OXFORD

BJS, 2021, **108**, 256–264
DOI: 10.1093/bjs/znaa107
Advance Access Publication Date: 24 January 2021
Systematic Review

Systematic review on reporting of components and outcomes in randomized clinical trials of paraoesophageal hernia mesh repair

A. C. Currie *, N. Penney , A. Kamocka , P. Singh , N. Abbassi-Ghadi and S. R. Preston

Regional Oesophagogastric Unit, Royal Surrey County Hospital, Guildford, UK

*Correspondence to: Regional Oesophagogastric Unit, Royal Surrey County Hospital, Egerton Road, Guildford GU2 7XX, UK (e-mail: andrew.currie@nhs.net)

Abstract

Background: Surgical interventions, such as paraoesophageal hernia (POH) repair, are complex with multiple components that require consideration in the reporting of clinical trials. Many aspects of POH repair, including mesh hiatal reinforcement and fundoplication type, are contentious. This review summarizes the reporting of components and outcomes in RCTs of POH repair.

Methods: Systematic searches identified RCTs of POH repair published from 1995 to 2020. The patient selection criteria for RCT involvement were noted. The components of the surgical interventions in these RCTs were recorded using the CONSORT guidelines for non-pharmacological treatments, Template for Intervention Description and Replication (TIDieR) and Blencowe frameworks. The outcomes were summarized and definitions sought for critical variables, including recurrence.

Results: Of 1918 abstracts and 21 screened full-text articles, 12 full papers reporting on six RCTs were included in the review. The patient selection criteria and definitions of POH between trials varied considerably. Although some description of trial interventions was provided in all RCTs, this varied in depth and detail. Four RCTs described efforts to standardize the trial intervention. Outcomes were reported inconsistently, were rarely defined fully, and overall trial conclusions varied during follow-up.

Conclusion: This lack of detail on the surgical intervention in POH repair RCTs prevents full understanding of what exact procedure was evaluated and how it should be delivered in clinical practice to gain the desired treatment effects. Improved focus on the definitions, descriptions and reporting of surgical interventions in POH repair is required for better future RCTs.

Introduction

Large or giant paraoesophageal hernias (POHs) account for around 50 per cent of all laparoscopic hiatal repairs[1]. There is no agreed definition on what constitutes a large POH, even amongst the guidelines of international societies[2,3]. With the introduction of the laparoscopic approach, repair of large POHs became more common[4,5]. Early series[6,7] reported recurrence rates in up to two-thirds of patients undergoing repair. This led to the concept of mesh cruroplasty to repair the hiatal defect. The use of mesh to repair the hiatal defect remains controversial, particularly as mesh erosions into the oesophagus can result in severe morbidity[8]. A number of RCTs have been conducted, but mesh types, reconstruction approaches, and primary outcomes differ between studies[9,10]. The varied conclusions from these RCTs mean that there is still no consensus regarding the optimal method for repair of large POHs.

There is increasing recognition that surgical procedures are complex, multicomponent interventions[11–14]. These components all need to be reported accurately and in detail if the surgical community is to adopt the findings from a trial. Recent evidence suggests that many surgical trials do not adequately report the trial intervention or define the studied clinical outcomes, and there is often limited consideration of operator expertise and quality assurance.[15] To address these deficiencies, the CONSORT guidelines for non-pharmacological treatments (CONSORT-NPT)[16] and the Template for Intervention Description and Replication (TIDieR)[17] frameworks recommend full descriptions of surgical interventions, performing quality assurance within the trial and demonstrating the degree of operator expertise. Recently, Blencowe and colleagues[18] developed a more comprehensive framework for the reporting of surgical trial interventions. To date, no studies have specifically addressed the quality of the description used to define the surgical intervention (quality of intervention description) and its delivery in RCTs performed to assess the potential benefit of mesh cruroplasty in the repair of large POH.

This study aimed to report the patient selection, quality of intervention description, and reporting of trial outcomes in RCTs of mesh cruroplasty for large POH repair.

Methods

A systematic review was undertaken to identify all published RCTs evaluating mesh cruroplasty for large POH repair. The

Received: July 15, 2020. **Revised:** October 20, 2020. **Accepted:** November 03, 2020

review was conducted in line with the PRISMA statement[19]. The review was registered in the PROSPERO database (CRD42020181971).

Search strategy and study selection

Searches were undertaken in MEDLINE, Embase and PubMed up to March 2020. Searches consisted of subject headings and text words, combining terms for POH repair with RCTs and excluding meta-analyses, using Boolean logic. The following terms were used: 'hiatal', 'para(o)esophageal', 'hiatus', 'hiatal herniorrhaphy', 'hiatal hernia', 'randomized controlled trial', 'random allocation', 'prospective studies', 'longitudinal studies', 'randomized', 'clinical trial', 'controlled study' not 'meta-analysis'.

Study eligibility

Searches were limited to studies in humans, written in English. RCTs comparing mesh cruroplasty with either sutured or an alternative mesh cruroplasty for the repair of large POH were eligible for inclusion. Where systematic reviews were identified, bibliographies were cross-checked to ensure that all eligible studies had been included. Abstracts and proceedings from conferences were excluded owing to the high probability of incomplete data.

