

Patient Empowerment Reduces Pain in Geriatric Patients After Gynecologic Onco-Surgery: Subgroup Analysis of a Prospective Randomized Controlled Clinical Trial

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Purpose: This study aimed to determine the effect of patient empowerment on acute postoperative pain. This research was part of the Patient Empowerment and Risk-Assessed Treatment to Improve Outcome in the Elderly After Onco-Surgery Trial.

Design: This research was a prospective randomized controlled interventional study.

Methods: Patients who underwent gynecologic onco-surgery were included in this analysis of demographic data, basic characteristics, pain intensity by numeric rating scale, and mode of pain therapy. The intervention included provision of detailed information booklet and patient diary.

Findings: Ninety-one patients were enrolled (treatment group, $n = 51$; control group, $n = 40$). With the same medications, pain on the first postoperative day was significantly less severe in the treatment group than in the control group ($P = .03$). On multivariate logistic regression, patient empowerment had a significant effect on pain intensity (odds ratio, 3.46; 95% confidence interval, 1.35 to 8.86; $P = .01$). The number needed to treat to decrease pain from severe to mild (numeric rating scale, 5 to 10 to 0 to 4) was 4.35.

Conclusions: Patient empowerment significantly reduces postoperative pain in elderly patients undergoing gynecologic cancer surgery.

Keywords: patient empowerment, geriatric, elderly, perioperative, information, pain, gynecologic oncology, outcome, onco-surgery.

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Conflict of interest: None to report.

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DESPITE NUMEROUS METHODS of pain therapy, management of postsurgical pain remains a challenge. As much as 59% of patients who were scheduled for surgery stated that pain after the procedure was their greatest concern.¹ Studies showed that up to 88% of patients reported pain after surgery, with 40% describing their pain as moderate to severe.^{2,3} Especially in older patients, pain is often not assessed well and is undertreated.⁴ This problem is gaining importance as the number of geriatric patients in hospitals rises because of higher life expectancy.⁵

In medicine, empowerment is described as a process that helps a patient gain control.⁶ This terminology encompasses different kinds of interventions, such as patient education, patient diary, shared decision making, and provision of preoperative information. Patient empowerment proved to be an effective means of pain reduction in different settings, such as when dealing with chronic diseases and cancer patients.⁷⁻⁹ The recently published guideline for the management of postoperative pain recommended patient empowerment as an additional tool to reduce pain through education, provision of information, and patient participation.¹⁰ However, published studies on the effect of patient empowerment on acute postoperative pain have been few and had varying results from negative to positive effects or no effect at all.¹¹⁻¹⁵ The aim of this study was to determine the effect of patient empowerment on acute postoperative pain in elderly female patients undergoing onco-surgery.

Methods

This study was a subgroup analysis of the Patient Empowerment and Risk-Assessed Treatment to Improve Outcome in the Elderly After Onco-Surgery (PERATECS) study, a prospective, randomized controlled trial.⁷ With approval of the ethics committee (EAI/241/08), data were collected at two major university hospitals in Berlin and Munich, Germany, between February 2011 and October 2013. The clinicaltrials.gov identifier of the study was NCT01278537. Data were collected and pseudonymized in accordance with the Declaration of Helsinki for Ethical Principles for Medical Research Involving Human Subjects.

Subjects

The patients eligible for the PERATECS study were those who were 65 years or older, would undergo surgery because of a malignant mass, scored 23 points or higher in the Mini-Mental State Examination,¹⁶ and were able to sign a written informed consent. Excluded patients were those who had insufficient knowledge of the German language, were currently enrolled in another study, had more than one carcinoma, were scheduled for emergency surgery, had outpatient surgery, and were not able to give informed consent. Patients who met the inclusion criteria were randomized to either an intervention group or a control group (cf. study protocol of the main study).¹⁷ Of all the patients enrolled in the PERATECS study ($n = 690$), only those who had gynecologic surgeries were included in this subgroup analysis ($n = 92$) to obtain a homogeneous group of patients with similar surgeries. Gynecologic patients were recruited only at the university hospital in Berlin.

The intervention comprised distribution of age-appropriate information brochure (big letters, explanatory pictures, so forth) and use of a patient diary.¹⁷ The brochure was given to the patients at least 1 day before surgery and contained detailed information on what to expect before and after surgery, as well as the epidural catheter and other analgesics used for postoperative pain control. It also presented information on how the patients could affect their own healing process; eg, by doing respiration exercises. Both the information brochure and diary were discussed in detail with the patients. They were encouraged to take notes in their diary and to include symptoms and complaints (pain, nausea, so forth), as well as improvements (feeding, mobilization, so forth). The details that the patients indicated in the diary did not affect the way that they were treated. The control group received exactly the same medical care as did the intervention group, but they did not receive information brochure or patient diary.

Among the 1,451 subjects screened for eligibility, 690 were enrolled in the PERATECS study; 38 of 690 patients dropped out because of a benign histology result or withdrawal of consent. Of the remaining patients, only those who had surgery for a gynecologic malignancy ($n = 92$) were included in the present investigation. There was one case in

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