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A Meta-analysis Comparing Lightweight Meshes With Heavyweight Meshes in Lichtenstein Inguinal Hernia Repair

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Abstract

Background. To evaluate the influence of lightweight and heavyweight mesh on postoperative recovery in Lichtenstein inguinal hernia repair. **Methods.** PubMed, EMBASE, and the Cochrane library were used to search for published clinical randomized controlled trials (RCTs), which compared lightweight meshes with heavyweight meshes in Lichtenstein inguinal hernia repair. Two independent reviewers assessed the trials for eligibility and quality, and all the related data matching our standards were abstracted for meta-analysis by RevMan 5.0 software. The evaluation criteria included recurrence, pain, seroma, hematoma, the sensation of a foreign body, wound infection, urine retention, and testicular atrophy. **Results.** A total of 2231 hernias from 11 RCTs were included. Compared with a heavyweight polypropylene mesh, the lightweight mesh led to less postoperative chronic pain (odds ratio [OR] = 0.64, 95% confidence interval (CI) = 0.51-0.82; $P < .05$) and less sensation of a foreign body (OR = 0.56; 95% CI = 0.40-0.78; $P < .05$), regardless of whether the mesh was made of partially absorbable or nonabsorbable material. There was no significant difference in postoperative recurrence, seroma, hematoma, wound infection, urine retention, and testicular atrophy. **Conclusion.** Current evidence suggests that the use of a lightweight mesh is associated with less postoperative pain and less sensation of a foreign body, without increasing the incidence of recurrence. Further high-quality, long-term follow-up RCTs are needed to provide more reliable evidence.

Keywords

hernias, lightweight mesh, meta-analysis

Introduction

Inguinal hernias occur in approximately 16% of adult men.[1] Globally, more than 20 million hernias are estimated to be repaired every year.[2,3] The Lichtenstein technique is the most widely practiced repair and remains a gold standard because of its simplicity, reproducibility, lack of contraindications, efficacy, and low cost.[4,5] The use of prosthetic meshes has become increasingly popular in inguinal hernia surgery, and the literature shows that groin hernia repair with prosthetic reinforcement significantly influences the incidence of recurrences, even in the long term.[6,7] Approximately 1.5 million meshes per year are implanted for hernia repair worldwide, and successful treatment of groin hernias is, therefore, of major socioeconomic importance.[8]

Heavyweight standard polypropylene mesh is the most commonly used material for hernia repair with markedly reduced incidence of hernia recurrences, but it is associated with strong foreign-body reaction with potentially harmful side effects, such as chronic inflammation and decreased abdominal wall compliance.[9] Experimental studies confirm that the extent of foreign-body reaction with scar tissue formation and inflammatory reaction depends on the amount and structure of material used for implantation.[9] Because the goal in repair is reinforcement of the abdominal wall without reducing the movement by the scar disc that is formed by the inflammatory reaction, much work has been tied to the improvement of mesh construction by changing the mesh weight and size of the pores.

In recent years, lightweight meshes have allowed for less foreign material being incorporated in the tissue, and

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they range from weight-reduced implants to partially absorbable to material-reduced and titanium-coated meshes.[8] As a result, the weight of an implant has become the most discussed feature of its construction, and the developers of all new meshes aim for lighter construction to achieve better biocompatibility. Opponents, however, argue that there is a higher incidence of recurrence in the lightweight mesh groups—reportedly as high as 5%.[10]

Several previous randomized controlled trials (RCTs) showed the relative merits and risks of lightweight meshes versus heavyweight standard polypropylene meshes in Lichtenstein inguinal hernia repair.[11-20] To clarify some of the issues, a meta-analysis was undertaken, concentrating on 8 treatment variables of importance in Lichtenstein inguinal hernia repair.

