

Systematic review and meta-analysis of the use of lightweight *versus* heavyweight mesh in open inguinal hernia repair

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Background: The objective of this study was systematically to analyse published randomized trials comparing lightweight mesh (LWM) with heavyweight mesh (HWM) in open inguinal hernia repair.

Methods: Randomized trials on LWM *versus* HWM were selected from the standard electronic databases. Reported outcomes were analysed systematically using RevMan. Pooled risk ratios were calculated for categorical outcomes, and mean differences for secondary continuous outcomes, using the fixed-effects and random-effects models for meta-analysis.

Results: Nine randomized trials containing 2310 patients were included. There was significant heterogeneity among trials. There was no difference in duration of operation, postoperative pain, recurrence rate, testicular atrophy and time to return to work between LWM and HWM groups. The two mesh types had a similar risk of perioperative complications, but LWM was associated with a reduced risk of developing chronic groin pain (risk ratio (RR) 0.61, 95 per cent confidence interval 0.50 to 0.74) and a reduced risk of developing other groin symptoms, such as stiffness and foreign body sensations (RR 0.64, 0.50 to 0.81).

Conclusion: The use of LWM for open inguinal hernia repair was not associated with an increased risk of hernia recurrence. LWM reduced the incidence of chronic groin pain as well as the risk of developing other groin symptoms.

Paper accepted 18 August 2011

Published online 31 October 2011 in Wiley Online Library (www.bjs.co.uk). DOI: 10.1002/bjs.7718

Introduction

An estimated 16 per cent of groin hernias in general surgical patients are symptomatic, for which laparoscopic and open inguinal hernia repairs are among the most common operative interventions¹. Approximately 20 million groin hernioplasties are performed each year worldwide, over 17 000 operations in Sweden, more than 12 000 in Finland, over 80 000 in England and more than 800 000 in the USA²⁻⁴. Tension-free mesh repair of inguinal hernia, the 'Lichtenstein repair', has become the standard of care because of its lower recurrence rates compared with posterior wall darning or Shouldice repair^{5,6}. Since the introduction of mesh to inguinal hernioplasty, the reported rates of postoperative chronic groin pain and groin symptoms have increased, and range from 10 to 54 per cent among patients undergoing hernia surgery^{7,8}.

The aetiological factors leading to chronic postoperative groin pain include inguinal nerve irritation by the sutures

or mesh⁹, inflammatory reactions against the mesh¹⁰ or simply scarring in the inguinal region incorporating the inguinal nerves^{11,12}. The chronic postoperative groin pain associated with mesh inguinal hernia repair is possibly related to local tissue inflammatory reactions to foreign material, bioincompatibility and reduction in abdominal wall compliance¹³.

Lightweight mesh (LWM) is either a composite mesh, containing both absorbable and non-absorbable synthetic material (sometimes coated with titanium), or a mesh containing a reduced weight of non-absorbable components. LWM is thought to reduce the incidence of chronic groin pain and foreign body sensation compared with conventional heavyweight mesh (HWM) because it has greater biocompatibility and its elasticity is similar to that of the abdominal wall^{14,15}.

The objective of this meta-analysis was systematically to analyse published randomized controlled trials comparing the effectiveness of LWM *versus* HWM in reducing the

incidence of chronic groin pain and recurrence following open inguinal hernia repair.

Methods

Identification of trials

Randomized controlled trials, irrespective of language, country of origin, hospital of origin, blinding, sample size or publication status, that compared the use of LWM *versus* HWM in open inguinal hernia repair were included in this review. The Cochrane Colorectal Cancer Group Controlled Trials Register, the Cochrane Central Register of Controlled Trials in the Cochrane Library, MEDLINE, Embase and Science Citation Index Expanded were searched for articles published up to May 2011 using the medical subject headings (MeSH) terms 'inguinal hernia' and 'groin hernia'. Equivalent free-text search terms, such as 'mesh repair of inguinal hernia', 'Lichtenstein repair', 'inguinal hernioplasty' and 'tension-free inguinal hernia repair' were used in combination with 'lightweight mesh' and 'heavyweight mesh', 'polypropylene mesh', 'composite mesh', 'partially absorbable mesh', 'titanium coated mesh', 'polyglactin mesh', 'poliglecaprone mesh', 'Prolene mesh' and 'Vypro II mesh'. A filter for identifying randomized controlled trials recommended by the Cochrane Collaboration¹⁶ was used to filter out non-randomized studies in MEDLINE and Embase. The references from the included trials were searched to identify additional trials.

