

BMJ Open Evaluation of the impact of an enhanced recovery after surgery (ERAS) programme on the quality of recovery in patients undergoing a scheduled hysterectomy: a prospective single-centre before-after study protocol (RAACHYS study)

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ABSTRACT

Introduction The enhanced recovery after surgery (ERAS) programmes following hysterectomies have been studied since 2010, and their positive effects on clinical or economic criteria are now well established. However, the benefits on health outcomes, especially rapid recovery after surgery from patients' perspective is lacking in literature, leading to develop scores supporting person-centred and value-based care such as patient-reported outcome measures. The aim of this study is to assess the impact of an ERAS programme on patients' well-being after undergoing hysterectomy.

Methods and analysis This is an observational, prospective single-centre before-after clinical trial. 148 patients are recruited and allocated into two groups, before and after ERAS programme implementation, respectively. The ERAS programme consists in optimising factors dealing with early rehabilitation, such as preoperative patient education, multimodal pain management, early postoperative fluid taken and mobilisation. A self-questionnaire quality of recovery-15 (QoR-15) on the preoperative day 1 (D-1), postoperative day 0 evening (D0) and the postoperative day 1 (D+1) is completed by patients. Patients scheduled to undergo hysterectomy, aged 18 years and above, whose physical status are classified as American Society of Anesthesiologists score 1–3 and who are able to return home after being discharged from hospital and contact their physician or the medical department if necessary are recruited for this study. The total duration of inclusion is 36 months. The primary outcome is the difference in QoR-15 scores measured on D+1 which will be compared between the 'before' and the 'after' group, using multiple linear regression model.

Ethics and dissemination Approval was obtained from the Ethical Committee (Paris, France). Subjects are actually being recruited after giving their oral agreement or non-objection to participate in this clinical trial and following the oral and written information given by the anaesthesiologist practitioner.

Strengths and limitations of this study

- RAACHYS (Réhabilitation Améliorée Après Chirurgie type Hystérectomie) is the first study of its kind to assess the impact of an enhanced rehabilitation programme after hysterectomy using the QoR-15 score as a primary outcome measure.
- This is a before-and-after study type where the collection is entirely carried out prospectively.
- RAACHYS is an observational study with a lower level of evidence than a randomised interventional study.
- This study is monocentric but could be conducted in other hospitals.
- The before-after study design gives rise to possible confusion bias, in particular with the occurrence of the COVID-19 pandemic which has changed recruitment periodically.

Trial registration number: ClinicalTrials.gov: NCT04268576 (Pre-result).

INTRODUCTION

Current state of knowledge

Since the early 2000s, the paradigm of perioperative management of the enhanced rehabilitation types has been established in a wide range of surgical specialties. These programmes, also known as 'fast track' or enhanced recovery after surgery (ERAS) or enhanced recovery pathway (ERP), were first introduced over 20 years ago by Kehlet *et al*^{1 2} who questioned the effectiveness of long-standing, unsubstantiated perioperative care practices. ERAS programmes support whole patient care; its main principles are



the optimisation of preoperative fasting, with minimally invasive surgery, multimodal analgesia, early postoperative refeeding and mobilisation.³ The patient has a central place in his care with information and reinforced follow-up. Initially developed around colorectal surgery, ERP has since expanded to all kinds of surgeries, including gynaecological interventions. With the rise of minimally invasive techniques, allowing a shortened operating time and intraoperative blood loss,⁴⁻⁶ ERAS programmes have been recommended in France since 2016 for scheduled hysterectomies.³ Several international learnt societies have developed to promote these protocols. Among them, the ERAS society who establishes frequently updated rehabilitation programmes according to each type of surgery.⁷ The impact of ERP in gynaecological surgery, and more specifically with regard to hysterectomies has been studied for about 10 years. Since 2010, several studies have confirmed a reduction in the length of stay,⁸⁻¹⁰ the costs of treatment^{11 12} and the consumption of postoperative opioids¹³⁻¹⁵ after their implementation. However, patients' views on their recovery using a recognised medical measurement tool have never been studied as a primary endpoint.