Methods

All RCTs and comparative studies concerning Lichtenstein inguinal hernia repair with lightweight meshes were identified. The electronic databases PubMed, EMBASE, and the Cochrane Library were used to search for relevant articles published in any language from 1966 to 2011 using the following terms and/or combinations in their titles, abstracts, or keyword lists: *RCTs, double-blind*, "*lightweight*," *Polyglactin, Polypropylene, VYPRO, VYPRO II, Ultrapo, inguinal hernia*, and *Lichtenstein procedure*. Where applicable, these terms were used with "[MESH]" (PubMed and the Cochrane Library); otherwise, the terms were combined with "AND/OR" and asterisks. In addition, the abstracts from national and international conferences were searched using online search engines corresponding to the particular conference. Studies needed to be published as full-length articles or letters in peer-reviewed journals, and we contacted authors for additional data if included outcomes were not published or if median (rather than mean) outcomes were reported.

These trials assessed at least 1 of the following outcomes: pain, recurrence, seroma, sensation of a foreign body, hematoma, wound infection, urine retention, and testicular atrophy. Two reviewers independently assessed potentially relevant citations for inclusion. Disagreements were resolved by consensus. Variables such as the authors' names, publication year, journal, country of origin, study design and intervention, and outcome, were extracted from each article.

The quality was assessed using the *Cochrane Handbook for Systematic Reviews of Interventions*, Version 5.0. Each included trial was assessed independently to ascertain the following methodological qualities: sequence generation, allocation concealment, blinding of participants, personnel and outcome assessors, incomplete outcome data, selective outcome reporting, and other sources of bias. To assess the effect of trial quality on the effect of size, sensitivity analysis was done by comparison of studies that fulfilled quality criteria with those that did not.

We summarized available data for all trials reporting results of postoperative recurrence or complication, computing pooled odds ratios (ORs) and their respective 95% confidence intervals (CIs) by means of a fixed-effects meta-analysis model. All statistical analyses were performed with Review Manager (RevMan, version 5.0), the Cochrane Collaboration's software for preparing and maintaining Cochrane systematic reviews. We used the χ^2 test to assess heterogeneity between trials and the I^2 statistic to assess the extent of inconsistency. Subgroup analysis was performed to explore important clinical differences among trials that might be expected to alter the magnitude of treatment effect.

Results

Figure 1 shows the flowchart of studies from initial results of publication searches to final inclusion or exclusion. The electronic searches yielded 498 items from PubMed, the Cochrane Library, EMBASE, SCI, and the Chinese Biomedical Literature Database. After reviewing each publication, we identified 11 original studies that met the inclusion criteria. Publication dates ranged from 2004 to 2011. A total of 2231 patients were involved. After reading the full text, we found 3 articles that had similar patients but different follow-up outcomes.

Table 1 contains specific information on study design, surgical method, type of inguinal hernia, sample size, intervention, outcome measures, and follow-up. Table 2 shows the methodological quality of the included studies, which was assessed using the *Cochrane Handbook* 5.0.

Chronic Pain

Compared with a heavyweight mesh, chronic pain was significantly lower with lightweight mesh implants, regardless of whether they were partially absorbable (OR = 0.66; 95% CI = 0.50-0.88) or nonabsorbable (OR = 0.59; 95% CI = 0.36-0.96). Total chronic pain was also lower with lightweight mesh implants (OR = 0.64; 95% CI = 0.51-0.82), and there was no heterogeneity in any of the studies (Figure 2).

Recurrence

There was no significant difference between the incidences of recurrence in the 2 groups (OR = 1.29; 95% CI = 0.72-2.28), and there was no heterogeneity of the studies ($P = .39$, $I^2 = 5\%$; Figure 3).