LWM^{13,17} was defined as surgical mesh with a tensile strength of 16 N/cm, elasticity of 20–35 per cent at a tensile strength of 16 N/cm, pore size more than 1 mm, and containing woven lightweight polymers of biomaterial usually weighing less than 50 g/m².

Data extraction

Two authors independently identified the trials for inclusion and exclusion, and extracted the data. The accuracy of the extracted data was further confirmed by a third author. It was agreed that the lack of an adequate randomization technique and an intention-to-treat analysis would result in the trials being classified as having a high risk of bias.

Statistical analysis

The software package RevMan 5.1.2¹⁸, provided by the Cochrane Collaboration, was used for statistical analysis to achieve a combined outcome. The risk ratio (RR) with 95 per cent confidence interval (c.i.) was calculated for

binary data, and the mean difference with 95 per cent c.i. for continuous variables. Random and fixed-effects models were used to calculate the combined outcomes of both binary and continuous data^{19,20}. In cases of heterogeneity, only the results of the random-effects model were reported. Heterogeneity was explored using the χ^2 test, with significance set at $P < 0.050$; it was quantified¹⁶ using I^2 , low heterogeneity being defined as an I^2 value of 33 per cent or less²¹. If the standard deviation was not available, it was calculated according to the guidelines of the Cochrane Collaboration¹⁶. This process involved assumptions that both groups had the same variance, which may not have been true, and variance was estimated either from the range or from the P value. Forest plots were used for graphical display of the results. Subgroup analysis was performed to determine whether follow-up time influenced the overall incidence of recurrence and chronic groin pain.

The methodological quality of the included trials was assessed initially using the published guidelines of Jadad and colleagues²² and Chalmers and co-workers²³. Based on the quality of the included trials, the strength and summary of the evidence were further evaluated by GradePro²⁴, a tool provided by the Cochrane Collaboration.

Results

The literature search strategy and trial selection are summarized in *Fig. 1*. Twelve published articles^{25–36} on nine randomized controlled trials^{25,28–34,36}, encompassing 2310 patients, were analysed systematically to achieve a summated outcome. For studies reporting outcomes for the same groups of patients at different follow-up times, data from the last follow-up were used^{27,35}. There were 1156 patients in the LWM group and 1154 in the HWM group. The characteristics of the included trials are shown in *Table 1*. The salient features and treatment protocols adopted are summarized in *Table S1* (supporting information).

Pooled data were analysed by combining the results of the nine randomized trials. In addition, data were analysed for immediate results (follow-up from 1 to 6 months)^{25,30,33,36}, short-term results (1-year follow-up)^{26,29,31,34} and long-term results (follow-up more than 1 year)^{27,28,32,35}.

Methodological quality of included studies

According to the published guidelines^{22,23}, all trials scored highly enough to suggest good quality of the included trials. Based on the quality of the trials (*Table 2*), the strength and

