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Slowly absorbable mesh versus standard care in the management of contaminated midline incisional hernia (COMpACT-BIO): a multicentre randomised controlled phase III trial including a health economic evaluation

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ABSTRACT

Introduction Incisional hernia (IH) is the most frequent mid-term and long-term complication after midline laparotomy. The current standard treatment includes repair using a mesh. In a contaminated field, the use of a non-absorbable mesh increases the risk of surgical site infection and the costs. Slowly absorbable meshes are safe in contaminated fields, but no data have been reported regarding their long-term recurrence rate. COMpACT-BIO is a multicentre prospective randomised controlled phase III trial designed to compare the 3-year recurrence rate in patients undergoing contaminated IH repair with either a slowly absorbable mesh or standard care.

Methods In patients undergoing midline IH repair in a contaminated surgical field (grade III of the modified Ventral Hernia Working Group classification), the COMpACT-BIO study compares the use of a slowly absorbable mesh with that of conventional care according to standardised surgical procedures (primary closure, non-absorbable synthetic mesh or biologic mesh, at the discretion of the surgeon). Randomisation is done during surgery before closure the fascia with an allocation ratio of 1:1. The choice of the slowly absorbable mesh is left to the criteria of each centre. The primary endpoint is the proportion of patients with scan-confirmed IH recurrence within 3 years after repair.

Ethics/dissemination This trial is conducted in compliance with international standards for research practice and reporting. Written informed consent will be obtained from patients prior to inclusion. All data were identified and anonymised prior to analysis. The protocol has been approved by an Institutional Review Board (2020-A0823-36/SI:20.07.03.66831), and will be conducted in compliance with the CONSORT (Consolidated Standards of Reporting Trials) statement. Results will be submitted for publication in peer-reviewed medical journals and presented to patients and healthcare professionals.

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STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Standardised surgical procedure with limitation of bias related to surgical heterogeneity.

⇒ Use of the modified Ventral Hernia Working Group classification allows the inclusion of 'clean-contaminated' and 'contaminated' surgical fields representing two different populations.

⇒ Heterogeneity of the control group is left to the surgeon's discretion, as well as the mesh used in the experimental group.

INTRODUCTION

Incisional hernia (IH) is the most common long-term complication after midline laparotomy,[1] and occurs most of the time within 3 years after primary surgery.[2] IH often requires a surgical repair, with a synthetic definitive mesh placement.[3–7] The use of non-absorbable mesh in a contaminated field is a major risk factor for surgical site infection,[8] and chronic infection of the implant is a potentially devastating complication.[9] Several studies reported the safety of non-absorbable mesh use in emergency settings of strangulated hernias.[10 11] However, in a contaminated surgical field, use of non-absorbable mesh remained controversial due to the related risk of infection.[12–15] To clarify this point, the Ventral Hernia Working Group (VHWG) proposed a classification based on the risk of surgical site infection, which was modified recently.[16] Modified VHWG classification defined grade I and II as low risk of surgical site infection, and grade III as high risk of

infection. Recent developments on biological meshes offered new perspectives for IH repair in contaminated field, as they were supposed to resist potential infection and be integrated into patients' tissues.[17 18] However, clinical findings did not support this hypothesis.[19] More recently, slowly absorbable meshes were developed with interesting opportunities for IH repair in contaminated field.[20–22] Slowly absorbable meshes were designed to resist infections. However, there were absorbed within 12–18 months, leading to a low risk of long-term complications related to the mesh, but a theoretically higher risk of hernia recurrence.

Due to the lack of data in the current literature regarding the interest of slowly absorbable meshes used to reduce the long-term recurrence rate, we proposed this randomised control trial. COMpACT-BIO is a phase III randomised control trial that aimed to compare the 3-year recurrence rate for patients presenting contaminated IH repair between patients treated with slowly absorbable mesh and conventional care.

METHODS AND ANALYSIS
Study design
The COMpACT-BIO study is a prospective, multicentre, phase III, comparative, randomised, two parallel-group, single-blind trial including a health economic evaluation.

The COMpACT-BIO study is a superiority trial on a medical device (RIPH (Recherches Impliquant la Personne Humaine) 1 DM (Dispositifs Médicaux)) already used in this indication but not recommended.