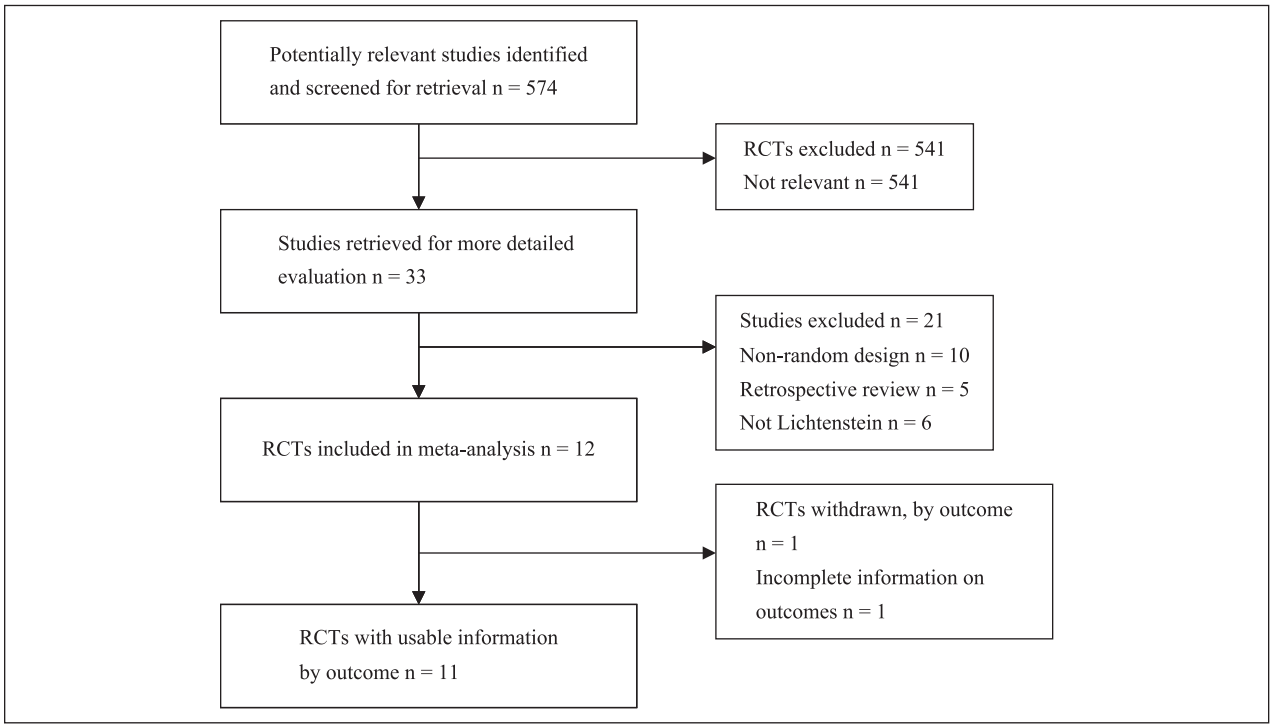

Figure 1. Flow diagram of trial selection

Table 1. Basic Information of the Studies

Study	Type of Inguinal Hernia	Sample Size (L:H)	Experimental Group	Control Group	Outcome[a]	Follow-up
Nikkolo et al[11]	Primary, unilateral	67:64	Opilene; 36 g/m^2; monofilament, polypropylene	Premilene; 82 g/m^2; polypropylene	(2), (3)	6 months
Post et al[12]	Primary, recurrent, unilateral, bilateral	64:53	VYPRO; 27-30 g/m^2; multifilament; with absorbed; polyglactin fibers	Surgipro; 100-110 g/m^2; polypropylene	(1), (2), (3), (5), (7)	6 months
O'Dwyer et al[13]	Primary, unilateral	162:159	VYPROII; 32 g/m^2; multifilament; with absorbed; polyglactin fibers	Atrium; 85 g/m^2; Polypropylene	(1), (2), (6), (7)	1 year
Paajanen[14]	Primary, recurrent, unilateral, bilateral	79:78	VYPROII; 50 g/m^2; multifilament; with absorbed; polyglactin fibers	Polypropylene; 82 g/m^2	(1), (2), (3), (4), (6)	2 years
Śmietański et al[10]	Primary	101:101	Surgimesh; 38 g/m^2; polypropylene	Polypropylene	(1), (2), (4), (8)	5 years
Polish Hernia Study Group and Śmietański[15]	Primary	215:177	Ultrapo	Polypropylene	(1), (2), (4), (6), (8)	1 year
Koch et al[16]	Primary, unilateral	156:161	Timesh; 35 g/m^2; monofilament; titanium coated	Prolene; >80 g/m^2	(1), (2), (7)	1 year
Bringman et al[17]	Primary, unilateral	296:295	VYPROII; <30 g/m^2	Prolene; >80 g/m^2	(4), (5), (6), (8)	2 months
Bringman et al[18]	Primary, unilateral	263:263	VYPROII; <30 g/m^2	Prolene; >80 g/m^2		1 year
Bringman et al[19]	Primary, unilateral	251:243	VYPROII; <30 g/m^2	Prolene; >80 g/m^2	(1), (2), (3), (7)	37 months
Paradowski et al[20]	Primary	25:25	Surgimesh; 43 g/m^2; polypropylene;	Prolene; >80 g/m^2	(1), (2)	1 year