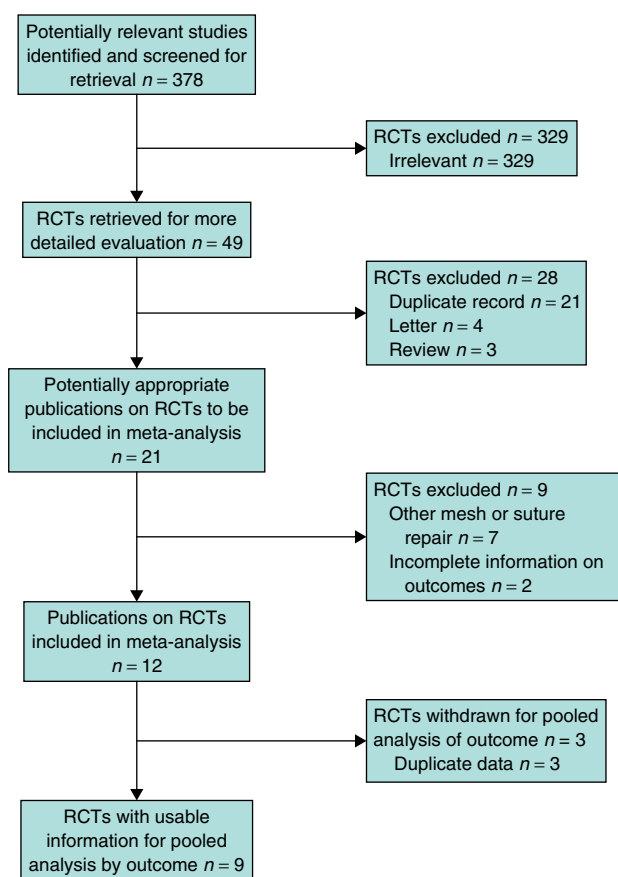


Fig. 1 PRISMA flow chart for the review. RCT, randomized controlled trial

summary of evidence analysed on GradePro²⁴ are shown in Fig. S1 (supporting information).

Combined analysis of nine trials

Duration of operation

Eight trials^{25,29–34,36} contributed to the analysis. There was significant heterogeneity among trials ($\tau^2 = 4.71$, $\chi^2 = 15.55$, 7 d.f., $P = 0.030$, $I^2 = 55$ per cent). In the random-effects model, the duration of operation was statistically similar following the use of either LWM or HWM: mean difference 1.85 (–0.36 to 4.06) min ($Z = 1.64$, $P = 0.100$).

Postoperative pain

Five trials^{25,29,32,33,36} contributed to the calculation. There was significant heterogeneity among trials ($\tau^2 = 2782.02$, $\chi^2 = 32081.42$, 4 d.f., $P < 0.001$, $I^2 = 100$ per cent). In the random-effects model, postoperative pain in the LWM and HWM groups was statistically similar: mean difference

in pain score –17.99 (–64.23 to 28.25) ($Z = 0.76$, $P = 0.450$).

Perioperative complications

Data from seven trials^{25,29–34} were included in the analysis. There was no heterogeneity among trials ($\chi^2 = 2.96$, 6 d.f., $P = 0.810$, $I^2 = 0$ per cent). In the fixed-effects model, the risk of developing perioperative complications was similar in both groups (RR 0.85, 0.58 to 1.23; $Z = 0.87$, $P = 0.380$).

Return to work

Four trials^{25,29,31,36} contributed to the calculation. There was significant heterogeneity among trials ($\tau^2 = 4.41$, $\chi^2 = 16.0$, 3 d.f., $P < 0.001$, $I^2 = 81$ per cent). In the random-effects model, the time taken to return to work by the LWM group was not significantly different from that in the HWM group: mean difference –2.23 (–4.64 to 0.17) days ($Z = 1.82$, $P = 0.070$).

Recurrence

Results from eight trials^{27–33,35} contributed to the analysis. There was no heterogeneity among trials. In the fixed-effects model, the risk of hernia recurrence following the use of LWM and HWM was not significantly different (Fig. 2).

Chronic groin pain

The analysis included nine trials^{27–33,35,36}. There was no heterogeneity among trials. In the fixed-effects model, the risk of developing chronic groin pain was significantly greater following the use of HWM compared with LWM (Fig. 3).

Other symptoms

Five trials^{27,29,30,32,33} contributed to the calculation. These trials reported two types of chronic groin symptoms following open inguinal hernia repair with mesh: chronic groin pain and ‘other symptoms’. ‘Other symptoms’ included groin discomfort, groin stiffness, feelings of regional hardness, sensory impairment, point tenderness and foreign body sensation. Therefore, these symptoms were analysed together. There was no heterogeneity among trials. In the fixed-effects model, the risk of developing other groin symptoms was statistically greater following the use of HWM compared with LWM (Fig. 4).

Testicular atrophy

Four trials^{27,29,31,33} were included in the analysis. There was no heterogeneity among trials ($\chi^2 = 0.66$, 2 d.f.,

