

Study Protocol and Statistical Analysis Plan

Determination of factors affecting early mobilization of patients who have undergone knee and hip arthroplasty

Document date: It was approved by Bursa Uludag University Clinical Research Ethics Committee on 03/10/2017.

NTC Number: No

STUDY PROTOCOL

Methods

Aim: This study was conducted in order to determine the factors that affected the early mobilization after surgery of patients who had undergone knee and hip arthroplasty.

Design: This study is descriptive and cross-sectional. STROBE checklist was used to compile the study's report.

Universe and sample: The universe of the study consisted of a total of 80 patients who were hospitalized between November 2017 and September 2018 in the Orthopedics and Traumatology Clinic of a State Hospital to undergo knee or hip arthroplasty, and who met the inclusion criteria. The improbable sampling method was used in the study. The sample of the study consisted of 60 patients who were in the universe of the study, who met the inclusion criteria and who voluntarily agreed to participate in the study.

Inclusion and exclusion criteria: Patients who were 18 years old or older, who were hospitalized in the Orthopedics and Traumatology Clinic for the first time in order to undergo knee or hip arthroplasty, who could communicate, who had no hearing or speaking impairment, and who agreed to participate in the study, were included. The patients who were undergoing revision surgery, who had a history of lower extremity orthopedic interventions which may have prevented mobilization, who had neurological and medical problems that may have caused locomotor disabilities, who had unmanageable heart and lung diseases, who had a history of neurological disease (Alzheimer's, dementia, etc.), and who had gout, metabolic diseases or septic arthritis, were excluded from the study.

Data collection: In this study, the data were between November 2017 and September 2018, collected using a 60-item Patient Information Form detailing the patient's characteristics which was developed by the researcher after making a literature review, the Functional Ambulation Classification (FAC), and the American Society of Anesthesiologists (ASA) classification. The Patient Information Form was pre-applied to 10 patients before the study.

In study, early mobilization was defined, on the basis of the ERAS protocol, as mobilization of a few steps or a few meters from the bed within the first 24 hours after surgery with another person's support/control and/or a walking aid.

STATISTICAL ANALYSIS

Data obtained from the study were processed and analyzed using SPSS 24 software. For the data determined to be abnormally distributed, the Mann-Whitney U test was used to compare two independent groups, and the Kruskal Wallis test was used to compare three or more independent groups. Spearman correlation coefficients were used to evaluate whether there was a linear relationship between variables. Statistical significance was accepted as $p < .05$.