The COMpACT-BIO study compares the placement of a slowly absorbable mesh versus current care according to standardised surgical procedures for midline IHs in a contaminated surgical environment, grade III according to the definition of the modified VHWG (primary closure, non-absorbable synthetic mesh and biological mesh at the discretion of the surgeon).

Patient enrolment took place after preoperative workup and anaesthetic consultation.

Randomisation was done during the surgical procedure with an allocation ratio of 1:1. The choice of the type of slowly absorbable mesh was left to the discretion of each centre, depending on the availability of the different types of prosthesis. Currently, the Phasix Mesh prosthesis from Bard Davol and the BIO-A prosthesis from W.L. Gore are both available on the French market.

Phasix was made of poly-4-hydroxybutyrate, which is a monomer derived from a transgenic form of Escherichia coli already used in marketed surgical sutures (Phasix, Beckton-Dickinson, USA). The GORE BIO-A Tissue Reinforcement was a slowly absorbable mesh comprised of a bioabsorbable polyglycolide-trimethylene carbonate copolymer, which is gradually absorbed by the body.

Recruitment began in May 2021 and is planned to last until April 2022 with a follow-up of 3 years after surgery.

Surgical procedure standardisation for mesh placement
To reduce potential bias related to heterogeneity in surgical technique, a standardised technique was defined using a Delphi method consensus prior the study has been initiated. Cognitive task analysis method was used to describe all steps and potential errors occurring during a surgery. A structured protocol was then extracted from the thoughts and clinical practices of the expert panel. Assessment tools to evaluate intraoperative performance of the learner can then be devised. Inspired by Madani *et al* protocol of thyroidectomy standardisation, qualitative methods to extract subject-matter experts' (SME) thoughts, opinions and behaviour necessary to a well-conducted operation were used.[23] Literature, observations and expert survey were realised. Ventral hernia surgery experts from all centres were solicited to participate in a survey. The panel of expert surgeons were asked to outline the major steps and tasks required to perform midline ventral hernia using sublay mesh. They were then prompted to elaborate on each procedural. In practice, this was done in the form of a detailed operative protocol with comments on pearls and tips to increase surgical safety. Using detailed protocols received from the panel experts, a comprehensive list of items was realised. This list was sent to all SMEs and to ensure it was exhaustive, they added to any missing information and shared their tips and tricks to ensure the realisation of a safe operation with the caveat that they could not remove any steps. Three rounds of review were conducted before the final list of items was completed.

The main steps of the surgical technique were:
► Complete resection of the sac.
► Retro rectus dissection preserving neurovascular bundles.
► Posterior fascia closure using small bites technique with slowly resorbable tread.
► Mesh placement in retro rectus position with a 5 cm overlap.
► Mesh fixation using slowly resorbable tread.
► Anterior fascia closure using small bites technique with slowly resorbable tread.

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

Research setting
The primary endpoint is the proportion of patients with abdominal-pelvic contrast-enhanced CT scan-confirmed IH recurrence within 3 years of its repair.

Recurrence would be assessed on data from a CT scan guided by clinical examination. The CT imaging would be reviewed by two independent expert radiologists. In case of discordance, a joint reading would be performed to validate the criterion of recurrence or non-recurrence.

The secondary endpoints are:

1. Length of hospital stay (in days) related to the initial IH surgical repair within 3 years.
2. The number of reoperations related to the initial IH surgical repair within 3 years.
3. The proportion of patients who presented within 30, 90 days and then at 6, 12, 24 and 36 months following the surgical repair with at least:
   – Infectious complication.
   – Superficial: wall abscess, haematoma, seroma, skin necrosis.
   – Deep: intraperitoneal abscess, peritonitis.
   – General: sepsis and septic shock.
   – And/or
     – A parietal complication.
     – Evisceration (covered or uncovered).
     – IH recurrence.

Infectious complications were defined by all fluid collection in the surgical field, either associated with general sepsis sign or not. When feasible, fluid collection would be drawn for bacteriological assessment. All parietal complications would be confirmed by a CTscan.

