Healthcare Improvement Scotland | SHTG Advice on health technologies

SHTG Advice

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In response to an enquiry from the Scottish Government

Surgical mesh repair of primary inguinal hernia in men

Advice for NHSScotland

Surgical mesh should be used for elective repair of primary inguinal hernia in adult males in Scotland. Mesh repair of inguinal hernia provides lower rates of hernia recurrence, lower rates of serious adverse events and similar or reduced risk of chronic pain, compared with non-mesh procedures. Mesh repair of inguinal hernias is a cost-effective treatment option.

All elective inguinal hernia repairs should be preceded by a detailed discussion with patients to help manage post-surgery expectations. These conversations should cover the potential consequences of not repairing an inguinal hernia, the relative risks of mesh inguinal hernia repair compared with non-mesh repair, and the risk of chronic post-operative pain for some patients.

Appropriate systems should be in place to routinely collect and use data from all inguinal hernia repairs in Scotland to inform clinical practice and the assessment of new types of mesh as they become more widely used.

NHSScotland is required to consider the Scottish Health Technologies Group (SHTG) advice.

What were we asked to look at?

The Scottish Government asked us to assess the evidence on the use of surgical mesh for elective repair of primary inguinal hernia in male patients compared with repairs without surgical mesh (non-mesh/suture repair). In particular, we were asked to consider safety and patient aspects relating to surgical mesh repair of inguinal hernias.

Why is this important?

Surgical mesh has become an important topic in the last few years following women's experiences of severe, chronic pain after surgical mesh was used to treat pelvic organ prolapse. In Scotland, inguinal hernia repair using surgical mesh is a common procedure accounting for around 5,000 surgeries per year. Following the media and political spotlight on surgical mesh for prolapse in women, there is an awareness that similar issues need to be considered in relation to using surgical mesh to repair inguinal hernias.

What was our approach?

We produced SHTG Advice based on a review of published evidence on the clinical effectiveness, cost effectiveness, safety and patient aspects of surgical mesh repair compared with non-mesh repair (suture repair) of inguinal hernia in men. In autumn 2019 we conducted a public engagement exercise using a survey to elicit the views of patients and the public on groin hernia repair. Information on our SHTG Advice product can be found at http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/shtg/health_technologies_assessed.aspx

What next?

The Scottish Government will use the SHTG Advice to inform NHSScotland about the evidence base for using surgical mesh for inguinal hernia repair. The SHTG Advice will also be made available to surgeons who currently perform hernia repair procedures in NHSScotland.

Key points from the evidence review

- In this evidence review 'surgical mesh' refers to all mesh types and implantation techniques. Similarly, 'non-mesh' encompasses all suture-based repair techniques.
- A Cochrane systematic review compared inguinal hernia repair using any mesh technique with any non-mesh technique (n=6,293; approx. 96% male; studies published 1997-2014).
    - Compared with non-mesh repair, patients treated with surgical mesh were significantly less likely to have a hernia recurrence: relative risk (RR) 0.46, 95% confidence interval (CI) 0.26 to 0.80.
    - Patients treated with mesh were significantly less likely to experience neurovascular or visceral injury (RR 0.61, 95% CI 0.49 to 0.76) or suffer from urinary retention (RR 0.53, 95% CI 0.38 to 0.73) compared with non-mesh repair.
    - There was a significantly higher risk of developing a seroma (RR 1.63, 95% CI 1.03 to 2.59) or post-operative wound swelling (RR 4.56, 95% CI 1.02 to 20.48) in patients treated with mesh compared with non-mesh repair.
- The incidence of prosthetic mesh removal in Scotland is low, with 70 procedures (0.3%) to remove mesh from patients with a previous inguinal hernia repair over a 5 year period (2013-2018) during which 25,188 inguinal hernia mesh repairs were performed.
- Two registry studies using data from 2002-2010/11 reported significantly lower rates of serious adverse events for hernia repair using surgical mesh compared with non-mesh repair. These adverse events included cardiovascular complications, deep infections, severe neuropathic pain, and injuries requiring additional surgery or having long-term consequences.
- Two meta-analyses evaluated chronic pain after hernia repair using surgical mesh compared with non-mesh repair.
    - An individual patient data meta-analysis (n=11,174; data from 58 studies published 1993-2000) of mesh versus non-mesh repair reported significantly lower odds of persistent pain with mesh repair: odds ratio (OR) 0.60, 95% CI 0.42 to 0.84.
    - The second meta-analysis (studies published 1998-2016) compared individual mesh and non-mesh techniques – maximum of three studies in each analysis – and found no statistically significant differences in risk of chronic pain in any comparison.
- A qualitative study exploring patient experiences of inguinal hernia repair in Scotland 2006-2008 found that pain gave rise to concern when it differed from expectations. Patients demonstrated considerable diversity in how post-operative pain was experienced, but all sought to interpret their pain and assess what was within normal parameters.
- Factors that may be associated with increased risk of chronic pain after hernia repair with surgical mesh include younger age, a history of chronic pain, low preoperative optimism, pain or heat sensitivity, and perceived pain control one week after surgery.

- The only comparative study reporting quality of life outcomes for men with inguinal hernias treated using surgical mesh versus non-mesh repair (2001-2006), found significantly greater short-term improvements in quality of life in the mesh group. Non-comparative studies suggest that experiencing pain after hernia repair using mesh is associated with significant reductions in quality of life and limitations on daily activities, irrespective of mesh type or pain severity.

- A UK cost-effectiveness study comparing open mesh repair with non-mesh repair demonstrated that, over a 5 year time horizon, open mesh repair resulted in fewer people experiencing hernia recurrence (180 less per 1,000 patients; 95% CI 145 to 293) or persisting pain (45 less per 1,000; 95% CI 6 to 73) and more time spent performing usual activities (10.7 days; 95% CI 9.3 to 12), all based on a cumulatively lower cost (mean saving £134; 95% CI £81 to £192).
    - Cost data in the analysis were derived from three RCTs published 1998-2001. Scottish procedure costs in 2019 were much higher: £2,517 for mesh repair and £2,559 for non-mesh repair. It is likely the cost-effectiveness of mesh repair would improve further if these estimates were applied in the published analysis.

SHTG Committee considerations

- Clinical experts described how surgical mesh has changed over time, referencing as examples the introduction of different weights of mesh, the creation of mesh with different pore sizes, and development of mesh that incorporates two different materials. The Committee acknowledged that mesh composition has probably changed during the time period covered by the evidence reviewed and will likely continue to change in future.

- The Committee discussed the importance of communicating with patients about risks associated with inguinal hernia repair using surgical mesh, particularly the risk of chronic pain for a subset of patients, including those with significant preoperative pain. These clinician-patient discussions were felt to be critical for informed patient consent and management of post-surgery expectations.

- It was noted that inguinal hernias are considerably more common in men compared with women, which was the reason for focusing this SHTG Advice on hernia repair using mesh versus non-mesh in the adult male population. The Committee noted the limited volume of evidence on mesh versus non-mesh repair of inguinal hernia in women; approximately 6% of participants in studies described in the evidence review were women.

- The Committee discussed the value of gathering data on the use of mesh for inguinal hernia repair in Scotland.

- Committee members noted the need for caution when interpreting the results of the public engagement survey. Respondents to the survey were self-selected and unlikely to be a representative sample of the Scottish population who have had an inguinal hernia repair. Also, 42 people is a very small sample compared with the estimated 5,000 repair procedures per year in Scotland.

Contents

Definitions

Strangulated hernia:	The blood supply to tissues trapped in the hernia is cut off. This can lead to tissue necrosis and tissue death, and is considered a medical emergency[1].
Seroma:	A mass or lump caused by a build-up of clear fluid in a tissue, organ or body cavity[2].
Lichtenstein technique:	An open hernia repair technique using tension-free polypropylene surgical mesh[3].
Transabdominal preperitoneal repair (TAPP) & totally extraperitoneal repair (TEP):	Laparoscopic hernia repair procedures involving the use of surgical mesh.

A list of abbreviations used in this document are provided in appendix 1.

Literature search

A systematic search of the secondary literature was carried out between 28 March and 4 April 2019 to identify systematic reviews, health technology assessments and other evidence-based reports. Medline, Medline in process, Embase and Web of Science databases were also searched for systematic reviews and meta-analyses.

Additional searches were carried out to identify literature on adverse events and patient aspects. These searches were not limited to specific study designs.

Key websites were searched for guidelines, policy documents, clinical summaries, economic studies and ongoing trials.

