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Minimal impact of a care pathway for geriatric hip fracture patients

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ABSTRACT

Background: Adherence to guidelines for patients with proximal femur fracture is suboptimal.
Objective: To evaluate the effect of a care pathway for the in-hospital management of older geriatric hip fracture patients on adherence to guidelines and patient outcomes.
Design: The European Quality of Care Pathways study is a cluster randomized controlled trial.
Setting: 26 hospitals in Belgium, Italy and Portugal.
Subjects: Older adults with a proximal femur fracture (n = 514 patients) were included.
Methods: Hospitals treating older adults (>65) with a proximal femur fracture were randomly assigned to an intervention group, i.e. implementation of a care pathway, or control group, i.e. usual care. Thirteen patient outcomes and 24 process indicators regarding in-hospital management, as well as three not-recommended care activities were measured. Adjusted and unadjusted regression analyses were conducted using intention-to-treat procedures.
Results: In the intervention group 301 patients in 15 hospitals were included, and in the control group 213 patients in 11 hospitals. Sixty-five percent of the patients were older than 80 years. The implementation of this care pathway had no significant impact on the thirteen patient outcomes. The preoperative management improved significantly. Eighteen of 24 process indicators improved, but only two improved significantly. Only for a few teams a geriatrician was an integral member of the treatment team.
Discussion: Implementation of a care pathway improved compliance to evidence, but no significant effect on patient outcomes was found. The impact of the collaboration between surgeons and geriatricians on adherence to guidelines and patient outcomes should be studied.
Trial registration: ClinicalTrials.gov: NCT00962910.

Introduction

Hip fractures are a leading cause of disability and mortality in older people. In the United States, the incidence of hip fracture is expected to increase to over 500,000 per year by 2040 [1]. Recent mortality 6 months after fracture is about 23% [2]. Readmission rates are also high. Up to 46.5% of patients are readmitted within 6-months after discharge [3]. Patients also experience a decreased quality of life and a decline in functional status [4]. Functional status at discharge strongly predicts functional status and quality of life one year after the fracture [5]. Patient outcomes are influenced by an adequate pre-, peri- and postoperative management of the fracture [6]. Several guidelines on geriatric hip fracture treatment have been developed [1–9] but care remains suboptimal [10,11].

Care pathways (CPs) facilitate the implementation of evidence through the integration of evidence-based key interventions [12,13]. Findings on the effectiveness of CP are however inconclusive [1–16]. A possible explanation is that each CP only deals with a few aspects of the care process [17]. Further investigation of their

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impact on adherence to guidelines and patient outcomes is warranted. The aim of this international cluster randomized controlled trial is to evaluate the effect of a care pathway for the in-hospital management of older proximal femur fracture patients on adherence to guidelines and patient outcomes.

Materials and methods

Study design and participants

A pragmatic cRCT was conducted in Belgium, Ireland, Italy and Portugal. General hospitals with hospitalized patients with a proximal femur fracture (PFF) were randomized to either an intervention group, where a CP was implemented, or a control group, where usual care was delivered. The CP was developed and implemented at hospital level and hospitals randomized in the control group were offered the opportunity to develop a CP one year after the study. An overview of the study design is shown in figure Appendix 2. More information of the methods, Appendix 1, is presented as supplementary data.

The intervention

Hospitals were asked to develop and implement a CP, based on the 7-phase protocol [18]. The clinical evidence for the CP was provided by the researchers based on an extensive literature review and international Delphi study and the intervention contained three active components [13]. The first active component was the assessment of the quality and the organization of the care process. Second, a set of evidence-based key interventions was provided to the hospitals, which have a significant impact on patient outcomes. Teachings sessions were organised by an interdisciplinary faculty consisting of an expert in CP and orthopaedic surgeon, during the implementation phase, focusing on key interventions for which team experienced implementation difficulties. The last active component was training on developing and implementation. In each hospital a CP facilitator was trained to develop and implement a CP based on the findings of the evaluation of the care process and the set of key interventions [18]. A CP was developed over a 6-month period. In the control group no intervention was implemented, meaning usual care was provided. In Appendix 1 more information of the intervention can be found.

Variables and outcome measures

The process and outcome indicators were selected based on a literature review, an international Delphi survey and expert advice by using an 8-step method [19]. (see figure Appendix 3) Primary patient outcome was 6-month mortality rate. Secondary patient outcomes included 30-day mortality rate, 30-day and 6-month PFF specific readmission rate and functional status, length of stay, mobility status and proportion of patients returning to previous residential status at 30 days and 6 months after discharge. EQ5D (EuroQol 5D) and SF36 (Short Form Health Survey 36) were measured at 30 days after discharge. For 30-day and 6-month outcomes, except for mortality, evidently only patients still alive were included in the analyses. The 24 process indicators are characterized by interventions related to preoperative management (n = 7), perioperative management (n = 2) and postoperative management (n = 15). Also, three additional process indicators relating to not-recommended care were measured. Finally, twelve variables, including demographic and PFF-specific data, were measured.

The measurements started 2- to 3-months after the end of the implementation period [13]. The study coordinator performed the analysis to prevent assessment bias. All data were collected centrally in each hospital. Data-input was performed in a central database at KU Leuven - University of Leuven, and guided by using a rigorous data-input protocol.

Statistical analysis

Patient and hospital characteristics were compared by using the Chi-square test, Mann-Whitney *U* test and independent samples *t*-test for categorical, ordinal, and continuous variables, respectively.

Outcome and process indicators were analyzed by using a two level mixed-effects logistic and linear regression model for categorical and continuous variables respectively. For the outcome indicators, following covariates were included in the model: age, gender, type of surgery and Charlson comorbidity index. For the process indicators, no covariates were included because only patients who were found eligible for these individual process indicators were included. Adherence to all the process indicators was calculated as the rate of individually applicable process indicators that were adhered to. First, the data of the intervention group after implementation of a CP was compared to the control group (figure Appendix 2, cRCT). Second, as this is also a quality improvement project, the data of the intervention group were analyzed as a pre-posttest (figure Appendix 2, pre-posttest). Statistical significance was defined as a two-sided *P*-value of 0.05. All analyses were intention-to-treat, performed by using R package Ime4 software version 3.1.0 and Mplus 7.3 for ICC calculations.

Results

Description of study population

Initially, 69 hospitals agreed to participate in the study. After receiving the detailed study protocol, 26 hospitals decided to participate (Figure Appendix 4). Thirty-four hospitals did not participate due to internal reorganization or a high workload. One country, Ireland, including 9 hospitals, dropped out.

Fifteen hospitals were allocated to the intervention group, and 11 hospitals to the control group. In total 514 patients participated to the study, with 301 patients included in the intervention group and 213 patients included in the control group. Belgian hospitals included patients between October 2010 and January 2012 while Italian and Portuguese hospitals included patients between January 2013 and May 2014. The lost patients could not be reached by the study coordinator.

Demographics

The intervention and control group were highly comparable regarding the patient and hospital characteristics (see Table 1). Two in five (40.3% in the intervention group and 41.0% in the control group) admitted patients needed help with their daily activities. Four in five (81.5% in the intervention group and 82.8% in the control group) patients lived at home before the fracture. About 3 in 4 patients were treated for a displaced fracture, and the type of fracture was almost equally distributed for extracapsular and intracapsular fractures. One in five hospitals had more than 600 beds and treated more than 300 patients with PFF yearly. No significant difference was found in the team disciplines between intervention and control group (Table 1).

Impact of a CP on patient outcomes

Unadjusted and adjusted results on outcome indicators between the intervention and control group are shown in Table 2. Implementation of a CP had no impact on PFF specific

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