To assess how the patients felt about their recovery, scores were created, in particular the quality of recovery-15 (QoR-15), which is a measure of the results reported by the patient (patient-reported outcome measure or PROM) of the quality of postoperative recovery.¹⁶ It includes 15 items that assess the patient's perioperative comfort. It was developed from the QoR-40 (40 items), which has been widely used and validated as a measure of the quality of postoperative recovery.^{17 18} QoR-15 has equivalent psychometric properties compared with QoR-40, and it is easier to use and meets the requirements of the consensus-based standards for the selection of health measurement instruments (COSMIN) group.¹⁹ In this context, its translation into different languages is the subject of numerous publications¹⁹⁻²⁴ and will ultimately lead to better comparability of studies. In accordance with the recommendations of French National Authority for Health (HAS), an ERP for patients undergoing a hysterectomy will be implemented during 2020 at the Regional Hospital Center of Metz-Thionville who performs more than 200 hysterectomies per year. Thus, we aim to assess the impact of an enhanced rehabilitation after surgery programme on postoperative recovery after scheduled hysterectomy through a score using the patient's source of information, the QoR-15 (RAACHYS: Réhabilitation Améliorée Après Chirurgie type HYStéréctomie). RAACHYS is a prospective, observational, before-after study evaluating the impact of an ERAS programme on patients undergoing a scheduled hysterectomy in the gynaecology department of the hospital. The applied measures should speed up the return to baseline status of patients and therefore reduce the length of their stay in the hospital.

Study objectives

The main objective of this study is to assess the impact of the implementation of a postoperative rehabilitation protocol on postoperative recovery. The primary outcome measure is the QoR-15 scores in patients undergoing a planned total hysterectomy in the gynaecology department of the hospital centre before and after ERAS programme implementation, on D+1. We hypothesise that QoR-15 scores on D+1 will be significantly higher after the implementation of the posthysterectomy rehabilitation programme.

The secondary objectives are to evaluate the impact of the implementation of the postoperative rehabilitation protocol on the overall length of stay, the duration of the preoperative and postoperative fasting, the onset of nausea vomiting, the maximum visual analogue scale (VAS) pain scores, the presence of a urinary catheter or peritoneal drains after surgery and the time before getting up for the first time. The rate of laparotomy and the occurrence of complications are also assessed postoperatively. The impact of the ERAS programme in patients undergoing an invasive surgical approach such as laparotomy and in patients undergoing a non-invasive approach, that is, vaginal or laparoscopy route, separately is also evaluated by measuring the QoR-15 scores preoperatively and postoperatively as well as the VAS pain scores postoperatively.

METHODS AND ANALYSIS

Study design and setting

RAACHYS is a prospective, observational, single-centre, before-after study. An early rehabilitation programme after hysterectomy has been set up at the Regional Hospital Center of Metz-Thionville in 2020. The inclusion of patients in the 'before' phase began on 1 November 2019. The inclusion schedule provides for a total inclusion period of 18 months with a duration of 6 months for the inclusion of patients in the 'before' group, a period of 6 months for the implementation phase of the protocol and a period of 6 months for the inclusion of patients in the 'after' phase. This protocol follows the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

Impact of the SARS-CoV-2 pandemic

Due to the SARS-CoV-2 pandemic, the inclusion of patients from the 'before' group has been delayed and the implementation of the ERAS protocol is taking place during 2021. The duration of the protocol implementation was extended for 12-month period. The total duration of the inclusion of the 'before' and 'after' groups as well as the protocol implementation period will extend for a total of 36 months, from November 2019 to November 2022 (figure 1). The study protocol was recorded prior to patient enrolment on ClinicalTrials.gov (NCT04268576). The initial inclusion period was 18 months. An extension request for a total of 36 months is being validated

