





BMJ Open Incisional hernia prevention: risk-benefit from a patient perspective (INVITE) – protocol for a single-centre, mixed-methods, cross-sectional study aiming to determine if using prophylactic mesh in incisional hernia prevention is acceptable to patients

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ABSTRACT

Introduction Incisional hernia (IH) is a common complication of abdominal surgery affecting between 10% and 20% of patients and is associated with significant morbidity along with cost to the National Health Service. With high recurrence rates following repair, focus must be on prevention of IH rather than cure. There is an increasing evidence that patients at high risk of developing IH may benefit from prophylactic mesh placement during their index operation. With recent controversy surrounding the use of mesh in the UK, however, there is little understanding of whether this intervention would be acceptable to patients.

Methods and analysis INVITE is a mixed-methods, cross-sectional study to explore patient perceptions of the use of mesh as prophylaxis to prevent IH. Patients with and without IH who have undergone colorectal surgery between 2017 and 2020 in a single UK health-board will be approached to participate. 120 participants will be asked to complete a questionnaire and a subgroup of 24 participants will be invited to semistructured interviews. The primary outcome is to assess the acceptability of prophylactic mesh to patients. Secondary outcomes include understanding patients' knowledge of IH, and factors that may influence or alter the acceptability of mesh. Questionnaires have been developed using a 5-point Likert scale to allow quantitative analysis. Qualitative analysis of interviews will be conducted using NVivo software and thematic analysis. Data will be presented using the Journal Article Reporting Standards for mixed-methods research.

Ethics and dissemination Ethical approval has been granted by REC Wales (22/PR/0678), and the study is currently in setup. All participants will be required to provide informed consent prior to their participation in the study. We plan to report the results of the study in peer-reviewed scientific and medical journals and via presentations at scientific meetings. Results from this study will aid the design of interventional trials using prophylactic mesh.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The study aims to address a key area of understanding, necessary to further research into mesh prophylaxis.
- ⇒ Mixed-methods study design will allow the research question to be investigated from different perspectives leading to a more comprehensive understanding of the outcome.
- ⇒ Lack of validated questionnaires in literature means that novel, unvalidated questionnaires have been developed.

Trial registration number NCT05384600.

INTRODUCTION

Incisional hernia is defined as a bulge or protrusion that occurs through a previously made incision and affects 10%–15% of patients following abdominal surgery.¹ It carries a substantial cost to healthcare services, estimated at between US\$21 000 and US\$26 000 per patient, and impact on patient health and well-being.² Patient morbidity arises from symptoms related to the hernia, such as pain and incarceration, alongside reduced quality of life in areas of emotional and social functioning, as well as body image concerns.^{3 4} While incisional hernia repair has been linked to an improvement in quality of life, operations are technically difficult and associated with high recurrence rates of between 10% and 30%, suggesting that prevention may be better than cure.^{3 5 6}

The main risk factors for incisional hernia are well understood. Raised body mass index

and smoking status, postoperative surgical site infection and location of incision are all associated with higher risk of developing incisional hernia.^{7–9} Large multi-centre randomised control trials have focused on identifying optimal closure methods and suture choice to try and reduce incidence of incisional hernia. These have lowered the incidence of incisional hernia, but not eliminated it completely.^{10 11}

Several studies have attempted to identify patients at high risk for incisional hernia preoperatively and assess whether these patients may benefit from different closure methods, or the use of prophylactic mesh.^{12 13} The development of risk-predictive tools for incisional hernia, such as the model produced by Basta *et al*, may help clinicians to quantify risk to patients, use prophylactic mesh in high-risk cases and subsequently reduce the incidence, and therefore economic burden of incisional hernia on healthcare services.^{14 15} Evidence for the use of mesh prophylaxis is increasing, with systematic reviews demonstrating an overall risk reduction in incisional hernia when compared with primary suture closure in elective midline incisions, alongside evidence to suggest low rates of complications, yet despite this evidence, uptake of mesh prophylaxis remains slow.

The use of mesh in surgery in the UK has come under scrutiny following media coverage and public concerns relating to the use of mesh in urogynaecological procedures, culminating in the Cumberledge report in 2020.¹⁶ With the growing controversy and media coverage, public concerns about the use of mesh in hernia surgery lead to the Royal College of Surgeons issuing a statement in 2018 defending its use for hernia surgery.^{17 18} Currently, there is little published on the patients' perspective of the use of prophylactic mesh in the prevention of incisional hernia.

Aims

1. To determine if the use of prophylactic mesh is acceptable to patients who have undergone, or are undergoing, abdominal surgery.
2. To identify factors that patients consider important when considering the use of mesh as a prophylaxis for the prevention of incisional hernias.

