Single-center retrospective study on safety of total knee replacement surgery before and after the implementation of enhanced recovery program

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OBSERVATIONAL STUDY (research on retrospective data)

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This protocol was designed and written from version 3.0 of 01/02/2017 of the GIRCI SOHO model protocol

CONTENTS

1. SUMMARY OF THE RESEARCH

Title of the study	Single-center retrospective study on safety of total knee replacement surgery before and after the implementation of enhanced recovery program
Sponsor	Groupe Hospitalier de la Rochelle Ré Aunis
NCT number	NCT05028426
PI	Dr Fontaine Vivien
Primary and secondary objectives	The objectives are to compare the number of adverse events at 1 month, the number of thromboembolic events, the average length of stay and the improvement of mobility before and after the implementation of rapid rehabilitation protocols after surgery
Methodology of reference (in France)	☒ MR-004 ☐ MR-005 ☐ MR-006
Data sources	☒ Medical records ☐ Survey / Cohort / Register including data from the national health data system ☐ Medicalization Program of Information Systems ☐ Other source of Data
Study population	Patients over 18 years of age treated between 2015 and 2018 by the Orthopaedic Surgery and Traumatology Department of the Groupe Hospitalier de la Rochelle Ré Aunis for total knee replacement
Background	Enhanced Recovery After Surgery (ERAS) is a management method that aims to allow the patient to recover as quickly as possible their physical and mental capacities. It was initially developed for colon surgery and has recently been extended to orthopaedic surgery protocols.
Contexte of the study	This innovative method has been practiced by the Orthopaedic Surgery and Traumatology Department of the La Rochelle Ré Aunis Hospital Group since January 2017.
Methodology	Single center retrospective study
Statistical analysis plan	Epidemiological analysis : - Description of Patients classified into three groups according to the type of care management they received: traditional care, some elements of a fast-track program during a transition period, and full enhanced recovery program. - Using means +/- standard deviations, counts, and percentages to describe continuous and categorical variables, respectively Comparative analysis of the three groups : - Normal distributions will be verified and T-test or Mann-Whitney tests will be used to compare continuous data of independent samples where appropriate. - Chi-square test of homogeneity will be used for categorical variables. - An alpha level of 0.05 will be used for all statistical tests.
Justification of the public interest character of the study	Evaluation of the effectiveness and safety of a recent management protocol
Timetable for the study and provisional schedule for communicating the results	September 2019: drafting of the information leaflet, the protocol and the CRF From October 2019 to June 2020 : data collection End of 2020 : exploitation of the results and writing of a report/scientific manuscript

2. SCIENTIFIC JUSTIFICATION

Enhanced recovery programs are an organizational evolution in surgical patient management, in which the patient becomes an actor of his or her own recovery. This multimodal approach aims at optimizing patient physiological and psychological states across preoperative, intraoperative and postoperative domains of care. First described by Kehlet[1], these programs have been gradually modified and used for many surgery specialties, including the perioperative management of hip and knee replacements[2]. Convincing results for the benefit of the patients have been achieved in the reduction of perioperative complications, shorter hospital stays, and some improvements in quality of life (rapid restoration of physical and mental capacities)[3]. These programs also contributes to optimizing the production of care in light of human and material constraints, as they participate in 1) limiting the presence of patients in hospital by reducing the length of stay ; 2) a better control of the organization, with a better responsiveness to new challenges, like infection ; and 3) possible increase in the number of patients treated, which will be necessary according to various projections[4, 5].

Despite the proven benefits and numerous publications on enhanced recovery programs for total knee arthroplasty, physicians are still faced with the knowing-doing gap of translating the scientific data into daily clinical practice[6, 7].

In our center, the decision to take the step happened at the end of 2016. It was proposed by a young surgeon that have been trained on this new approach during his studies and who convinced the head of the surgery department of the benefits for the patients, the healthcare workers, and the institution. The transition took place in two stages, first operative and postoperative techniques were modified, and then preoperative education and counselling were added. Our hypothesis was that the shift from a traditional method of care to an enhanced recovery program can be implemented in a secondary-care hospital while ensuring the same safety and effectiveness for patients.

3. OBJECTIVES

3.1. Main objective

The main objective is to measure early complication rate after total knee arthroplasty.

It will be determined by the number of patients with complication detected within 3 months after surgery.

3.2. Secondary objectives

Secondary objectives are to measure:

- Late complication rate (within 2 years after surgery)
- Length of Hospital Stay
- Preoperative Knee Extension
- Postoperative Knee Extension
- Preoperative Knee Flexion
- Postoperative Knee Flexion

4. RESEARCH DESIGN

This is a retrospective single-center cohort study.

5. ELIGIBILITY CRITERIA

5.1. Inclusion criteria

- Patients operated on for posterior-stabilized total knee arthroplasty between January 2015 and December 2018
- unilateral arthroplasty
- a known address for mailing the study information letter

5.2. Exclusion criteria

- revision arthroplasty
- patients who refused to the use of their data

5.3. Feasibility and recruitment procedures

Perioperative arthroplasty data will be collected from medical records.

Five orthopedic surgeons performed total knee replacements.

The inclusion period last from January 2015 to December 2018.