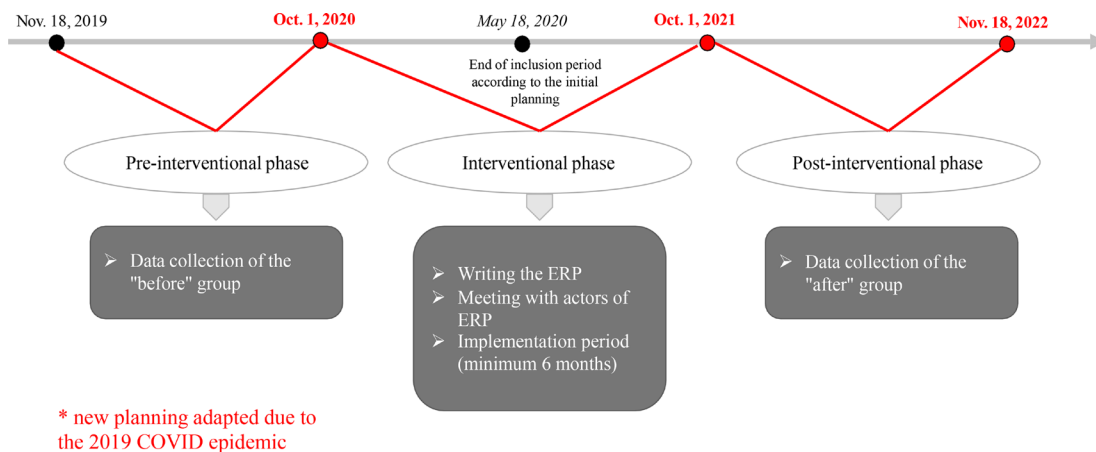


Figure 1 Intervention planning scheme. ERP, enhanced recovery pathway.

secondarily by ethical French committee. The early rehabilitation protocol was developed collegially between the anaesthesiology and the gynaecology teams of the hospital in accordance with the recommendations of HAS.

Participant eligibility and consent

The patient inclusion visit is carried on by the investigating anaesthesiologist at the time of the preanaesthetic visit. After checking the eligibility criteria, he delivers oral and written information on the context and objectives of the study. As a non-interventional research, the investigator makes sure that the patient did not express her opposition to participate in the study (research type 3 according to the French Jardé law classification). The only change in management, for the patients participating in the study, is the completion of the QoR-15 self-questionnaire preoperatively and postoperatively (D-1, D0 and D+1); consent to the surgical intervention is a separate question, previously asked by the gynaecologists during a previous consultation. The additional data constituting the secondary judgement criteria are collected in a database by the paramedical team as well as on the basis of the computerised medical file in relation to the available schedule (figure 1).

The inclusion criteria are the same as those defining eligibility for the ERAS programme: (1) patients aged 18 years old and above, (2) with scheduled planned hysterectomy regardless of the approach, (3) an American Society of Anesthesiologists (ASA) score between 1 and 3 and (4) possible postoperative return home and the possibility of contacting their attending physician or the department if necessary. The non-inclusion criteria are as follows: (1) patients deprived of their liberty by a judicial or administrative decision, (2) patients undergoing psychiatric care under articles L.3212-1 and L.3213-1 of the French Public Health Code, (3) patients included in another study, (4) refusal of their data use and (5) patients with associated severe or poorly balanced conditions. Recruitment is carried out according to the availability of the anaesthetist responsible for the preanaesthesiologist visit the day before the surgery.

INTERVENTION

An early rehabilitation protocol is being implemented for all patients undergoing a planned hysterectomy at the hospital following start-up meetings, training activities and audit with a medical and paramedical team composed by medical doctors, nurses, physiotherapists, psychologists, methodologist as well as clinical research staff. The implemented protocol is based on the latest HAS³ 2016 recommendations on early postoperative rehabilitation and follows the programme models elaborated by the SFOG (Société Française d'Onco-Gynécologie) and GRACE (French-speaking group for improved rehabilitation after surgery). It aims to optimise the preoperative, intraoperative, and postoperative factors (table 1). Eligibility for the ERAS programme is checked at the time of consultation with the gynaecological surgeon. In our initial schedule, 6 months were planned for the inclusion of patients in the 'before' group, then 6 months for the implementation of the ERP and finally 6 months to include patients in the 'after' group. The only intervention for the patients participating in the study is the completion of the QoR-15 type self-questionnaire on preoperative and postoperative periods (D-1, D0 and D+1) and the collection of data from their medical file. Actually, the inclusion period for the 'before' group has ended and has 78 patients. Four months were necessary for the development of the ERAS programme and its clinical path, in agreement with all the anaesthesiology, surgical and paramedical teams (from 1 October 2020 to 1 February 2021). The hysterectomy ERAS programme has been implemented since 1 February 2021. The inclusion period for the 'after' group is due to start on 1 October 2021.