Identification and selection of papers

Titles and abstracts were screened independently by at least two authors. After title and abstract screening, the full-text articles were assessed further for eligibility. Disagreements were first discussed between the reviewers, and any remaining disagreements were referred to the wider study team to achieve consensus. Bibliographies of included articles were searched manually for additional relevant articles. Data from full-text papers were extracted independently by at least two assessors.

Data collection

The key areas for data collection reflected aspects of the CONSORT-NPT[16], TIDiER[17] and Blencowe[18] framework recommendations. These included details of: patient selection for POH repair; intervention description, standardization and adherence; intervention context; operator expertise; and outcome definition, measurement and reporting. Where multiple papers were reported for an individual RCT, the outcome data were extracted from all articles and combined as one RCT in the review. This permitted an approach where data could be acquired for both short- and long-term outcomes.

Patient selection for paraoesophageal hernia repair (CONSORT-NPT item 4)

Papers were reviewed for reporting details of how participants were selected for POH repair (inclusion and exclusion criteria). Information was sought on how RCTs defined large POH. Information was also sought on patients who were eligible for but did not undergo POH repair. General demographic details about trial participants were also recorded.

Intervention description, standardization and adherence (CONSORT-NPT item 5, TIDiER items 6 and 8–12, and Blencowe framework)

All descriptions of the techniques used for POH repair were extracted verbatim and assessed using CONSORT-NPT, TIDiER and Blencowe typology (which allows subcategorization of an intervention into individual components and steps[18,20]). Descriptions of each component (such as incisions and access, dissection, and reconstruction) were then standardized (to enable comparison) and tabulated to identify whether there was clear reporting of what had been performed and comparisons made between RCTs. The reporting of whether trial interventions were standardized in the RCT (yes/no) and, if relevant, methods used to standardize intervention delivery were recorded. The reporting of information related to treatment adherence was identified (yes/no), and details of processes to measure adherence were documented.

Intervention context (CONSORT-NPT items 4 and 15, and TIDiER item 7)

Details of the types of centre undertaking POH repair in the RCTs were recorded, including the numbers of participating centres, type of institution (specialist or general) and caseload data. Any study entry criteria were noted, along with the rationale of these criteria, if recorded.

Operator expertise (CONSORT-NPT item 15 and TIDiER item 5)

The numbers and grades of participating surgeons were recorded. Reporting of individual operator experience with the procedure was recorded, including information about specific training, mentorship or credentialing before trial involvement. The number of surgeons performing procedures in each trial group was noted, including whether they undertook interventions within one or more trial groups.

Outcome definition, measurement and reporting (CONSORT-NPT items 6 and 11)

Articles were assessed for reporting of primary and secondary outcomes, and any definitions associated with these outcomes. Outcomes were considered 'defined' if text was provided of their clinical meaning, if details of calculations or techniques for assessing variables was provided, or if supported by a citation. Where none of this was provided, the outcomes were considered 'not defined'. The methods of measurement and time point of outcome assessment was recorded, along with details regarding the blinding status of the assessor. Specifically, details on how recurrence was defined, measured, and when it was reported were recorded. The overall conclusions of the RCTs were reported and, where multiple follow-ups occurred, the stability of RCT conclusions was noted.

Data synthesis

Results were summarized in a narrative synthesis, with descriptive statistics where appropriate. As the study did not aim to draw conclusions about the effectiveness of mesh cruroplasty over other treatments, meta-analyses were not performed.

Results

Systematic searches of the literature identified 1918 articles; after exclusions and deduplication, 21 full-text articles were screened. A total of 12 full papers that were published between 1999 and 2020 were included in the review[21–32] (*Fig. 1*). The 12 articles included a number of sequential or additional trial reports from single RCTs. Therefore, this review represents an assessment of six RCTs evaluating mesh cruroplasty for POH repair.

