Metaanalysis of the safety and efficacy of an adhesion barrier (Interceed TC7) in laparotomy

Wiseman D M, Trout J R, Franklin R R, Diamond M P

Authors' objectives
To evaluate the safety and efficacy of an oxidised, regenerated, cellulose adhesion barrier (Interceed TC7) in the reduction of pelvic adhesions.

Searching
MEDLINE was searched from 1989 up to the end of December 1994 (search terms not stated) for published studies. Unpublished manufacturer-sponsored studies were included (not stated how these were identified).

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs).

Specific interventions included in the review
Good surgical technique (not defined) with either no adjuvant treatment (controls) or the barrier (treatment). All subjects underwent laparotomy for gynecologic procedures followed by second-look laparoscopy.

Participants included in the review
Not stated.

Outcomes assessed in the review
Proportion of patients adhesion free at second look on the indicated site. The reduction in the extent of adhesions calculated from the raw surface area after adhesiolysis performed at laparotomy minus the raw surface area after the adhesiolysis performed at laparoscopy (second-look). The change in the severity of lesions was also assessed. Any adverse effects reported by the studies included in the review.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the authors performed the selection.

Assessment of study quality
The authors do not state that they assessed validity.

Data extraction
All data points were independently retrieved from each study report to the extent that the report contained the relevant information.[A:Data was extracted on extent or severity of lesions]

Methods of synthesis
How were the studies combined?
A weighted estimate of the effect of barrier treatment as compared to controls, and the significance of this effect was calculated (authors do not state which method was used to combine studies and whether a fixed-effect or random-effects model was used).

How were differences between studies investigated?
A test for the comparability of the effects among studies was calculated (no details were provided on the test used).
**Results of the review**

Ten studies were included in the review relating to 560 patients. All 10 studies were included in the analysis of safety, data from 7 studies (389 patients) were included in the analysis of the ability of the barrier to reduce the incidence of adhesions and five studies (311 patients) for determining its effectiveness in reducing the adhesion extent. The study sites included ovaries (153 patients), sidewalls (224 patients), fallopian tubes (66 patients), fimbrae (66 patients) and uteri (12 patients).

Overall there was a mean difference of 24.2% (se=3.3) in the incidence of adhesions between the barrier and control groups at second look. The test for heterogeneity (do not state which test) was not significant at the 5% level (p=0.69) suggesting that there was little heterogeneity and thus that it was valid to pool results. The odds ratio was 2.89 (95% CI: 2.15, 3.90) favouring the barrier. The mean difference was in the extent of adhesions between the barrier and control groups was 1.6 cm² (se=0.3). The calculation for effect (raw surface area after adhesiolysis performed at laparotomy minus the raw surface area after the adhesiolysis performed at laparoscopy (2nd look)) was 0.41 (se=0.08, p<0.001) in favour of the barrier. However the test for heterogeneity produced a p-value of 0.03 suggesting that there was significant heterogeneity between the studies. Only 4 adverse effects were reported in the studies considered in the review, none of these events was considered related to the use of the barrier by the investigators.

**Authors’ conclusions**

The barrier is safe and effective in reducing the incidence and extent of adhesions in gynaecologic procedures performed by laporotomy. Approximately twice as many sites were adhesion free after the use of the barrier than after surgery alone.

**CRD commentary**

A poor review of the area. The literature was limited. [A: The field is very small and it is unlikely that any studies would have been missed] Only MEDLINE was searched and the search terms were not presented by the authors. [A:Company sponsored studies were also included.] Inclusion and exclusion criteria were clearly stated. There was insufficient information on what data were extracted from the studies and the methods by which the relevance of the studies were assessed and how data extraction was performed are not presented. The authors did not conduct a validity assessment. The statistical analysis performed was not described in sufficient detail to judge whether it was appropriate. Although heterogeneity was investigated the test used to investigate it was not discussed. The authors conducted a meta-analysis but they not state whether they used a fixed-effect or random-effects model and do not discuss the methods used to combine the studies or exactly what effect size were calculated. Based on these limitations it is difficult to draw any conclusions from the results presented.

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

Practice: The author states that the conclusion from this meta-analysis are limited to those procedures and sites that were included in the study (pelvic sidewall, ovaries and tubes where adhesiolysis and/or other procedures such as removal of endometriosis, ovarian cysts and tubal repair were performed).

Research: Well-controlled studies remain to be performed to demonstrate the utility of the barrier in general surgical procedures such as bowel resection. Further work is required prior to extending the conclusions from this review to the use of the barrier in laparoscopic procedures and to the reduction of outcome-based measures such as bowel obstruction, infertility and pain.

**Bibliographic details**


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