Early Assisted Discharge for COPD Exacerbations With Telemonitoring.

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Protocol:

The TELEMED-COPD study is a randomized clinical trial with 2 parallel groups (both with early discharge; intervention group: home hospitalization with telemonitoring / control group: traditional follow-up based on face-to-face visits by healthcare personnel). It was carried out at the Puerta de Hierro Hospital from March 2012 to July 2018. Once the informed consent was given by the participants, they were randomly distributed between the two groups using a table of pseudo-randomized numbers in variable blocks generated by computer. The randomization sequence was kept hidden by the randomization system itself. Substitution of patients withdrawn from the study was not performed.

Participation criteria:

Patient admitted with exacerbation of COPD in the Pulmonology Service, with no age limit and who, after an initial phase of clinical stabilization not exceeding 4 days, meets the inclusion criteria: 1) Diagnosis of COPD (prior or during admission according to GOLD 2020), 2) absence of serious decompensated concomitant diseases, 3) arterial blood gas: pH> 7.35, pO2> 50 mmHg with O2 at maximum 3 bpm, Oxygen saturation> 90%, pCO2 <55, 4) afebrile more than 48 h, 5) need for administration of maximum bronchodilators every 6 hours, 6) corticosteroids <40mg / 12 hours, 7) chest radiograph without new onset pathology, 8) subjective improvement, and 9) adequate family environment.

Exclusion criteria: 1) Neoplasms or other end-stage chronic diseases, 2) alcoholism, 3) need for intravenous medication, 4) inability to understand the program and participate in it, 5) have required ICU care or need mechanical ventilation non-invasive during exacerbation, 6) institutionalized patient.

Withdrawal criteria: unsuccessful inability to use telemonitoring, complications derived from hospital admission or at the express request of the patient.

Study variables:

The main variable was the time to the first exacerbation after discharge (exacerbation was defined as an acute and sustained deterioration in the patient's clinical condition, greater than the daily fluctuation and requiring a change in the usual medication)

The secondary variables analyzed were: the use of healthcare resources measured as the number of home visits by healthcare personnel (scheduled and unscheduled), average time hospitalized at home, exacerbations after discharge and readmissions for this reason. Other secondary variables: 1)degree of satisfaction with home care (Satisfad questionnaire10) and for the intervention group also a specific survey, consisting of four questions with answers using a five-level Likert scale (assessment from 1 to 5, from lower to greater satisfaction and / or need for help) and a fifth open-ended question about their experience with the monitor. 2) Measurement of anxiety and depression using the STAI questionnaire (trait-trend) in the home hospitalization phase. 3) Impact on well-being and quality of life using the CAT (COPD Assessment Test) questionnaire. 4) Therapeutic compliance through the Morinsky-Green-Levine questionnaire at the beginning and at the sixth month; additionally for the intervention group, adherence to telemonitoring was determined based on compliance with the protocolized shipments.

Comparative interventions:

The first phase of the study was hospitalization at home (with or without telemonitoring depending on the assigned group) and the second phase was follow-up after medical discharge (identical for both groups, without telemonitoring); with one consultation a month and another at 6 months. In these consultations, outpatient and / or hospital exacerbations were collected, as well as other study variables.

Control group (conventional home hospitalization):

** Visiting regime: a first visit is made in the hospital (doctor and nurse who will follow up), making a clinical evaluation and management of the bronchodilators.

The rest of the visits are daily at home and will initially be carried out only by the infirmary, except for the final visit in which the doctor accompanies him to discharge the patient, if he meets the following criteria:

- Clinical stability, with recovery from daily activities, with dyspnea similar to its baseline.
- Saturation levels> 90% with or without oxygen and lower requirements for short acting adrenergic beta2 agonists.
- Correct use of medication.

Constants are taken, physical examination, clinical evaluation and health education (involving knowledge of your disease, inhalation technique, therapeutic compliance, exercise respiratory, nutritional advice and smoking cessation if needed).

Intervention group (Home Hospitalization with Telemedicine):

** Regimen of home visits: 1) An initial visit to the hospital (doctor and nurse), 2) an intermediate visit by the nurse, 3) the last visit :discharged the patient by the nurse and the doctor. The nursing actions in the visits, the hours of attention and the discharge criteria are the same as those detailed in the control group. On the first day that the patient was at home, he received a visit from the technician, who installed the telemonitoring equipment and trained the patient and family members in its handling (leaving them a contact telephone number for incidents).

** Telemonitoring: to carry it out, a multi-parameter recording equipment with communication capacity over the GSM network was used, which sent the data to an online web platform, which was reviewed by the responsible doctor.

The parameters recorded were: ECG (leads I, II, III), O2 Saturation (%), heart rate, blood pressure, temperature and respiratory rate.

The patient sent them twice a day (morning and afternoon), at approximately the same time (weekdays), and later received a phone call from the doctor to assess their clinical situation (symptoms, degree of dyspnea (mMRC), changes in appearance and amount of sputum, compliance and complications) and decide the action to follow.

Thresholds of normal intervals were established in the before mentioned parameters, outside these ranges, a warning was generated in the form of sms

to the medical phone. If an intervention was necessary, they contacted the patient and explained the action plan (home visit, going to the emergency room, changing medication, etc.).

Statistic analysis:

The main hypothesis is to verify that after the early discharge, the health results caused by the experimental treatment (intervention) are not inferior to the reference treatment (control). The scientific literature states that the median of the “exacerbation-free time” of the reference treatment is 2 months, and therefore, the “non-inferiority” condition requires that the median in the experimental group be similar. It is considered appropriate to set a “noninferiority” limit of 0.60 units in multiplicative terms with respect to the reference treatment; In other words, an attempt will be made to demonstrate that the experimental treatment provides at least a median of the exacerbation-free time of not less than 1.2 months (36 days), if it is exacerbated before this period of time the study didn’t comply the “non inferiority” condition. Thus, we calculated that a minimum sample of 58 patients per treatment group (in total 116) wasrequired to ensure a power of 80% and a significance level of 5%. Exacerbation-free time was defined as the interval between discharge from the home and the moment of exacerbation, until the end of the study when it did not occur or in the event of loss of follow-up until the last recorded time. All analyzes were performed according to the principle of intention to treat.

The statistical analysis of the main variable was carried out using the Kaplan-Meier method and the statistical test of the log-rank test.

The comparison between the two groups was made with the Student t test for continuous variables and the non-parametric Mann-Whitney test when the normality test was rejected.

The statistical package used was Stata V.15.1.