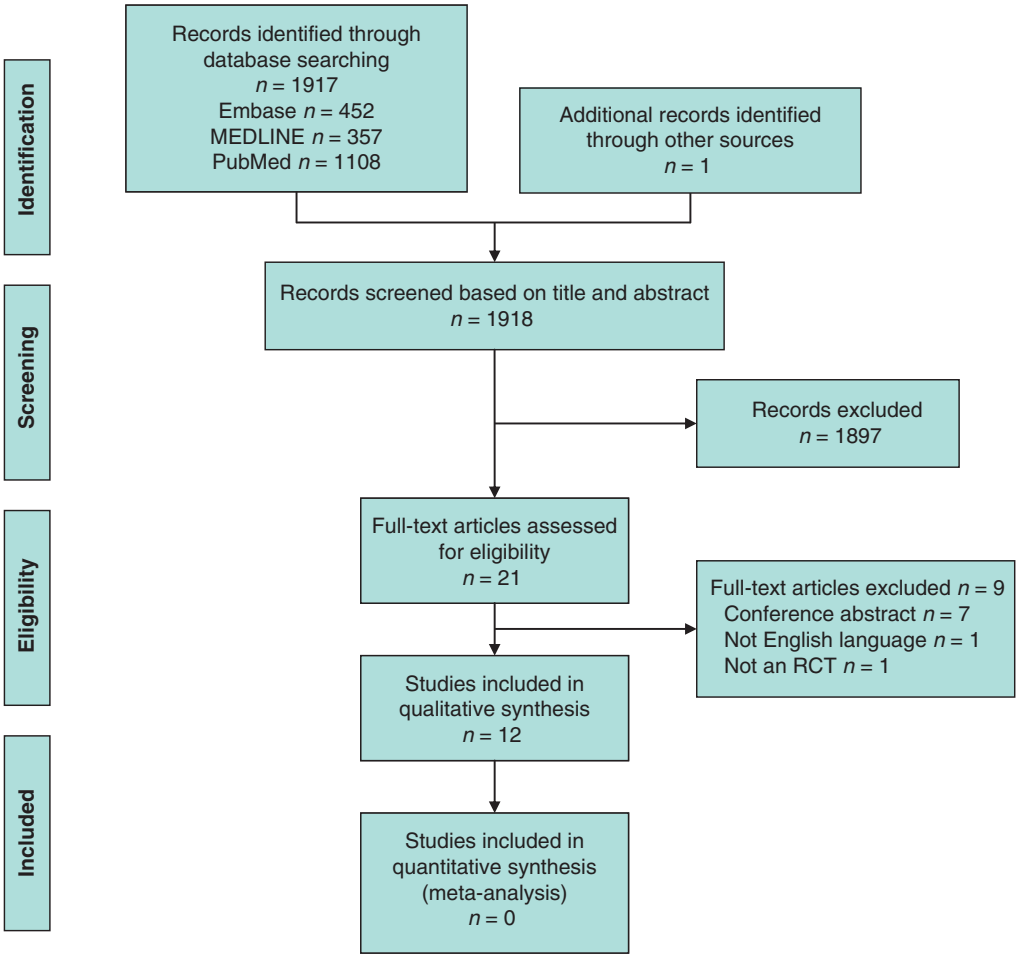

Fig. 1 PRISMA diagram for the review

Lack of detail on the surgical intervention in paraoesophageal hernia repair RCTs prevents full understanding of what exact procedure was evaluated and how it should be delivered in clinical practice to gain the desired treatment effects.

Patient selection for paraoesophageal hernia repair

The trials' patient selection criteria and patient characteristics are shown in *Table 1*. All RCTs involved adult patients aged 18 years and over. Inclusion criteria were included in all RCTs, whereas exclusion criteria were recorded in five of the six RCTs. The reported inclusion criteria demonstrated considerable variation. Five of the six RCTs recruited only patients with large POH. The definition of large POH varied between RCTs, including greater than 50 per cent stomach in chest[26,30,31], hiatal defect of 5 cm or more with evidence of stomach or other viscera in hernia sac on imaging[29], 8 cm or larger hiatal defect[21–23], hiatal defect surface area greater than 10 cm^2 (reference 32), and size 5 cm or greater size hernia with symptoms[27,28]. In the Granderath RCT[24,25], patients with gastro-oesophageal reflux were recruited, but the RCT recorded a subset of patients with large POH defined as 5 cm or greater in size. Previous hiatal or gastro-oesophageal surgery were exclusions in four of the trials, with oesophageal dysmotility (undefined) being an exclusion in two trials. With regard to demographics, the RCTs included 576 patients overall, with 184 men and mean age over 60 years in trials where these details were reported.

Intervention description, standardization and adherence

Reporting of intervention descriptions in the RCTs is summarized in *Table 2*. The trials evaluated seven different interventions including six different types of mesh or buttressing material and suture cruroplasty. At least some description was provided for the seven interventions in the included RCTs. The techniques were referenced in all six trials.

Details regarding cruroplasty before mesh placement (or alone for non-mesh trial participants) varied with respect to anterior and posterior suture placement and suture type. Only one trial[26,30,31] specified an intended desired hiatal diameter after cruroplasty. The analysis of individual components using Blencowe's framework revealed considerable variation (*Table S1*). Operative components were reported with different degrees of detail, and omitted in some RCTs. In particular, the reports' dissection differed with respect to degree of oesophageal mobilization, division of the short gastric vessels and use of Collis gastroplasty. The reconstruction elements displayed variation in mesh positioning (U-shaped in 5 trials and encircling the oesophagus in 1) and type of fundoplication used.

Table 1 Patient selection criteria and characteristics in paraoesophageal hernia trials

