

Efficacy and safety of a resorbable collagen membrane COVA+™ for the prevention of postoperative adhesions in abdominal surgery

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Abstract

Background This clinical study was designed to assess the efficacy and safety of COVA+™, a collagen membrane (CM), for the prevention of postoperative adhesions in abdominal surgery.

Methods This prospective multicenter study concerned one hundred and thirteen patients undergoing two-stage abdominal surgeries between 2011 and 2014: either bariatric surgery (BS) or reversal of a diverting stoma (DS). They were divided into two groups, according to whether a CM was placed at the end of the first procedure or not. The primary endpoint was the evaluation of adhesions (incidence, severity, and extent) on the operative site during the second surgery using standard grading scales and a combined adhesion score. Secondary endpoints were the duration of reoperation and the overall postoperative morbidity.

Results Sixty-five patients were included in the BS group, and forty-eight patients in the DS group. Mean time interval between surgeries was 33.2 ± 51.1 weeks for BS and 14.1 ± 10 weeks for DS. In both indications, results in the CM group were better compared to the control group regarding incidence, severity, and extent of adhesions. Mean combined adhesion scores were lower in the CM

group: respectively, 2.1 ± 1.6 versus 3.6 ± 1.7 ($p < 0.001$) for BS and 1.1 ± 1.7 versus 3.1 ± 2.2 ($p < 0.005$) for DS. In BS group, the operative duration at reoperation was significantly shorter if a CM was used: 56 ± 34 versus 77 ± 47 min ($p < 0.03$). No adverse events related to the use of the CM were observed. Overall complication rate was 13.5 % in the CM group versus 27.9 % in the control group. Ease of handling and application of the CM were rated as satisfying or very satisfying in the great majority of cases.

Conclusions In abdominal surgery, COVA+™ acts efficiently on the prevention of postoperative adhesions with lower incidence, severity, and extent levels. The CM can be used safely and might render reoperations less difficult.

Keywords COVA+™ · Postoperative adhesions · Two-stage abdominal surgery · Adhesion prevention · Bariatric surgery · Diverting stoma

Following surgical interventions with peritoneal trauma, abnormal scar tissue may form between two contiguous peritoneal surfaces that are normally unattached, resulting in definitive adhesion formation [1, 2]. After abdominal and pelvic surgeries, adhesions develop over 90 % of the time [3, 4]. Adhesions are commonly reported after upper and lower abdominal surgeries. For the patients, complications such as bowel obstruction or women infertility may appear overtime and may require reoperations [2, 5–9]. Indirect complications of peritoneal adhesions (such as difficult reoperations, prolonged operative time, pre- and postoperative complications) are also often encountered at surgical reoperations [2]. For example, lysis of adhesions may prolong the operative duration and increase the risk of intraoperative complications such as bleedings [6]. During

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