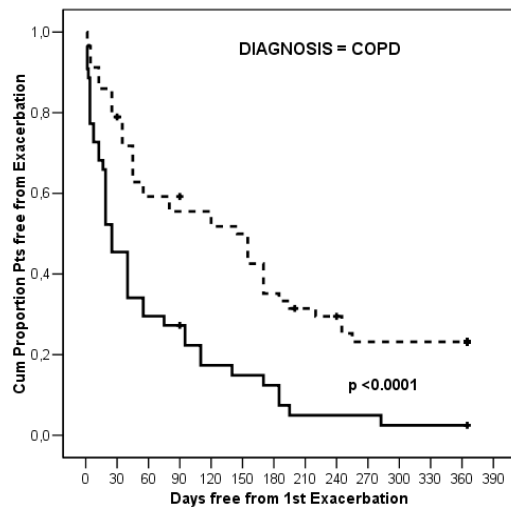


B: COPD patients

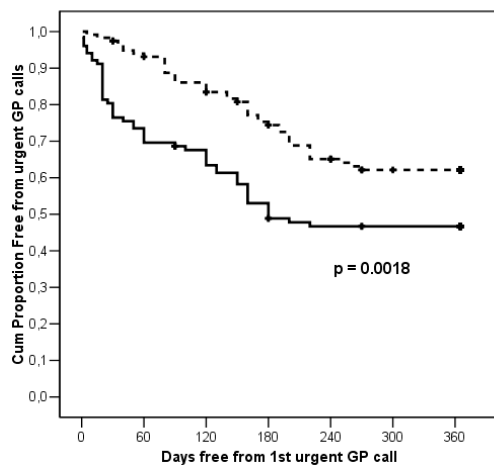
Figure 2 Comparison between studied groups (TA: dashed line and controls:continuous line) for probability to be free from exacerbations; A): all patients B): COPD patients



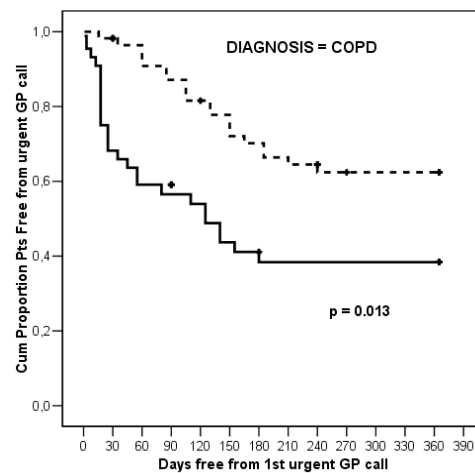
A)



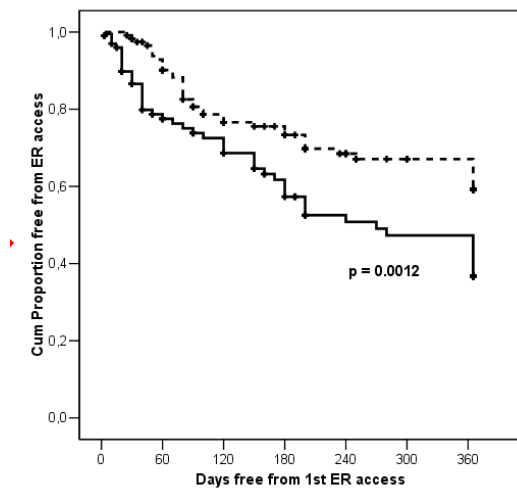
B)



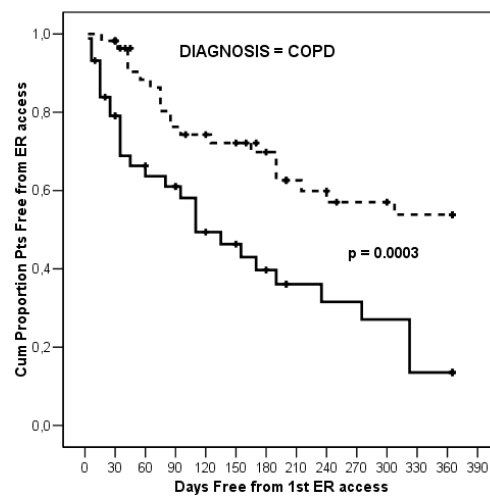
C)