METHODS AND ANALYSIS

Study design

INVITE is a prospective, mixed-methods cross-sectional study with two components:

1. A patient survey assessing patient knowledge and understanding of incisional hernia and the acceptability of management options including prophylactic mesh using quantitative research methods.
2. Semistructured qualitative interviews to explore patients' opinions further and determine factors that would affect acceptability of mesh to patients.

A subgroup of patients will be approached to take part in a qualitative interview based on their answers to the

questionnaire and their willingness to participate further as indicated on their consent form. These patients will be invited to take part in semistructured interviews with a member of the research team who is trained in qualitative research methods.

Due to the nature of the data collected, a combination of qualitative and quantitative analytical methods will be employed in order to address the study aims. This will be supported by CEDAR, an in-house trials methodology group and analysed with the help of NVivo software.

Study population

The clinical care team will identify patients who have undergone elective colonic resections for colorectal cancer and those who have undergone emergency laparotomy (Emlap) from established databases, including the Cardiff and Vale national emergency laparotomy audit database, and the Cardiff and Vale University Health Board Colorectal cancer database over a 3-year period (2017–2020). Patients who have died since their operation can be identified through this method, and will not be contacted. Most patients develop incisional hernia within 18 months of surgery and this will allow sufficient time from surgery without introducing excessive recall bias. A continuous cohort of patients who are scheduled for elective colonic resection will be identified prospectively through the Cardiff and Vale Colorectal and Inflammatory Bowel database over a 3-month time period.

Patients with incisional hernia will be identified through retrospectively maintained colorectal databases containing elective and emergency patients that have undergone colorectal resections in Cardiff and Vale University Health Board. This will be cross-referenced with a list of primary care referrals for 'Incisional Hernia' for the period 2017–2020 accessed through the General Surgical directorate.

Eligibility criteria

Inclusion

Patients who have undergone elective or emergency colonic resection within Cardiff and Vale UHB.

Group 1 (with incisional hernia): 60 patients

- ▶ Over the age of 18 years old.
 - ▶ Able and willing to provide valid informed consent.
 - ▶ Undergone elective or emergency colonic resection >12 months ago.
 - ▶ Clinical or radiological diagnosis of incisional hernia.
- Group 2 (without incisional hernia): 60 patients

- ▶ Over the age of 18 years old.
 - ▶ Able and willing to provide valid informed consent.
 - ▶ Undergone emergency abdominal surgery >12 months ago or elective colonic resection >12 months ago.
 - ▶ Do not have a clinical or radiological diagnosis of Incisional hernia (or suspected incisional hernia).
- Group 3 (about to undergo laparotomy): 20 patients

- ▶ Over the age of 18 years old.
- ▶ Able and willing to provide valid informed consent.

- ▶ Scheduled for elective colonic resection in Cardiff and Vale UHB.
 - ▶ No history of previous laparotomy.
- Where possible, attempts will be made to identify patients undergoing colonic resection for benign disease.

Exclusion

All participants (groups 1, 2 and 3)

- ▶ Patients who are unable or unwilling to give informed consent.
- ▶ Any patient with a palliative diagnosis either at time of surgery, or since.
- ▶ Inability to understand or complete study questionnaires
 - Due to intellectual or cognitive impairment.
 - Due to insufficient English-language skills.

Recruitment

Eligible patients will be first approached by a member of the clinical team either face to face, if identified at routine clinical appointments or by post. Potential participants approached by post will receive a letter of invitation signed by their treating clinician, along with a copy of the participant information sheet and reply slip. All those that wish to participate in the study will be instructed to contact the research team either by phone, or by return of the reply slip.

A total of 400 patients have been identified through databases as being eligible for inclusion. Based on an accepted response rate of 40%, we have set a recruitment target of 120 patients (60 with incisional hernia and 60 without incisional hernia) for the quantitative component. A subgroup of patients will be invited to participate in face-to-face interviews and will be selected based on their responses to the questionnaire and their willingness to participate further as indicated on their consent form. Interviews will be conducted with 12 patients per group or until saturation occurs.

Patients who indicate they would like to participate will be contacted either by post or email with a patient information sheet, consent form and questionnaire. Participants will be given a prepaid envelope to return the consent form and questionnaire. If there has been no response after 2 weeks, further information will be sent. If there is still no response, then no further attempt at contact will be made.

Assessments

Questionnaire

Following a review of literature, no validated tools were identified relating to incisional hernia and patient perspective on medical mesh. A questionnaire was subsequently developed using the Health Belief Model as a framework for understanding health-related behaviours and drivers for change, alongside input from a public and patient involvement (PPI) representatives. The questionnaire will be composed of baseline demographics and surgical history, including assessing for presence of

incisional hernia and the patient's previous knowledge of incisional hernia. The acceptability of risk-predictive models, and acceptability of prophylactic mesh will also be assessed.

We will seek feedback on the questionnaire, from the first 10 participants that receive it. Their feedback will be collated, analysed and, if necessary, used to revise the questionnaire.