Table 1 Characteristics of included trials

Reference	Year	Country	No. of patients	Age (years)*	Sex	Duration of follow-up	Hernia details	
Bringman <i>et al.</i> ²⁵	2004	Sweden and Finland	LWM	260	55(14)	All men	2 months	Unilateral primary inguinal hernia
			HWM	251	55(14)			
Bringman <i>et al.</i> ²⁶ ‡	2005	As above	LWM	263	55(14)	As above	12 months	As above
			HWM	263	55(14)			
Bringman <i>et al.</i> ²⁷ §	2006	As above	LWM	251	55(14)	As above	37 (30–48) months†	As above
			HWM	243	55(14)			
Champault <i>et al.</i> ²⁸	2007	France	LWM	53	54 (18–84)†	Mixed group of men and women	24 months	Primary unilateral, primary bilateral and recurrent inguinal hernia
			HWM	179				
Koch <i>et al.</i> ²⁹	2008	Sweden	LWM	156	56 (22–75)†	All men	12 months	Unilateral primary inguinal hernia
			HWM	161	57 (25–75)†			
Nikkolo <i>et al.</i> ³⁰	2010	Estonia	LWM	69	59.2	Mixed group of men and women	6 months	Unilateral primary inguinal hernia
			HWM	66	57.2			
O'Dwyer <i>et al.</i> ³¹	2005	UK and Germany	LWM	162	55.7(16.4)	Mixed group of men and women	12 months	Primary and recurrent inguinal hernia
			HWM	159	57.3(15.8)			
Paajanen ³²	2007	Finland	LWM	155	56(13)	Mixed group of men and women	24 months	Primary, recurrent, unilateral and bilateral inguinal hernia
			HWM	78	59(15)			
Post <i>et al.</i> ³³	2004	Germany	LWM	60	60 (31–84)†	Mixed group of men and women	6 months	Primary, recurrent, unilateral and bilateral inguinal hernia
			HWM	48	62 (20–85)†			
Smietanski <i>et al.</i> ³⁴	2008	Poland	LWM	215	56 (18–80)†	Mixed group of men and women	12 months	Primary inguinal hernia according to Rutkow classification
			HWM	177	56 (23–87)†			
Smietanski <i>et al.</i> ³⁵ ¶	2011	As above	LWM	92	As above	Mixed group of men and women	60 months	As above
			HWM	90				
Torcivia <i>et al.</i> ³⁶	2011	France	LWM	24	54.5	Mixed group of men and women	30 days	Primary unilateral inguinal hernia
			HWM	23	53.4			

*Values are mean(s.d.), except †median (range). ‡One-year and §3-year results of reference 25; ¶5-year results of reference 34. LWM, lightweight mesh; HWM, heavyweight mesh.

$P = 0.720$, $I^2 = 0$ per cent). In the fixed-effects model, the risk of developing testicular atrophy was no different following the use of either LWM or HWM in open inguinal hernia repair (RR 1.89, 0.57 to 6.23; $Z = 1.04$, $P = 0.300$).

Immediate results

Four trials^{25,30,33,36} published data on follow-up between 1 and 6 months. There was no heterogeneity among trials ($\chi^2 = 5.49$, 3 d.f., $P = 0.140$, $I^2 = 31$ per cent). In the fixed-effects model, LWM was associated with a lower incidence of chronic groin pain (RR 0.66, 0.46 to 0.93; $Z = 2.34$, $P = 0.020$) and other symptoms, such as groin stiffness and foreign body sensation (RR 0.48, 0.32 to 0.73; $Z = 3.45$, $P < 0.001$). LWM was not associated with an

increased risk of hernia recurrence (RR 0.83, 0.12 to 5.66; $Z = 0.19$, $P = 0.850$).

Short-term results

Four trials^{26,29,31,34} reported 1-year follow-up. There was no heterogeneity among trials ($\chi^2 = 1.60$, 3 d.f., $P = 0.660$, $I^2 = 0$ per cent). In the fixed-effects model, LWM was associated with a lower incidence of chronic groin pain (RR 0.70, 0.56 to 0.89; $Z = 2.93$, $P = 0.003$). The risk of developing other symptoms was similar in the two groups (RR 0.82, 0.63 to 1.07; $Z = 1.43$, $P = 0.150$). LWM was not associated with an increased risk of hernia recurrence (RR 1.95, 0.87 to 4.33; $Z = 1.63$, $P = 0.100$).

