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RESEARCH ARTICLE

Prophylactic Sublay Mesh Placement During Stoma Closure to Prevent Incisional Hernias: a Pilot Study

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ABSTRACT

Introduction: There are many methods to prevent hernia following stoma closure; however, there is a lack of evidence of the efficacy of prophylactic sublay synthetic mesh placement. This study aimed to investigate the safety of sublay mesh placement during stoma closure.

Methods: Patients with rectal cancer who underwent stoma closure with prophylactic sublay mesh placement following low anterior resection at N.N. Blokhin Cancer Research Center between June and July 2023 were included in this pilot study. The inclusion criteria were age 18-75, TNM stage I-III, and written informed consent. The exclusion criteria included patients with synchronous and metachronous cancers, human immunodeficiency virus, an Eastern Cooperative Oncology Group score of >2, and those undergoing chemotherapy. The sublay mesh placement technique was used, with the endpoints being surgical site infection rate at 30 days, operative time, mesh placement time, and postoperative morbidity (Clavien-Dindo classification).

Results: Ten patients were included in the study. Among them, one patient (10%) had a postoperative surgical site infection, which did not require mesh removal. There was no other morbidity. The median operative time was 105.5 min, whereas the median mesh placement time was 25.5 min.

Conclusion: A low surgical site infection rate makes it possible to consider preventive sublay mesh placement during stoma closure. We initiated a prospective randomized clinical trial after this pilot study (ClinicalTrials.gov, NCT05939687).

Keywords: Hernia, stoma closure, sublay mesh, rectal cancer

Introduction

Up to 20-40% of patients suffer from incisional hernias following stoma closure.[1-3] Approximately 20% of patients require surgical repair of parastomal hernia.[4] There exist many methods to prevent this complication, but there is a lack of evidence of the efficacy of prophylactic sublay mesh placement. The main reasons for the reluctance to use synthetic meshes are increased risk of surgical site infection and the risk of mesh removal in this case.[5] Only one randomized controlled trial on prophylactic biological mesh stoma site reinforcement has been reported, in which the hernia rate at 2 years was 12% in the mesh group and 20% in the control group [odds ratio (OR): 0.62; 95% confidence interval: 0.43-0.90; p=0.012].[6] However, biological mesh is expensive and the inlay method used in the above study may be difficult to reproduce.

Synthetic meshes are more widely available, but no randomized clinical trials have been published on their efficacy in stoma site reinforcement. Not only is the choice of mesh a matter of debate but also the method of placement. The onlay method is considered to be associated with increased surgical site infection risk when used at the stoma site, whereas the sublay method is technically more challenging.[7]

A lack of evidence-based data on the efficacy of mesh placement in patients who underwent stoma closure makes further study of this topic important. The aim of the present research was thus to investigate the safety of sublay mesh placement during stoma closure.

Materials and Methods

In this pilot study, we recruited patients who underwent ileostomy or colostomy closure and prophylactic sublay mesh placement following low anterior resection (open or laparoscopic) for rectal cancer at N.N. Blokhin Cancer Research

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Center between June and July 2023. We included patients aged 18-75 years with stage I-III disease. Written informed consent was a prerequisite for patient inclusion in the study. The study was approved by the N.N. Blokhin Cancer Research Center Ethics Committee (approval number: 35981, date: 16.11.2023). Exclusion criteria were synchronous and metachronous cancers, human immunodeficiency virus, and an Eastern Cooperative Oncology Group score of >2. Patients undergoing chemotherapy were also excluded.

The mesh placement technique in all these cases was as follows. Following colostomy closure, the hernia sack was removed. The space between rectus abdominis muscle and posterior rectus sheath was then opened. Following this, the anterior and posterior rectus sheath were divided before the posterior rectus sheath was sutured. Prior to sublay mesh placement, the size was adjusted according to the available space, with the minimal margin =3 cm. Anterior rectus sheath and skin were also sutured (Figures 1-3).

The primary endpoint was surgical site infection rate at 30 days, whereas the secondary endpoints were operative time, mesh placement time, and postoperative complication rate (Clavien-Dindo classification).