All search results were limited to those published in English in the last 10 years (2009-2019).

On 6 August 2019, an update search was run in Medline without any publication date limits, following a request during the peer review process. Studies from before 2009 were not subsequently included in the clinical effectiveness section due to the availability of recent, good-quality systematic reviews with meta-analyses.

Concepts used in all searches included: primary inguinal hernia, groin hernia repair, open or laparoscopic hernia repair, surgical mesh. A full list of resources searched and terms used are available on request.

Research question

What is the clinical effectiveness, safety and cost effectiveness of using surgical mesh for elective repair of primary inguinal hernias compared with repair without surgical mesh (non-mesh/suture repair) in adult males?

Introduction

An inguinal hernia occurs when an organ, piece of intestine, or fatty tissue protrudes through the abdominal wall causing a swelling in the groin[4]. The majority of hernias are a result of a combination of increased internal pressure and an opening or weakness in the surrounding muscle or connective tissue. A hernia can be uncomfortable or can be accompanied by intense pain which gets worse during a bowel movement, urination, heavy lifting or straining[5].

Hernia repairs are one of the most common surgical procedures performed globally, with an estimated 20 million hernia repair procedures each year[5]. Inguinal hernias are the most common form of hernia, comprising 70%–80% of hernia cases[4, 5]. Approaches to the management of inguinal hernias include watchful waiting for asymptomatic patients, elective laparoscopic or open surgery to repair a symptomatic hernia, and emergency surgery to repair a strangulated inguinal hernia[4]. Surgical repair can be performed either using surgical mesh to reinforce the body tissues or using sutures to draw connective tissues together (multiple techniques available). The decision on whether to use mesh for surgical repair of an inguinal hernia currently depends on the anatomy of the hernia, whether the hernia is primary or recurrent, the surgeon's experience, and the wishes of the patient[3]. The majority of inguinal hernia repairs in adults in Scotland, and worldwide, currently use surgical mesh.

Health technology description

Surgical mesh is a class II(b) medical device designed to provide additional support to weakened or damaged tissues, such as the section of abdominal wall where a hernia has protruded[4]. Mesh products can be made of synthetic materials, such as polypropylene, or organic animal-derived tissues[3, 5]. Synthetic meshes are available in a variety of materials, sizes, weights and pore sizes. Bioprostheses are meshes based on collagen scaffolds derived from cadaveric skin tissues or porcine intestinal mucosa. In the UK, bioprostheses are not routinely used for elective inguinal hernia repair.

The suture material used in non-mesh repair of inguinal hernia is made of polypropylene, the same material as surgical mesh.

A review in 2017 found more than 70 surgical mesh products designed for use in inguinal hernia repair available on the market[5]. Six suppliers have been awarded a contract by National Procurement to provide mesh products for hernia repair in NHSScotland: B Braun, Bard Ltd, Covidien (UK) Ltd, Elemental Healthcare Ltd, Johnson & Johnson Medical Ltd and PFM Medical UK Ltd (Mr P Hornby, Head of Strategic Sourcing & Commercial, National Procurement. Personal communication,

08 May 2019). Organic mesh products are no longer within the scope of this national contract, but may be contracted separately if required.

Epidemiology

Risk factors for developing an inguinal hernia include having a personal or family history of hernia, older age, being male, chronic cough, prolonged constipation, abdominal wall injury and smoking[6]. The estimated lifetime risk of a groin hernia (inguinal or femoral hernia) is 27% in men compared with 3% in women[6]. In 2014–2015, audit data from NHS England indicated that 92% of patients undergoing an inguinal hernia repair were men[3]. Incidence of inguinal hernia increases with age. In a UK study of 30,000 inguinal hernia repairs (1976–1986) approximately 25% were in patients aged 65 or older[3].

Scottish data (2017–2018) on elective primary inguinal hernia repairs using surgical mesh and non-mesh/suture repair are reported in table 1. The number of elective hernia repair procedures in Scotland during this period is similar to the previous four years. Between 1 April 2013 and 31 March 2018, the majority of inguinal hernia repair procedures were performed as day-case surgeries (60.4%) and 98.6% of elective hernia surgeries used mesh.

Table 1: elective primary inguinal hernia repair procedures in Scotland,1 April 2017 to 31 March 2018 (Mr C Scott, Public Health & Intelligence, ISD Scotland. Personal communication, 24 May 2019)

	Total same-day procedures	Total inpatient procedures	Total procedures
Mesh	3,010	1,435	4,445
Non-mesh/suture	32	9	41
All primary repairs	3,042	1,444	4,486

Clinical effectiveness

Guidelines

The European Hernia Society and the HerniaSurge Group guidelines both recommend the use of mesh-based surgical techniques for repair of primary inguinal hernias in adult males[7, 8]. Both guidelines make provision for offering repair of primary inguinal hernias using a non-mesh technique (for example the Shouldice suture repair) in selected patients, such as those who refuse a mesh-based procedure.

Clinical effectiveness

Evidence on the clinical effectiveness of mesh versus non-mesh repair of primary inguinal hernias consisted of two Cochrane systematic reviews[6, 9] and a meta-analysis[10]. The most recent Cochrane systematic review compared repair of inguinal or femoral hernias using surgical mesh with hernia repair using any non-mesh/suture technique[6]. Randomised controlled trials (RCTs) published from 1997 to 2014 were included in the systematic review regardless of whether the procedure was open or laparoscopic, which specific repair technique was used, or the type of mesh involved. The majority

of the twenty-five included RCTs (n=6,293) compared Lichtenstein open mesh repair with Shouldice suture repair in patients with a unilateral primary inguinal hernia. All included studies were in patients with inguinal hernias. Approximately 96.2% of RCT participants were male. Study quality was assessed by the review authors using the Cochrane risk of bias tool. Although the RCTs were rated as overall good quality, seven studies had high risk of bias in one or more domains: selection bias (1), performance bias (1), detection bias (4) and reporting bias (2). The review authors downgraded the evidence quality for several outcomes using the GRADE tool due to heterogeneity, wide confidence intervals and inconsistency. Results from this Cochrane review are presented in table 2.

Patients undergoing mesh repair of inguinal hernias were significantly less likely to have a recurrent hernia compared with patients undergoing a non-mesh repair (eight studies reported no hernia recurrence in either group). Patients who had mesh repair of an inguinal hernia were significantly less likely to experience neurovascular or visceral injury or to suffer from urinary retention, compared with patients who had a non-mesh repair. The moderate heterogeneity in some of these analyses may be partly due to variations in the mesh and non-mesh techniques used in individual studies, the use of open versus laparoscopic approaches, and variations in length of follow-up (range 6 days to 5 years). Mesh repair was associated with significantly shorter surgery duration, shorter length of hospital stay, and a quicker return to daily living. However, for these outcomes, the meta-analysis displayed very high levels of heterogeneity. Acute and chronic pain could not be assessed by meta-analysis due to variation in the measures used, methods of data collection and timeframes for analysis. Studies proclaiming to use the same gauge for pain levels often used different values to represent 'significant pain'.

The second Cochrane systematic review compared open inguinal hernia repair using the Shouldice suture technique with open repair using mesh[9]. Since only two relevant studies in this review were not included in the more recent analysis described above, minimal detail is provided on the results from this analysis. Findings for the outcomes of hernia recurrence, duration of surgery, wound infection and haematoma formation were all consistent with the more recent Cochrane review. In this analysis there were no statistically significant difference in risk of seroma formation or length of hospital stay. The authors of this review decided to perform a meta-analysis on chronic pain which they defined as pain persisting for more than three months. The analysis appears to convert pain measures reported in individual RCTs into a dichotomous outcome (pain or no pain) to allow studies to be combined in a meta-analysis. There were no statistically significant differences in the odds of chronic pain between the Shouldice suture repair and open mesh repair groups: odds ratio (OR) 0.87, 95% confidence interval (CI) 0.55 to 1.39, p=0.57, 5 studies, n=1,371, I^2=60%.

