

A Prospective multi-center registry concerning the clinical performance of laparoscopic colorectal surgery using an absorbable adhesion barrier (INTERCEED®) made of oxidized regenerated cellulose

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Abstrak

ABSTRACT

The aim of this prospective multi center registry was to evaluate the safety and clinical performance of INTERCEED® in laparoscopic colorectal surgery.

Methods

This study was a prospective, multi center, single arm registry wherein patients who received INTERCEED® in laparoscopic colorectal surgery were registered consecutively (UMIN CTR 00001872). The primary outcome was the incidence rate of postoperative adhesive small intestinal obstruction within 6 months. The secondary outcomes were reoperation related to postoperative bleeding and anastomotic leak, surgical site infection (SSI) and anastomotic leak.

Results

Between March 2012 and March 2015, a total of 202 patients were enrolled from six institutions. INTERCEED® was not applied in two patients, so 200 patients were analyzed using the full analysis set population. The incidence rate of postoperative adhesive intestinal obstruction was 1,0% (2/200). The total SSI rate was 3,5% (7/200), the deep incisional SSI rate was 0,0% (0/200), and the organ SSI rate was 0,0% (0/200). The incidence of anastomotic leak was 1,0% (2/200). Reoperation was performed in two cases: one for anastomotic leak and the other as cardiac surgery due to heart disease.

Conclusions

Using INTERCEED® in laparoscopic colorectal surgery is safe and may be useful for preventing postoperative adhesive small intestinal obstruction.