Early non-compliance to ERAS in gynecological open surgery for malignancies, and post-operative complications: a multicenter, prospective, observational, cohort study

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ABSTRACT

Background Open surgical procedures for gynecological malignancies have a potential risk of post-operative complications and hence prolonged hospitalization, despite adherence to an Enhanced Recovery After Surgery (ERAS) protocol.

Primary Objective To investigate the relationship between non-compliance to an ERAS protocol in the post-operative setting and the rate of post-operative complications, in women who underwent open surgery for gynecological malignancies.

Study Hypothesis Early non-compliance with the ERAS protocol increases the risk of post-operative complications.

Trial Design Multicenter, prospective, observational, cohort study.

Major Inclusion Criteria Patients with histologically proven gynecological cancer (endometrial, uterine, tubo-ovarian, and cervical) undergoing elective open surgery and managed according to ERAS guidelines.

Exclusion Criteria Patients with post-operative recovery in an intensive care unit, undergoing anterior or total pelvic exenteration or intraperitoneal chemotherapy. Previous radiotherapy or previous non-gynecological major abdominal surgery.

Primary Endpoint Association of non-compliance with the ERAS protocol using five selected indicators on post-operative day 2 with the rate of 30-day post-operative complications.

Sample Size 600 patients will be enrolled in the study.

Estimated Dates for Completing Accrual and Presenting Results At present, 106 patients have been recruited. Based on this, the accrual should be completed in 2025. Results should be presented at the end of 2025.

Trial Registration NCT05738902

INTRODUCTION

Enhanced Recovery After Surgery (ERAS) is an evidence-based medicine pathway developed for the early recovery of patients undergoing major surgical procedures.[1] ERAS can reduce post-operative complications while improving outcomes and includes several items addressing the pre-operative, intra-operative, and post-operative period.[2] Many items of the ERAS protocol can be considered standard care and are commonly used across different healthcare providers, such as the elimination of pre-operative fasting, the use of minimally invasive surgery when feasible, the use of short-acting anesthetic agents, and the use of non-opioid oral post-operative analgesia together with an early return to drinking, eating, and active mobilization.[3] However, there are still barriers to full implementation for some other items, such as the lack of professionals, funding and coordination, and ERAS unawareness,[4 5] although it has been shown that the adoption of ERAS is associated with improvements in the post-operative setting.[6 7] For this reason, non-compliance with the ERAS protocol can be associated with underlying complications, as suggested for colorectal surgery.[8]

Most of the evidence derives from the use of the ERAS protocol in colorectal surgery, whereas relatively few data are available for gynecological surgery.[9] However, specific guidelines for gynecological surgery have been published to date and have also been adopted in surgical oncology by various institutions in the United States and Europe.[10 11] Surgical treatment of gynecological malignancies involves highly invasive and complex procedures that are potentially associated with post-operative complications, which can lead to prolonged hospital stays and delays in adjuvant therapy.[12] In fact, the adoption of ERAS may provide an earlier return to intended oncologic treatment.[13] Timely management of a post-operative complication is critical to reduce the likelihood of a clinically significant delay that might, in the end, adversely affect prognosis.[14]

The aim of this study is to investigate the association between early non-compliance with the ERAS protocol and post-operative complications in patients undergoing open surgery for gynecological malignancies.