Table 2: results from a Cochrane review of RCTs comparing any mesh repair with any non-mesh repair of primary inguinal hernia[6]

	N studies (patients)	Mesh: n events/ n patients	Non-mesh: n events/ n patients	Findings (95% CI) Relative risk (RR) Mean difference (MD)	p-value	I^2	NNTB	Anticipated absolute effect* Mesh vs. non-mesh (per 100 patients)	GRADE
Primary outcomes									
Hernia recurrence	21 (5,575)	52/2,834 (1.8%)	110/2,741 (4.0%)	RR 0.46 (0.26 to 0.80)	0.0055	44%	46	2 vs. 4	Moderate
Neurovascular or visceral injury	24 (6,293)	125/3,289 (3.8%)	185/3,004 (6.2%)	RR 0.61 (0.49 to 0.76)	<0.00001	0%	22	4 vs. 6	High
Testicular injury or complications (including testicular swelling or atrophy)	14 (3,741)	26/1,981 (1.3%)	24/1,760 (1.4%)	RR 1.06 (0.63 to 1.76)	0.83	0%	2,000	1 vs. 1	Low
Urinary retention	8 (1,539)	48/819 (5.9%)	89/720 (12.4%)	RR 0.53 (0.38 to 0.73)	0.0001	56%	16	7 vs. 12	Moderate
Wound infection	20 (4,540)	61/2,354 (2.6%)	46/2,186 (2.1%)	RR 1.29 (0.89 to 1.86)	0.17	0%	200	3 vs. 2	Low
Post-operative wound swelling	2 (388)	9/194 (4.6%)	2/194 (1.0%)	RR 4.56 (1.02 to 20.48)	0.048	33%	72	5 vs. 1	Moderate
Wound dehiscence	2 (329)	2/166 (1.2%)	4/163 (2.5%)	RR 0.55 (0.12 to 2.48)	0.44	37%	77	1 vs. 2	Low
Haematoma	15 (3,773)	104/1,940 (5.4%)	111/1,833 (6.1%)	RR 0.88 (0.68 to 1.13)	0.31	0%	143	5 vs. 6	Low

Seroma	14 (2,640)	46/1,373 (3.4%)	25/1,267 (2.0%)	RR 1.63 (1.03 to 2.59)	0.038	0%	72	3 vs. 2	Moderate
Secondary outcomes[∞]									
Duration of surgery (min)	20 (4,148)	–	–	MD -4.22 (-6.85 to -1.60)	0.0016	97%	–	–	Very low
Length of hospital stay (days)	12 (2,966)	–	–	MD -0.6 (-0.86 to -0.34)	<0.00001	98%	–	–	Low
Time to return to activities of daily living (days)	10 (3,183)	–	–	MD -2.87 (-4.42 to -1.32)	0.00028	96%	–	–	Low

*The risk in the intervention group and its 95% CI is based on the assumed risk in the comparison group and the relative effect of the intervention and its 95% CI.

[∞]Negative mean difference (MD) values indicate shorter surgery duration, shorter length of hospital stay and quicker return to daily living for mesh surgery compared with non-mesh repair

NNTB = number needed to benefit; CI = confidence interval

An additional meta-analysis compared a different non-mesh repair technique (Desarda) with open Lichtenstein mesh repair in patients with a primary inguinal hernia[10]. Six RCTs with 2,159 patients (89% men) were included in the review. Most of these trials were performed in developing countries and published between 2012 and 2016. Only one study was included in the most recent Cochrane review[6]. Quality of studies was assessed by the review authors using the Cochrane risk of bias tool: four were found to have low overall risk of bias and two had moderate risk of bias (mainly due to unclear blinding or lack of intention-to-treat analysis). Duration of follow-up in included studies ranged from 0.5 months to 78 months. Two studies were excluded from the meta-analysis on hernia recurrence because they had less than 6 months follow-up. Results from the meta-analysis are presented in table 3. There was no statistically significant difference in the risk of hernia recurrence between mesh and Desarda non-mesh groups. Overall post-operative complications, seroma formation and surgical site infection were all significantly more common in the Lichtenstein open mesh repair groups. No statistically significant differences were found for scrotal oedema, haematoma, hydrocele, nerve injury, orchitis, or testicular atrophy (meta-analysis results were not reported for these outcomes). Meta-analyses on pain, duration of surgery and time to return to work were not performed due to between-study variation in measurements used and reporting.

Table 3: results from a meta-analysis of RCTs comparing inguinal hernia repair using Desarda suture with Lichtenstein mesh repair[10]

Outcome	N studies (patients)	Mesh: n events/ n patients	Desarda: n events/n patients	OR (95% CI)	p-value	I^2
Hernia recurrence (>6 months follow-up)	4 (1,795)	9/913 (1.0%)	8/882 (0.9%)	0.95 (0.35 to 2.55)	0.91	0%
Overall post-operative complications	6 (2,159)	131/1,091 (12.0%)	77/1,068 (7.2%)	1.86 (1.36 to 2.55)	<0.001	0%
Seroma	6 (2,159)	39/1,091 (3.6%)	18/1,068 (1.7%)	2.17 (1.23 to 3.80)	0.007	–
Surgical site infection*	6 (2,159)	25/1,091 (2.3%)	11/1,068 (1.0%)	2.17 (1.08 to 4.36)	0.03	–

*Seven patients required removal of the surgical mesh following surgical site infection

Safety

Based on adverse event reports and published literature, the US Food & Drug Administration (FDA) describe the most common adverse events following hernia repair using surgical mesh as pain, infection, tissue adhesion (scar-like tissue that sticks tissues together), hernia recurrence and bowel obstruction[4]. Other adverse events described by the FDA include mesh migration[a] and mesh shrinkage/contraction. In the Cochrane review by Lockhart *et al* (2018) early complications of hernia repair surgery included seroma or haematoma, urinary retention and bladder injury[6]. Longer-term

[a] Mesh migration is not defined by the FDA or in the Cochrane review by Lockhart *et al* (2018)[6]. Emile *et al* (2018) describe mesh migration as "migration of the mesh to the intestine, preperitoneal space or scrotum".

complications comprised neuralgia, testicular complications (including atrophy) and mesh migration/erosion. The meta-analysis by Emile *et al* (2018) reported adverse events including foreign body sensation, perceived abdominal wall stiffness, mesh rejection, and surgical site infection requiring removal of infected mesh[10]. Seroma, haematoma and urinary retention have been addressed in the clinical effectiveness section. The focus of this section is on chronic post-operative pain, male fertility, mesh migration/erosion, and Scottish adverse event data.

Chronic pain

The aetiology of chronic pain following repair of inguinal hernias, with or without using mesh, is poorly understood but may relate to tissue inflammation, tension in repaired tissues, or damage to nerves in the groin. Two meta-analyses were identified that assessed chronic pain following inguinal or groin hernia repair using mesh versus non-mesh techniques[11, 12].

One meta-analysis used individual patient data from RCTs (published 1993 to 2000) to assess risk of persistent post-operative pain following groin hernia repair with mesh versus non-mesh[11]. Persistent pain was defined by the meta-analysis authors as "any pain, even slight, in the groin or testicles that persisted at 1 year post-surgery or the closest time-point to 1 year reported in the studies, provided it was more than 3 months post-surgery". Randomised and quasi-randomised trials were included in intention-to-treat analyses using individual patient data or aggregated data if individual patient data were not available. Fifty-eight trials were incorporated in the meta-analysis (n=11,174), with 35 studies providing individual patient data (n=6,901). Mean age of participants in studies with individual patient data available was 54.6 years (standard deviation (SD) 15.6). Participants were predominantly male (95.3%), 8.7% had recurrent hernias and 1% had a femoral hernia. Mean or median follow-up in studies ranged from 6 days to 72 months, consequently the odds of persistent pain varied considerably between trials.

The overall analysis compared all mesh techniques versus all non-mesh techniques using both individual patient and aggregated data, and found that the odds of persistent pain were significantly lower for mesh repair: OR 0.36, 95% CI 0.29 to 0.46, p<0.001. This lower risk of chronic pain following mesh repair was maintained in all stratified analyses irrespective of mesh placement method or non-mesh technique used. In sensitivity analyses based entirely on individual patient data the effect estimate was more conservative but still favoured mesh repair: OR 0.60, 95% CI 0.42 to 0.84. When the meta-analysis was restricted to trials with "more secure methods of randomisation", results continued to favour mesh repair: OR 0.40, 95% CI 0.31 to 0.53. The meta-analysis authors noted that caution should be used in interpreting these results due to the broad definition of pain and the dominance of two large trials that contributed half the weight in the analysis (if removed the results were closer to the conservative estimate).

