Annals of Medicine and Surgery 30 (2018) 1–6

Contents lists available at ScienceDirect

Annals of Medicine and Surgery

journal homepage: www.elsevier.com/locate/amsu

Mid-term absorbable monofilament is safe and effective for gastrointestinal anastomosis – PROMEGAT - A single-arm prospective observational study

Petra Baumann[a,*], Jongwon Kim[b], Sang-Hoon Ahn[c], Hyung-Ho Kim[c], Hoong-Yin Chong[d], Moritz N. Wente[a]

[a] Aesculap AG, Medical Scientific Affairs, 78532, Tuttlingen, Germany
[b] GangNam Severance Hospital, Department of Surgery, Seoul, South Korea
[c] Seoul National University Bundang Hospital, Department of Surgery, Gyeonggi-do, South Korea
[d] University Malaya Medical Centre, Department of Surgery, Kuala Lumpur, Malaysia

ARTICLE INFO

Keywords:
Anastomotic leak
Gastrointestinal tract
Anastomosis
Monofilament suture

ABSTRACT

Introduction: Various suture materials and suture techniques are used to perform gastrointestinal anastomosis after tumour resection, but the best combination is still a matter of debate.

Methods: This multi-centre, international, single-arm, prospective observational study aimed at demonstrating the non-inferiority of a mid-term absorbable monofilament in comparison to braided sutures in gastrointestinal anastomosis. Monosyn suture was used to create the gastrointestinal anastomosis and the frequency of anastomotic leakage until day of discharge was chosen as the primary parameter. The outcome was compared to the results published for braided sutures in the literature. Secondary parameters were the time to perform the anastomosis, length of hospital stay, costs, and postoperative complications.

Results: The anastomosis leakage rate was 2.91%, indicating that Monosyn suture was not inferior to braided sutures used in gastrointestinal anastomosis. Of the reported anastomotic suture techniques, the single layer continuous method was the fastest and most economical technique in the present observational study.

Conclusion: Monosyn suture is safe and effective in gastrointestinal anastomosis and represents a good alternative to other sutures used for gastrointestinal anastomosis. With regard to safety, time and cost-efficiency, the single-layer continuous technique should be considered a preferred method. The transfer of results from clinical studies into daily practice with regard to surgical techniques for gastrointestinal anastomosis should be further evaluated in larger studies or in nationwide registries.

1. Introduction

To maintain the continuity of the gastrointestinal tract (GIT) after an intestinal resection, the construction of a gastrointestinal anastomosis (GIA) is a very important step. Gastrointestinal anastomoses have been performed for more than 150 years [1]. Due to a variety of different approaches, the best suture technique and ideal suture material for performing gastrointestinal anastomosis is still a matter of debate among surgeons. Currently, the single and double-layer technique are used and the suture material is applied using either the continuous or the interrupted suture technique [1–3].

Several studies and meta-analyses have compared the effectiveness of the single-layer versus the double-layer technique for GIA [1–9]. The most significant complication after a GIA is an anastomotic dehiscence at any level along the GIT, followed by a stricture or a sepsis developing due to the failure of the GIA. The results of several studies indicate that the incidences of anastomotic dehiscence, perioperative complication rate and mortality are comparable between the two suture techniques [2,3]. However, the single-layer technique was superior in terms of time to perform the anastomosis [1–3,7,10,11] and was more cost-effective due to a shorter operation time and a lower amount of used suture material. Authors have concluded that the single-layer continuous technique is simple and easy to learn. The technique is reported to be as safe and effective as the double-layer technique or the single-layer interrupted technique [4,10–15]. Furthermore, the single-layer continuous technique has been evaluated as cheaper than stapling [1,3]. It has also been reported that patients receiving the single-layer continuous technique were able to tolerate oral fluids earlier than patients in whom the double-layer technique was used [3]. In addition, the risk of a stricture is lower with the single-layer continuous technique, most probably due to a reduction of ischemia and tissue necrosis compared to the double-layer technique [1]. Therefore, the single-layer

* Corresponding author.
E-mail address: petra.baumann@aesculap.de (P. Baumann).

https://doi.org/10.1016/j.amsu.2018.04.003
Received 5 July 2017; Received in revised form 26 March 2018; Accepted 2 April 2018

continuous technique may be used routinely for GIA within the GIT [1–3].

The hypothesis of this prospective cohort study is that the monofilament mid-term absorbable suture (Monosyn®) used to create gastrointestinal anastomosis is not inferior to braided sutures, which were still in use during the planning phase of the PROMEGAT study, in terms of safety and efficacy.

2. Methods

2.1. Registration and ethics approval

In accordance with the declaration of Helsinki, this observational study was registered with www.clinicaltrials.gov under the registration number [NCT02080702]. The final study protocol has been approved by the ethics committees responsible for the participating clinics (Institutional Review Board of the Seoul National University Bundang Hospital, Institutional Review Board of the University of Malaya Medical Centre). Ethics approval was needed due to national requirements. A clinical study protocol was developed a priori but not published in a peer-reviewed journal.

