A meta-analysis of randomized controlled trials of fixation versus nonfixation of mesh in laparoscopic total extraperitoneal inguinal hernia repair

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CRD summary
The authors concluded that non-fixation of the mesh appeared to have been a safe alternative to fixation. It did not increase the risk of early hernia recurrence and appeared to have advantages in terms of hospital stay and operative time. The uncertain quality of the included studies limits the reliability of this review.

Authors’ objectives
To compare the effectiveness and safety of fixation versus non-fixation of mesh in laparoscopic total extraperitoneal inguinal hernia repair.

Searching
PubMed, EMBASE, Science Citation Index databases, Cochrane Central Register of Controlled Trials (CENTRAL) and the Chinese Biomedical Literature Database were searched, without language or publication status restriction, from 1992 to 2010. Search terms were reported. Google Scholar and the reference lists of all relevant studies were scanned for additional articles.

Study selection
Eligible for inclusion were randomised controlled trials (RCTs) that compared mesh fixation with non-fixation in total extraperitoneal inguinal hernia repair in patients (aged over 18 years) with a clinical diagnosis that required surgery. The primary outcomes of interest were hernia recurrence and postoperative pain. Eligible secondary outcomes were length of hospital stay (days), time to return to normal activities (days), operative time (minutes) and seroma. Patients with high anaesthetic risk, previous surgery of the lower abdomen, underlying coagulopathy and mental disorders, were excluded.

Included trials were conducted in Australia, China, the United States, India and Spain. The age range of included patients was between 46 and 61 years. Characteristics of hernias varied (indirect, direct, mixed, femoral and recurrent). Mesh fixation was carried out by staples, tacks or autosuture. All except one of the trials used a polypropylene mesh.

The authors did not state how many reviewers selected the studies for inclusion.

Assessment of study quality
Trial quality was assessed using Cochrane criteria, which covered sequence generation, allocation concealment, blinding, completeness of outcome data, selective reporting and other sources of bias. Authors were contacted for missing information, where necessary.

Two reviewers independently carried out the quality assessment. Disagreements were resolved by consensus involving a third reviewer.

Data extraction
Data were extracted to enable the calculation of risk ratios (RR), odds ratios (OR) or mean differences (MD) with 95% confidence intervals (CI).

Data were extracted independently by two reviewers.

Methods of synthesis
Risk ratios, odds ratios and standardised mean differences (SMDs) were pooled in fixed-effect or random-effects meta-analyses. A random-effects model was used where statistical heterogeneity was found (measured by $X^2$ and $I^2$; and where $I^2$ was greater than 50%). Subgroup analyses were carried out for postoperative pain on different days, and operative time according to bilateral and unilateral groups. Sensitivity analysis was performed by excluding poor-quality
studies. Publication bias was not assessed due to the limited number of included studies.

**Results of the review**

Six trials (772 patients) were included. Follow-up ranged from eight to 36 months. All trials used adequate methods for sequence generation; allocation concealment was reported in three trials; blinding in two trials; there was no loss to follow-up in one trial; two trials reported missing data or loss to follow-up. The overall risk of incomplete outcome data and other biases was unknown.

There were no statistically significant differences between study groups for hernia recurrence (six trials, including two trials for the meta-analysis; $I^2=48\%$; four events were recorded in total; four trials reported no events) or postoperative pain (using the visual analogue scale) on day one or day seven (five trials, three for day one and two for day seven; $I^2=0\%$). Two trials not included in the meta-analysis showed decreased pain in the non fixation group and increased pain in the fixation group. Length of hospital stay was significantly longer in the fixation group (MD -0.37 days, 95% CI -0.57 to -0.17, three trials; $P=0\%$). Operative time was significantly shorter in the non-fixation group (MD -4.19 minutes, 95% CI -7.77 to -0.61; three trials; $I^2=0\%$); statistical significance remained in the subgroup analysis for unilateral hernia (MD -6.60 minutes, 95% CI -12.84 to -0.36; one trial). There were no statistically significant differences between groups for time to return to normal activities (three trials) or seroma (three trials).

Sensitivity analysis did not alter the result for recurrence. Other sensitivity analyses were not conducted due to absence of data.

**Cost information**

Four trials carried out an economic evaluation. Most trials reported lower costs with non-fixation (375 AUD and $120 per patient; two trials).

**Authors’ conclusions**

Non-fixation of the mesh in total extraperitoneal inguinal hernia repair appeared to have been a safe alternative to fixation. It did not increase the risk of early hernia recurrence, and appeared to have advantages in terms of hospital stay and operative time.

**CRD commentary**

The review question was clear and inclusion criteria were sufficiently detail to enable replication. The search strategy included several relevant sources and attempts were made to minimise publication and language biases. Quality assessment and data extraction were carried out with sufficient attempts to minimise error and bias, but this was unclear for the selection of studies. The included trials appeared to have been of limited quality, and this was highlighted by the authors. Study details were presented, and the chosen method of synthesis appeared to have been appropriate. The authors’ conclusion and recommendations for research reflect the evidence presented, but uncertainty regarding the quality of the included studies limits the reliability of this review.

**Implications of the review for practice and research**

Practice: The authors did not state any implications for practice.

Research: The authors stated that RCTs with long follow-up (performed and reported according to the CONSORT statement) were needed to compare non-fixation with fixation of mesh in patients with different defect sizes and types of hernia. The total extraperitoneal operation should be performed by experienced surgeons who were trained before trials to ensure baseline comparability of groups in terms of surgeon learning curves. Loss to follow-up should be sufficiently reported and explained.

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