Trial	Dates of operations	Inclusion criteria	Exclusion criteria	Total RCT population	No. of men	Mean age (years)
Frantzides *et al.*[21–23]	January 1991 to December 2000	Hiatus hernia diagnosis: endoscopy and barium swallow Diaphragmatic defect measurements: ≥8 cm (confirmed during surgery after initial dissection) Sac contents: n.s. Emergency/elective: not described	n.r.	72	n.r..	n.r.
Granderath *et al.*[24,25]	May 2001 to May 2002	Hiatus hernia diagnosis: endoscopy and oesophageal manometry and 24-h pH monitoring Diaphragmatic defect measurements: >5 cm measured during surgery with endoscopic ruler Sac contents: n.s. Emergency/elective: n.s.	Oesophageal dysmotility (manometry: <30 mmHg in lower oesophageal segments in response to wet swallows or severely disordered peristalsis (<40% simultaneous contractions in wet swallows)	100	62	n.r.
Ilyashenko *et al.*[32]	January 2011 to January 2014	Hiatus hernia diagnosis: barium swallow study, upper gastrointestinal endoscopy, and 24-h pH monitoring. CT of chest and abdomen performed in selected patients Diaphragmatic defect measurements: surface area larger than 10 cm^2 (10–20 cm^2) measured during surgery Sac contents: type III hiatal hernia (>50% stomach) Emergency/elective: elective	Previous LARS Emergency procedures	98	32	63
Oor *et al.*[29]	April 2013 to March 2016	Hiatus hernia diagnosis: endoscopy, barium swallow radiology, or thoracic and/or abdominal CT Diaphragmatic defect measurements: >5 cm on imaging as above Sac contents: stomach/other viscera present in hernia on objective assessments above Emergency/elective: n.s.	Previous LARS Oesophageal dysmotility	72	23	63
Oelschlager *et al.*[27,28]	July 2002 to May 2005	Hiatus hernia diagnosis: >5 cm hiatal hernia on OGD Diaphragmatic defect measurements: n.s. Sac contents: stomach or other viscera present in hernia and does not reduce spontaneously from mediastinum Emergency/elective: elective Additionally: significant symptoms or signs of paraoesophageal hernia: heartburn, dysphagia, chest pain, shortness of breath, postprandial abdominal pain, early satiety, odynophagia, or chronic anaemia	Previous oesophageal or gastric operation Emergency procedures Associated gastrointestinal diseases that require extensive medical or surgical intervention that might interfere with quality of life assessment (such as Crohn's disease)	108	27	n.r.
Watson *et al.*[26,30,31]	February 2006 to September 2012	Hiatus hernia diagnosis: endoscopy and barium swallow. Oesophageal manometry and pH monitoring used selectively in patients with significant reflux symptoms Diaphragmatic defect measurements: n.s. Sac contents: >50% of stomach Emergency/elective: elective	Previous oesophageal or gastric operation If any additional procedure to hiatus hernia repair required	126	40	68

n.r., Not recorded; n.s., not specified; LARS, laparoscopic antireflux surgery (including hiatal hernia repair); OGD, oesophagogastroduodenoscopy.

Four of the included RCTs reported efforts to standardize the trial interventions used. Two trials used a consensus meeting between the participating surgeons where a standard technique was agreed[26,29–31]. One[26,30,31] of these trials used surgeons' videos to discuss and standardize the operative technique. One further trial[21–23] attempted standardization by using a single surgeon for all trial participants. The fourth trial[24,25] reported use of a 'standardized' technique, but offered no further details. The remaining trials

Table 2 Operative components in paraoesophageal hernia trials

Trial	Intervention 1	Intervention 2	Intervention 3	Technique described	Technique referenced	How mesh applied	Suture type for cruroplasty
Frantzides *et al.*[21–23]	Suture cruroplasty	PTFE (non-absorbable)	–	Yes	Yes	Stapled. Onlay oval mesh with 3-cm defect cut and radial slot applied encircling oesophagus	Non-absorbable
Granderath *et al.*[24,25]	Suture cruroplasty	Polypropylene (non-absorbable)	–	Yes	Yes	Sutured. 1×3-cm posterior patch	Non-absorbable
Ilyashenko *et al.*[32]	Suture cruroplasty	ProGrip™ (non-absorbable)	–	Yes	Yes	Pressure only	Non-absorbable
Oor *et al.*[29]	Suture cruroplasty	TiMesh® (non-absorbable)	–	Yes	Yes	Sutured or ProTack™ over posterior hiatal repair	Non-absorbable
Oelschlager *et al.*[27,28]	Suture cruroplasty	Biological (absorbable)	–	Yes	Yes	U formation 7×10 cm. Secured with sutures	n.s.
Watson *et al.*[26,30,31]	Suture cruroplasty	Surgisis™ (absorbable)	TiMesh™ (non-absorbable)	Yes	Yes	Sutured or ProTack™ to overlay posterior hiatal repair but never to encircle the oesophagus	n.s.

ProGrip™ monofilament polyester and polyglactic acid grips (Covidien, Atlanta, GA, USA); TiMesh® (polypropylene; Medtronic, Minneapolis, MN, USA). ProTack™ (Covidien, Atlanta, GA, USA); Surgisis® (Cook Medical, Bloomington, IN, USA). PTFE, polytetrafluoroethylene; n.s., not specified.

either left operative elements to the discretion of the operating surgeon[27,28] or made no comment regarding standardization[32].

One RCT[26,30,31] reported crossover between treatment arms. Only one study[26,30,31] reported a fidelity assessment. In that RCT, routine barium swallows were performed before discharge to identify wrap migration and early recurrence. If any concerns were identified on this imaging assessment, reoperation was planned. Early reoperations were described in that RCT[26,30,31], but the number performed due to the imaging assessment was unclear.

Intervention context

Two of the trials were multicentre and the remaining four were conducted in a single centre. Two of the trials took place in the USA, with one trial in each of Australia, Austria, the Netherlands and Ukraine. The nature of the included centre was detailed in five of the six trials: four of the trials were conducted in university-affiliated hospitals or associated private institutions, and the fifth was completed in a tertiary centre. No RCTs reported usual centre caseload or specified centre requirements for trial involvement.

Operator expertise

The number of different participating surgeons was reported in five trials (ranging from 1 to 9 participants). All five reported some information about the expertise of these surgeons, but to varying degrees. Descriptions of expertise included 'surgery was performed or supervised by specialist upper gastrointestinal surgeons'[26,30,31], 'specialist GI surgeons'[29], 'senior surgeon'[21–23] and 'experienced surgeons'[27,28,32]. One trial[29] reported that surgeons were past their learning curve by performing 30 POH repairs a year (referencing a paper that 40 POH repairs developed proficiency[33]). In these five trials, the participating surgeons operated on patients in all trial arms. No specific information was reported in any trial about requisite standards or operative volume for trial involvement or pretrial training for participating surgeons.

