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Guideline

Reporting guideline for interventional trials of primary and incisional ventral hernia repair

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Abstract

Background: Primary and incisional ventral hernia trials collect unstandardized inconsistent data, limiting data interpretation and comparison. This study aimed to create two minimum data sets for primary and incisional ventral hernia interventional trials to standardize data collection and improve trial comparison. To support these data sets, standardized patient-reported outcome measures and trial methodology criteria were created.

Methods: To construct these data sets, nominal group technique methodology was employed, involving 15 internationally recognized abdominal wall surgeons and two patient representatives. Initially a maximum data set was created from previous systematic and panellist reviews. Thereafter, three stages of voting took place: stage 1, selection of the number of variables for data set inclusion; stage 2, selection of variables to be included; and stage 3, selection of variable definitions and detection methods. A steering committee interpreted and analysed the data.

Results: The maximum data set contained 245 variables. The three stages of voting commenced in October 2019 and had been completed by July 2020. The final primary ventral hernia data set included 32 variables, the incisional ventral hernia data set included 40 variables, the patient-reported outcome measures tool contained 25 questions, and 40 methodological criteria were chosen. The best known variable definitions were selected for accurate variable description. CT was selected as the optimal preoperative descriptor of hernia morphology. Standardized follow-up at 30 days, 1 year, and 5 years was selected.

Conclusion: These minimum data sets, patient-reported outcome measures, and methodological criteria have allowed creation of a manual for investigators aiming to undertake primary ventral hernia or incisional ventral hernia interventional trials. Adopting these data sets will improve trial methods and comparisons.

Introduction

Ventral hernias can be large and difficult to repair[1]. High recurrence rates after repair have attracted increased research interest over the past 20 years[2]. In response, a new surgical subspecialty has emerged, abdominal wall reconstruction, targeted to improved outcomes and reduced recurrence. Interventional trials aim to advance surgical repair techniques and improve patient outcomes. However, they frequently collect data that are poorly defined and inconsistent, and report postoperative outcomes that are detected and/or measured in many different ways[3,4]. Such data are highly heterogeneous, which hampers comparisons by both narrative and systematic review and meta-analysis.

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The aim was to construct a minimum data set for primary and incisional ventral hernia trials, thereby standardizing data collection and facilitating interpretation. These data sets contain defined preoperative, intraoperative, and postoperative variables for collection, and also standardized patient-reported outcome measures andmethodological criteria.

Methods

A full explanation and elaboration of this work is available online (*Appendix S1*). In summary, a consensus group of expert abdominal wall surgeons was formed and nominal group technique methods were used. Nominal group technology facilitates effective group decision-making by giving each individual an equal chance to provide input into a defined problem[5]. This methodology consists of four phases: silent generation of ideas, ideas sharing, group discussion, and voting and ranking. This was used to create the minimum data sets. Lead researchers acted as facilitators throughout and did not vote. Before study initiation, a maximum data set was assembled by a lead researcher from two previous systematic reviews[3,4]. This was then sent to panellists to scrutinize and supplement with additional variables that they felt important for ventral hernia trials (phase 1: silent generation of ideas). Next, at the European Hernia Society meeting in Hamburg, September 2019, panellists met face to face (phase 2: sharing ideas; phase 3: group discussion). Afterwards, panellists were sent the finalized maximum data set via electronic mail and proceeded to select variables for the minimum data sets by means of multiple rounds of voting (phase 4: voting and ranking). Voting rounds followed three stages. First panellists were asked to vote for the number of variables in each data set. They then voted on data set contents. Finally, they voted on variable definitions and detection methods.

Fig. 1 shows the stages of minimum data set development, with use of the nominal group technique to guide the methodology.

Results

Panellist selection

All 15 expert hernia surgeons approached agreed to participate. Two patients of one of the authors also agreed, resulting in 17 panellists.