D)



E)



F)

Figure 3 Comparison between studied groups (TA:dashed line and controls:continuous line) for probability to be free from exacerbations in the whole group (A) and COPD (B), from further urgent General Practitioner calls in the whole group (C) and COPD (D) and from further Emergency Room access in the whole group (E) and COPD (F)

## Appendix 1

Respicard<sup>R</sup>

Name \_\_\_\_\_ age \_\_\_\_\_ date \_\_\_\_\_ hour \_\_\_\_\_

O<sub>2</sub>(L/m): \_\_\_\_\_ IMV: \_\_\_\_\_ NMV: \_\_\_\_\_ tracheostomy: \_\_\_\_\_

Rest \_\_\_\_\_ after effort \_\_\_\_\_ during exacerbation \_\_\_\_\_

	0	1	2	3	4
SpO <sub>2</sub>	> 92% under room air and O <sub>2</sub>	91% on air and 90-92% under O <sub>2</sub>	< 90% under room air	< 90% in O <sub>2</sub>	< 80% in O <sub>2</sub>
Heart rate	<90	90-100	100-110	110-120	> 120
Dyspnoea	Under strong activity	Speed walk or climb	Moderate activity with stops	Light activity, stop after few steps	At rest during daily activities
Cough	Spontaneous and strong	Weak no productive	Strong but extremely productive	Weak, productive, frequent	No spontaneous cough need of suction
Sputum	No need for sputum	Moderate	Copious	Very copious	Unbearable
Sputum color	No sputum	White	yellow	Yellow-green	Green-brown or with blood
Wheezes	never	Occasional	Under strong efforts	Under moderate efforts	At rest
Height, oedema	No oedema stable height	Increase of < 2 kg in two days	2-4 kg in two days	2-4 in one day	> 4 kg in one day
Temperature	Normal	> 37° < 37.5° without antipiretic	> 37° < 38° with antipiretic	> 38 ° with antipiretic and antibiotic since 1 day	> 38 ° with antibiotic since 3 days
Neurological status	Normal, wake	Slow but answer	Confuse, diurnal drowsiness	Difficult posture and verbal answer	No answer to manual stimulus
Ventilator interaction	No troubles or no ventilator	Occasional alarms on ventilator	Alarms + need for suction or mask discomfort	Alarms, occasional contrasts and dispnoea under ventilator	Ventilator break; Alarms and fighting against ventilator
Walk	autonomous	Walk with stops, no dyspnoea	Walk with stick and dyspnoea	Assisted walk , few steps, armchair use	No deambulation, bedridden
Sum					
Total sum		XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXXXXXX

Score Legend:

Normality (green zone: 0-5 score)

Moderately pathological condition (yellow zone: 6-12 score caution; 13-36 score alarm zone)

Extremely severe condition (red zone:36-48 score)

FONDAZIONE SALVATORE MAUGERI IRCCS  
Centro Medico di Riabilitazione di Lumezzane (BS)  
Divisione di Pneumologia  
Tel. 39 030/8253168

Lumezzane 5/08/08

Dear Associate Editor ERJ

Please find attached the **2° revision** of manuscript entitled “*Tele-assistance in Chronic Respiratory Failure Patients: a Randomised Clinical Trial*” by M. Vitacca, L. Bianchi, A. Guerra, C. Fracchia, A. Spanevello, B. Balbi, S. Scalvini. which we are submitting to ERJ for possible publication.

All the authors certify the following:

- the material is original except for a previously published short pilot feasibility study (ref 22);
- it is not being considered for publication elsewhere, including publicly accessible websites or e-print servers;
- no part of the presented research has been funded by tobacco industry sources;
- all authors have read the manuscript and approve its submission,
- the trial has been registered in a public trial registry although it started before 2006.

Sincerely yours

Michele Vitacca MD

Correspondence

Michele Vitacca MD

S. Maugeri Foundation IRCCS

Pulmonary Unit, Weaning Center

Via Mazzini 129

25065 Lumezzane (BS) Italy

email: michele.vitacca@fsm.it