Outcome definition, measurement and reporting

The details regarding outcome definitions and time point for measurement are shown in *Tables* 3 and 4. Recurrence of the POH was the primary outcome in five of the trials, with reflux recurrence in the remaining trial[24,25]. Only two RCTs[26–28,30,31] defined recurrence. The time points for measurement varied across the trials with multiple trial publications. A combined objective assessment using endoscopy and radiology to identify recurrence was described in four trials[21–26,30–32], contrast radiology (plus or minus endoscopy) in one trial[29], and contrast radiology alone in one further trial[27,28]. These assessments for recurrence were performed by blinded assessors in four trials[24–31]. Although symptom scales were used in all RCTs, formal quality-of-life measures, such as the gastro-oesophageal reflux disease quality of life (GERD-QOL) questionnaire, were reported in only three trials. A comparison of symptoms or quality of life between patients who developed recurrence and those who did not was made in two RCTs, but no trial examined the effect of mesh reinforcement on the development of a symptomatic recurrence of POH. Where reoperative procedures were performed, most trials did not define the indication for reoperation. In three of the RCTs[21–25,32], the overall conclusion was in favour of mesh reinforcement, whereas the remaining three trials reported no overall difference[26–31]. In one of the trials reporting no long-term difference, the early trial reports supported use of mesh to prevent POH recurrence[27,28].

Table 3 Primary and secondary outcome definitions and reporting in paraoesophageal hernia trials

Trial	Primary outcome				Secondary outcomes		
	Primary study outcome	Defined?	How was it measured?	When assessed	Secondary study outcomes	Defined?	When assessed
Frantzides *et al.*[21–23]	Hiatus hernia recurrence	No	Endoscopy and barium swallow	Endoscopy and barium swallow at 3 months then barium swallow every 6 months	Operating time Length of stay Complications Reoperation Cost	Quantitative data	Index admission. Recurrence at 3, 6, 12 months
Granderath *et al.*[24,25]	Reflux recurrence	No	Clinical symptoms, manometry and 24-h pH monitoring	Clinical:1 and 6 weeks, 3 months and 1 year. Physiology: 3 months and 1 year	Operating time Complications Wrap migration	Endoscopy and barium swallow	Endoscopy at 6 weeks; barium swallow at 3 months
Ilyashenko *et al.*[32]	Hiatus hernia recurrence	No	Endoscopy and barium swallow	Barium swallow: 3 months and then yearly. Endoscopy: 6–12 months and then yearly	Operating time Length of stay Complications Long-term quality of life (GERD-HRQL)	Yes	3, 6, 12, 24 and 48 months
Oor *et al.*[29]	Hiatus hernia recurrence	No	With contrast study and/or endoscopy by blinded radiologists and blinded gastroenterologists	At 12 months	Operating time Complications Reoperation Postoperative dysphagia Gas-related symptoms and reflux Satisfaction with surgery	Yes	3,6 and 12 months after surgery
Oelschlager *et al.*[27,28]	Hiatus hernia recurrence	Yes	Measured using barium swallow. Reviewed by two independent and blinded experienced radiologists	At 6 months and every 3–5 years	Operating time Complications Symptom frequency and severity Quality of life (SF-36®)	Yes	2–4 weeks, 6 months and 3–5 years
Watson *et al.*[26,30,31]	Hiatus hernia recurrence	Yes	Barium swallow, by blinded radiologist and reporting checked by experienced UGI surgeon. Endoscopy, by blinded experienced UGI surgeon	At 6 months and 3–4 years	Clinical symptom scores Clinical recurrence of hernia leading to reintervention	Yes	1, 3, 6 and 12 months, 2, 3 and 5 years

GERD-HRQL, Gastroesophageal Reflux Disease–Health Related Quality of Life; SF-36 ®, Short Form 36; UGI, upper gastrointestinal.

Table 4 Reporting of paraoesophageal hernia recurrence and overall trial conclusions in paraoesophageal hernia trials

Trial	Recurrence			Overall RCT conclusion
	Defined?	How was it measured?*	When assessed*	
Frantzides *et al.*[21–23]	No	See primary outcome	See primary outcome	In favour of mesh
Granderath *et al.*[24,25]	No	Endoscopy and barium swallow	Endoscopy at 6 weeks; barium swallow at 3 months	In favour of mesh
Ilyashenko *et al.*[32]	No	See primary outcome	See primary outcome	In favour of mesh
Oor *et al.*[29]	No	See primary outcome	See primary outcome	No difference between mesh and suture cruroplasty
Oelschlager *et al.*[27,28]	Yes	See primary outcome	See primary outcome	No difference between mesh and suture cruroplasty
Watson *et al.*[26,30,31]	Yes	See primary outcome	See primary outcome	No difference between mesh and suture cruroplasty

* See *Table 3* for 'See primary outcome' entries.