Development of maximum data set

The two systematic reviews[3,4] contributed 245 variables. An additional 109 variables were added by panellists (phase 1: silent generation of ideas). Thirty variables were eliminated during face-to-face discussion, leaving 324 in the final maximum data set (phases 2 and 3: sharing ideas and group discussion).

Voting and ranking

Stages 1 and 2: number of variables and variables included in data sets

After multiple rounds of voting and facilitator intervention, the group reached consensus on 32 preoperative, intraoperative, and postoperative variables for the primary ventral hernia data set; 40 preoperative, intraoperative, and postoperative variables for the incisional ventral hernia data set; 25 patient-reported outcome measures for both data sets; and 40 methodological criteria (phase 4: voting and ranking).

Stage 3: variable definitions and detection methods

Variable definitions were proposed by the facilitators. After review and feedback, two definitions were altered. The existing European Registry of Abdominal Wall Hernias definition of smoking was selected, and a new definition proposed for mesh infection. Panellists then selected their preferred variable detection methods. The chosen detection method for each variable can be found in column 3 of *Table 1*. Overall, panellists chose CT as the optimal method for assessment of both primary and incisional ventral hernias before and after operation. Although CT was selected as the preferred method for preoperative

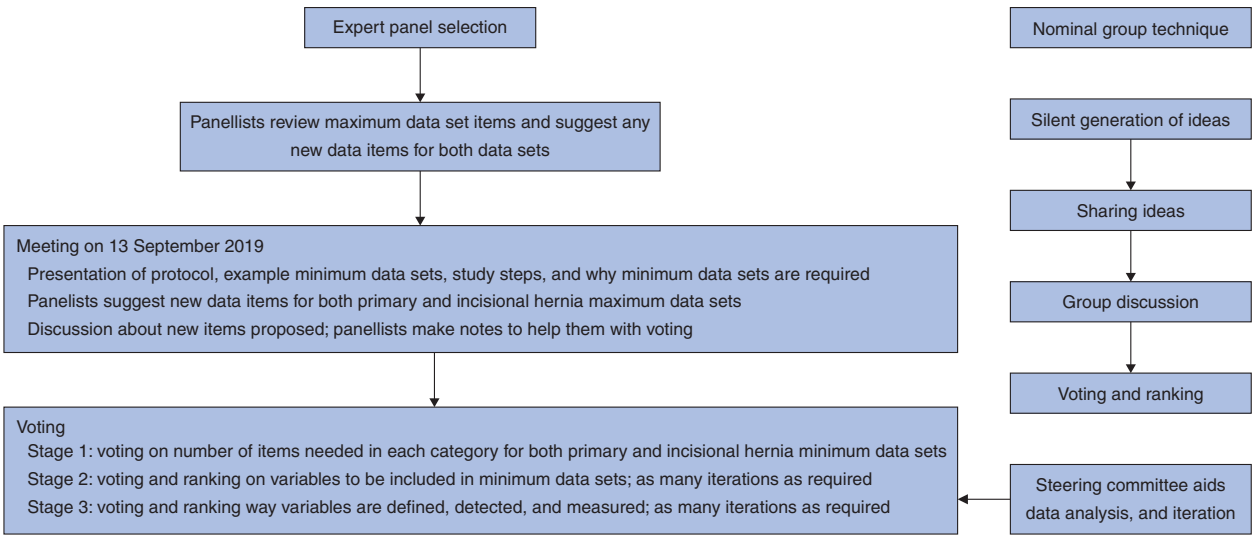

Fig. 1 Flow chart showing the stages of minimum data set development

The nominal group technique was used to guide the methodology.