4. The rate of patients requiring revision surgery, or radiological intervention for a complication, within 90 postoperative days.
5. The rate of patients presenting with recurrent IH at 6, 12 and 36 months, clinically symptomatic and confirmed on the abdominopelvic CT scan.
6. Quality of life at 30, 90 days then at 6, 12, 24 and 36 months postoperatively according to a questionnaire inspired by the CCS (Carolinas Comfort Scale[24] in order to specifically assess postoperative recovery (7–9).
7. The delay between surgery and the end of care for the mid line scar (following initial IH surgical repair to the last dressing day).
8. The proportion of patients who could not receive the surgical procedure proposed by the study and the associated reasons.
9. The incremental cost-effectiveness ratio (ICER) at 3 years from the collective perspective. The ICER will be expressed as the extra cost per quality-adjusted life-years (QALYs) gained by a slowly absorbable mesh strategy use versus standard care.

Study participants

All the following inclusion criteria must be fulfilled:
► Age≥18 years old.
► Physical status ASA <4.
► Patient with a midline IH.
► Patient presenting with an IH without loss of domain.[25]
► Surgical indication in elective surgery.
► 'Potentially contaminated' grade III surgical environment according to the classification of the modified VHWG.[16]
► Cure of mid line IH feasible according to the defined standard technical modality (placement of a retromuscular prosthesis).
► No emergency surgical procedure.
► Status of social insured or entitled to a social insurance.

► Informed and signed consent of the patient after clear and appropriate information.
The exclusion criteria are as follows:
► Pregnancy, breast feeding, parturient or childbearing patients without contraception.
► Known allergy to tetracyclines.
► Persons protected by law.

Data management

Through the combination of our electronic eCRF (Ennov EDC), internal cross-validation of the data for complex errors, and regular on-site monitoring, the quality and completeness of the data is reflective of the state of the art in clinical trials. The monitors review the source documents as needed, to determine whether the data reported in the electronic data capture system are complete and accurate. The monitors will confirm that the regulatory binder is complete and that all associated documents are up to date. Scheduling monitoring visits will be a function of patient enrollment, site status and other commitments.

Data analysis

Sample size calculation

According to studies, the proportion of recurrent hernias at 3 years after being masked in a contaminated environment (grade III of the VHWG) treated according to the recommended technique reaches 75%.[26]

The COBRA study reported a clinical recurrence rate at 2 years of 17% with the use of slowly absorbable mesh in a contaminated environment.[27] This study was not comparative, and the relatively low rate of recurrence was possibly underestimated by the clinical definition of recurrence. Indeed, asymptomatic recurrences were not diagnosed.

It was considered that 75% of patients would present with recurrent IH at 3 years in the control group. An absolute difference of 30% between the experimental group and the control group was expected. Under these assumptions, the inclusion of 47 patients in each group, for a total of 94 patients, would reveal a statistically significant difference between the two groups with a power of 80%. Numbers were calculated using Fisher's exact test and a two-sided alpha risk of 5%.[28] To take into account possible patients lost to follow-up and premature withdrawal, the number of patients needed would be increased by 15% to reach a total of 108 patients included (54 patients per group).

Statistical analysis plan

The intention-to-treat (ITT) population was defined as all the patients included in the study according to the arm allocated at the time of randomisation, regardless of the eligibility criteria, whether they were evaluable or not evaluable for the endpoints. The description of the population at inclusion would be ITT.

The primary endpoint and the secondary endpoints would be analysed in ITT among evaluable patients (modified ITT).

The per-protocol population was defined as the ITT population from which patients with major deviation from the protocol would be excluded. The major deviations from the protocols were:

► Failure to carry out the surgery as defined in the protocol.
► Failure to respect the surgical protocol.

Cases of major deviation would be reviewed be an evaluating committee, during which other cases can be blinded in the therapeutic arm. They would be specified in the statistical analysis plan. Patients would be considered in the therapeutic arm actually administered.

A secondary analysis of the primary endpoint would be performed per-protocol.

The safety population was defined as the population of patients who benefited from the surgical intervention according to the therapeutic arm actually administered. The safety and tolerance criteria would be evaluated according to this population.

Statistical method

The quantitative data would be described by their parameters of central position (mean, median) and of dispersion (SD, IQR); qualitative data would be described by their number and proportion.

The alpha risk was fixed at 5% without correction and bilateral for all analyses.

The primary analysis of the primary outcome would be performed using a logistic regression model on the modified ITT population.

The adjustment variables would be:

► Randomisation group.
► Centre.
► Continuous BMI.
► Size of the midline IH in centimetres.
► Possibly the statistically unbalanced variables between the treatment arms despite randomisation and known in the literature to modify the risk of IH within 3 years.