Table 2 Quality assessment of included trials

Reference	Randomization technique	Power calculations	Blinding	Intention-to-treat analysis	Concealment
Bringman <i>et al.</i> ²⁵	Computer-generated	Yes	Yes	Yes	Yes
Bringman <i>et al.</i> ²⁶	As above	As above	As above	As above	As above
Bringman <i>et al.</i> ²⁷	As above	As above	As above	As above	As above
Champault <i>et al.</i> ²⁸	Based on patient's consent	No	Yes	Not given	No
Koch <i>et al.</i> ²⁹	Computer-generated	Yes	Yes	Yes	Yes
Nikkolo <i>et al.</i> ³⁰	Blind envelope system	Yes	Not given	No	Yes
O'Dwyer <i>et al.</i> ³¹	Computer-generated	Yes	Yes	Yes	Yes
Paajanen ³²	Sealed and numbered envelopes	Yes	Yes	Yes	Yes
Post <i>et al.</i> ³³	Computer-generated	Yes	Yes	Yes	Yes
Smietanski <i>et al.</i> ³⁴	Wichmann–Hill pseudorandom number generator modified by McLeod	Yes	Yes	Yes	Yes
Smietanski <i>et al.</i> ³⁵	As above	As above	As above	As above	As above
Torcivia <i>et al.</i> ³⁶	Randomization using alternation principle	No	No	No	No

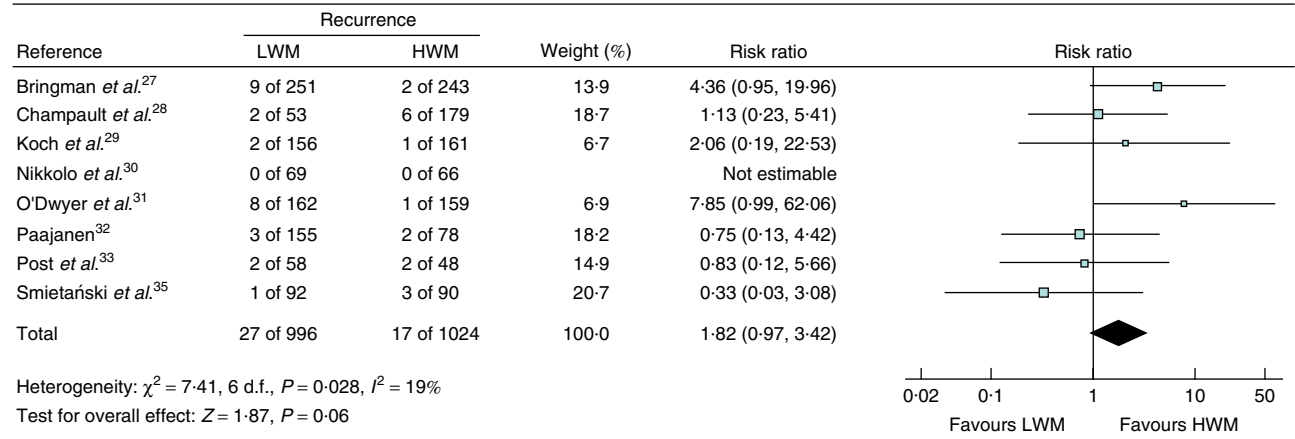


Fig. 2 Forest plot comparing inguinal hernia recurrence in all trials following the use of lightweight mesh (LWM) versus heavyweight mesh (HWM) in open inguinal hernia repair. A Mantel–Haenszel fixed-effects model was used for meta-analysis. Risk ratios are shown with 95 per cent confidence intervals