In the second meta-analysis, pairwise and network meta-analyses were conducted comparing chronic pain after primary inguinal hernia repair using non-mesh repair versus surgical mesh[12]. Chronic pain was defined by the review authors as pain lasting a minimum of 6 months. Fourteen relevant RCTs (n=3,168) published between 1998 and 2016 were identified. Subsets of these studies were combined in meta-analyses if there were two or more homogeneous studies, which the meta-analysis authors defined as heterogeneity (I^2) less than 75%. Each direct pairwise meta-analysis incorporated a maximum of three studies. This owed largely to the homogeneity requirement, the variation in measures of pain used in studies, and comparisons of different mesh and non-mesh techniques. The quality of included studies was assessed by the review authors using the Cochrane

risk of bias tool. Overall risk of bias was low or unclear. Six studies had high risk of bias in one or more domains – mainly allocation concealment or blinding. In the non-mesh group, 96.8% of participants were male and 97.7% of participants were male in the mesh group. Median follow-up in RCTs was 1.4 years (range 0.5 to 10 years). Median crude rate of pain of any severity at last follow-up was 6.4% in the non-mesh group and 7.4% in the mesh group. When analyses were limited to moderate or severe pain, the median crude rate was 3.5% for non-mesh and 2.9% for mesh. There were no statistically significant differences in risk of chronic pain between mesh and non-mesh groups in any pairwise meta-analysis, nor in the frequentist network meta-analysis that reported absolute risk differences.

Male fertility

Two systematic reviews assessed the impact of hernia repair on male fertility[13, 14]. One of these reviews included only two studies that compared outcomes following mesh versus non-mesh repair and the review results were not clearly reported[14]. This review is not described further.

The systematic review by Kordzadeh *et al* (2017) compared the effects of inguinal hernia repair using mesh versus non-mesh repair in 10 studies of unclear study design (n=35,740) that were published between 1991 and 2014[13]. Infertility was defined as "a disease of the reproductive system and inability of a sexually active, non-contracepting couple to achieve pregnancy in one year". Meta-analysis was deemed not possible due to population heterogeneity and lack of consistency or uniformity of data available. Patient characteristics from included studies are not reported in the review. Study quality was assessed using a CASP checklist, although it is not stated which one, and studies were judged by the review authors to be of reasonable methodological quality (total score 5/8 to 8/8).

Across three studies twenty percent (n=7,223) of participants had open non-mesh hernia repair. The three studies reported no significant differences between pre- and post-operative sperm quality, volume, motility, hormonal levels, testis position or testis volume. The review authors concluded non-mesh repair had no impact on male fertility, irrespective of laterality. Eighty percent of the review participants had an open hernia repair using mesh (79.9% unilateral, 10.4% bilateral). Data on preoperative fertility were not available for the majority of studies of open hernia repair using mesh. Infertility was detected in 0.8%, and obstructive azoospermia in 0.03%, of men who underwent open hernia repair with surgical mesh. Only 0.04% (n=160) of patients had undergone laparoscopic hernia repair using mesh. Obstructive azoospermia was reported for 2.5% of patients treated with laparoscopic mesh repair (n=4, bilateral repair). The review authors noted that, even if infertility occurs due to obstruction and/or damage to the spermatic cord and vessels, male fertility would often be preserved on the non-operated side in men undergoing unilateral hernia repair.

Mesh migration/erosion

Mesh migration/erosion is a rare clinical event, the definition of which has not yet been standardised. A recent narrative review collated published cases of mesh migration in patients who had undergone an abdominal hernia repair, including inguinal hernia repair[15]. In the review mesh migration/erosion was defined as "mesh invasion of any anatomical region other than the area intended for repair". Eighty-nine cases were reported in 84 publications between 1996 and 2017. Patients were mainly men (76.2%), with an average age of 59.8 years (SD 13.8). Inguinal hernias

represented 62.9% of cases of mesh migration. This finding is likely due to the high volume of inguinal hernia repair procedures, rather than a high incidence of mesh migration/erosion in this patient group. Mesh plugs were implicated in 35.7% of cases of mesh migration in patients with inguinal hernias. Multiple organs were affected in 31.5% of mesh migration/erosion cases; the small bowel in 25.8%, the colon 16.9% and the bladder 16.9%. Most mesh migration cases (91%) were managed operatively, with 79% requiring resection of an organ.

All adverse events

Two registry studies assessed a range of adverse events relating to inguinal hernia repair using mesh versus non-mesh[16, 17]. The study by Nilsson *et al* (2016) extracted data from the Swedish Hernia Register (2002–2011) on severe cardiovascular complications, severe adverse surgical events, and intra-operative complications in patients undergoing groin hernia repair, and linked it to the National Patient Register[16]. The majority of patients were male (92%). Mean age of participants was 65 years and 99% had an inguinal hernia. Results were reported separately by gender; the results described here are for men only (n=131,041). Overall, 0.3% of men having an elective groin hernia repair experienced a severe cardiovascular complication, 0.5% had intraoperative complications, and 0.2% had a severe surgical adverse event. Severe cardiovascular complications (OR 1.7, 95% CI 1.2 to 2.3, p=0.003), severe surgical complications (OR 2.3, 95% CI 1.5 to 3.4, p<0.001) and intraoperative complications (OR 1.7, 95% CI 1.3 to 2.2, p<0.001) were all significantly more common in patients who had a non-mesh/suture repair compared with open mesh repair.

The second registry study compared adverse events following open repair using mesh with open non-mesh repair of groin hernias using data from the Finnish Patient Insurance Centre (FPIC)[17]. All healthcare providers in Finland must register with the FPIC, but reporting of complications is a voluntary, patient-initiated process linked with compensation claims. Out of 91,043 groin hernia repairs (98.4% inguinal hernias) performed in 2002–2010, a total of 335 (0.4%) patients reported experiencing a complication. Mean age of patients reporting a complication was 55.3 years and 10.7% had a recurrent hernia. It is not clear how many patients were male. The overall complication rate was 3.2 per 1,000 groin hernia repairs using surgical mesh compared with 7.5 per 1,000 non-mesh hernia repairs (p<0.001). Early reoperation, visceral injuries and neuropathic pain were all significantly more common in patients who underwent non-mesh hernia repair (p<0.001). There were no statistically significant differences in infection rate or haemorrhagic complications between mesh and non-mesh repair. Severe complications were also significantly more common in the non-mesh group compared with the mesh group: 3.9 per 1,000 procedures compared with 1.5 per 1,000 procedures, p<0.001.

Data from the UK and Scotland

Adverse event data relating to inguinal hernia repair were requested from ISD Scotland, the Scottish Incident Reporting and Investigation Centre (IRIC) and the Medicines and Healthcare Products Regulatory Agency (MHRA).

ISD recorded 70 procedures to remove prosthetic material from previous repairs of an inguinal hernia in the 5 year period from 1 April 2013 to 31 March 2018 (Mr C Scott, Public Health & Intelligence, ISD Scotland. Personal communication, 24 June 2019). This equates to 0.3% of all inguinal hernia mesh repairs performed in Scotland over the same time period.

Data provided by IRIC and the MHRA were overlapping as all the records identified by IRIC were based on voluntary Yellow Card Scheme reports to the MHRA by Scottish patients. Incidents recorded in the MHRA and IRIC databases are not always attributable to a specific device or procedure. In the past 5 years the MHRA received 289 incident reports relating to surgical mesh repair of any hernia type, ten of these incidents were in Scotland. In 2017, the MHRA created separate categories for incidents relating to specific hernia types. Since the creation of these new categories, 14 incidents relating to inguinal hernia repair using surgical mesh have been reported in the UK as a whole. Incidents relating to hernia repair in Scotland recorded in the IRIC and MHRA databases are described in appendix 2. Due to the voluntary, patient-reported nature of these incidents, a limited amount of detail is available. These data needs to be treated with caution as patients can report an incident multiple times or not report a relevant adverse event at all.

Patient and social aspects

Studies included in this section were not required to report comparisons between hernia repair using surgical mesh and non-mesh/suture repair. This section relates to patient experiences of inguinal hernia repair[18], health-related quality of life[19-25], how chronic pain impacts on quality of life[26-28], how hernia repair impacts on caregivers[29], and factors that predict chronic post-operative pain[30-32].

Patient experience

A single, good quality[b], qualitative study explored mens' experiences, understanding of pain and activity limitations, before and after surgical repair of an inguinal hernia[18]. Powell *et al* (2013) interviewed seven men scheduled for elective inguinal hernia repair in Scotland (pre-surgery, then 2 weeks and 4 months post-surgery) and 10 men who reported experiencing pain 4 months after hernia surgery. It is not stated whether participants had hernia repair procedures using surgical mesh, however, as this is common practice in Scotland, it is likely that most participants had their hernia repaired using mesh. The seven patients interviewed at three time-points were aged 34 to 77 years and five had a primary inguinal hernia. The ten men interviewed after experiencing pain at 4 months follow-up were aged 34 to 69 years and all had primary unilateral hernia repairs.