Table 1 Minimum data sets for primary and incisional ventral hernia

	Definition	Detection method
Preoperative variables		
Age*	Years since birth	Age on day of surgery
Sex*	M; F	Sex on day of surgery
BMI*	Weight (kg)/height^2 (m^2)	Calculated on day of surgery
COPD*	Diagnosis of COPD	Taking repeat COPD medication
Smoker*	EuraHS[6] (never smoker, ex-smoker > 12 months; occasional smoker; daily smoker)	Status on day of surgery
Diabetes (types 1 or 2)*	Diagnosis of type 1 or 2 diabetes	Taking repeat diabetic medication
Immunosuppression/steroids*	Diagnosis requiring immunosuppression or chemotherapy	Immunosuppression or chemotherapy taken regularly on day of surgery
ASA fitness grade*	ASA fitness grade[7]	Score on day of surgery
Hernia variables		
Hernia width*	Maximum defect width; EHS classification[8]	Preoperative CT
Loss of domain*	Volumetric measurement: Sabbagh Method[9]	Preoperative CT
European Hernia Score*	EHS classification; primary ventral hernia[8]	Clinical examination
No. of hernia defects†	No. of defects in anterior abdominal wall	Preoperative CT
Divarification†	Separation > 2 cm between rectus muscles[10]	Preoperative CT
Reducibility†	Reducible; irreducible, no skin changes; irreducible, with skin changes; irreducible, causing bowel obstruction	Clinical examination +/– preoperative CT
Previous abdominal operations‡	No. of midline, subcostal, and transverse incisions	Clinical records
No. of previous hernia repairs +/– mesh‡	No. of previous hernia repairs and mesh[11]	Clinical records; ICAP nomenclature[11]
Previous wound infection (SSI)‡	Previous SSI at site of hernia repair (yes; no)	Clinical records
Hernia defect area‡	Defect area where hernia sac passes through abdominal wall	Preoperative CT (area of an ellipse)
Stoma present‡	Abdominal wall ostomy present (yes; no)	Clinical records; intraoperative details
Previous component separation‡	Previous anterior component/transversus abdominis release	Clinical records; intraoperative details
Current mesh infection‡	Chronic infection, sinus or abscess at location of mesh	Purulent discharge *or* positive fluid culture
Perioperative variables		
Mode of surgery*	Mode of surgery (laparoscopic; open; robotic)	Intraoperative details
Mesh or suture*	Method of repair	Intraoperative details
Ventral Hernia Working Group assessment*	Low risk; co-morbid; contaminated; dirty[12]	Clinical records; intraoperative details
CDC assessment*	Clean; clean-contaminated; contaminated; dirty[13]	Intraoperative details
Preoperative botulinum toxin‡	Preoperative injection of botulinum toxin to strap muscles	Clinical records
Component separation‡	Anterior component/transversus abdominis release	Intraoperative details
Concomitant gastrointestinal procedure‡	Bowel resection; cholecystectomy; stoma formation	Intraoperative details
Mesh repair		
Exact mesh name*	Trade name and mesh type (biological; biosynthetic; synthetic)	Intraoperative details
Mesh fixation technique*	Sutures or tacks (absorbable; non-absorbable)	Intraoperative details
Position of mesh*	ICAP nomenclature[11]	Intraoperative details
Mesh size*	Intraoperative measurement (cm^2)	Intraoperative details
Bridging *versus* fascial closure*	EHS definitions[6]. Anterior fascia completely closed or not completely closed	Intraoperative details
Mesh overlap‡	Mesh overlap area/defect area ratio. Ellipse: Overlap = $\pi AB - \pi ab$[14]	Intraoperativedetails
Suture repair		
Suture type*	Absorbable or non-absorbable material used	Intraoperative details
Postoperative outcomes		
SSI*	CDC definition of SSI[15]: a) Superficial; b) deep; c) organ space	Wound infection involves a) skin and subcutaneous tissue b) muscle or fascia of the abdominal wall c) tissue deep to abdominal wall
SSO*	Any adverse wound event. SSI, seroma, haematoma, fistula, etc.[16]	Clinical records; clinical examination
SSO requiring intervention*	SSOs requiring procedural intervention[17]	Clinical records; clinical examination
Mesh infection*	Chronic infection, sinus or abscess at location of mesh	Purulent discharge *or* positive fluid culture
Chronic pain*	Pain lasting longer than 3 months after surgery	Clinical records
Hernia recurrence*	EHS definition[6]: a protrusion of the contents of the abdominal cavity or preperitoneal fat through a defect in the abdominal wall at the site of a previous repair of an abdominal wall hernia	Clinical examination +/– CT
Clavien–Dindo grade*	Grades I–V. Grade IIIb: intervention under general anaesthesia[18]	Clinical records
30-day reoperation rate*	Abdominal operation under general or regional anaesthesia within 30 days of primary ventral hernia repair	Clinical records

