PROJECTION OF VISUAL MATERIAL ON POSTOPERATIVE DELIRIUM IN PATIENTS UNDERGOING CARDIAC SURGERY: A DOUBLE BLIND RANDOMIZED CLINICAL TRIAL

The general objective of this study is to evaluate the impact of visual projection of images of relatives or loved ones in patients undergoing cardiac surgery in the immediate postoperative period, and its influence on the incidence and development of postoperative delirium.

METHODOLOGY

Design

A double-blind randomized clinical trial (RCT) with an intervention group (IG) and a control group (CG). The study is carried out among patients undergoing cardiac surgery at León University Assistance Complex between July 2021 and January 2022.

The control group received the usual treatment from the unit for postoperative delirium, based mainly on the use of haloperidol and/or dexmedetomidine, as well as mechanical restraints when the patient required it, while the intervention group received a visual projection of images of relatives or loved ones as a method of prevention and treatment of postoperative delirium.

The study followed the Consolidated Statement of Reporting Trials (CONSORT) guidelines. The protocol complied with the Declaration of Helsinki and has been approved by the Drug Research Ethics Committee (CEIm) of León University Assistance Complex with number/reference 2155.

Population

The study population consisted of patients undergoing heart surgery (aortic valve replacement, mitral valve replacement and/or coronary bypass) in the immediate postoperative period during their stay in the cardiac resuscitation unit. All patients included in the study are over 18 years of age. The patients decided to participate voluntarily, after having been informed of the purpose of the study, as well as what their participation consisted of, by signing an informed consent.

Sample

The estimated sample size for a difference between two proportions, with a statistical power of 80% for an alpha significance level of 0.05 with a prevalence of postoperative delirium of 30% and a rate of loss to follow-up of 10%, is 52 patients per group.

Randomization and blinding of the sample

A control group is established, on which the usual practice of the unit regarding postoperative delirium is carried out, as well as an intervention group on which visual material is projected in the resuscitation box. Randomization of participants into one or the other group is ensured using OxMaR computer software.

The masking of the sample is double blind. Neither the observer who administered the measurement scale nor the investigator who analyzed the data knew whether the subjects had received the study intervention or not.

Inclusion and exclusion criteria

The inclusion criteria involved: undergoing elective cardiac surgery, the requirement of admission to the cardiac resuscitation unit, being over 18 years of age, agreeing to participate in the study, not being sedated for at least 24 hours, presenting an adequate level of consciousness and being able to communicate in Spanish. All patients who did not meet any of the inclusion criteria are excluded, as well as those who underwent emergency surgery or those who did not require admission to the cardiac surgical resuscitation unit.

Variables

These consisted of sociodemographic variables such as age and gender, anthropometric weight, height, BMI. Social variables consisted of whether the patient lived alone or accompanied etc., as well as surgical, anesthetic and postoperative care characteristics such as the type of intervention, use of drugs, time mechanical ventilation or extracorporeal circulation, etc.

Variables related to postoperative delirium are also collected, such as the positive or negative result of the CAM-ICU scale, as well as those related to the projection of visual material, pharmacological measures or mechanical restraints used.

Finally, the objective score obtained in the Mini-mental State Examination (MMSE) is recorded in order to assess the patient's prior cognitive status.

Instrument

An "ad hoc" registration sheet is prepared in order to facilitate data collection. The record sheet contained sociodemographic data, surgical and anesthetic characteristics, as well as postoperative and postoperative delirium care. In addition, the CAM-ICU scale as well as the Mini-Mental State Examination is applied to the patients included in the study. The CAM-ICU scale is a validated scale and it is the most frequently used scale to assess the presence of delirium in critical care units, while the Mini-Mental State Examination scale is used to assess the patient's previous cognitive state.

The estimated time for completing the record sheet is 4 minutes and 7 minutes for the administration of each of the both scales. Confidentiality is ensured at all times through alphanumeric coding so as to avoid the recording of their personal data.

Development of the intervention

Patients are randomized into two groups (control group and intervention group) after explaining the study and offering voluntary participation.

Initially, regardless of the group to which they belonged, all patients are administered the MMSE scale to assess their initial cognitive state and their sociodemographic and anthropometric data are collected.

In the intervention group, patients and/or companions are asked to provide visual material, which could consist of photographs of loved ones and/or places known to the patient. Once the surgical intervention is completed, the patients are transferred to the Cardiac Resuscitation Unit. 30 minutes after the extubation of the patients, the CAM-ICU scale is administered, recording its value as R0. Next, the projection of images provided by the patient began until 11:30 p.m., at which time these images are replaced by a nocturnal visual projection (night sky with stars and moon), ensuring that the patient is able to identify that it is nighttime. Later, at 7:00 p.m. the visual projection is removed and the record sheet is completed with the anesthetic and surgical data. Finally, at 9:00 a.m., a nurse who had not worked at night and therefore did not know which patients had received the intervention, administered the CAM-ICU scale again, recording its value as R1.

In the control group, we proceeded as follows: after the surgical intervention and after the patient is admitted to the Unit, we waited 30 minutes after the patient's extubation to administer the CAM-ICU scale, recording its value as R0. The following day, at 7:00 a.m., the record sheet is completed with the anesthetic and surgical data, and finally, at 9:00 a.m., another nurse administered the CAM-ICU scale, noting its value as R1, without knowing which patients belonged to each group. If postoperative delirium is detected during the day and night, the unit's usual treatment is followed: administration of haloperidol and/or dexmedetomidine if the patient showed agitation.

Finally, a member of the research team, who did not know which patients had received the intervention, analyzed the data obtained without knowing what each variable referred to.

Statistical analysis

The information is recorded in a database created with the Excel computer program. Statistical analysis is performed with Epi Info™ 7.2 software and R Studio version 1.3.1093.

For the descriptive analysis of the variables, the mean, standard deviation, minimum, and maximum values are calculated for the quantitative variables, and the relative frequencies and percentages are calculated for the qualitative variables.

For the study of the association between categorical variables, the chi-square statistic or Fisher's exact test is used when the data are independent, while for the related data the McNemar test is used for two groups, transforming the variables into dichotomous ones for its analysis. Stratified analysis is performed using the Mantel-Haenzsel test.

For the multivariate analysis, the logistic regression model is used, including the variables included in the analysis. The stepAIC function from the R MASS package is used.

To validate the results, in terms of significance, a confidence level of 95% is used and any value of $p < 0.05$ is considered significant.