Making sense of pain was an important theme identified by the study authors. Accounts from patients demonstrated considerable diversity in how pain is experienced. All participants sought to interpret their pain and assess what was within normal parameters, with some patients interpreting pain within the context of natural healing. Patients in both groups of interviewees reported experiencing preoperative discomfort, which they tended to characterise as bearable. All participants reported post-operative pain but this only led to concern when the pain differed from expectations. Since all patients received an information leaflet about chronic pain, it is possible their awareness of the risk of post-surgical pain was heightened prior to the interviews.

Prior to surgery, patients described limiting certain behaviours, such as lifting, and viewed pain as an indication they should reduce an activity. Two weeks after surgery patients in both groups of interviewees (single interview participants responded based on recall) reported limiting activity to avoid pain or facilitate wound healing and avoid causing further damage. At 4 months follow-up,

[b] Study quality was assessed using the Quality of Reporting Tool (QuaRT)[33]. The study adequately reported its aims and design, sampling strategy, and the conduct of methods of data collection and analysis.

some participants in the multi-interview group were still limiting activity, despite little or no pain, in an effort to reduce the risk of hernia recurrence. Some patients in the single interview group considered limiting activity a positive lifestyle change, for example reducing the number of items lifted simultaneously.

In summary, a single qualitative study conducted in Scotland found that pain was an important theme among patients that had an inguinal hernia repair. All patients sought to understand and interpret their pain. This only led to concern if the pain was different from expectations. Some patients continued to modify their daily activities after hernia repair to avoid recurrence or further damage.

Quality of life

Seven studies considered the impact of inguinal/groin hernia repair on patients' quality of life[19-25]. Only one of these studies (n=300) compared quality of life following unilateral inguinal hernia repair using surgical mesh (mesh-plug) with quality of life after Shouldice non-mesh repair[20]. This study was included in the Cochrane systematic review by Lockhart *et al* (2018)[6], however quality of life was not an outcome reported in the review. The study is self-described as a prospective double-blind randomised study, but no information is provided on randomisation or blinding. The validated Short-Form 36-item Health Survey (SF36) was completed preoperatively and then at 8 and 45 days post-surgery. The study authors created an additional *de novo* quality of life tool consisting of yes/no questions that was completed during post-operative weeks 1-4. Mean age of patients was 49.8 years (SD 16.1) in the Shouldice group and 52.9 years (SD 14.6) in the mesh group. Eight days after surgery there were statistically significant improvements favouring the mesh group in SF36 domains for physical functioning, physical role functioning, bodily pain, social role functioning, and emotional role functioning. At 45 days follow-up significant improvements favouring mesh were reported only for the physical functioning (p=0.049) and bodily pain domains. In the *de novo* quality of life questionnaire, statistically significant differences favouring the mesh group were reported for time to resumption of driving, ability to walk more than 15 minutes, and reduced limitations on activities of daily life (table 4). Total time off work for patients who were employed was significantly shorter in the mesh group: 25.4 (SD 8.6) days versus 21.2 (SD 8.4) days, p<0.002.

Table 4: resumption of routine tasks in the 4 weeks following inguinal hernia repair using Shouldice non-mesh versus mesh plug repair[20]

	N patients resuming driving	N patients with difficulty walking >15min	N patients with limitations on activities of daily life
Week 1	28 vs. 59 p=0.0004	118 vs. 76 p<0.0001	131 vs. 132 NS
Week 2	81 vs. 126 p<0.0001	68 vs. 29 p<0.0001	108 vs. 84 p=0.0001
Week 3	118 vs. 140 p=0.04	23 vs. 14 NS	64 vs. 44 p=0.003
Week 4	128 vs. 143 NS	14 vs. 7 NS	23 vs. 24 NS

NS = not statistically significant

The NHS England patient reported outcome measures (PROMS) programme asked all patients undergoing groin hernia repair between April and September 2017 to complete the EQ5D quality of life instrument and the EQ VAS (visual analogue scale) measure of general health preoperatively and post-operatively[24]. It is unclear how long pre- and post-operatively the questionnaires were completed or how many respondents had their hernia repaired using surgical mesh. There were 33,443 groin hernia procedures during the 6 month period described. Preoperative questionnaires were completed by 55.8% of patients and 53.1% of patients responded post-operatively. The majority of patients were male (90.6%) and aged over 50 (75.2%). Approximately half the respondents (52.3%) reported an improvement in quality of life, with an average health gain of 0.086 following hernia repair. Prior to surgery approximately 25% of patients reported a maximum EQ5D score; after surgery this increased to over 50% of patients. Overall, 39.1% of patients reported an improvement in general health on EQ VAS. However, the average change in scores was -1.0 points indicating a slight deterioration in general health following surgery.

One prospective observational study assessed patient outcomes using a hernia-specific tool in 120 patients undergoing laparoscopic inguinal hernia repair using mesh[25]. Patients completed the validated hernia-specific Core Outcomes Measurement Index (COMI) preoperatively and then at 6 weeks and 1 year after surgery. The COMI index assesses five domains: general quality of life, function, well-being, pain, and social and work disability. Participants had a median age of 61 years (range 32 to 86) and 94.2% were male. COMI scores for quality of life and function improved significantly at 6 weeks and 1 year follow-up compared with preoperative scores. Quality of life was described as good or very good by 58% of patients preoperatively, 94% at 6 weeks follow-up and 97% at 1 year post-surgery. Prior to surgery, 65% of patients reported experiencing a little or moderate functional impairment and 10% reported a lot or extreme impairment. Six weeks after surgery 66% of patients reported no impairment and this increased to 81% at 1 year follow-up. More than half of patients (64%) felt very dissatisfied with their preoperative well-being. By 6 weeks post-surgery 19% of patients reported they were somewhat or very dissatisfied with their general well-being. Working ability was limited for 66% of patients at 6 weeks follow-up and was more severely limited than preoperatively. These limitations do not appear to have affected perceived quality of life or well-being which both improved by 6 weeks post-surgery. At 1-year follow-up, 90% of patients reported no limitations to working ability.

Another prospective cohort study evaluated quality of life in patients undergoing laparoscopic groin hernia repair using surgical mesh (n=293) using the SF36 tool, the Surgical Outcomes Measurement System (SOMS) and the validated hernia-specific Carolinas Comfort Scale (CCS)[19]. Participants were asked to complete the questionnaires preoperatively and then at 3 weeks, 6 months, 1 year and 2 years after surgery. Not all patients completed all three instruments and not all questionnaires were provided at all time-points (the CCS tool only applies post-operatively). Patients were predominantly male (93%), with a mean age of 56 years (SD 15). Eighty-five percent of participants had a primary hernia and 98.7% had an inguinal hernia. Responses to the SF36 showed no significant change in scores for role limitation due to emotional problems, energy/fatigue, emotional well-being, social functioning, or general health at any follow-up. Physical functioning scores significantly improved by 2 years follow-up, with no significant changes prior to then. Role limitation due to physical health scores were significantly improved at 6 months post-surgery and continued to improve significantly at each subsequent follow-up point. The SOMS Pain Impact on Quality of Life score improved significantly between baseline and 2-year follow-up and patients were highly satisfied with their quality of life at all post-operative time-points. Responses to the CCS questionnaire indicated

patients were unaffected by sensations of mesh (98%), pain (95%), or movement limitations (97%) at 2-year follow-up.

A prospective observational study also assessed quality of life using the SF36 and CCS score in men (n=47) undergoing laparoscopic primary inguinal hernia repair using surgical mesh[21]. The questionnaires were completed preoperatively and then at 7-10 days, 6 months and 1 year after surgery. There was considerable loss to follow-up by 1 year post-surgery when only 40.4% of patients responded. Patients had a mean age of 43.2 years (SD 13.2). Significant improvements in SF36 and CCS scores for pain and physical function/movement were observed at 1-year follow-up. Mean SF36 scores for bodily pain, physical function and role physical functioning initially worsened in the 7-10 days following surgery, but then improved by 6 months and 1 year follow-up to better than preoperatively.