Variables marked with * should be collected for primary and incisional ventral hernia trials, variables marked with † should be collected for primary ventral hernia trials only, and those marked with ‡ should be collected for incisional ventral hernia trials only. COPD, chronic obstructive pulmonary disease; EuraHS, European Registry of Abdominal Wall Hernias; EHS, European Hernia Society; ICAP, International Classification of Abdominal Wall Planes; SSI, surgical site infection; CDC, Centers for Disease Control and Prevention; SSO, surgical-site occurrence.

Table 2 Patient-reported outcomes for interventional trials assessing ventral hernia repair

Pain at hernia site	Score/response
Pain at rest (lying down)	0–10
Pain during activities (walking, cycling, sports)	0–10
Pain felt during the last week	0–10
Restriction of activities because of pain or discomfort at hernia site	
Restriction in daily activities (inside the house)	0–10
Restriction outside the house (walking, biking, driving)	0–10
Restriction during sports	0–10
Restriction during heavy labour	0–10
Cosmetic discomfort	
Shape of abdomen	0–10
Site of hernia	0–10
General health questions	
In general, would you say your health is	Excellent; very good; good; fair; poor
Moderate activities, such as moving a table, getting dressed, cooking, bowling, or playing golf	Yes, limited a lot; yes, limited a little; no, not limited at all
Climbing several flights of stairs	Yes, limited a lot; yes, limited a little; no, not limited at all
Due to physical health problems over the past 4 weeks, have you accomplished less than you would like?	Yes; no
Due to physical health problems over the past 4 weeks, have you been limited in the kind of work/other activities?	Yes; no
Due to emotional health problems over the past 4 weeks, have you accomplished less than you would like?	Yes; no
Due to emotional health problems over the past 4 weeks, have you been limited in the kind of work/other activities?	Yes; no
During the past 4 weeks, how much did pain interfere with your normal work	Not at all; a little bit; moderately; quite a bit, extremely
Over the past 4 weeks, have you felt calm and peaceful?	All of the time; most of the time; a good bit of the time; some of the time; a little of the time; none of the time
Over the past 4 weeks, did you have lots of energy?	All of the time; most of the time; a good bit of the time; some of the time; a little of the time; none of the time
Over the past 4 weeks, have you felt downhearted and blue?	All of the time; most of the time; a good bit of the time; some of the time; a little of the time; none of the time
Over the past 4 weeks, how much have your physical or emotional problems interfered with your social activities?	All of the time; most of the time; a good bit of the time; some of the time; a little of the time; none of the time
My mental health currently is	Awful; poor; fair; good; very good; excellent
My sexual activity currently is	Awful; poor; fair; good; very good; excellent
Having the operation was the right decision	Strongly agree; agree; neither agree or disagree; disagree; strongly disagree
I would go for the same choice if I had to do it over again	Strongly agree; agree; neither agree or disagree; disagree; strongly disagree

A combination of European Registry of Abdominal Wall Hernias quality-of-life score[6], Short Form 12[19], and expert patient questions.

primary ventral hernia characterization, panellists advise that, if there is no clinical indication beyond research, targeted low-dose CT should be used (phase 4: voting and ranking). Panelists selected standardized follow-up durations of 30 days, 1 year, and 5 years ; post-operative outcomes should be measured at these time points.