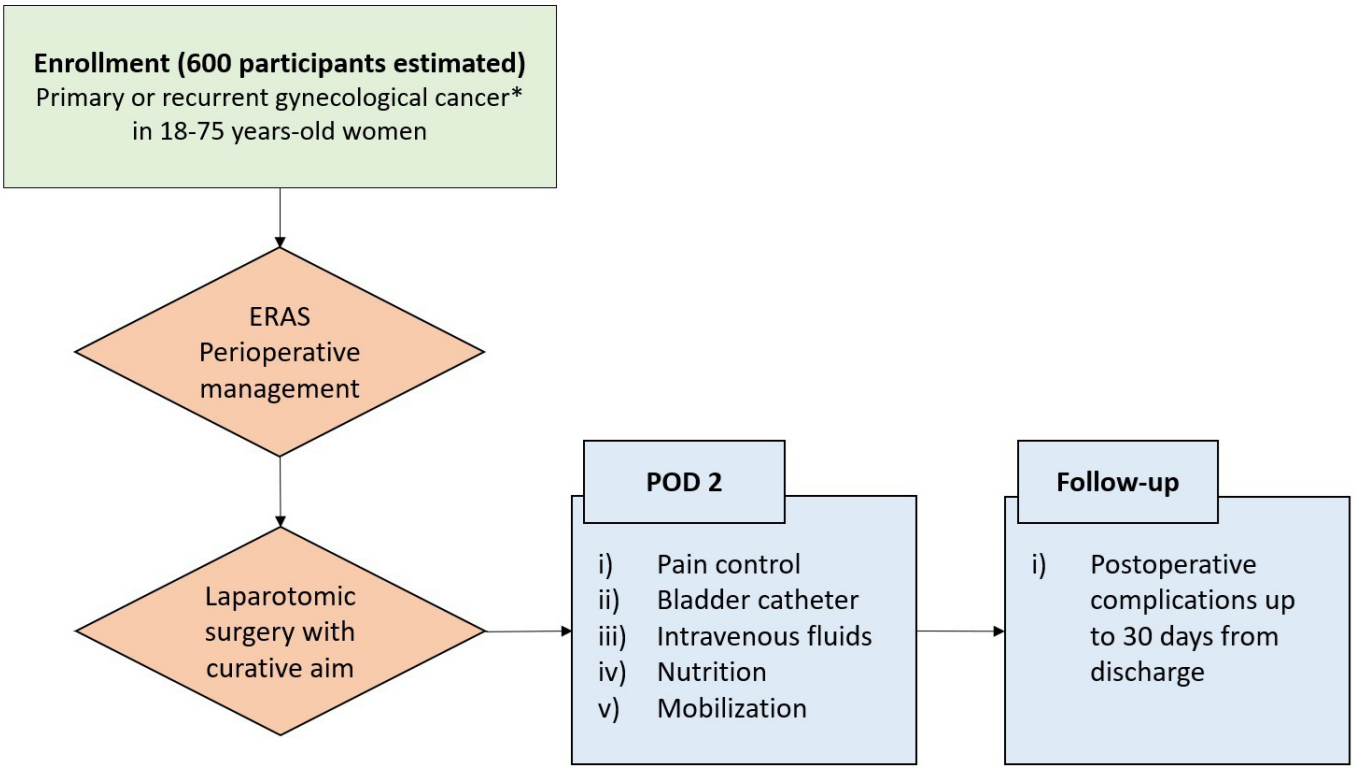

Figure 1 Study design. In green the patient criteria, in orange the procedures criteria, and in blue the planned assessments. *Endometrial, uterine, cervical, and tubo-ovarian cancer. ERAS, enhanced recovery after surgery; POD2, post-operative day 2.

METHODS AND ANALYSIS

Trial Design

This is a multicenter, prospective, observational, cohort study, registered at ClinicalTrials.gov (NCT05738902) on February 22, 2023. All consecutive women diagnosed with gynecological malignancies who undergo open surgery are eligible. Peri-operative management should be conducted according to the most recently published ERAS guidelines, and the compliance with specified items of the ERAS protocol is prospectively recorded. Post-operative complications up to 30 days from discharge are gathered and graded according to Clavien-Dindo classification.[15]

This study is not funded. The study is run and coordinated by the Department of Clinical and Experimental Science of the University of Brescia (Italy) in collaboration with the Department of Obstetrics and Gynecology of ASST Spedali Civili of Brescia (Italy). Any hospital, university or center treating gynecological malignancies with open surgery and adopting ERAS guidelines can apply for this study (please visit www.erasgynbs.eu). In Figure 1, we provide an overview of the study design, describing the principal phases.

Participants

Inclusion Criteria

Patients are eligible if they have a final histologically proven gynecological malignancy, either as primary or recurrent diagnosis, including endometrial, uterine, tubo-ovarian (including borderline tumors of the ovary), and cervical cancer at any International Federation of Gynecology and Obstetrics (FIGO) stage. Only patients undergoing laparotomy are included. Abdominal incision can be transverse or longitudinal, based on disease extension and the preference of the surgeon, and the aim of the surgery should be curative. Patients are eligible if aged 18–75 years and demonstrate an adequate compliance during the pre-operative counseling. Written informed consent is granted for women to participate in the study when required by local ethics committees. Participants do not receive financial compensation.

Exclusion Criteria

Women who have received previous abdominal or pelvic radiotherapy or underwent previous abdominal surgery for non-gynecological malignancy or a benign condition (except appendectomy and cholecystectomy) in any time during their lives, are excluded. Patients receiving anterior or total pelvic evisceration, lateral extended endopelvic resection or intraperitoneal chemotherapy are excluded. Patients with post-operative admission to the intensive care unit are excluded as well.

Primary Endpoints

The primary endpoint is the 30-days post-operative overall complications rate. The secondary endpoints are the 30-days post-operative complications rate in women diagnosed with advanced stage tubo-ovarian cancer, the adherence to ERAS, and grade III or higher complications rates.