QoR-15 questionnaire

The QoR-15 score is a self-administered questionnaire of 15 items, each rated from 0 to 10. These items assess five dimensions of postoperative recovery: pain, physical comfort, functional autonomy, emotions and psychological support. These 15 items represent the quality of postoperative rehabilitation in its physical and psychological dimensions.¹⁶

Table 1 Summary of the ERP implemented at the Regional Hospital Center of Metz-Thionville

Preoperative	Intraoperative	Postoperative
Identification of eligible patients by gynaecologists (all-approach hysterectomy)	Minimally invasive first approach	Promote the withdrawal of nasogastric tubes and urinary catheters on awakening
Patient information: dedicated ERP nurse consultation	Prevention of PONV (dexamethasone and droleptan if Apfel score >1)	Catheter plugged on return to service
Screening and treatment of iron deficiency anaemia	Monitoring of anaesthetic depth	Early mobilisation (the day of surgery)
Screening and treatment of undernutrition	Morphine savings	Early feeding (the day of surgery), chewing gum
Prioritise entry on the day of the operation, consider outpatient surgery	Intravascular fluid for vascular loading according to fluid challenge	Oral relocation of analgesics (on the day of the operation)
Optimisation of preoperative fasting (solids up to 6 hours before the operation, clear liquids up to 2 hours before surgery)	Locoregional anaesthesia: EA in the event of midline laparotomy, TAP block or multiperforated periscarring catheter in the event of Pfannenstiel-type laparotomy, infiltration of the trocar openings by Ropivacaine 2 mg/mL 20 mL in the event of laparoscopy	Multimodal analgesia with paracetamol and systematic NSAIDs 48 hours, morphine prescribed if necessary
Contribution of carbohydrate solutions (amount equivalent to 100 g of carbohydrates the day before the operation, and 50 g in the morning)		
Avoid premedication		
Non-systematic mechanical preparation of the colon		

EA, epidural anaesthesia ; ERP, enhanced rehabilitation protocol; NSAIDs, non-steroidal anti-inflammatory drugs; PONV, postoperative nausea vomiting; TAP, transversus abdominis plane.

OUTCOME MEASURES

Primary outcome

The main endpoint is the QoR-15 score in ERP implementation before-after groups on the postoperative day 1 (D+1). The choice of the database on D+1 is due to the quick positive impact expected from the ERP measures. Most of measures should take place in preoperative and from D0: better information with dedicated ERP nurse consultation, psychological support, less tubes, fast mobilisation and refeeding process.

Secondary outcomes

The secondary endpoints are the QoR-15 scores obtained in the 'before' and 'after' groups on D-1 and D0, as a preoperative baseline. In addition, (1) the overall length of stay in days, (2) the duration of the preoperative and postoperative fasting in hours, (3) the onset of postoperative nausea/vomiting (yes/no), (4) the mean and maximum VAS values in the postoperative period out of 100, (5) the time to return of gastrointestinal function in hours, (6) whether or not chewing gum is taken, (7) the presence of a urinary catheter, a postoperative drain (yes/no), (8) the time between the end of surgery and the first time to get up in hours, (9) the rate of laparotomy, (10) the occurrence of postoperative complications and (11) the resumption of surgery between the 'before' and

the 'after' groups are evaluated at different time points according to [table 2](#).

Sample size

The expected mean QoR-40 score on D+1 after hysterectomy is 175 with a SD of 15.²⁵ No published study has yet documented the use of QoR-15 for hysterectomies, but it can be assumed that the expected SD is similar.²⁶ The minimum clinically important difference for QoR-15 is 8 points.²⁶ To be able to identify a difference of at least 8 points between the two groups ('before' and 'after'), with an expected SD of 15, an alpha risk of 5% and a beta risk of 10%, it is necessary to include a total of 148 patients (n=74 per group).