2.2. Study design

The study was designed as an international, multi-centre, prospective, observational, single-arm study. Enrolment took place between February 2014 and March 2016 at two academic institutions and one community hospital. Of the participating clinics two were located in South Korea (Seoul National University Bundang Hospital, Department of Surgery, Seoul; Gyeonggi-do and GangNam Severance Hospital, Department of Surgery, Seoul) and one in Malaysia (University Malaya Medical Centre, Department of Surgery, Kuala Lumpur). Patients were monitored until day of discharge. The data collection and clarification was completed in May 2016.

2.3. Population and intervention

A population undergoing elective resection in the gastrointestinal tract due to a tumour disease (stomach, small intestine, colon) was recruited.

Patients were treated under routine clinical conditions and the surgical intervention as well as the suture technique used to perform the gastrointestinal anastomosis (GIA) were performed according to the clinic's standard or to the surgeon's preference.

Monofilament, mid-term absorbable suture (Monosyn® manufactured by B. Braun Surgical SA, Rubi, Spain) was applied in all the operations to create the GIA through the following potential suture techniques: single-layer continuous; single-layer interrupted; double-layer continuous inner and interrupted outer; double-layer continuous inner and outer; double-layer interrupted inner and outer. The suture material was applied by senior physicians, consultants and residents who had been trained in, and were familiar with, the use of a monofilament. Monosyn suture 2/0 and 3/0 in combination with a HR needle were used to create the GIA. A perioperative antibiotic prophylaxis was administered to all patients. Subgroup analysis of the anastomosis leakage rate according to the suture technique was performed.

2.4. Inclusion and exclusion criteria

Patients older than 18 years, scheduled for an elective resection in the gastrointestinal tract due to a tumour were eligible for this cohort study. All enrolled patients gave their written informed consent to the scientific analysis of their pseudonymized data set in accordance with the data protection law.

2.5. Exclusion criteria were

- ASA > 3
- Emergency operations
- Surgical interventions in the pancreas, oesophagus and rectum
- Patients with traumatic perforations
- Patients who had received chemotherapy within the last 4 weeks or radiotherapy on the treated region within the last 2 weeks
- Patients who were receiving immunosuppressant therapy.

2.6. Recruitment and follow-up

Patients were recruited from the patient population treated at the participating hospitals as part of daily clinical routine according to the clinic's standard. No additional follow-up visits were performed for this cohort study. On discharge from the hospital, the patient had completed the study.

2.7. Sample size calculation

The study was designed to prove the hypothesis of non-inferiority of a monofilament suture (Monosyn) to a braided suture for gastrointestinal anastomoses, which was still in use at the time point, when the PROMEGAT study was planned. A literature search performed on studies using either a braided or monofilament suture to create a gastrointestinal anastomosis was carried out in 2013. The summary of the studies [1,4–11,16–18] using a braided suture indicated an average anastomotic leakage rate of 8.3% compared to a leakage rate of 2.5% in monofilament sutures [1,6,8,10,12–15,19–31].

The non-inferiority hypothesis was considered proven, if the observed leakage rate for the Monosyn suture was significantly lower than the upper equivalence limit for braided sutures used for GIT. As the latter leakage rate averages 8.3% according to the summarized scientific literature, the upper equivalence limit for braided sutures is 11.3% with an equivalence margin of 3%. For sample size calculation, the expected anastomosis leakage rate in the study group was also set to 8.3%. Using this model, a sample size of 630 patients was calculated to show non-inferiority, using a one-sided binomial test with a significance level of 0.025 and a power of 80%.

2.8. Statistical methods

A one-sided binomial test was used to prove the non-inferiority of the Monosyn suture compared to the standard braided sutures in terms of the leakage rate.

The one-sided test significance level was set to 0.025.

With the inferiority hypothesis rejected, the nested hypothesis of a difference between the observed rate and the reported rate of 8.3% in braided sutures may also be proved without inflation of type 1 error. The analysis was performed using the SAS 9.4 software (SAS Inc., Cary, NC).

Subgroup-analysis of the anastomosis leakage rate according to the type of suture technique was performed.

2.9. Outcomes

An anastomotic leak is considered the standard outcome parameter for judging the efficacy of a GIA. Therefore, this parameter was chosen as the primary outcome and was compared to the results published for braided sutures in the literature. Occurrence of an anastomosis leak was confirmed by diagnostic measures (CT or MRI Scan) or by reoperation. In addition, the time to perform the anastomosis, the postoperative complication rate (peritonitis, wound infection, bleeding, abscess, fistula, perforation, obstipation, stenosis), costs and length of hospital stay were considered secondary outcomes.

This observational study was reported in accordance with the