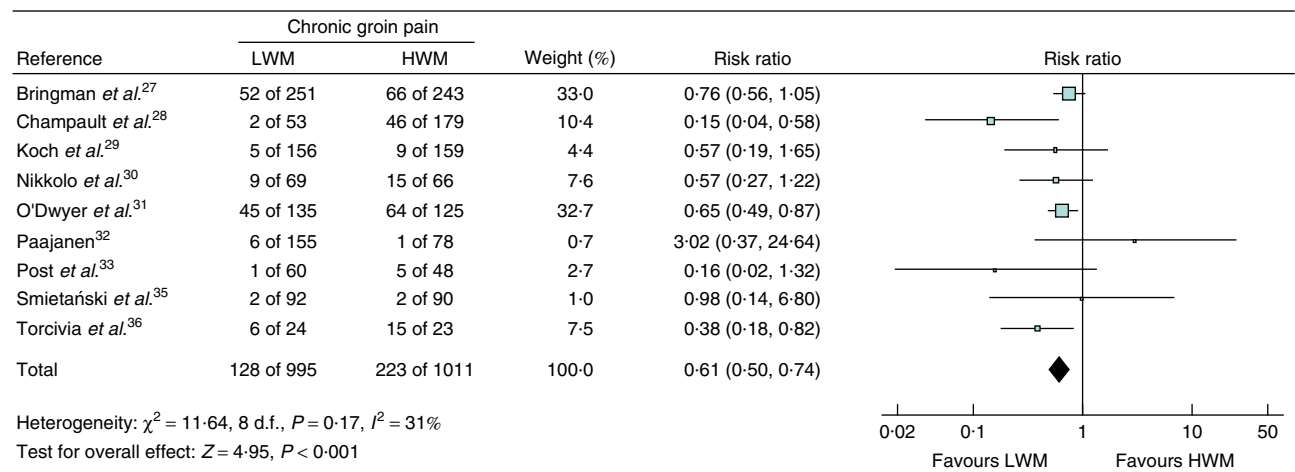


Fig. 3 Forest plot comparing chronic groin pain in all trials following the use of lightweight mesh (LWM) versus heavyweight mesh (HWM) in open inguinal hernia repair. A Mantel–Haenszel fixed-effects model was used for meta-analysis. Risk ratios are shown with 95 per cent confidence intervals

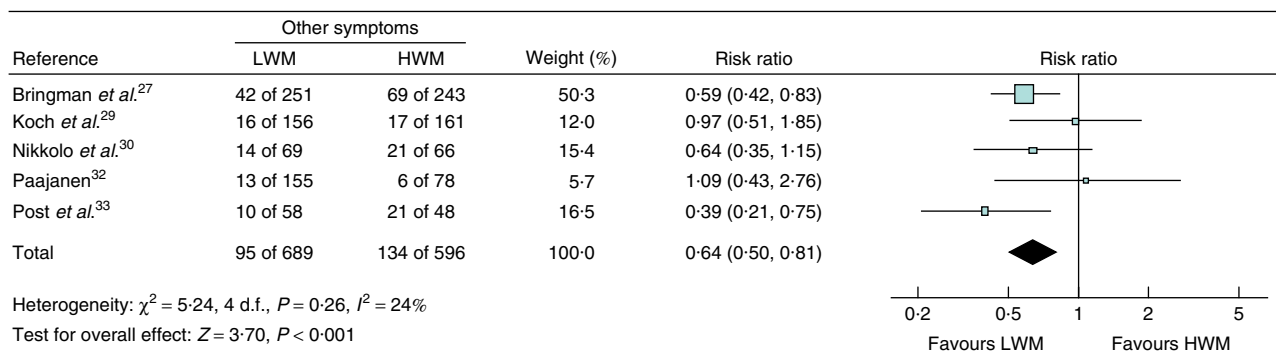


Fig. 4 Forest plot comparing other symptoms following the use of lightweight mesh (LWM) *versus* heavyweight mesh (HWM) in open inguinal hernia repair. A Mantel–Haenszel fixed-effects model was used for meta-analysis. Risk ratios are shown with 95 per cent confidence intervals

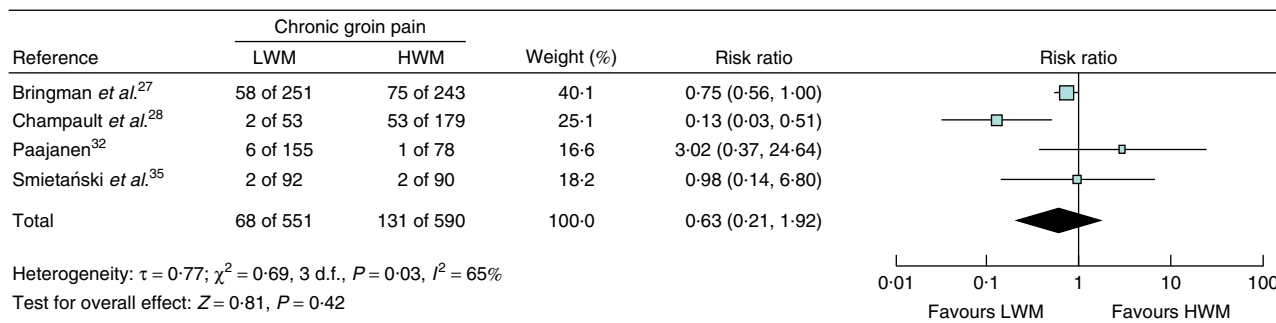


Fig. 5 Forest plot comparing chronic groin pain in trials with follow-up of more than 1 year after the use of lightweight mesh (LWM) *versus* heavyweight mesh (HWM) in open inguinal hernia repair. A random-effects model was used for meta-analysis. Risk ratios are shown with 95 per cent confidence intervals