We arbitrarily decided to include 10 patients in the pilot study and deemed that the method would be considered safe for further investigation if the surgical site infection rate was no more than 20% and there were no cases of mesh removal.

Statistical Analysis

Statistical analysis was performed using the SPSS program (IBM SPSS Statistics 26).

Results

Patient characteristics that could affect the prognosis are presented in Table 1. The median age was 61.5 years (range: 45-74). Only one patient had diabetes mellitus and one patient had an American Society of Anaesthesiologists classification of class II. Transrectal stoma placement was used in nine patients and lateral pararectal in one. The median body mass index was 25.05 kg/m^2 (range: 19.2-38.0 kg/m^2). The median mesh size was 63 cm^2 (range: 58-66 cm^2), the median operative time was 105.5 min (range: 69-148 min), and the median mesh placement time was 25.5 min (range: 18-33 min).

One patient (10%) had a postoperative surgical site infection (Clavien-Dindo grade II), which was successfully managed using bedside wound care. There was no other morbidity.

The median follow-up was 10.8 months. No cases of incisional hernias were observed.

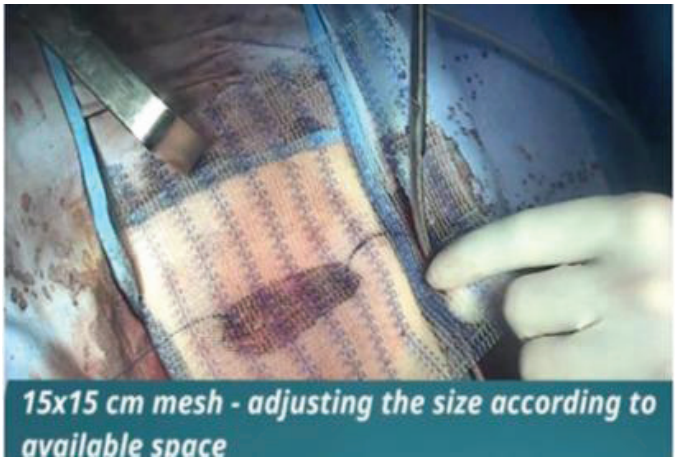

Figure 1. 15x15 cm mesh-adjusting the size according to avaliable space

Discussion

In this pilot study, no increased surgical site infection risk associated with synthetic mesh placement was observed. Mesh placement increased the operative time by 25.5 min. In a systematic review including six comparative studies, there was no significant difference in surgical site infection risk between groups with and without mesh placement (OR: 1.09, p=0.59).[1] The surgical technique was pre-peritoneal mesh