The finalized minimum data sets complete with simplified definitions and detection methods are shown in *Table 1*. A detailed description of these variables and their respective detection methods can be found in the online manuscript (*Appendix S1*). The chosen patient-reported outcome measures are shown in *Table 2* and the finalized methodological criteria selected in *Table 3*.

Discussion

Informed by systematic review and expert consensus, minimum data sets were constructed for interventional trials of primary and incisional ventral hernias. Not only have two recent systematic reviews[3,4] indicated a requirement for minimum data sets, so too have calls from hernia surgeons, asking that a common language be used for outcome reporting and research[26,27]. Indeed, Debord and colleagues[28] called for 'an international task force to establish the definitions for wound events after hernia repair'. The present work has used an international group to both standardize postoperative wound events, and define preoperative patient variables, hernia characteristics, reported perioperative variables, postoperative outcomes, and patient-reported outcomes for ventral hernia trials. Trial methodology criteria have also been included to help create a handbook or manual to aid researchers planning ventral hernia trials. A greater wealth of standardized data will facilitate pooling and comparisons, including meta-analysis, so that new knowledge regarding optimal treatment options and outcome predictors has a more substantial evidence base.

Table 3 Forty methodological recommendations for primary and incisional ventral hernia interventional trials

General
Funding source and other support (such as supply of drugs or supplies), role of funder
Protocol location
Registered trial no.
Ethical approval (with reference no.)
Introduction
Background and rationale
Primary aim or objective (distinguishing prespecified from exploratory)
Additional objectives (distinguishing prespecified from exploratory)
Methods
Trial design
Important changes to methods after study commencement, with reasons
Trial setting (single centre/multicentre), names of centres where data will be collected
Eligibility, inclusion, and exclusion criteria for study participants
Intended recruitment and follow-up dates
Intervention and standard-care descriptions, with sufficient detail to allow replication
Primary outcome, with methods and references for detection and measurement
Secondary outcomes, with methods and references for detection and measurement
Methods of follow-up
Intended sample size and study power, and how these were determined
RCTs: method of generating random allocation sequence
RCTs: method of implementing random allocation
RCTs: method of concealment (blinding) of participants and care providers to intervention received
Methods of study group/arm participant allocation, highlighting inherent selection biases and any methods used to reduce bias where possible
Method of concealment (blinding) of outcome assessors to intervention received
Statistical methods for comparing groups; for primary and secondary outcomes
Statistical methods for additional analyses such as subgroup and adjusted analyses
Statistical methods for handling missing data
Results
Participant flow chart: for each group, the numbers of participants meeting inclusion criteria, assigned to intervention, receiving intervention, analysed for primary outcome (including reasons for non-participation at each step)
Study dates: start and finish of recruitment, end of follow-up
Table of baseline characteristics and preoperative variables for each intervention group or by main predictor
No. of participants eligible, included, and analysed
Non-adherence to intended protocol by group: number of participants, important changes to interventions, outcomes or follow-up
Analysis
For each group, no. of participants (denominator) included in each analysis and whether the analysis was by original assigned groups (intention to treat) or by treatment (per protocol).
For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
Results of any other analyses, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory. Report adjustment factors
All important harms or unintended effects by group: no., definition, method of collection, start, and duration
Follow-up by group: no. by method, length of follow-up (median)
No. of participants with missing data
Discussion
Summary of key results with reference to study objectives
Trial limitations, addressing sources of potential bias, imprecision
Interpretation consistent with results; balancing benefits and harms
Generalizability (external validity, applicability) of study findings

These criteria were devised using existing methodological tools: Downs and Black[20], ROBINS-I[21], CONSORT statement[22], STROBE[23], TIDieR checklist[24], and Newcastle–Ottawa Scale[25].

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Supplementary material

Supplementary material is available at *BJS* online.

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