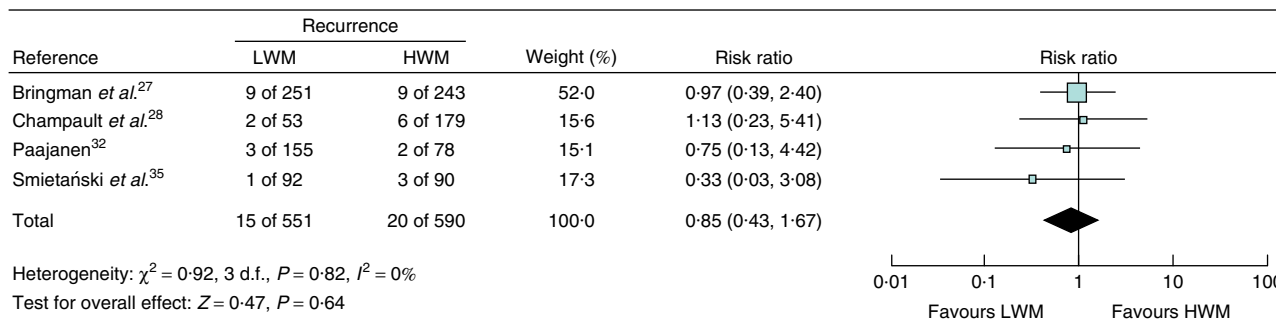


Fig. 6 Forest plot comparing recurrence in trials with follow-up of more than 1 year after the use of lightweight mesh (LWM) *versus* heavyweight mesh (HWM) in open inguinal hernia repair. A Mantel–Haenszel fixed-effects model was used for meta-analysis. Risk ratios are shown with 95 per cent confidence intervals

Long-term results

Four trials^{27,28,32,35} reported data on follow-up of more than 1 year. There was significant heterogeneity among trials. In the random-effects model, LWM was not associated with a lower incidence of chronic groin pain

(Fig. 5). However, the risk of developing other symptoms, such as groin stiffness and foreign body sensation, was lower in the LWM group (RR 0.64, 0.47 to 0.88; $Z = 2.74$, $P = 0.006$). LWM was not associated with an increased risk of hernia recurrence (Fig. 6).

Discussion

According to the results of this review and meta-analysis, the duration of operation, postoperative pain, hernia recurrence rate, risk of testicular atrophy and time to return to work were comparable between LWM and HWM. LWM was associated with a similar risk of postoperative complications, a reduced risk of developing chronic groin pain and a lower risk of developing other groin symptoms.

Since the introduction of surgical meshes for hernia repair in 1959^{37,38}, investigators have worked to find solutions to mesh-specific complications, such as decreased abdominal wall mobility and increased incidence of chronic groin pain. As a result of the higher incidence of chronic groin pain and groin stiffness following mesh repair of inguinal hernia, two fundamental principles have been developed over time: the classical concept of conventional HWM with small pores and the relatively new approach, including LWM with larger pores. HWM offers maximum mechanical stability, resulting in stiff and non-flexible thick scar formation to ensure a resilient hernia repair. However, it produces a segment of abdominal wall with excessive tensile strength that does not adapt to local tissue, leading to stiffness and foreign body sensations. Polymers of biomaterial used to construct mesh are considered physically and chemically inert, non-immunogenic and non-toxic, but they can still trigger an extensive local inflammatory adverse reaction^{17,39}. Apart from the influences of the nociceptive system and intraoperative nerve injury, this inflammatory reaction and excessive scar tissue are considered responsible for chronic groin pain, stiffness and foreign body sensations. LWM was introduced to reduce the reactive component of the mesh, matching elasticity and tensile strength with those of abdominal wall fascia and muscle. Textile and mechanical characteristics of the HWM used for mesh design, in the form of small pores and dense heavyweight polymers, confer maximum stability at the site of hernia defect¹⁷. In contrast, LWMs are designed to replicate the physiological qualities of the abdominal wall and inguinal region⁴⁰. They are made from lightweight polymers of biomaterial, usually weighing less than 50 g/m², that resemble the biomechanical compliance of the abdominal wall, with a pore size of more than 1 mm, tensile strength of 16 N/cm, and elasticity of 20–35 per cent at a tensile strength of 16 N/cm¹⁷.

