The PROMISE trial – Implementation and evaluation of an extended perioperative process-optimized interdisciplinary and cross-sector approach in hip and knee replacements

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Objectives

The implementation of perioperative process-optimized protocols, such as the ERAS-Society ¹ one’s, has tremendously improved the patient’s postoperative outcome and costs ². By including the rehabilitation-sector, a perioperative approach could be extended to a cross-sectoral treatment concept that bridges the typical gap between the two elements of the health process. Treatment is aiming at a preoperatively and mutually with the patient defined individual goal of functioning, activity and participation. Hospital and Rehabilitation-Center share the patient’s data on a digital database (Fig.1). The protocol focuses on: the patient is incorporated as an active partner in the therapy, optimized preparation, reduction of the "stress response" to surgery, and elimination of postoperative mobility barriers to promote early and extensive postoperative activity (Fig.2). The PROMISE trial introduces this new approach for patients with hip and knee replacements in a cooperative net of diverse German facilities and evaluates the effects on a broad basis. The project is financially supported by the "Innovationsfonds" of the Federal Joint Committee (G-BA) with € 5.1 million ³.

Method

An interdisciplinary and cross-sectoral process-optimized approach was implemented in three hospitals that cover different German hospital settings and 6 in- and outpatient rehabilitation facilities. A common database was developed, which is used for evaluation and data exchange. Some data is automatically imported from existing data pools. Others are entered by the study centers or the patients themselves (PROMs). The network is extended by partners from project implementation and external evaluation, from a participating health insurance company (generating and providing the data of the control group) and a patient representative (Fig.3). Patients will be followed for one year postoperatively. An extensive test battery including pre-operative parameters, functional level, anxiety and depression values, expectations, quality of life indicators, complications and costs is recorded (Fig.4). Qualitative interviews with selected patients and representatives of the different involved occupational groups complete data acquisition. Patients who received their replacement in one of the cooperating hospitals but were not treated in a rehabilitation center of the network will be analyzed as a subgroup. The aim is to enroll 2000 patients until 12/2019. The evaluation will end 12/2020.

Results

The implementation process has been completed and the first patients have already been included (at May 15th 2019: total n=946; hip n=477; knee n=466; hip & knee n=3; age: mean=66.2 years, SD=10.2; ASA: mean=2.3, SD=0.6; BMI: mean=29.1, SD=5.8; LOS: mean=5.7 days, SD=2.9; Leaving the bed on the day of surgery: 84.5%). Response rates of the follow-up questionnaires are high (3 months=85%; 6 months=77%).

Conclusions and next steps

It is feasible to implement an interdisciplinary and cross-sectoral process-optimized extended perioperative treatment approach in hip and knee replacements in hospitals and rehabilitation facilities of different kind. The prospective and multicentric evaluation of the process and its various effects will be published in 2021.

References

Conflict of Interest

X No, nothing to disclose

Paper

1. http://eras-society.org
2. Ole Langøjer, Michael Scott; Kenneth C. Fearon: Enhanced Recovery After Surgery (ERAS) Society
3. https://innovationsfonds.g-b.de/projekte/

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