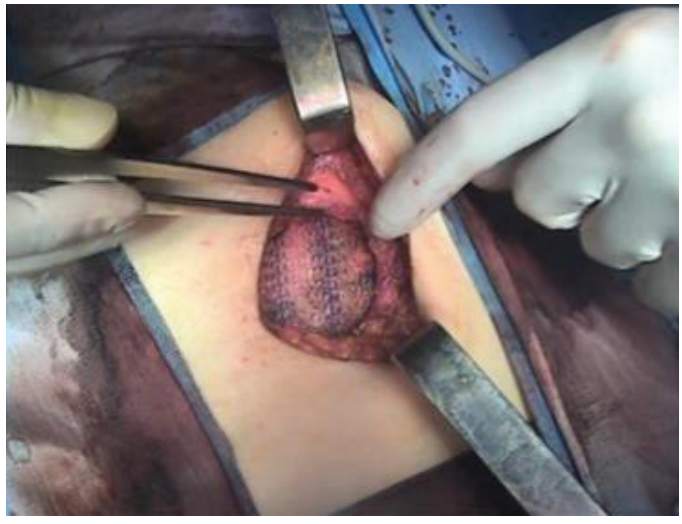

Figure 2. The sublay-installed mesh

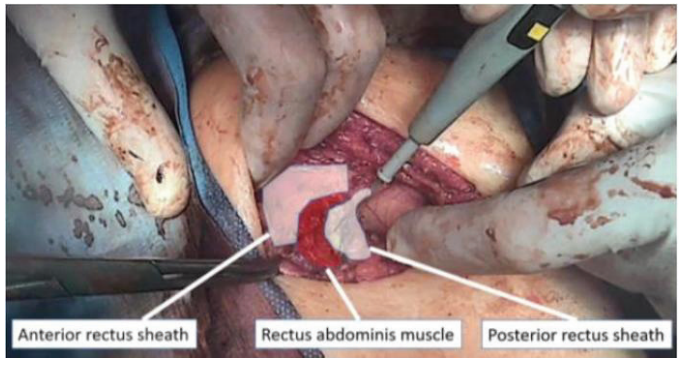

Figure 3. Opening of the space between rectus abdominis muscle and posterior rectus sheath

Table 1. Patient characteristics

Characteristic	Number of patients (n=10)	Percentage (%)
Gender		
•Women	5	50
•Men	5	50
Diabetes mellitus		
•Presence	1	10
•Absence	9	90
Eastern Cooperative Oncology Group score		
•0	7	70
•1	3	30
American Society of Anaesthesiologists classificaton		
•II	9	90
•III	1	10
Stoma type		
•Colostomy	6	60
•Ileostomy	4	40
Stoma placement		
•Transrectal	9	90
•Lateral pararectal	1	10
Surgical site infection		
•Presence	1	10
•Absence	10	100
Postoperative morbidity (Clavien-Dindo classification)		
•0	9	90
•I	0	0
•II	1	10

placement in 59.5% of patients, onlay placement in 23%, and sublay placement in 17.5%. In this review, mesh placement was associated with significantly increased operative time (mean difference: 47.78, p=0.02). In a blinded case-matched study conducted by Maggiori et al.,[8] there were no differences in the wound abscess rate between the sublay mesh placement group (30 patients) and the non-mesh group (64 patients) (7% vs. 5%; p=0.238).[8]

In a randomized clinical trial conducted by Bhangu et al.,[4] the authors observed an identical surgical site infection rate at 30 days in the mesh group (16%; 60/371 patients) and in the non-mesh group (13%; 49/369 patients) (p=0.32).[6]

A retrospective study conducted by Lee et al.[9] compared 15 (45.5%) patients who underwent mesh placement during ileostomy closure and 18 (54.5%) patients who underwent primary ileostomy closure. There were no cases of mesh removal due to mesh-related complications. Two patients (13.3%) in the mesh group and one patient (5.6%) in the primary closure group had a postoperative hernia (p=0.579).

In an unpaired case-control study involving 164 patients, hernia history of parastomal hernia was established as the main risk factor for future hernia development (OR: 5.90, 95% CI: 1.97-17.68).[10] Prophylactic mesh placement may need to be considered only in high-risk patients.

Study Limitations

The main strength of our research is that we used synthetic meshes, which are not well covered in the literature. The limitations of the study are the small sample size and the short follow-up; however, we believe that this was sufficient to determine the safety of the method in a pilot study.

In this pilot study, while we investigated the safety of synthetic mesh placement, the results should be confirmed through a prospective randomized clinical trial. Such a trial has been initiated based on the findings in this pilot study (ClinicalTrials.gov, NCT05939687).

Conclusion

In this pilot study, we obtained important data on the efficacy of sublay mesh placement in patients with rectal cancer who underwent stoma closure following low anterior resection. Prophylactic sublay mesh placement during stoma closure may reduce incisional hernia rates. The results of this research can be used for parastomal hernia prevention.

Ethics

Ethics Committee Approval: The study was approved by the N.N. Blokhin Cancer Research Center Ethics Committee (approval number: 35981, date: 16.11.2023).

Informed Consent: Written informed consent was a prerequisite for patient inclusion in the study.

Footnotes

Authorship Contributions

Surgical and Medical Practices: S.G., N.M., Concept: S.G., Z.M., Design: S.G., Z.M., Data Collection or Processing: Y.B., Analysis or Interpretation: Y.B., Literature Search: Y.B., Writing: Y.B.

Conflict of Interest: No conflict of interest was declared by the authors.

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