Follow-up and data collection

No specific follow-up has been planned for participants except for standard routine healthcare. Data are collected prospectively from case report form, completed by patients and paramedical staff and from computerised medical records. They are then transcribed in a pseudonymised manner in a database. The data include the primary and secondary endpoints, the epidemiological criteria (ASA score, age, surgical approach, type of anaesthesia), and the occurrence of revision surgery on D+30. The epidemiological criteria, the surgical and anaesthetic

Table 2 Calendar of registrations, interventions and evaluations

	D-1	D0	D+1	Discharge from hospital (D+X)	D+30
Patient information	x				
Patient oral consent/non-opposition collection	x				
QoR-15 score measurements	x	x	x		
Length of stay in days	x			x	
Duration of the preoperative and postoperative fasting				x	
Onset of nausea/vomiting and time of onset		x	x	x	
Mean and maximum VAS		x	x	x	
Time to return gastrointestinal function				x	
Factors favouring the resumption of transit (chewing gum)		x	x	x	
Presence of a urinary catheter, a postoperative peritoneal drain		x			
Time before first ambulation				x	
Rate of laparotomy		x			
Occurrence of complications		x	x	x	
Resumption of surgery					x

D-1, preoperative day 1; D0, postoperative day 0 evening; D+1, first postoperative day; D+30, postoperative day 30.

QoR-15, quality of recovery-15; VAS, visual analogue scale.

characteristics will be compared between the before-after groups. The data collection process will be monitored by trained research staff.

Statistical analyses

The QoR score means (\pm SD), medians (min-max) values on D+1 will be compared in the before-after groups as primary endpoint, as well as on D-1 and D0, as secondary endpoints using Student's *t*-test. All other secondary endpoints of the before-after groups will be compared for quantitative variables using Student's *t*-test by the mean values (\pm SD) or Fisher's exact test for qualitative variables by the number of individuals and percentages. The alpha risk will be set at 5%. Questionnaire completion rate will be calculated as percentage and missing data will be replaced or extrapolated.

Safety reporting

Since this is an observational, non-clinical trial of investigational medicinal products, only reports of unexpected serious adverse events or any adverse drug-related effect will be pointed out to the concerned regional pharmacovigilance centre. The declaration of any adverse effects related to a medical device or software will be carried out to the device vigilance.

Patient and public involvement

Patients and the public were not involved in the conception of this clinical trial. The results will be shared in conferences, published in journals and disseminated to teams at Mercy Hospital who participated in the RAACHYS study protocol (doctors, nurses, physiotherapists, psychologists).

DISCUSSION

The current challenge in medical research is to obtain evidence that ERAS programmes improve recovery from a patient perspective. In 2014, Neville *et al* observed in their review that among 38 studies aimed at evaluating ERP (all surgery combined), only 7 used a quality-of-life score and only 1 study was interested in assessing the state of anxiety or depression of patients.²⁷ In this context, measurement tools such as QoR-15 have been developed and the conduction of trials taking into account the opinion of the patient has since been encouraged²⁸ knowing that their point of view is essential to assess the benefit of treatment or care.^{29 30} In addition, studies evaluating rehabilitation programmes for hysterectomies are rare. In 2015, no prospective randomised studies evaluating oncological hysterectomy have been found in literature review conducted by Lu *et al*.³¹ In 2019, Kalogera *et al* carried out a review of the literature on ERP in minimally invasive gynaecologic surgery and found 12 cohort studies but no prospective randomised study considered PROM as a primary endpoint.³² To date, there is only one study evaluating recovery after hysterectomy via the QoR-15 score on D+1 and the day of discharge in a prospective randomised trial, where a significant increase in QoR-15 scores between the 'traditional care' and 'fast track protocol' groups with 94.0 versus 123.1 total points on D+1 ($p < 0.001$) and 120.6 versus 134.2 versus total points on the day of hospital discharge ($p < 0.001$) were observed.³³ Unlike our protocol, the QoR-15 score was considered as a secondary endpoint, without completing a preoperative questionnaire on D-1. The principle of recovery after surgery has been very well described by



Lee³⁴ where the goal is to return to a baseline ‘preoperative’ state. To have a better reflection of this baseline state, our protocol provides for the completion of a QoR-15 questionnaire on D-1 for a better interpretation of the QoR evolution.¹⁹ Indeed, additional arguments on the beneficial interest of ERP in hysterectomy through female patients are absolutely needed.