[a]Outcome: (1) recurrence; (2) chronic pain; (3) feeling of foreign body; (4) hematoma; (5) seroma; (6) wound infection; (7) testicular atrophy; (8) urine retention.
Abbreviations: L:H;Light:Heavy

Table 2. Characteristics of Trials Included in the Final Meta-analysis

Study	Randomization	Allocation Concealment	Blinding	Incomplete Outcome Date	Jadad Evaluated
Nikkolo et al[11]	Mentioned random	Sealed envelopes	Not mentioned	Yes	4
Post et al[12]	Computer generated	Sealed envelopes	Double blind	Yes	7
O'Dwyer et al[13]	Computer generated	Unclear	Double blind	Yes	6
Paajanen[14]	Computer generated	Sealed envelopes	Double blind	Yes	7
Śmietański et al[10]	Computer generated	Unclear	Single blind	Yes	5
Polish Hernia Study Group and Śmietański[15]	Computer generated	Unclear	Single blind	Yes	5
Koch et al[16]	Computer generated	Unclear	Double blind	Yes	6
Bringman et al[17]	Computer generated	Central allocation	Single blind	Yes	6
Bringman et al[18]	Computer generated	Central allocation	Single blind	Yes	6
Bringman et al[19]	Computer generated	Central allocation	Single blind	Yes	6
Paradowski et al[20]	Mentioned random	Unclear	Double blind	Yes	5

Note: Jadad scale, also known as the Jadad score or Oxford scoring system , the tools independent evaluate the quality of clinical trial methodological.