Discussion

This systematic review has summarized the reporting standards of how trial intervention components and delivery are described in RCTs of POH repair. Patient selection criteria between trials varied considerably, and there was no consensus on the definition of a large POH. Although some description of trial interventions was provided in all RCTs, this varied in depth and detail. A minority of the trials described efforts to standardize the trial

intervention, and only one trial assessed fidelity of the delivered procedure. Outcomes were reported inconsistently and were rarely defined fully. Conflicting conclusions regarding the efficacy of mesh reinforcement for POH repair were present between RCTs, and even within RCTs at varying follow-up time points. This lack of detail and uncertainty of what was undertaken surgically precludes understanding of what intervention was really evaluated and how it should be instituted in clinical practice to gain the desired treatment effects for patients with POH. This review has demonstrated the need for improved focus on the definitions, descriptions, and reporting of surgical interventions in POH management to assist in the development of better RCTs in the future.

The reporting of complexity of surgical interventions more generally has been described in previous systematic reviews[15,34,35]. One previous systematic review[15] was undertaken on 80 surgical RCTs reporting on 160 trial interventions. It demonstrated that descriptions of the intervention were provided for 80 per cent of interventions, with attempts to standardize in nearly 50 per cent and assessments of fidelity in only 28 per cent of RCTs. Some information regarding the context of the intervention was provided in 90 per cent of RCTs, but only 34 per cent provided detail on the expertise of the participating surgeons[15]. A recent paper[36] examined the reporting of otolaryngology RCTs against the TIDiER reporting standards and noted that, in the 173 RCTs reviewed, there was less than 60 per cent adherence to the TIDiER standards. Although approximately 70 per cent of trials reported details regarding the context of where the intervention was provided, less than 50 per cent reported the expertise of those providing the intervention, and less than 10 per cent of trials reported an effort to assess treatment adherence or fidelity[36]. However, the variable adherence to elements of CONSORT-NPT and TIDiER demonstrated in these reviews may relate to the lack of detail illustrating how these standards can be met in surgical trials[15]. Development of more specific and more fully explained reporting standards for surgical trials would improve the quality of research in the field.

There remains equipoise amongst the surgical community regarding the optimal management strategy for POH. Huddy and colleagues[8] surveyed members of the European Association for Endoscopic Surgery (EAES) about their practice for POH management. Of the 503 surgeons who participated in the survey, 7 per cent routinely used mesh to reinforce the hiatus, 60 per cent used mesh selectively, and 33 per cent never used mesh. Of those who used mesh, 67 per cent preferred synthetic mesh to biological absorbable mesh. Interestingly, this survey[8] was conducted in 2015 and 58 per cent of participating surgeons stated they had not changed their practice in the previous 5 years. Recognizing that most of the RCTs that are the subject of the present study had been published before this EAES survey indicates that these trials may not have had a significant influence on practice for this surgical group.

The equipoise extends into specialist society clinical practice guidelines. The EAES recommendations on gastro-oesophageal disease[2] state that hiatus hernias should be graded using an appropriate classification, but then also state that this grading has little relevance to the operative strategy for an 'experienced' surgeon. This guideline states that mesh reinforcement is indicated for 'large hiatal defects', but does not further define this. The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) guidelines on hiatal hernia[3] recommend management of POH according to Barrett's topographical classification[37]. This guideline further recognizes that there is discrepancy on the definition of large POH in the literature, but goes on to define it as greater than one-third of the stomach in the chest. However, how this assessment should be made, by either endoscopy, contrast studies or cross-sectional imaging, is not detailed. Finally, it states that there is inconclusive long-term evidence to support or refute the placement of mesh at the hiatus[37]. Neither guideline indicates how best to define recurrence and what investigations should be completed to evaluate for this outcome. In the RCTs included in the present review, many used contrast imaging to grade the size of hiatus hernia and define recurrence, but research indicates that this may not be the most accurate method of assessment[38]. This suggests further efforts need to be made to establish agreement on POH management.

This article has uniquely summarized the definitions and operative components used in all published RCTs on POH to date, but it is subject to some limitations. The CONSORT-NPT, TIDiER and Blencowe frameworks were published between 2014 and 2017, after the included RCTs were designed. However, the elements described are not especially novel and relate to how surgical interventions are delivered in clinical practice. The literature search has been restricted to the English language, which may mean that some non-English RCTs have been missed. Finally, as this study relied on the full-text RCT publications, it is possible that aspects of trial practice or operative management may have occurred but not been documented. However, these publications are the most common way for the RCTs to influence clinical practice.

This study's findings suggest the research field could be improved considerably by an international consensus guideline and the construction of a core outcome set. The recent International Consensus Regarding Preoperative Examinations and Clinical Characteristics Assessment to Select Adult Patients for Antireflux Surgery (ICARUS) guidelines[39] developed definitions and standards for the preoperative work-up for patients undergoing antireflux surgery. Similar work to develop agreed definitions in POH, in particular for POH size, preoperative assessment, and how to assess for and define recurrence, would address many of the deficiencies in the literature that this study has identified. Encouraging journals and funders to adopt the CONSORT-NPT, TIDiER and Blencowe frameworks in the reporting of surgical trials would facilitate a greater understanding of what has been conducted in RCTs and what needs to be done to replicate their findings in clinical practice. Finally, a standardized set of outcomes that should be measured and reported in trials of POH, known as a core outcome set, should be developed. These have been applied successfully in oesophagectomy[40] and bariatric surgery[41]. From this study, important factors to consider in a core outcome set may include patient perspectives such as dysphagia, symptomatic recurrence and quality of life, as well as objective surgical factors such as recurrence and how defined (*Appendix S1*). This will facilitate trial interventions to be compared more accurately and permit better discussion between patients and surgeons about POH management.