6. RESEARCH STRATEGY(IES)/ PROCEDURE(S)

Three phases:

Phase 1

The traditional care consisted of patients attending a surgical consultation during which the date of the operation was scheduled, followed by a pre-operative anesthesia consultation. Patients at risk of postoperative nausea and vomiting were screened and given multimodal prophylaxis and treatment. In case of anemia, erythropoietin was injected preoperatively[8]. Tranexamic acid was given by intravenous injection to reduce perioperative blood loss[9]. Patients received antimicrobial and antithrombotic prophylaxis treatment. Normal body temperature was maintained perioperatively[10]. During surgery, a femoral nerve block was placed for postoperative pain management. At the end of the operation, one or two drains were put in place to evacuate the blood and avoid post-operative hematomas. A Zimmer knee brace was used to immobilize the knee. Postoperative analgesia was provided by the self-controlled administration of local anesthetics via the femoral nerve catheter, and supplemented by systemic analgesics (paracetamol, oxycodone, nonsteroidal

anti-inflammatory drugs in the absence of contraindications). The first mobilization took place with the orthosis at day one or day two after surgery.

Phase 2

By the end of 2016, several operative and post-operative modifications were set up. Femoral nerve block was replaced by adductor canal block in combination with local infiltration analgesia[11], which has been shown to provide equivalent analgesia, while preserving quadriceps motor strength[12]. Zimmer Knee Splints was replaced by compressive cryotherapy knee brace for pain and bleeding management[13]. Only, one drain was used to evacuate the blood and avoid post-operative hematomas. The first mobilization happened at day zero, assisted by an Artromot®[14].

Phase 3

To complete this program, from 2018 onwards, educational therapy with a nurse has been added. Patients were more comprehensively informed about the global care pathway. If necessary, counselling to assist with smoking cessation and addiction[15] could be offered in order to reduce risk of postoperative complications. Nutritional care could be set up on demand. If patients wished to be discharged to a rehabilitation center, the demand for beds was anticipated in order to reduce hospital waiting times. Operative and post-operative management was the same as before, except that draining was not systematic as it has not been used in well-documented hip and knee enhanced recovery programs, with no increase in complications[11].

7. CONDUCTING THE RESEARCH

7.1. The research schedule

Eligible patients are those who underwent total knee arthroplasty from January 2015 to December 2018.

7.2. Information of the persons concerned

The doctor invites the patient to participate in this research and will inform him/her of:

- the objective,
- the digital processing of data concerning the patient that will be collected during this research and will also specify the patient's rights of access, opposition and rectification to these data.

8. STATISTICAL ASPECTS

8.1. Calculation of study size

According to the hospital information system, 470 patients were taken care for total knee arthroplasty surgery over the study period.

8.2. Statistical methods employed

Patients will be classified into three groups according to the type of care management they received: Phase 1, 2 or 3.

Means +/- standard deviations, counts, and percentages will be used to describe continuous and categorical variables, respectively.

Normal distributions will be verified and T-test or Mann-Whitney tests will be used to compare continuous data of independent samples where appropriate.

Chi-square test of homogeneity will be for categorical variables.

An alpha level of 0.05 will define statistical significance.

XLSTAT (Addinsoft) will be used for statistical analysis.

9. RIGHTS OF ACCESS TO DATA AND SOURCE DOCUMENTS

9.1. Access to data

Agreeing to participate in the protocol implies that the people who carry out the research will make the documents and personal data that are strictly necessary for the monitoring, quality control and auditing of the research, available in accordance with the laws and regulations in force.

9.2. Source data

All information contained in original documents, or in authenticated copies of these documents, relating to clinical examinations, observations or other activities conducted as part of a research study and necessary for the reconstitution and evaluation of the research. The documents in which the source data are saved are called the source documents.

9.3. Data confidentiality

In accordance with the legislative provisions in force, persons having direct access to source data will take all the necessary precautions to ensure the confidentiality of information relating to research, to participants, especially as regards their identity and the results obtained. These people, like the people who direct and monitor the research, are subject to professional secrecy.

During or at the end of the research, the data collected on the participants and sent to the manager by the people who direct and monitor the research (or any other specialised contributor) will be codified. The data must never explicitly mention the names of the persons concerned or their addresses.

The manager will ensure that each research participant has been informed of access to the individual data concerning them and strictly necessary for the quality control of the research.

10. ETHICAL AND REGULATORY CONSIDERATIONS

The study director who directs and supervises the research commit himself to ensure that this research is carried out in accordance with the Declaration of Helsinki (which can be found in full at http://www.wma.net/en/30publications/10policies/b3/).

The data recorded during this research are the subject of a computerised processing in accordance with the law no. 78-17 of 6 January 1978 on data processing, files and liberties as amended by Law 2004-801 of 6 August 2004. This research is part of the "Reference Methodology" (MR-004). The Groupe Hospitalier de la Rochelle Ré Aunis has signed a compliance commitment to this "Reference Methodology".

This research has been registered on the site http://clinicaltrials.gov/

11. RULES FOR PUBLICATION

11.1. Scientific communications

The data analysis provided by the centres is carried out by Groupe Hospitalier de la Rochelle Ré Aunis. This analysis results in a written report which is submitted to the manager. This report allows the preparation of one or more publications.

Any written or oral communication of the results of the research must have the prior consent of the person who directs and supervises the research and, where appropriate, of all committees set up for the research.

The publication of the main results must mention the name of the manager, all the investigators who helped in the inclusion or follow-up of patients in the research, methodologists, biostatisticians and data managers who participated in the research, members of the committee(s) constituted for the research. International rules of writing and publication will be taken into account (Vancouver Convention, February 2006).

11.2. Communication of results to patients

At their request, research participants are informed of the overall results of the research.

11.3. Transfer of data

The collection and management of data is provided by Groupe Hospitalier de la Rochelle Ré Aunis. The conditions for the transfer of all or part of the research database are decided by the research manager are the subject of a written contract.

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