Study Procedures

Investigators assess five selected indicators—namely, five potential predictors of complications: (i) poorly controlled pain with numerical rating scale score >3, measured using a patient-reported outcome form administered at 20:00 on POD2; (ii) failure to remove the bladder catheter on POD2, keep the catheter after 08:00 on POD2; (iii) administration of intravenous infusion as hydration therapy after

08.00 on POD2; (iv) lack of adequate oral nutrition (failure to take any of the proposed meals, which therefore causes a reasonable caloric deficit compared with real needs); (v) poor mobilization, defined as <4 four hours out of bed during the entire POD2. Every POD is defined from 08.00 of the same day until 08.00 of the day after. POD0 is the day of surgery, while POD1 is the first day after surgery, and so on up to the POD of discharge.

Sample Size

According to the literature, the 30-days complication rate for gynecological operations in gynecologic oncology is approximately 25%.[16 17] A sample of 600 patients, 150 of whom have complications, yields a 95% CI of 21.5% to 28.5%, with an estimated accuracy (half-width of the CI) of 3.5%. By considering a logistic regression model, this sample achieves 80% power at a 0.05 significance level (type I error α) to detect an OR (odd ratio) of complication rate up to 2.5 when considering a 40% non-compliance with a given ERAS indicator. The estimated sample size is also consistent with the general rule of 10 events for each independent adjustment variable considering a model including 15 predictors, including the five aforementioned ERAS indicators.

With regards to the secondary endpoint, we expect that approximately 60% of the planned sample will include women diagnosed with advanced tubo-ovarian cancer. In this group of approximately 360 women, the estimated accuracy of the 30-day complication rate will be 4.2%, with a 95% CI ranging from 20.6% to 29.8%.

Statistical Methods

Categorical variables are synthetized in terms of absolute and relative frequencies, while continuous variables are summarized as mean and SD or median and range, as appropriate. The X^2 test for categorical variables and the t-test for continuous variables are used to assess potential differences across groups of patients with and without post-operative complications. For continuous variables, if normality assumptions are satisfied, appropriate transformations of variables are first considered. In cases where normality continues to be unmet, a non-parametric test is fitted. When comparing variables across categories of compliance to ERAS as measured in terms of the number of indicators (at least 1, 2, 3, … out of 5), the analysis of variance test, or the non-parametric Kruskal-Wallis test, as appropriate, is considered. Univariate analyses are conducted to assess the association between selected independent variables and (i) the primary (rate of post-operative complications) and (ii) secondary outcome (rate of post-operative complications in women with tubo-ovarian cancer, compliance with ERAS, and rate of grade III complication). A multivariate logistic regression model is then fitted to quantify the magnitude of the association between the five individually considered indicators of non-compliance to ERAS and the primary outcome represented by the rate of post-operative complications, after taking into account the adjustment variables.

A p value <0.05 is deemed to be statistically significant.

Data Management Plan and Sharing

A detailed explanation of how data are collected and treated throughout the life of the project and after its competition is supplied in the 'data management plan and sharing document' that is provided as Online supplemental material together with the Online supplemental raw metadata list.

DISCUSSION

We designed the study to demonstrate that early non-compliance with selected ERAS items in POD2 can serve as a predictor of post-operative complication in open surgery for gynecological malignancies. According to our hypothesis, we aim to confirm that non-compliance with one, two, three or more items is associated in a dose–risk framework with post-operative complications up to 30 days from discharge. This finding can be useful for the clinician in planning the time of discharge of the patients, delaying those with a low compliance, while speeding-up the discharge of those with full and early compliance, and can be suggested as a potential tool to guide the peri-operative management.

Nonetheless, the adoption of ERAS can hide or impair the perception of post-operative complications, resulting in delayed diagnosis, and hence future studies are warranted. The studies should evaluate the efficacy of any interventions within the framework of the ERAS pathway, including objective measures of symptoms burden and control, measures of the functional recovery, and quantification of the outcomes of the program in relation to the rates of adherence to the key elements of care in gynecologic oncology, such as oncologic outcomes, and return to intended oncologic therapy.

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Contributors FF, EG, MR, FO: conceptualization, methodology, software. FF, NB, AF, GS, HSM: data curation, writing- original draft preparation. All authors: visualization, investigation. AF, GS, FO: supervision. FF, MR: software, validation. All authors: writing - reviewing and editing. FF: guarantor.

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Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Comitato Etico Provinciale di Brescia, NP5810. Date of approval: March 14, 2023. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Commissioned; internally peer reviewed.