The lack of detail on the surgical intervention and outcomes in the included RCTs on POH repair prevents full understanding of what intervention was delivered and the associated effects. This review has demonstrated that there is need for greater focus on the definitions, descriptions and reporting of surgical interventions in POH management to facilitate the design of practice-changing clinical trials. Greater use of the CONSORT-NPT, TIDiER and Blencowe frameworks would enhance understanding and real-world application of future trials of mesh hiatal reinforcement. The next step in the area should be a core outcome set and international consensus work on POH repair.

Disclosure. The authors declare no conflict of interest.

Supplementary material

Supplementary material is available at *BJS* online.

References

1. Engstrom C, Cai W, Irvine T, Devitt PG, Thompson SK, Game PA *et al.* Twenty years of experience with laparoscopic antireflux surgery. *Br J Surg* 2012;**99**:1415–1421
2. Fuchs KH, Babic B, Breithaupt W, Dallemagne B, Fingerhut A, Furnee E *et al.*; European Association of Endoscopic Surgery (EAES). EAES recommendations for the management of gastroesophageal reflux disease. *Surg Endosc* 2014;**28**:1753–1773
3. Kohn GP, Price RR, DeMeester SR, Zehetner J, Muensterer OJ, Awad Z *et al.*; SAGES Guidelines Committee. Guidelines for the management of hiatal hernia. *Surg Endosc* 2013;**27**:4409–4428
4. Stylopoulos N, Gazelle GS, Rattner DW. Paraesophageal hernias: operation or observation? *Ann Surg* 2002;**236**:492–500
5. Bonrath EM, Grantcharov TP. Contemporary management of paraesophaegeal hernias: establishing a European expert consensus. *Surg Endosc* 2015;**29**:2180–2195
6. Dallemagne B, Kohnen L, Perretta S, Weerts J, Markiewicz S, Jehaes C. Laparoscopic repair of paraesophageal hernia. Long-term follow-up reveals good clinical outcome despite high radiological recurrence rate. *Ann Surg* 2011;**253**:291–296
7. Hashemi M, Peters JH, DeMeester TR, Huprich JE, Quek M, Hagen JA *et al.* Laparoscopic repair of large type III hiatal hernia: objective followup reveals high recurrence rate. *J Am Coll Surg* 2000;**190**:553–560
8. Huddy JR, Markar SR, Ni MZ, Morino M, Targarona EM, Zaninotto G *et al.* Laparoscopic repair of hiatus hernia: does mesh type influence outcome? A meta-analysis and European survey study. *Surg Endosc* 2016;**30**:5209–5221
9. Memon MA, Siddaiah-Subramanya M, Yunus RM, Memon B, Khan S. Suture cruroplasty *versus* mesh hiatal herniorrhaphy for large hiatal hernias (HHs): an updated meta-analysis and systematic review of randomized controlled trials. *Surg Laparosc Endosc Percutan Tech* 2019;**29**:221–232
10. Muller-Stich BP, Kenngott HG, Gondan M, Stock C, Linke GR, Fritz F *et al.* Use of mesh in laparoscopic paraesophageal hernia repair: a meta-analysis and risk–benefit analysis. *PLoS One* 2015;**10**:e0139547
11. Dimick JB, Sedrakyan A, McCulloch P. The IDEAL framework for evaluating surgical innovation: how it can be used to improve the quality of evidence. *JAMA Surg* 2019;**154**:685–686
12. Ergina PL, Cook JA, Blazeby JM, Boutron I, Clavien PA, Reeves BC *et al.* Challenges in evaluating surgical innovation. *Lancet* 2009;**374**:1097–1104
13. Hirst A, Philippou Y, Blazeby J, Campbell B, Campbell M, Feinberg J *et al.* No surgical innovation without evaluation: evolution and further development of the IDEAL framework and recommendations. *Ann Surg* 2019;**269**:211–220
14. McCulloch P, Altman DG, Campbell WB, Flum DR, Glasziou P, Marshall JC *et al.* No surgical innovation without evaluation: the IDEAL recommendations. *Lancet* 2009;**374**:1105–1112
15. Blencowe NS, Boddy AP, Harris A, Hanna T, Whiting P, Cook JA *et al.* Systematic review of intervention design and delivery in pragmatic and explanatory surgical randomized clinical trials. *Br J Surg* 2015;**102**:1037–1047
16. Boutron I, Altman DG, Moher D, Schulz KF, Ravaud P, Group CN. CONSORT statement for randomized trials of nonpharmacologic treatments: a 2017 update and a CONSORT extension for non-pharmacologic trial abstracts. *Ann Intern Med* 2017;**167**:40–47
17. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D *et al.* Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;**348**:g1687
18. Blencowe NS, Mills N, Cook JA, Donovan JL, Rogers CA, Whiting P *et al.* Standardizing and monitoring the delivery of surgical interventions in randomized clinical trials. *Br J Surg* 2016;**103**:1377–1384
19. Moher D, Liberati A, Tetzlaff J, Altman DG, Group P. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Ann Intern Med* 2009;**151**:264–269
20. Blencowe NS, Brown JM, Cook JA, Metcalfe C, Morton DG, Nicholl J *et al.* Interventions in randomised controlled trials in surgery: issues to consider during trial design. *Trials* 2015;**16**:392
21. Carlson MA, Richards CG, Frantzides CT. Laparoscopic prosthetic reinforcement of hiatal herniorrhaphy. *Dig Surg* 1999;**16**:407–410
22. Frantzides CT, Madan AK, Carlson MA, Stavropoulos GP. A prospective, randomized trial of laparoscopic polytetrafluoroethylene (PTFE) patch repair *vs* simple cruroplasty for large hiatal hernia. *Arch Surg* 2002;**137**:649–652
23. Frantzides CT, Richards CG, Carlson MA. Laparoscopic repair of large hiatal hernia with polytetrafluoroethylene. *Surg Endosc* 1999;**13**:906–908
24. Granderath FA, Carlson MA, Champion JK, Szold A, Basso N, Pointner R *et al.* Prosthetic closure of the esophageal hiatus in large hiatal hernia repair and laparoscopic antireflux surgery. *Surg Endosc* 2006;**20**:367–379
25. Granderath FA, Schweiger UM, Kamolz T, Asche KU, Pointner R. Laparoscopic Nissen fundoplication with prosthetic hiatal closure reduces postoperative intrathoracic wrap herniation: preliminary results of a prospective randomized functional and clinical study. *Arch Surg* 2005;**140**:40–48
26. Koetje JH, Irvine T, Thompson SK, Devitt PG, Woods SD, Aly A *et al.* Quality of life following repair of large hiatal hernia is improved but not influenced by use of mesh: results from a randomized controlled trial. *World J Surg* 2015;**39**:1465–1473
27. Oelschlager BK, Pellegrini CA, Hunter J, Soper N, Brunt M, Sheppard B *et al.* Biologic prosthesis reduces recurrence after laparoscopic paraesophageal hernia repair: a multicenter, prospective, randomized trial. *Ann Surg* 2006;**244**:481–490
28. Oelschlager BK, Pellegrini CA, Hunter JG, Brunt ML, Soper NJ, Sheppard BC *et al.* Biologic prosthesis to prevent recurrence after laparoscopic paraesophageal hernia repair: long-term follow-up from a multicenter, prospective, randomized trial. *J Am Coll Surg* 2011;**213**:461–468
29. Oor JE, Roks DJ, Koetje JH, Broeders JA, van Westreenen HL, Nieuwenhuijs VB *et al.* Randomized clinical trial comparing laparoscopic hiatal hernia repair using sutures *versus* sutures reinforced with non-absorbable mesh. *Surg Endosc* 2018;**32**:4579–4589
30. Watson DI, Thompson SK, Devitt PG, Aly A, Irvine T, Woods SD *et al.* Five year follow-up of a randomized controlled trial of laparoscopic repair of very large hiatus hernia with sutures *versus* absorbable *versus* nonabsorbable mesh. *Ann Surg* 2020;**272**:241–247
31. Watson DI, Thompson SK, Devitt PG, Smith L, Woods SD, Aly A *et al.* Laparoscopic repair of very large hiatus hernia with sutures *versus* absorbable mesh *versus* nonabsorbable mesh: a randomized controlled trial. *Ann Surg* 2015;**261**:282–289

