Sealing of gastrointestinal anastomoses with fibrin glue coated collagen patch.

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Abstract:

BACKGROUND: Colorectal cancer (CRC) is the most common cancer of the gastrointestinal tract. In Denmark is CRC the 3. most frequent form of cancer and the 3. leading cause of cancer-related death. Anastomoses: Surgical resection is the only curative treatment of CRC and in Denmark about 85% of patients with CRC are therefore operated. An anastomosis will be established in most cases. Colorectal anastomoses are established in the treatment of benign diseases too, i.e. as part of the surgical treatment of inflammatory bowel disease and in acute surgery. Furthermore anastomoses are conducted in other parts of the gastrointestinal tract i.e. esophagus, stomach, small bowel and bile system. Anastomotic leakage (AL): AL is the most serious complication of gastrointestinal surgery with a 30-day mortality of 13-27%. The reported AL rate ranges from 1 to 39%. In addition to immediate clinical consequences AL is an independent predictor of reduced general and cancer-specific survival. Leakage can manifest as generalized peritonitis, requiring acute resurgery or as a more localized accumulation/abscess or as a subclinical leakage. Sealing of anastomoses: Numerous studies on anastomotic sealing have been conducted with the aim of reducing the number of AL's. The results of these are conflicting and predominantly disappointing. The drug Tacho-Sil (TS) consists of a collagen patch, which on the one side is coated with fibrin glue (FG), which gives it an adhesive property. TS is registered for use in surgical hemostasis. Animal models: Spontaneous AL in animals is infrequent. It is therefore necessary to use a model of AL. No such model exists and must be developed.

OBJECTIVE: To clarify if the sealing of anastomoses with TS is feasible and safe in an experimental design. To develop a standardized model of AL in pigs. To clarify if sealing of colon-anastomoses with TS can reduce the number of clinical ALs in an experimental design. To clarify whether there is evidence that FG influences healing of gastrointestinal anastomosis.

STUDIES: Safety study, that examines whether it is safe to seal anastomoses with a TS. Experimental study on pigs. Two anastomoses on each pig, one sealed with TS. After 1-6 weeks of observation the anastomosis were examined for AL, stenoses, strength and compared microscopic.

RESULTS: No difference between sealed and unsealed anastomosis. This study is completed and published. Model study, to develop model of AL on pigs. A total of 22 pigs had an anastomosis of colon. All anastomoses were left with a standardized defect on 5-21 mm. The pigs were observed in order to assess how big the defect should be before the pigs developed visible leakage and/or fecal peritonitis.

RESULTS: Model developed. 21 mm defect significant. This study is completed and published. Efficacy study, testing if TachoSil can seal an AL and thus prevent that this becomes clinically significant. A total of 20 pigs had a colon-anastomoses with a standardized defect of 21 mm. The pigs were randomized to sealing with TS or no sealing. Re-laparotomy after 7 days examining for visible leakage and/or fecal peritonitis.

RESULTS: TachoSil able to seal the defect ($p=0.0055$). This study is completed and published. Systematic review, with the purpose to study whether there is evidence that FG influence the healing of gastrointestinal anastomosis.

RESULTS: Conflicting. FG does not seem to have an effect. This study completed and published.

CONCLUSIONS: Sealing of GI-anastomosis with TachoSil is safe and feasible. A defect of at least 21mm must be left in colon anastomosis to induce clinical peritonitis. Sealing of defect colon-anastomosis in pigs with TachoSil can prevent clinical leakage and peritonitis. FG has no positive effect on microscopically healing of GI-anastomosis.