One of the strengths of our study is the use of a recommended score as a primary outcome measure. The QoR-15 score provides a valid evaluation of postoperative recovery, focusing on both physical recovery and mental health with assessment of patient mood and anxiety.¹⁶ This psychological state could influence the patient’s return to the basic state and especially in gynaecological surgery where the psychological aspect of rehabilitation can play an important role. In two qualitative studies published by Archer,^{35 36} the women interviewed reported a need for control, understanding of the instructions and the expected beneficial effect. This encouraged their adherence to the ERAS programme. They also explained the importance of encouragement from well-trained paramedical staff for mobilisation. These qualitative studies provide clues as to how we approach the best of recoveries. Our ERAS protocol will establish a dedicated ERP nurse to improve the information delivered to patients. Systematic psychological support will also be offered. We hope to improve the sense of anguish or sadness that these patients may experience through the ERP. Our main hypotheses are therefore to improve the QoR-15 scores on D0 and D+1 between the ‘before’ group and the ‘after’ group significantly.

If the QoR-15 score decreases between the ‘before’ and ‘after’ group, this will suggest that the rehabilitation manoeuvres put in place are not well perceived by the patients. Analysis of the different components of QoR-15 (psychological or physical) will determine how to improve our ERAS protocol.

Most of the studies published to date differentiate between hysterectomies according to indication. The goal of our protocol is to be applicable to all patients undergoing a scheduled hysterectomy, regardless of the indication but also regardless of the route of entry. Thus, we have chosen to screen patient profiles undergoing hysterectomies performed for benign and malignant purposes. Beyond a systematic minimally invasive approach when the indication allows it, the ERAS programme includes several measures allowing rapid rehabilitation (limitation of the number of postoperative drains, the duration of postoperative urinary catheterisation and the postoperative fasting time) (see [table 1](#)). Indeed, routine use of locoregional anaesthesia should allow faster recovery despite an invasive approach such as laparotomy. We believe that this programme will be as beneficial to patients who have undergone a laparotomy as to those who have had minimally invasive surgery. In this sense, one of our secondary objectives is to compare the QoR-15 on D+1 between the before and after group in a ‘laparotomy’ and ‘minimally invasive approach’ subgroup.

Our study conception is therefore quasiexperimental with a ‘before’ and ‘after’ group. In this way, the risk of performance bias is reduced since when collecting the ‘before’ group, the medical team will not have been trained or sensitised to ERP. In addition, this build-up study allows a fully prospective data recovery, a rare feature in the literature where the control group regularly uses retrospective data.^{32 37}

We are also interested in the rate of hysterectomy performed by minimally invasive approach to verify the external validity of our results. For information, in France in 2018, 42% of hysterectomies were performed by laparoscopy.³⁸ There are strong disparities between each centre, and between each country, which can be explained by surgical habits. For example, in 2018, 36% of hysterectomies were performed by laparotomy in Australia compared with 10%–15% in Poland, Finland or Slovakia.³⁹

The occurrence of the SARS-CoV-2 pandemic and the first lockdown during the inclusion period of the ‘before’ group may disrupt the comparability of the groups. It is possible that the ‘before’ group loses in homogeneity due to a modified recruitment during the 2 months of the French lockdown, which would lead to a selection bias. On the other hand, patients may have an increased sense of anxiety during this period. QoR-15 scores would be lower and would constitute a confounding bias. To highlight these biases, the ‘before’ group may be subject to additional descriptive analysis between the before and after COVID-19 phases. Another limitation of our study is being monocentric, but our study design can be implemented in other establishments secondarily.

In summary, our study is the first of its kind to assess the impact of an ERAS programme for hysterectomies on recovery, using the patient as a source of information. The QoR-15 score is used as the primary endpoint. If a significant difference in the QoR-15 score between the ‘before’ and ‘after’ group will be observed, the observational design of our study will not allow us to conclude a direct causal link, but it will expand the data in the literature, regarding ERAS programmes and patients’ perspective, which is still too rare.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication Not required.

Ethics approval This study involves human participants and was approved by French Ethical Committee (Comité de Protection des Personnes Ile de France 2 Paris) ID 19.04.04.64906. Participants gave informed consent to participate in the study before taking part.

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