A copy of the questionnaire can be seen in online supplemental appendix 1.

Qualitative interviews

Twelve patients from each group will be invited to take part in semistructured interviews with a trained researcher. Only patients that indicate they would like to be contacted further on their questionnaire will be approached. Interviews will take part remotely on a one-to-one basis through Microsoft Teams. Topic guides and preprepared questions will be developed by the interviewers, with input from stakeholders, and will be used to ascertain participant's views on risk-predictive models, along with acceptability of prophylactic mesh and factors that might make it more acceptable.

Interviews are anticipated to last approximately 30–60 min and will be recorded and transcribed verbatim using a transcription service. Thematic analysis will be conducted on the qualitative data using NVivo by suitably trained and experienced researchers in order to identify any relevant themes in relation to acceptability and what constitutes high risk.

Discontinuation/withdrawal of participants

Participants have the right to withdraw from the study at any time and the investigator may also withdraw participants from the study at their discretion. If a participant withdraws, or is withdrawn, their medical treatment of legal rights will not be affected.

Anonymised research data from withdrawn participants may continue to be used and stored for use in this and future research projects. This will not include personal information, which will be destroyed at the point of withdrawal.

Expenses and benefits

Participants will not be offered any form of incentive (financial or otherwise) in return for their participation in this study. Those that are involved in the qualitative interview section of the study will be offered reimbursement for any additional travel expenses incurred as a result of their participation in this study. All questionnaires or letters that require responses by post will be provided with preaddressed and prepaid envelopes.

End of study

Participant's involvement in the study will end on completion of interviews.

The study will end once the final interview has been transcribed, passed quality assurance procedures and is ready for analysis.

Data analysis

Number of participants

As the primary objective of this study relates to qualitative research methods, no power calculation has been performed.

Quantitative data

The questionnaire will be assessed using a 5-point Likert scale and basic descriptive statistics will be used to analyse participant responses and provide meaningful output.

Qualitative data

Recorded interviews will be transcribed and prepared for analysis. Quality assurance procedures will include simultaneously reading the transcript while listening to the audio recording.

Braun and Clarke's framework of thematic analysis will be used to address the research question. Initially, patterns will be identified by reading transcripts and summary notes. Line-by-line coding will allow further identification of emerging theme clusters, which will be refined as the analysis progresses. The process will be aided with the use of NVivo Qualitative Data Analysis software.

Data analysis will be supported by researchers from Cedar Health Technology Research Centre, and data will be presented using the American Psychological Association's Journal Article Reporting Standards for mixed-methods research as a framework.¹⁹

Patient and public involvement

PPI representatives have been involved at all aspects of study design and setup, in particular, in development of patient information leaflets and in the design and testing of study questionnaires.

ETHICS AND DISSEMINATION

Ethics approval and consent

This protocol and related documents (and any subsequent amendments) has received approval from REC Wales (22/PR/0678). Annual progress and safety reports and a final report at the conclusion to the study will be submitted to the REC within the timelines requested.

Informed consent will need to be received from all participants before any personal data can be collected. Potential participants will be afforded as much time as necessary to consider the pros and cons of study participation before signing and returning the consent form.

Data management and use

Data will be entered into an Excel database by a member of the research team. The database will be password protected. Anonymised data will only be accessible by investigators at the sponsor site. Data entry will be double checked to ensure accuracy of data entry. If there are discrepancies identified the entire data collection will be double checked to ensure complete accuracy.

Data collected during the course of the research will be kept strictly confidential and accessed only by members

of the study team. Participants' personal details (name, address) will be stored by sites under the guidelines of General Data Protection Regulation (GDPR). Participants will be allocated an individual specific study number, which will be used to identify their data. Audio-recordings from the focus group will only be kept until they have been transcribed. Transcripts will be stored on a password-protected computer. Qualitative interviews data will be stored for a minimum of 5 years and a maximum of 10 years for audit purposes.

Participant's anonymised research data will be stored for a period of 5 years following the end of this study, for use in future research. Data will be stored, curated and managed in-line with the sponsor data management policies and procedures. No personal identifiable information will be shared with external researchers. Sharing data with other bona-fide researcher(s) will be subject to appropriate contractual agreements.

Dissemination

We plan to publish the results of this study in the form of peer-reviewed scientific and medical journal articles, and the clinical study report will be used for publication and presentation at scientific meetings.

Summaries of results will also be made available to investigators for dissemination within their clinical areas (where appropriate and according to their discretion), and a newsletter with study outcomes will be distributed to participants who indicate they would like to receive it.

Summary and future work

The results of this study will be used to aid clinicians in understanding if mesh placement to prevent incisional hernia is acceptable to patients, along with factors, including the role of risk-predictive tools, which may influence the acceptability of mesh. This in turn will aid in the design and setup of future interventional trials looking at prophylactic mesh placement in the UK.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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