The OR of the treatment effect would be estimated and returned with its 95% CI and would correspond to the primary outcome of this trial.

The secondary analysis of the primary endpoint would be performed using a logistic regression model on the population in per protocol by adjusting for the same covariates.

The analysis of the secondary endpoints comparing the two therapeutic strategies would be carried out as follows:

1. The total number of hospital days within 3 years related to the initial IH surgery would be compared between groups by a non-parametric Wilcoxon rank sum test.
2. The total number of reoperations within 3 years related to the initial IH surgery would be compared between groups by a non-parametric Wilcoxon rank sum test.
3. The proportions of patients having presented at least one infectious and/or parietal complication would be described at the different times between the groups and modelled by Kaplan-Meier (KM) curves. The KM curves would be compared by a log-rank test.
4. The proportion of patients who required revision surgery, or radiological intervention for a complication within 90 days of the operation, would be compared between the groups using a Fisher's exact test.
5. The proportions of patients presenting a recurrence of IH at 6, 12 and 36 months, clinically symptomatic and objectified on the abdominopelvic scanner would be described at the different times between the groups and modelled by KM curves. The KM curves would be compared by a log-rank test.
6. The qualities of life at 30, 90 days then at 6, 12, 24 and 36 months postoperatively according to the CCS (Carolina Comfort Scale) would be described between the groups and modelled in a linear mixed effects model. The adjustment variables would be those used in the primary outcome analysis model. A random intercept per patient would be added.
7. The time between surgery and the end of midline scar care would be compared between groups by a Wilcoxon rank sum test in the absence of censorship, and by a log-rank test in the presence of censorship.
8. The proportion of patients who could not receive the surgical procedure proposed by the study would be compared between the groups using a Fisher's exact test.
9. Assessment of healthcare consumption related to healthcare status (Time frame: presurgery and postsurgery (1 month from surgery date, then 3, 6, 12, 24 and 36 months from surgery date)). The cost/quality ratio will be measured using the consumption of healthcare and the health status. In one hand, each healthcare action will be reported (by the patient or the caregiver) and then the total cost relative to the healthcare will be measured. In another hand, self-reported health status before and after IH repair will be done using the EQ-5D-5L questionnaire (EuroQol Group questionnaire 5 levels).

There are no interim analyses planned.

Management policy for missing data

There is no provision for imputation for missing data. They would be described according to the group. Aberrant data would be the subject of a request for confirmation from the investigating centre. If confirmed, their value would not be changed, and would be taken into account as it is during the analysis.

Health economic analysis

A health economics analysis at the individual patient level will be conducted alongside the clinical study and will follow the recommendation of French National Authority for Health. The aim is to assess the efficiency of slowly absorbable mesh strategy (Phasix Mesh BARD DAVOL and Bio-A, WL GORE) compared with the standard care. We assume that slowly absorbable mesh strategy should allow a reduction in the number of rehospitalisations for complications and, therefore, an improvement in the patients' quality of life compared with standard care.

Hence, we will performed a cost–utility analysis (CUA) at 36 months from collective perspective. The ICER will be defined by the difference in cost between the two interventions, divided by the difference in effect. The effects will be measure in QALYs.

Perspective

As recommended by the French National Authority for Health guideline, collective perspective will be adopted. We assume that the most of the costs impacted by the intervention are direct medical costs. By consequence, both social and domestic resources as informal care consumed will not be considered. However, we would also study in a complementary way the indirect costs related to the loss of production of the patient because they could represent an important part of the costs for this type of pathology.

Time horizon: Costs and consequences will be evaluated at 36 months after the initial hospitalisation. This time horizon seems to be the relevant minimum delay to assess efficiency of the strategies. Indeed, the potential adverse events are expected to occur within 3 years for later.

Costs estimation

For each group, all the healthcare consumptions linked to their pathology will be taken into account. The aim is to calculate an average cost per patient for each strategy.

The cost will include: consultations, nursing visits, imaging or biology exams, drugs, medical devices, transportations, emergency visits, hospitalisations for the initial surgery and for management of complications linked to pathology or treatments. Moreover, patients' productivity loss will be included but only in the sensitivity analysis as recommended. The French healthcare tariff will be used to cost out resource consumed except for hospitalisation stay. Indeed, we will use the production cost estimated in the 'French national cost study' database rather than reimbursement tariffs.