Finally, two prospective observational studies assessed quality of life using the hernia-specific EuraHS-QoL (European Registry of Abdominal Wall Hernias Quality of Life) score[22, 23]. In the most recent study, a cohort of 100 men undergoing laparoscopic bilateral primary groin hernia repair using surgical mesh completed the EuraHS-QoL tool pre-operatively and then at 1 month, 3 months and 12 months follow-up[22]. Mean patient age was 57 years (SD 13.4) and a small proportion (<5 patients) had a femoral hernia. There were statistically significant improvements in quality of life scores at all time-points for the overall score and the pain, activity restrictions and cosmetic domains ($p<0.0001$ for all). The second study incorporated 101 consecutive patients (94% male) having laparoscopic unilateral primary inguinal hernia repair using mesh[23]. Participants completed the EuraHS-QoL pre-operatively and then at 3 weeks, 3 months and 12 months after surgery. Patients had a mean age of 56 years (SD 14.9). There were statistically significant improvements in overall scores, pain, activity restrictions and cosmetic domain scores by 3 months after surgery. By 12 months follow-up, significant improvements were only seen for overall scores and the pain domain.

In summary, quality of life has been measured using several validated tools in patients who have had a groin hernia repair procedure. In all of these studies quality of life, or elements of it, improved significantly following hernia repair surgery using mesh. The only study that compared quality of life between patients treated with mesh and patients who had a non-mesh repair, found significant improvements in quality of life favouring mesh repair.

Pain and quality of life

Three studies explored the relationship between chronic post-operative pain and quality of life (SF36) in patients who had undergone hernia repair[26-28]. The first study assessed the effect of persistent pain on daily activities and quality of life in a prospective cohort of Scottish patients who reported experiencing severe or very severe pain 3 months after groin hernia surgery[26]. One-hundred and twenty-five patients (3% of patients) reported experiencing severe or very severe pain 3 months after surgery. These patients were significantly younger (54 versus 60 years, $p<0.001$) and more likely to be female (OR 1.73, 95% CI 1.07 to 2.81) compared with the total groin hernia population. Eighty-six (72%) patients who experienced severe/very severe pain completed the SF36 and the Wisconsin Brief Pain questionnaire at a median follow-up of 30 months. Ninety percent of these patients had open mesh repair, 9% open non-mesh repair and 1% laparoscopic mesh repair. Results were not reported separately for patients treated with and without mesh. Median age was 54 years (inter-quartile range (IQR) 40 to 66), 86% were male, 85% had a primary hernia and 97% had an inguinal hernia. Twenty-two patients (26%) were still experiencing severe or very severe pain

at last follow-up: 28% described their pain as continuous, 30% had returned to their surgeon and 15% had attended a pain clinic. The most common descriptors of the pain were aching (45%), throbbing (28%) and stabbing (23%). Chronic pain interfered significantly with all activities of daily living and reduced quality of life, irrespective of pain severity ($p<0.001$).

A second prospective cohort study measured post-operative pain and its effect on quality of life in men who had a unilateral inguinal hernia repair using surgical mesh (n=370)[28]. Patients completed an un-validated pain questionnaire, rated their pain on a VAS scale and completed the SF36, preoperatively and at 6 months follow-up. Mean age of patients was 57.3 years (SD 15.6). At 6 months follow-up, 125 men (33.8%) reported experiencing pain of any severity (VAS>0) when resting, coughing, rising from lying to sitting or during physical activity. Following surgery, quality of life scores improved significantly for all domains of the SF36. The VAS pain scores were negatively correlated with post-surgery quality of life on the SF36, with the strongest correlation between VAS score and the SF36 bodily pain domain. Compared with patients who reported no post-operative pain, patients with pain at 6 months follow-up had significantly lower quality of life scores for the SF36 bodily pain domain. Some patients reported pain on the VAS scale while simultaneously reporting the maximum score (no reduction in quality of life) for the SF36 bodily pain domain.

The third study was a retrospective comparison of quality of life in 100 patients with chronic post-operative pain (≥6 months) and 100 matched pain-free controls after groin hernia repair[27]. Patients were matched based on age, gender and method of hernia repair. After exclusion of patients where pain was determined not to relate to the hernia repair, there were 92 respondents in each group. Patients completed the Hospital Anxiety and Depression (HAD) questionnaire, the SF36, a modified McGill pain questionnaire, and the 91-item Karolinska Scales of Personality tool. Median age of participants was 59.5 years and 92.4% were male. Participants had undergone hernia repair surgery a mean of 4.9 years previously (80.4% mesh; 10.3% non-mesh) which may have affected their recall of post-operative pain and quality of life. Results were not reported separately for mesh and non-mesh repairs.

The pain-free group reported significantly better quality of life on all SF36 domains compared with the chronic pain group ($p=0.001$). The most common descriptors of pain were irritating (55%), worrying (32%), annoying (30%), tiring (23%), and troublesome (17%). Factors identified as aggravating the pain were sitting (38%), stress (35%), walking (34%), standing (32%), cold (22%) and light touch (10%). The biggest difference in quality of life scores was for the bodily pain domain. Mean depression and anxiety scores were significantly higher in the pain group compared with pain-free patients ($p=0.004$ and $p<0.001$ respectively). On the Karolinska Scales of Personality tool, patients who experienced chronic pain reported significantly higher levels of somatic and psychic trait anxiety, embitterment and mistrust, compared with pain-free patients. Since preoperative pain and quality of life were not measured, it is unclear if particular personality traits or anxiety/depression are associated with chronic post-operative pain and quality of life.

In summary, chronic pain following hernia repair is associated with significant reductions in quality of life. Quality of life is lower among patients who experience chronic pain compared with patients who had the same procedure but remained pain-free.

Impact on caregivers

Since most patients are discharged the same day as their surgery, much of their recovery takes place at home. One study was identified that assessed the impact on caregivers of men having an inguinal hernia repair using surgical mesh[29]. Caregivers (n=837) were defined as an "unpaid person who met the needs of, provided or arranged for care of, or provided support to the patient". Each caregiver completed a questionnaire at baseline (around the time the patient underwent surgery) and then at 2 weeks and 3 months after surgery. The majority (73%) of caregivers were the wife of a patient and 88% of caregivers lived with the patient. Caregiver concerns about patient's ability to engage in home, work, social and recreational activities were not related to treatment approach (open versus laparoscopic), hernia type (primary versus recurrent), or laterality (unilateral versus bilateral). The concerns of caregivers about patients' ability to perform all activities significantly decreased across the study period. When a patient had experienced complications following their hernia repair, the caregiver was significantly more likely to express concerns about the patient's ability to engage in activities. Caregivers were significantly more likely to spend additional hours performing a set of 10 common chores in the 2 weeks following a patient's hernia repair surgery. Three months after surgery, the odds of caregivers performing >1 additional hour of chores per week had decreased significantly. The degree of effort expended by caregivers on these chores was not related to treatment approach, laterality or hernia type. However, caregivers of patients with complications were significantly more likely to report moderate or great effort in performing additional chores.

Factors predicting post-operative pain

A systematic review explored risk factors for developing post-operative pain during the first seven days after laparoscopic groin hernia repair using surgical mesh[32]. The review included 71 studies (n=14,023): 44 RCTs, 23 prospective studies and 4 retrospective studies. These studies included a mix of patients with primary and recurrent hernias. Other patient characteristics are not detailed. Of the RCTs in the review, 14 were considered to be high quality, 16 moderate quality and 14 low quality by the authors of the review. Pain reported by patients was dominated by deep intra-abdominal pain which was aggravated by coughing and movement. Table 5 describes risk factors identified by the review authors.

Table 5: risk factors for post-operative pain within seven days of groin hernia repair using mesh[32]

Risk factor	Conclusion	Evidence level	N studies
Gender	Women (n=18) may have higher risk of post-operative pain compared with men (n=491)	Descriptive study	1
Age	Younger patients experience more pain than older patients	At least one quasi-experimental study	3
Bilateral versus unilateral hernia	No difference in pain intensity	At least one quasi-experimental study	6
Primary versus recurrent hernia	No difference in post-operative pain	At least one quasi-experimental study	4
Hernia size and type	Not predictors of early post-operative pain	Descriptive studies	2
Preoperative pain response	Increased pain response to preoperative heat stimulation (47 Celsius) related to early post-operative pain	Descriptive study	1
Early pain	Early pain may predict chronic pain (12-36 months) following TEP Early pain may not predict chronic pain (5 years) following TAPP	Descriptive studies	3

TAPP = transabdominal preperitoneal repair; TEP = totally extraperitoneal repair.