Data are available upon request.

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DATA MANAGEMENT AND SHARING PLAN

ERASGYNBS002 - Early non-compliance to ERAS in gynaecological open surgery for malignancies and postoperative complications: protocol of a multicenter, prospective, observational, cohort study.

https://clinicaltrials.gov/study/NCT05738902

Principal Investigator (PI): Federico Ferrari – federico.ferrari@unibs.it
Data manager: Federico Ferrari – federico.ferrari@unibs.it
Project administrator: Federico Ferrari – federico.ferrari@unibs.it
Contributor: Federico Ferrari – federico.ferrari@unibs.it

Element 1: Data Type

A. Types and amount of scientific data expected to be generated in the project:
Clinical data will be obtained from electronic health records (EHR) for nearly 600 women underwent open surgery for gynecological malignancy. Clinical data include demographic data, medical history, medication, surgical data, and postoperative data regarding the course of surgery, measurement of the pain and the clinical management and the compliance of the patient. Measurement of pain will be performed using a visual numerical scale. This project proposes to use clinical data to generate a predictor of postoperative surgical complication.

B. Scientific data that will be preserved and shared, and the rationale for doing so:
De-identified summary measures such as rate of compliance to ERAS items and assessment outcomes will be made available upon motivated request to the PI of the project. De-identified individual level data will be available through a controlled access plan requiring a confidentiality agreement and institutional approval upon motivated request to the PI of the project

C. Metadata, other relevant data, and associated documentation:
Metadata are enclosed as supplementary .csv file (NCT05738902_Metadata.csv)

Element 2: Related Tools, Software and/or Code

Data will be analyzed and data which would be shared on request will be formatted for widely available statistical packages such as R, SPSS, STATA, and SAS.

Element 3: Standards

No common data standard consensus exists for inter-operability of datasets and resources.

Element 4: Data Preservation, Access, and Associated Timelines

A. Repository where scientific data and metadata will be archived:
Data and metadata will not be deposited in any repository, but made available upon motivated request to the PI of the project.

B. How scientific data will be findable and identifiable:
Scientific data is not findable and identifiable.

C. When and how long the scientific data will be made available:
Scientific data will be made available upon motivated request to the PI of the study for 5 years since the publication of the results of the study.

Element 5: Access, Distribution, or Reuse Considerations

***A.* Factors affecting subsequent access, distribution, or reuse of scientific data:**
Individual-level data will be shared with controlled access as allowed by informed consent agreements approved by the Institutional Review Board (IRB).

***B.* Whether access to scientific data will be controlled:**
Scientific data will be made available upon motivated request to the PI of the study.

C. Protections for privacy, rights, and confidentiality of human research participants:
All data is de-identified at the moment of enrollment and is stored in an electronic database (Redcap) with a two steps login.

Element 6: Oversight of Data Management and Sharing

The PI will oversee archiving and sharing of the analysis codes generated from this project upon publication or at the end of the project period, whichever comes first. The final project report will summarize adherence to this data management and sharing plan.