To estimate more precisely, the cost of the hospitalisation stay for the initial surgery, the microcosting approach will be used. This approach consist to measure by direct observation all relevant cost components of the procedure: duration of the procedure, composition of the staff, drugs and medical devices used, type of operating room and the duration of the hospital stays as variables and cost out each component with unit production cost or purchasing prices for drugs and medical devices.

QALY estimation

QALYs are a composite measure which combines survival data and utility data collected using the EQ-5D-5L questionnaire. The EQ-5D measures health status in terms of mobility, self-care, usual activities, pain/discomfort and anxiety/depression, it will be completed at inclusion, and 1, 6, 12, 24 and 36 months after the IH cure. The QALYs will be calculated by the area under the curve assuming a linear change in the quality of life between the measurement times. The average number of QALYs will be calculated for each of the strategies under study.

Statistical analysis

The ICER will be defined by the difference in cost between the two strategies, divided by the difference in effect.

Costs and QALYs will be presented for each group with means and SD. The non-parametric bootstrapping method will be used to produce 95% CI of the ICER but also to test the differences in costs and QALYs between groups. Both cost and QALY will be discount at 2.5% as recommended by the French National Authority for Health guideline.

A sensitivity analysis to deal with structural and methodological uncertainty will be performed. The aim is to test the robustness of the CUA results. The impact of the variation of some parameters like cost of the slowly absorbable mesh will be tested. A Tornado diagram will be used to visualise the influence of theses variables on the ICER. Moreover, the results of the nonparametric Bootstrapped simulation will be represented with an acceptability curve if it is relevant. This acceptability curve will represent the probability that the slowly absorbable mesh strategy to be cost-effective according to different willingness to pay threshold for a QALY gained.

Moreover, if clinical analyses reveal differences in results according to patients' clinical characteristic analyses in subgroups will be considered.

ETHICS AND DISSEMINATION
Research ethics approval

This protocol and the informed consent forms was reviewed and approved by the sponsor and the applicable Ethics Committee (Comité de Protection des Personnes Sud Méditerranée 2, Marseille, France, number 220 B22) prior to the beginning of the study with respect to scientific content and compliance with applicable research and human subjects regulations.

Protocol amendments

Any modifications to the protocol which may impact on the conduct of the study, potential benefit of the patient or may affect patient safety, including changes of study objectives, study design, patient population, sample sizes, study procedures or significant administrative aspects will require a formal amendment to the protocol. Such amendment will be approved by the ethics committee prior to implementation and notified to the health authorities in accordance with French regulations.

Informed consent

For each patient recruited into the study, trained research nurses introduces the study to patients.

Patients receives also information sheets which details the intent of the study, the study regimen, potential associated risks and side effects as well as potential alternative therapies extensively.

Research nurses discuss the study with patients in light of the information provided by the investigator and information sheets previously.

Investigator obtains written consent from patients willing to participate in the study. A copy of the signed and dated written consent is provided to the patient. Another copy is held in a patient's hospital file.

The investigator is not proceeding with any diagnostic measures specifically required for the clinical trial until valid consent has been obtained from eligible patient.

Confidentiality

All study-related information are stored securely at the study site. All reports, data collection, process and administrative forms are identified by a coded ID number only to maintain participant confidentiality. All records that contain names or other personal identifiers, such as informed consent forms, are stored separately from study records identified by code number. All local databases are secured with password-protected access systems. The study has been previously registered in compliance with requirements from the French data protection authority ('CNIL' (Comission Nationale de l'Informatique et des Libertés).

Access to data

The sponsor of the study oversees the intra-study data sharing process, with input from the data management team.

All authors have access to the cleaned data sets, without any contractual agreements that limit such access.

Project data sets will be housed on the study database, and all data sets will be password protected. Coordinator investigator will have direct access to their own site's data sets, and will have access to other sites data by request. To ensure confidentiality, data dispersed to project team members will be blinded of any identifying participant information.

Dissemination policy

The findings from this study will be disseminated locally and internationally through manuscript publications in peer-reviewed journals and conference presentations. Authorship will be in accordance with the International Committee of Medical Journal Editors criteria. The full study protocol and the French informed consent form are available from the corresponding author. After study completion, the participant-level dataset and statistical code will be available on reasonable request.

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