Two additional primary studies explored specific factors as potential predictors of post-operative pain[30, 31]. The first study was a prospective cohort study in Scotland exploring psychological risk factors for developing pain following inguinal hernia repair[31]. Participants completed multiple questionnaires preoperatively (n=135) and at 1 week (n=119) and 4 months (n=115) post-surgery: Worst Pain Intensity and Number of Words Counted subscales of McGill Pain Questionnaire (MPQ); MPQ Present Pain Intensity; SF36 Physical Functioning subscale; Hernia Physical Functioning; Hospital Anxiety and Depression Scale (HADS); Tampa Scale for Kinesiophobia; Coping Strategy Questionnaire (CSQ) Catastrophising subscale; CSQ Expected Pain Control; Life Orientation Test short version; and five questions on activity avoidance developed for this study. Mean age of participants was 61.5 years (SD 12.0), over 90% were male, 91% had a primary inguinal hernia and 78% had their hernia repaired using mesh. Overall, pain decreased following hernia repair: 75.6% reported pain preoperatively, 88.3% at 1 week follow-up, and 39.5% at 4 months. Assuming everyone who did not return completed post-operative questionnaires were pain-free, a minimum of 33.3% of participants experienced some degree of pain at 4 months follow-up. After controlling for age, BMI and surgical variables, lower preoperative optimism was an independent risk factor for chronic post-surgery pain. Lower preoperative optimism and lower perceived control over pain 1 week after surgery were also significant predictors of higher pain intensity at 4 months follow-up.

The second study sought to establish whether the severity of preoperative pain, or a history of chronic pain conditions, were risk factors for chronic pain after inguinal hernia repair[30]. Twenty-four patients referred to a chronic pain clinic after inguinal hernia repair were age- and sex-matched with

24 pain-free patients (87.5% male). All but one patient had a hernia repair using mesh. Patients presenting with severe pain preoperatively were significantly more likely to experience severe chronic post-operative pain (14 versus three patients, p<0.005). There was a significant association between a history of chronic pain conditions and development of severe chronic pain after hernia repair (12 versus zero patients, p<0.005). There was no significant relationship between severity of preoperative pain and history of chronic pain conditions (p=0.09). These study results may have been affected by selection bias and may not generalise beyond patients referred to chronic pain clinics.

Public engagement

A 5-week public engagement exercise to gather views and experiences of groin hernia repair in Scotland was conducted to aid the SHTG Committee in developing advice on primary inguinal hernia repair using surgical mesh. Forty-two relevant responses were received from patients, the public, family members, and healthcare workers. Survey responses described a range of positive (n=16) and negative (n=10) experiences, with chronic post-operative pain being a key theme amongst the negative responses. Both having a groin hernia and having hernia repair surgery affected many aspects of patient's lives, including work/employment, exercise, mental health and relationships.

For a more detailed summary of the results of the engagement exercise, and a complete listing of relevant comments received, please see the Groin Hernia Public Engagement Survey Feedback Report which is available on the Healthcare Improvement Scotland website alongside this advice.

Organisational issues/Context

A groin hernia service commissioning guide was published in 2016 by the British Hernia Society and the Royal College of Surgeons[34]. It recommends all adults with an inguinal hernia undergo hernia repair using flat mesh, or non-mesh Shouldice repair if experience is available locally.

Repairing an inguinal hernia using non-mesh techniques can be technically demanding and has led to specialist hernia clinics developing their own techniques, for example the Shouldice repair (Mr R Molloy, Consultant Surgeon, Scottish Hernia Centre. Personal communication, 05 August 2019). Patient outcomes from non-mesh hernia repairs performed by non-specialist surgeons are therefore likely to be poorer than those reported in published studies conducted at specialist centres.

With over 98% of inguinal hernia repairs in Scotland currently using surgical mesh, mesh is the standard of care. Given this predominance of mesh-based hernia repair in Scotland, most surgeons in-training and many consultant surgeons would rarely, if ever, have performed a non-mesh hernia repair (Mr R Molloy, Consultant Surgeon, Scottish Hernia Centre. Personal communication, 05 August 2019). Therefore, any expansion in the use of non-mesh hernia repair techniques would require significant investment in training for surgical staff.

Cost effectiveness

Three relevant economic evaluations were identified, one conducted in the UK[35] and two in the US[36, 37]. The UK cost-effectiveness study compared laparoscopic[c] mesh repair with open mesh repair, and open mesh repair with non-mesh repair, in patients with an inguinal hernia[35]. The results indicate that over a 5-year time horizon open mesh leads to better outcomes and is less costly (in other words 'dominates') open non-mesh repair. Mesh provides greater benefits in terms of fewer recurrences (180 fewer per 1,000 patients; 95% CI 145 to 293), less persisting pain (45 fewer people per 1,000; 95% CI 6 to 73) and more time spent performing usual activities (10.7 days; 95% CI 9.3 to 12). The cumulative cost of mesh is lower with a mean saving of £134 per patient, 95% CI £81 to £192. This reduction in costs is because the costs of treating additional recurrent hernias after open non-mesh repair more than outweigh the higher initial material cost of open mesh repair. The cost saving remains robust when the assumption that all recurrences result in a repeat procedure is relaxed to as low as 5% of those having a recurrence.

Over the same 5-year time horizon, laparoscopic mesh repair compared with open mesh repair is associated with more time at usual activities (4.5 days for TEP, 95% CI 0.4 to 8.2; 3.2 days for TAPP, 95% CI 1.8 to 4.5) and fewer patients with long-term pain (67 fewer per 1,000 patients for TEP, 95% CI 41 to 107; 32 fewer per 1,000 patients for TAPP, 95% CI 12 to 57), but this is achieved at a higher cost (£141 for TEP, 95% CI £88 to £247; £225 for TAPP, 95% CI £193 to £284) and an increased risk of rare but serious complications (3.6 more per 1,000 procedures for both TEP and TAPP). The incremental costs in this analysis were based on reusable laparoscopic equipment. These costs increased when disposable laparoscopic equipment was assumed: £978 for TEP, 95% CI, £898 to £1,177; £1,065 for TAPP, 95% CI, £1,010 to £1,175. No direct comparison between laparoscopic mesh repair and open non-mesh repair was performed, however, based on the incremental costs reported, laparoscopic mesh repair is likely to be more costly than open non-mesh repair by a small margin while offering reduced recurrence rates, as well as less persisting pain and more time spent performing usual activities.

In the UK analysis, clinical data on recurrence rates, time to return to usual activities, proportion of people with long-term pain, and operation time were derived from three meta-analyses of randomised or quasi-randomised controlled trials performed by the EU Hernia Trialists Collaboration. These meta-analyses included 58 RCTs (n=11,174) and there was a high degree of overlap with the pre-2000 studies included in the Cochrane systematic reviews described in the clinical effectiveness section. Summary statistics were used to estimate transition probabilities and other rates required in the economic model. Absolute differences in outcomes between treatment arms were estimated by applying the relative rates derived in the EU Trialists' meta-analyses. Equal mortality between treatment arms was assumed and informed by Scottish life tables. Data on costs were extracted from three economic evaluations[d] conducted alongside trials included in the EU Trialists' meta-analyses and were expressed as 2000/2001 prices. The key clinical effectiveness and cost inputs utilised in the UK analysis are summarised in table 6.

[c] Transabdominal preperitoneal (TAPP) repair or totally extraperitoneal (TEP) repair.