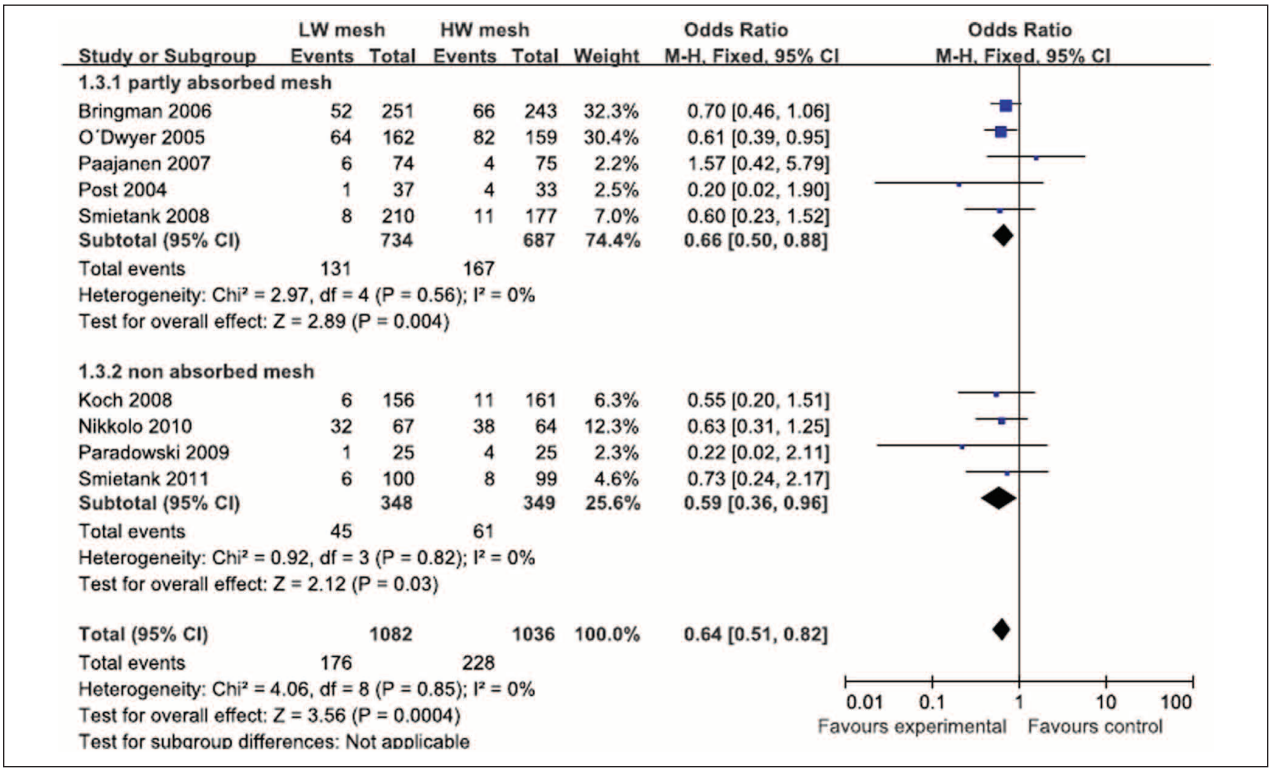

Figure 2. Postoperative chronic pain
Abbreviations: LW, lightweight; HW, heavyweight; CI, confidence interval; MH, mantel-haenszel.

Sensation of a Foreign Body

Four studies were included.[11-12,14,19] Compared with the heavyweight mesh, sensation of a foreign body with a lightweight mesh was significantly lower (OR = 0.56; 95% CI = 0.40-0.78). However, there was no heterogeneity of the studies (P = .21; I^2 = 33%; Figure 4).

Hematoma

In all, 5 studies were included.[10,12,14,15,17] There was no significant difference between the 2 groups for postoperative hematoma formation (OR = 0.77; 95% CI = 0.43-1.35), and there was no heterogeneity in the studies (P = .16; I^2 = 39%).