Some^{25,31,32}, but not all^{28,29,33,36}, studies reported no differences between LWM and HWM regarding pain scores. However, several randomized trials showed the risk of chronic groin pain to be greater following the use of HWM^{28,31,36} compared with LWM^{27,29,30,33}. The

findings of this review are in concordance with the published literature.

In earlier trials^{27,29,31}, concerns were raised about a higher risk of hernia recurrence following the use of LWM in inguinal hernioplasty. A recently published trial³⁵ has failed to establish any association between a higher recurrence rate and the use of LWM. The findings of this review are consistent with the outcomes of the majority of trials, showing no difference in recurrence rates between LWM and HWM.

A previous meta-analysis¹⁵ concluded that no difference existed between LWM and HWM in short-term effectiveness. However, that review comprised an analysis of six randomized trials on laparoscopic inguinal hernia repair and four on open inguinal hernia repair. Laparoscopic repair has been found to cause less postoperative pain than open inguinal hernia repair^{40,41}, probably because the site of incision and tissue dissection are different. In addition, LWM in the form of Vypro® II (Ethicon, Johnson & Johnson, Somerville, New Jersey, USA) was compared with polypropylene, whereas the present meta-analysis included all types of old- and new-generation LWMs, such as β -D-glucan, titanium-coated polypropylene and polypropylene–poliglecaprone (*Table S1*, supporting information). However, in agreement with the present study, use of LWM was found to be associated with a reduced feeling of foreign body sensation in the groin¹⁵.

There are several limitations to the present review. There was statistically significant heterogeneity among the included trials, especially for short-term outcomes. Possible causes of clinical and methodological heterogeneity of hernia mesh studies are shown in *Table S2* (supporting information). There were significant differences in inclusion and exclusion criteria among the included trials. There were also differences in definitions of ‘chronic groin pain’, ‘other symptoms’ and ‘measurement scales for postoperative pain’. Studies recruiting a small number of patients in this review may not have had sufficient power to recognize small differences in outcomes between LWM and HWM. Because there was no difference in primary outcomes between the two types of mesh, further trials to evaluate variables such as health-related quality of life, cost analysis and trials with longer follow-up are of interest.

Acknowledgements

The authors declare no conflict of interest.

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Supporting information

Additional supporting information may be found in the online version of this article:

Fig. S1 Summary and strength of evidence from trials, analysed on GradePro (Word document)

Table S1 Treatment protocols in included trials (Word document)

Table S2 Suggested causes of heterogeneity (Word document)

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Commentary

Systematic review and meta-analysis of the use of lightweight *versus* heavyweight mesh in open inguinal hernia repair (*Br J Surg* 2012; **99**: 29–37)

A surgical procedure for inguinal hernia repair should provide a low recurrence rate with a minimum of postoperative sequelae. The recurrence rate was markedly reduced by the introduction of mesh repair. Today the Lichtenstein procedure is widely seen as the standard operation for inguinal hernia. However, postoperative chronic complaints, including pain, stiffness and foreign-body sensation, are problems of greater magnitude than previously expected. There is a huge discrepancy between studies reporting chronic pain, with rates ranging from 1.2 to 51 per cent, indicating a lack of homogeneous definitions.

Kehlet and colleagues¹ have suggested a uniform assessment for postherniorrhaphy pain. With this as a model, the validated Inguinal Pain Questionnaire (IPQ) has been launched². The IPQ will facilitate future randomized clinical trials within this area.

Lightweight meshes were introduced to reduce the chronic complaints addressed in this meta-analysis. This well conducted study shows a markedly reduced risk of developing chronic pain and other groin symptoms (stiffness and

foreign-body sensation) without increasing the rate of recurrence when lightweight mesh is used. Although mesh weight seems to be of importance, other factors may influence outcome such as the structure, position and fixation of the mesh as well as the choice of mesh material. The importance of the mesh position has been demonstrated to reduce chronic pain for endoscopic hernia repair compared with open methods³. The present study provides clinically important knowledge for development of the Lichtenstein technique.

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DOI: 10.1002/bjs.7769

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