[d] Two of these economic evaluations were UK-based

Table 6: main modelling inputs used in the Vale *et al* (2004) UK economic evaluation[35]

	Baseline	Notes
Annual probability of recurrence		
Open non-mesh	5.84%	Average recurrence rates from open non-mesh study arms
Open mesh	1.52%	Based on OR 0.26 (95% CI 0.17 to 0.38) versus open non-mesh
TEP	1.47%	Based on OR 0.97 (95% CI 0.34 to 2.77) versus open mesh
TAPP	1.53%	Based on OR 1.01 (95% CI 0.56 to 1.85) versus open mesh
Probability of long-term pain		
Open non-mesh	12%	Average rates of chronic pain from open non-mesh study arms
Open mesh	8%	Based on OR 0.63 (95% CI 0.42 to 0.96) versus open non-mesh
TEP	1%	Based on OR 0.13 (95% CI 0.05 to 0.34) versus open mesh
TAPP	5%	Based on OR 0.59 (95% CI 0.43 to 0.83) versus open mesh
Time to return to usual activities in days (95% CI)		
Open non-mesh	18 (17 to 19)	
Open mesh	11 (11 to 11)	
TEP	7 (7 to 7)	
TAPP	8 (7 to 9)	
Operation length (minutes)		
Open non-mesh	49.53	Simple average of open non-mesh operation times
Open mesh	46.46	WMD -3.07 (95% CI 4.13 to -2.01) versus open non-mesh
TEP	51.75	WMD 5.29 (95% CI 2.84 to 7.73) versus open mesh
TAPP	61.10	WMD 14.64 (95% CI 13.32 to 15.96) versus open mesh
Intervention cost (operation staff + theatre + equipment + length of stay)*		
Open non-mesh	£253.87 to £272.95	Range based on input sources
Open mesh	£273.07 to £306.30	
TEP	£379.66 to £776.33	
TAPP	£379.66 to £776.33	

*Costs converted from euros to GBP using a rate of 1.59 euros per GBP as in the original publication and inflated to 2017/2018 prices using the GDP deflators at market prices series
WMD = weighted mean difference

In terms of the applicability of these results to Scotland the following issues should be taken into consideration:

- Despite data on costs being derived mainly from the UK, this economic analysis was published in 2004 and the data may be out-of-date. Comparing the key inputs in table 6 with clinical outcomes reported in the clinical effectiveness section, hernia recurrence seems lower in favour of open mesh repair, whereas operation duration and time to return to usual activities are similar. It is not clear what impact more conservative relative effectiveness estimates for hernia recurrence would have on the results since no sensitivity analyses were presented, however, it is unlikely the conclusions would change. In relation to cost data, estimates provided by ISD indicate much higher procedure costs: £2,517 for synthetic mesh repair and £2,559 for non-mesh repair. It is difficult to explain these differences in cost estimates. Nonetheless, it is likely the cost-effectiveness of mesh repair would improve further if the ISD estimates were applied in the Vale *et al* (2004) analysis. NHS England Reference Costs report similar values to ISD (ranging from £2,346 to £3,729) per inguinal, umbilical, or femoral hernia procedure, but these are not stratified by mesh/non-mesh repair type.

- The analysis assumed all patients would require general anaesthesia. In practice, open repair may be performed under local or regional anaesthesia, whereas laparoscopic repair would mostly be performed under general anaesthesia. In terms of cost-effectiveness, if open repair was performed under local or regional anaesthesia and laparoscopic repair under general anaesthesia, the difference in cost between laparoscopic and open repair would increase and laparoscopic repair would be less cost-effective.

- The cost-effectiveness results were expressed as ratios of incremental costs per change in specific clinical outcomes rather than generic measures, such as incremental cost per life-years gained or quality-adjusted life-years, which are comparable across disease areas and interventions. Nonetheless, based on the results of this analysis it is likely that open/laparoscopic mesh repair is cost-effective compared to open non-mesh repair.

The two US economic evaluations reached similar conclusions, showing that mesh repair is a cost-effective intervention and can result in overall cost savings[36, 37].

Conclusion

Hernia recurrence is the main clinical effectiveness outcome when comparing mesh and non-mesh techniques for inguinal hernia repair. Overall, evidence from meta-analyses found that, when all mesh techniques were compared with all non-mesh techniques, hernia recurrence was significantly less likely in patients treated using surgical mesh. Recurrence rates were also significantly lower in the mesh repair group in a meta-analysis comparing open mesh repair with Shouldice non-mesh repair. However, in a meta-analysis comparing the Desarda non-mesh technique with Lichtenstein open mesh repair, there were no statistically significant differences in hernia recurrence rates.

Among safety outcomes relating to inguinal hernia repair, the one of most concern is chronic pain. In meta-analyses, the risk of chronic pain was either similar for mesh and non-mesh groups, or significantly lower in the group treated with surgical mesh. Qualitative and quantitative

observational studies indicate that chronic pain following inguinal hernia repair is experienced by patients in a variety of ways, and can have a considerable impact on patient's quality of life and daily activities. Adverse event rates for other safety outcomes were either similar between mesh and non-mesh groups, or more frequent in patients who had non-mesh hernia repair.

A UK-based economic evaluation, which may generalise to Scotland, found that open mesh repair of inguinal hernia was more effective and less costly than repair using non-mesh techniques over a 5-year time horizon.

Equality and diversity

Healthcare Improvement Scotland is committed to equality and diversity in respect of the nine equality groups defined by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion, sex, and sexual orientation.

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References can be accessed via the internet (where addresses are provided), via the NHS Knowledge Network www.knowledge.scot.nhs.uk, or by contacting your local library and information service.

A glossary of commonly used terms in Health Technology Assessment is available from htaglossary.net.

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Appendix 1: abbreviations

BMI	body mass index
CASP	critical appraisal skills programme
CCS	Carolinas comfort scale
CI	confidence interval
COMI	core outcomes measurement index
CSQ	coping strategy questionnaire
EU	European Union
EuraHS-QoL	European Registry of Abdominal Wall Hernias Quality of Life score
FDA	Food and Drugs Administration
FPIC	Finnish Patient Insurance Centre
GBP	Great Britain pounds
GDP	gross domestic product
GRADE	Grading of Recommendations, Assessment, Development and Evaluations
HAD	hospital anxiety and depression score
IQR	inter-quartile range
IRIC	Incident Reporting and Investigation Centre
ISD	Information Services Division
MD	mean difference
MHRA	Medicines and Healthcare Products Regulatory Agency
MINORS	methodological index for non-randomised studies
MPQ	McGill pain questionnaire
NNTB	number needed to benefit
OR	odds ratio
PROM	patient reported outcome measure
RCT	randomised controlled trial
RR	relative risk/risk ratio
SD	standard deviation
SF36	short-form 36-item health survey
SOMS	surgical outcomes measurement system
TAPP	transabdominal preperitoneal
TEP	totally extraperitoneal repair
VAS	visual analogue scale
WMD	weighted mean difference

Appendix 2: adverse event data from the IRIC and MHRA databases

Table: adverse events relating to hernia repair surgery (any hernia type) reported to IRIC via the MHRA yellow card system from 2014 to 2019* (Ms S Lloyd-MacGilp, IRIC Coordinator, IRIC. Personal communication, 01 May 2019)

Adverse event reported	Mesh manufacturer & model (if known)	Date reported to MHRA	Notes
Pain	–	–	Umbilical hernia Date of incident 08/09/2009
Chronic abdominal pain; loss of feeling in legs	–	–	Date of incident 02/11/2017
Psychological symptoms; unexpected deterioration	Rocialle Healthcare Ltd	15/07/2018	
Constant pain; nerve damage	–	27/06/2018	
Chronic pain; nerve damage; incontinence issues	–	26/01/2018	
Slipped and cut off part of small bowel causing necrosis of the bowel and sepsis; infection	Johnson & Johnson Inc.	29/01/2018	Mesh implanted in 2009 Incident in 2012
Chronic pain	–	10/08/2017	Right-side inguinal hernia repair
Severe pain	Aspide® Medical, Surgimesh®, Prolene® mesh	20/06/2017	Mesh implanted 04/04/2012
Chronic pain ('cheese-grater' feeling, thereafter burning; recently double contraction-like 'grab and pull' pains which stop patient mid-stride which is believed to be dangerous for driving or	Aspide® Medical, Surgimesh®	06/11/2016	Mesh implanted 2012 Operated on twice due to failure of procedure Most recent incident of stopping mid-stride in 2016 [*Likely double reporting of this incident*]

when patient stops when crossing a road)			
Infection; rupture and scarring; pain	–	07/09/2016	The mesh ripped and scarred and got infected. Wound would not heal and protruding un-supported and sore.
Mesh erosion/migration/crumpling; calcification; nerve damage	Ethicon Inc Prolene® hernia mesh/patch	21/08/2015	–
Constant pain; swelling	–	–	Mesh implanted 08/08/2015
Leg contractions	Surgimesh®	–	Hernia mesh for femoral and inguinal tear (whole leg twisted causing two internal tears which needed two operations) Date of incident 21/03/2016 [*Likely double reporting of this incident*]
Pain	Surgimesh®	–	Hernia mesh for femoral and inguinal tear (whole leg twisted causing two internal tares which needed two operation) Date of incident 21/12/2012 [*Likely duplicate reporting of this incident*]

*These data are not specific to inguinal hernias. The data available are limited by what is provided on the yellow card, therefore patient characteristics such as gender are not always known. Incidents can be reported multiple times and it is not always possible to identify whether a report is a duplicate of a previous incident from the same patient.