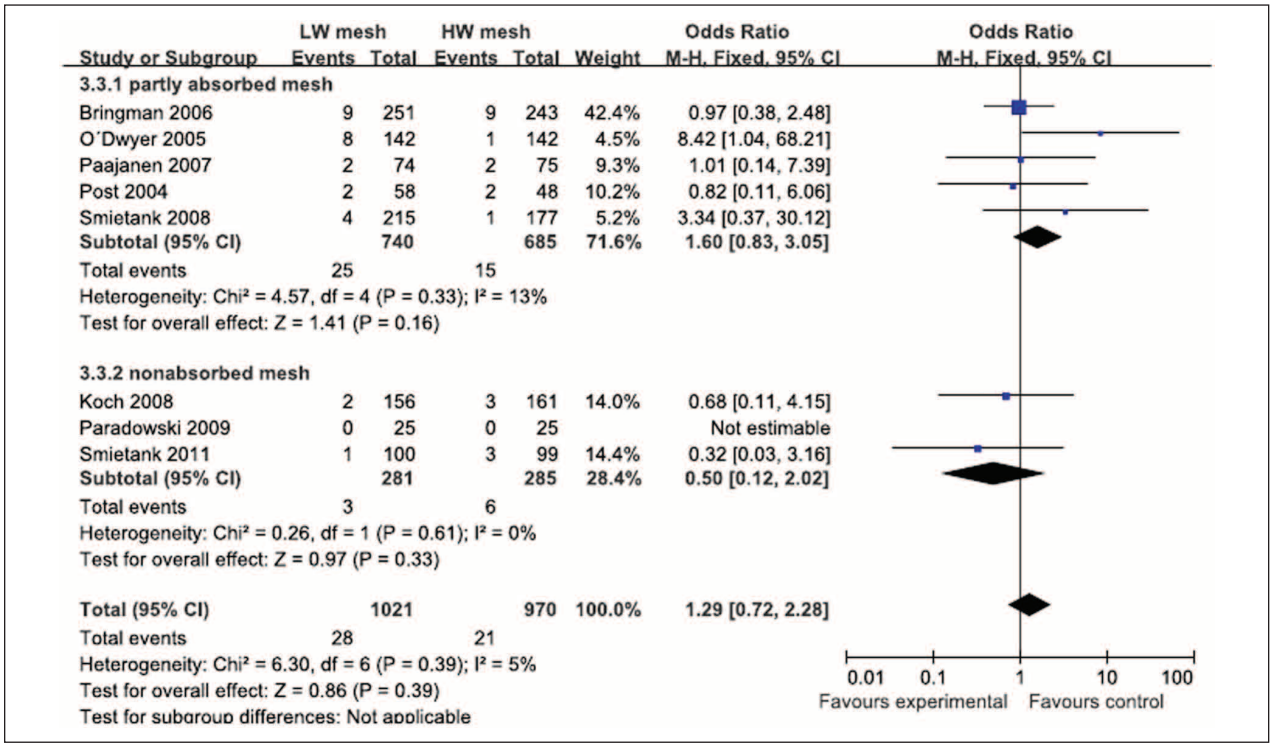

Figure 3. Postoperative recurrence
Abbreviations: LW, lightweight; HW, heavy weight; CI, confidence interval; MH, mantel-haenszel.

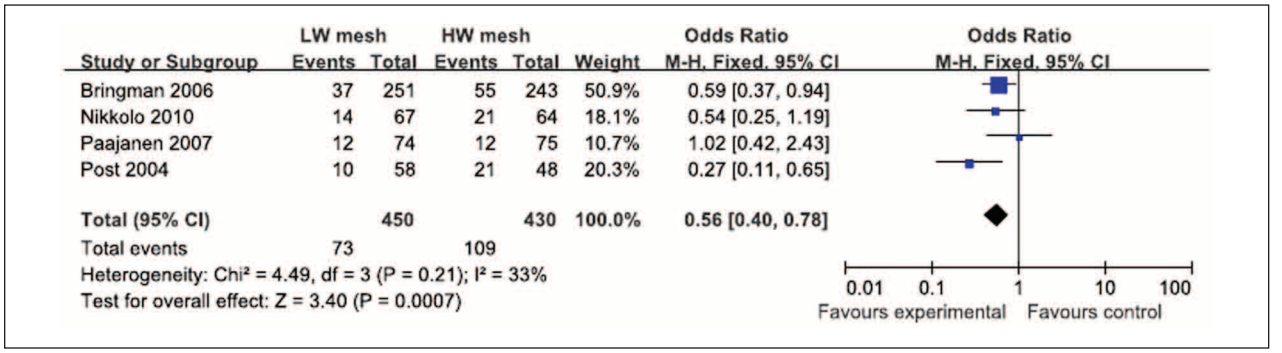

Figure 4. Feeling of foreign body
Abbreviations: LW, lightweight; HW, heavyweight; CI, confidence interval; MH, mantel-haenszel.

Seroma

This was reported in 2 studies.[12,17] The analysis comparing lightweight and heavyweight meshes was not significantly different (OR = 0.89; 95% CI = 0.44-1.79), and there was no heterogeneity in the studies.

Wound Infection

Data from 4 studies were available.[13-15,17] There was no significant difference between the 2 groups for wound infection (OR = 0.69; 95% CI = 0.32-1.46). The heterogeneity was not significant (P = .87; I^2 = 0%).