32. Ilyashenko VV, Grubnyk VV, Grubnik VV. Laparoscopic management of large hiatal hernia: mesh method with the use of ProGrip mesh *versus* standard crural repair. *Surg Endosc* 2018;**32**:3592–3598
33. Neo EL, Zingg U, Devitt PG, Jamieson GG, Watson DI. Learning curve for laparoscopic repair of very large hiatal hernia. *Surg Endosc* 2011;**25**:1775–1782
34. Balasubramanian SP, Wiener M, Alshameeri Z, Tiruvoipati R, Elbourne D, Reed MW. Standards of reporting of randomized controlled trials in general surgery: can we do better? *Ann Surg* 2006;**244**:663–667
35. Nagendran M, Harding D, Teo W, Camm C, Maruthappu M, McCulloch P *et al.* Poor adherence of randomised trials in surgery to CONSORT guidelines for non-pharmacological treatments (NPT): a cross-sectional study. *BMJ Open* 2013;**3**:e003898
36. Torgerson T, Johnson AL, Jellison S, Tanghetti M, Langley JM, Nguyen LHP *et al.* Reporting of clinical trial interventions published in leading otolaryngology–head and neck surgery Journals. *Laryngoscope* 2020;**130**:E507–E514
37. Barrett NR. Hiatus hernia: a review of some controversial points. *Br J Surg* 1954;**42**:231–243
38. Kahrilas PJ, Kim HC, Pandolfino JE. Approaches to the diagnosis and grading of hiatal hernia. *Best Pract Res Clin Gastroenterol* 2008;**22**:601–616
39. Pauwels A, Boecxstaens V, Andrews CN, Attwood SE, Berrisford R, Bisschops R *et al.* How to select patients for antireflux surgery? The ICARUS guidelines (international consensus regarding preoperative examinations and clinical characteristics assessment to select adult patients for antireflux surgery). *Gut* 2019;**68**:1928–1941
40. Avery KNL, Chalmers KA, Brookes ST, Blencowe NS, Coulman K, Whale K *et al.* Development of a core outcome set for clinical effectiveness trials in esophageal cancer resection surgery. *Ann Surg* 2018;**267**:700–710
41. Coulman KD, Hopkins J, Brookes ST, Chalmers K, Main B, Owen-Smith A *et al.* A core outcome set for the benefits and adverse events of bariatric and metabolic surgery: the BARIACT project. *PLoS Med* 2016;**13**:e1002187