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recruiting  >If is not correct please contact the PI of the study ( federico.ferrari@unibs.it) and halt data collection.</span></p></div>",,,,,,,,,,,[user-dag-name]
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albumin_level,baseline_data,,radio,"Albumin level","0, normal albuminemia | 1, hypoalbuminemia | 2, hyperalbuminemia",,,,,,,,,,,,
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type  of  cancer,surgical  and  cancer  data,,radio,"Type of cancer","0, Endometrial cancer | 1, Uterine sarcoma | 2, Cervical cancer | 3, Tubo-ovarian cancer | 4, Ovarian borderline tumor",,,,,,,y,,,,,
primary  or  recurrent,surgical  and  cancer  data,,radio,"Primary or recurrent disease","0, Primary | 1, Recurrent",,,,,,,y,,,,,
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surgical  technique,surgical  and  cancer  data,,radio,"Surgical technique","0, Open surgery - transversal incision (Pfannenstiel) | 1, Open surgery - median laparotomy below the umbilicus | 2, Open surgery - median laparotomy above the umbilicus",,,,,,,y,,,,,
date  of  surgery,surgical  and  cancer  data,,text,"Date of surgery",,,date  dmy,2023-05-30,2026-01-01,,,y,,,,,
sp_simple_hysterectomy,surgical_and_cancer_data,,yesno,"Surgical procedure: hysterectomy +/- BSO",,"BSO = bilateral salpingo-oophorectomy",,,,,,y,,,,,
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sp  rad  hysterectomy,surgical  and  cancer  data,,radio,"Surgical procedure: radical hysterectomy +/- BSO","0, No | 2, Yes","BSO = bilateral salpingo-oophorectomy",,,,,,y,,,,,
sp_sentinelbiopsy,surgical_and_cancer_data,,yesno,"Surgical procedure: lymph nodal biopsy (pelvic and/or aortic)",,,,,,,,y,,,,,
sp  bplnd,surgical  and  cancer  data,,yesno,"Surgical procedure: pelvic lymphadenectomy",,,,,,,,y,,,,,
sp  palnd,surgical  and  cancer  data,,yesno,"Surgical procedure: paraortic lymphadenectomy",,,,,,,,y,,,,,
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intraoperative  complication,surgical  and  cancer  data,,radio,"Intraoperative complications","0, no intraoperative complication(s) | 1, intraoperative complication with no need for treatment (grade I) | 2, intraoperative complication with need for treatment (grade II) | 3, intraoperative complication with life-threatening or permanent disability (grade III) | 4, intraoperative death (grade IV)",,,,,,,y,,,,,
intraop  complication  detail,surgical  and  cancer  data,,text,"Type of intraoperative complication:",,"Please provide a synthetic description of the ""Intraoperative surgical complication""",,,,,,,,,,
po_los,postoperative_data,,text,"Lenght of stay (LOS)",,"Number of nights spent in hospital from the night of the surgery day. In the count you should include the night of surgery day, while you should exclude any nights before surgery day.",integer,1,1000,,,y,,,,,
po  complication  grade,postoperative  data,,dropdown,"Postoperative surgical complication grade (up to 30 days)","0, No complications | 1, Grade I | 2, Grade II | 3, Grade IIIa | 4, Grade IIIb | 5, Grade IVa | 6, Grade IVb | 7, Grade V","Please select the worst postoperative complication according to Clavien Dindo Classification (including any reintervention)",,,,,,y,,,,,
po  day  of  complication  up30days,postoperative  data,,dropdown,"Postoperative day of complication occured","32, Not applicable | 0, 0 | 1, 1 | 2, 2 | 3, 3 | 4, 4 | 5, 5 | 6, 6 | 7, 7 | 8, 8 | 9, 9 | 10, 10 | 11, 11 | 12, 12 | 13, 13 | 14, 14 | 15, 15 | 16, 16 | 17, 17 | 18, 18 | 19, 19 | 20, 20 | 21, 21 | 22, 22 | 23, 23 | 24, 24 | 25, 25 | 26, 26 | 27, 27 | 28, 28 | 29, 29 | 30, 30 | 31, not applicable","Please select the day of complication occurred, counting the surgery day as day 0",,,,,,y,,,,,
po  reoperation,postoperative  data,,yesno,"Reoperation (up to 30 days)",,"If this is marked as ""Yes"" please ensure to select the grade complication in the field ""Postoperative surgical complication (up to 30 days)"".",,,,,,y,,,,,
po  blood  transfusion,postoperative  data,,yesno,"Blood transfusion (up to 30 days)",,"If this is marked as ""Yes"" please ensure to select the grade complication in the field ""Postoperative surgical complication (up to 30 days)"".",,,,,,y,,,,,
po  covid  19  positive  after,postoperative  data,,yesno,"Covid-19 positive after surgery during the stay in hospital.",,"If this is marked as ""Yes"" please ensure to select the grade complication in the field ""Postoperative surgical complication (up to 30 days)"".",,,,,,y,,,,,
po  readmission,postoperative  data,,yesno,"Readmission (up to 30 days)",,"If this is marked as ""Yes"" please ensure to select the grade complication in the field ""Postoperative surgical complication (up to 30 days)"".",,,,,,y,,,,,
po_complication_description,postoperative_data,,text,"Type of complication (up to 30 days)",,"Please provide a synthetic description of the ""Postoperative surgical complication (up to 30 days)""",,,,,,,,,,
pod2  pain  nrs3,postoperative  data,,yesno,"Postoperative day 2: Pain was well controlled (NRS < 4 )?",,,,,,,,y,,,,,
pod2  oral  feeding,postoperative  data,,yesno,"Postoperative day 2: oral feeding was successful?",,,,,,,,y,,,,,
pod2  foley  catether,postoperative  data,,yesno,"Postoperative day 2: foley vesical catheter was removed?",,,,,,,,y,,,,,
pod2_intravenous_fluid,postoperative_data,,yesno,"Postoperative day 2:  intravenous fluids were stopped?",,,,,,,,y,,,,,
pod2  mobilization  4hours,postoperative  data,,yesno,"Postoperative day 2:  mobilization (at least 4 hours) happened?
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