Testicular Atrophy

In all, 4 studies reported testicular atrophy after surgery.[12,13,16,19] The results show no statistically significant difference between the 2 groups (OR = 1.92; 95% CI = 0.57-6.43). The heterogeneity was not significant (P = .71; I^2 = 0%).

Urine Retention

The main meta-analysis with fixed-effect models from 3 studies illustrated no statistically significant difference between the 2 groups[10,15,17] (OR = 1.74; 95%

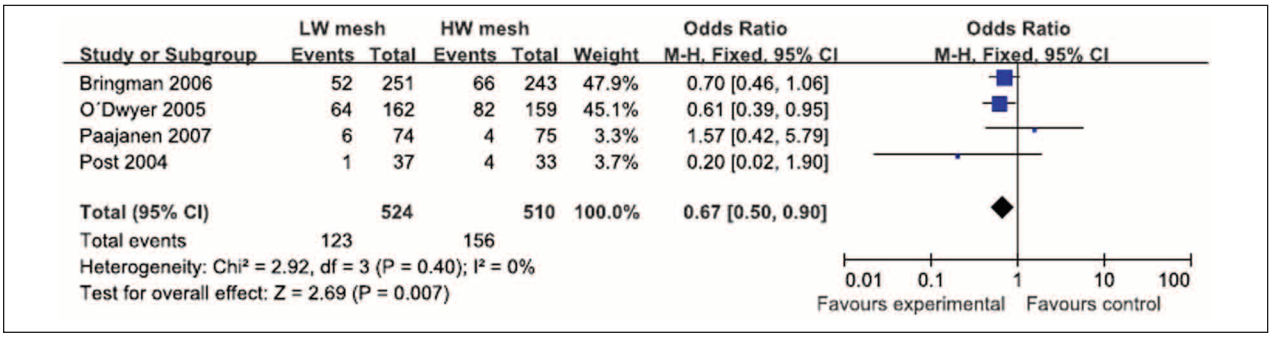

Figure 5. Chronic pain of VYPRO
Abbreviations: LW, lightweight; HW, heavyweight; CI, confidence interval.

CI = 0.69-4.39). The heterogeneity was not significant ($P = .54$; $I^2 = 0\%$).

Discussion

Many concerns have been raised regarding the lightweight mesh in recent years.[21] Proponents argue that these new implants are superior to the conventional polypropylene mesh because they are associated with better biocompatibility, less postoperative pain, and less foreign body sensation. Opponents, however, are still concerned that there is a higher incidence of recurrence owing to the smaller amount of material in the lightweight mesh. This controversy has encouraged a number of investigators to initiate randomized clinical trials in an attempt to address these issues. Two meta-analyses on a similar subject have been published.[22,23] However, comparisons were based on different operative techniques. In our opinion, any change in the operative technique might influence the results. Operative technique was an independent prognostic factor for the clinical outcome, and so to accurately compare the mesh in terms of postoperative parameters, other operative parameters must be unchanged. We restricted the 2 types of meshes to use with the Lichtenstein technique, which is the most popular technique.

No difference in hernia recurrence between the lightweight mesh and heavyweight mesh was demonstrated in this meta-analysis. This is most likely not related to the strength of the repair because the type of lightweight mesh used for these hernia repairs is not related to recurrence rates. It has been demonstrated in animal experiments that reducing the amount of polypropylene still guarantees the necessary mechanical stability,[24] and recent studies have found that the heavyweight mesh was more prone to shrinkage than the lightweight mesh.[25] So even though the lightweight meshes have less material, they can provide the same safety and efficacy as heavyweight meshes. Subgroup analysis found that there were no differences between the partly absorbable and nonabsorbable lightweight meshes in terms of postoperative recurrence rates when compared with heavyweight meshes, which indicates that absorbability has a minor relation to recurrence. However, because the follow-up duration of several outcomes in these trials was not consistent, more rigorous trials would be needed.

Of the 11 trials included in our review,[10-20] 9 reported the presence of postoperative pain.[10-16,19] According to the International Association for the Study of Pain, we defined chronic pain as lasting for longer than 3 months.[26] Pooling these trials revealed an overall significantly lower chronic pain in the lightweight group, regardless of absorbability of the mesh (Figure 2). The results suggest that the weight per surface area of the mesh may be the most important factor in the development of prolonged pain. Klinge et al[27] found that 3 and 12 months after the surgery, the inflammatory response to the lightweight mesh with a reduction of polypropylene to less than 30% of the heavyweight mesh was considerably reduced. Klosterhalfen et al[28] determined that there tends to be an increased prevalence of nerve entrapment with the use of the heavyweight mesh in inguinal repairs. However, Miller et al[29] believe that postherniorrhaphy inguinal neuralgia is not a simple entrapment syndrome but involves additional neuropathic changes resulting from secondary injury from mesh-associated inflammation. In animal experiments, because of a fibroblastic granulomatous reaction, marked inflammatory changes were observed in all specimens. Because a loss of myelinated axons occurred, a chronic inflammatory demyelinating peripheral neuropathy was observed.[30] Contrary to Gao et al,[22] when we compared the VYPRO mesh group with the heavyweight mesh group, a difference in degree of postoperative pain was found (Figure 5). This may be partly a result of the different effects of varied surgical techniques on the postoperative outcome.

Previous meta-analyses have shown that a lightweight mesh leads to less sensation of a foreign body.[22] This finding was universal among the reported trials and was confirmed by the present analysis of all pooled data. Previous animal experiments have confirmed that the inflammatory reaction of the recipient tissues is significantly reduced followed by a reduction in connective tissue formation and increased abdominal wall flexibility[31] with the use of a lightweight mesh, which may explain this result.

There was no significant difference in postoperative complications, such as seroma formation, hematoma, wound infection, urine retention, and testicular atrophy, although there was a tendency toward increased risk of hematoma and wound infection in the heavyweight group. These complications may depend largely on the surgical technique, revealing no obvious material-dependent differences. Continuous outcome variables such as the time to return to work and normal daily activities were reported as medians and variable ranges, and no standard deviations and confidence intervals were available. Therefore, more standardized methods for reporting outcomes based on published recommendations would greatly help future analysis.

Although the quality of life (measured by the Medical Outcomes Study Short-Form 36 Questionnaire [SF-36]) after surgery was an important index, it was given in the form of box plots or bar charts, and data could not be extracted for meta-analysis. Only 3 studies evaluated the quality of life (SF-36) after surgery. In the Bringman and Nikkolo studies, there were no differences in quality of life between the 2 groups, but Śmietański and others found that the lightweight group received a high score in physical function and pain measured after surgery.[11,15,17,18]

The evidence included in this review was limited to RCTs. However, the meta-analysis was adversely affected somewhat by the poor methodology of the studies. Heterogeneity, which represents the variations between different studies of meta-analysis and can be classified into clinical heterogeneity, methodological heterogeneity, and statistical heterogeneity, was noted both within and between studies with respect to the construction of the mesh. Although the included trials all used meshes that were lightweight in terms of weight, the texture of the meshes varied (Optilene, VYPRO, Ultrapo, Surgimesh, and Timesh), and even though the control groups all received the pure polypropylene mesh, results could have been affected. It is recommended that the appropriate organizations determine the characteristics for each mesh. Additionally, in several instances, the outcomes were subjective or easily influenced by the prejudices of the care providers and outcome assessors (eg, clinically significant seromas and hematomas). Furthermore, the variability of clinical factors, including type of hernia and duration of follow-up, all contribute to the heterogeneity encountered in this review. Further affecting the quality of the evidence is the lack of baseline data.

The above notwithstanding, the available evidence suggests that the lightweight mesh in Lichtenstein inguinal hernia repair does not influence recurrence rates but improves chronic pain and the sensation of foreign body. Clearly, a large, multicenter RCT with rigorous methodology and longer follow-up is needed to measure long-term outcomes.

Declaration of Conflicting Interests

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