Use of Polypropylene Strips for Reinforcement of the Cruroplasty in Laparoscopic Paraesophageal Hernia Repair: A Retrospective Cohort Study

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Keywords
Laparoscopic correction · Paraesophageal hernia · Mesh · Polypropylene strips · Recurrence

Abstract
Introduction: Laparoscopic paraesophageal hernia repair is an effective treatment for symptomatic paraesophageal hernias. To reduce recurrence rates, the use of prosthetics for the crural repair has been suggested. Mesh-related complications are rare but known to be disastrous. To address another form of crural repair, polypropylene strips are suggested. This study aimed to assess peri- and postoperative complications of reinforcement of cruroplasty with polypropylene strips. Methods: From 2013 to 2020, patients with a primary or recurrent type 2, 3, or 4 paraesophageal hernia that underwent cruroplasty with polypropylene strips were retrospectively reviewed. Intra- and postoperative complications were graded according to the Clavien-Dindo classification. The incidence of symptomatic recurrent hiatal hernia (CT or endoscopy proven) and hospital stay were assessed. Results: One hundred fifty-eight patients were included. Mean age was 65 years (standard deviation 10.4), and 119 patients were female (75.3%). Almost 50% of surgeries took place between 2018 and 2020. Median follow-up was 7 months (interquartile range 17.5). Mean operation time in the primary hernia group was 159 min (standard deviation 39.0), and length of stay was 4.4 days. In 3/158 patients (2.0%), intraoperative complications occurred. Two patients developed a grade 4 and seven patients a grade 3 postoperative complication. No mortality was recorded. Twelve recurrences (8.2%) were detected in the primary hernia group and one (9.1%) in the recurrent hernia group. Conclusion: There were no mesh-related complications seen and symptomatic recurrence rate was low, but longer follow-up is needed.

Introduction
Laparoscopic repair of a paraesophageal hernia (PEH) is performed to relieve disabling symptoms and to prevent complications. The majority of patients have satisfactory outcomes [1–4]. However, recurrence rates after 1 year in patients who underwent laparoscopic PEH repair are reported to be 19.4% [5]. To reduce the recurrence rates after laparoscopic PEH repair, the use of prosthetics has been studied. Oelschlager et al. [6] evaluated the use of an absorbable mesh for re-
inforcement of the posterior hiatal closure in a randomized clinical trial. The recurrence rates at 5-year follow-up were 54% in the absorbable mesh group and 59% in the primary suture group. No mesh-related complications were reported. Recently, Oor et al. [5] also published a randomized clinical trial in which non-absorbable mesh closure and suture closure of the hiatal defect were compared. After 1 year, no significant differences in the proportion of recurrent hiatal hernias were found (19.4 vs. 11.4%), and both groups had similar dysphagia and satisfaction scores. No mesh-related complications occurred. Other studies reported similar outcomes for symptomatic recurrence rates and complications [7, 8].

Although studies do not support the routine use of meshes for PEH defect repair, some surgeons feel that mesh is indicated for large PEH repair. However, complications associated with the use of mesh are erosion in the oesophagus or stomach, migration, and oesophageal stenosis due to fibrosis [9]. These complications may be explained by the dynamics of the crural pillars, which induces friction between the mesh and other viscera [9].

To minimize the risk of these mesh related complications, the use of small polypropylene strips to reinforce the cruroplasty has been suggested [10]. The concept of this technique is to induce mesh-related fibrosis and strengthening of the cruroplasty to reduce recurrences, while preventing friction between the prosthetics and viscera. The purpose of the present study was to evaluate perioperative complications and to assess recurrence rate of the polypropylene strip-reinforced cruroplasty (PSRC) technique.

Materials and Methods

This retrospective observational study was conducted according to the STROBE and STROCSS statements [11, 12].

Study Design

All patients who underwent primary or recurrent laparoscopic hiatal hernia repair with PSRC in a non-academic referral (the Alrijne) hospital in the Netherlands between 2013 and 2020 were identified from the hospital records. The Local Ethics Committee of the Alrijne hospital approved the study protocol. Study data analysed were stored on the server of the Alrijne hospital.

Patients with a primary or recurrent symptomatic type 2, 3, or 4 PEH were included, confirmed by preoperative endoscopy and barium swallow test and/or CT. Patients were excluded if they had an American Society of Anaesthesiologists (ASA) classification of >3, did not wish to receive PSRC, received other strips than polypropylene strips, were pregnant, had an emergency procedure, or were younger than 18 years of age. The type 1 hiatal hernias were excluded considering the different epidemiology, pathophysiology, and relatively small hernia sizes.

Patients were first seen at the outpatient clinic by a surgeon who performed all surgical procedures (W.H.) and a gastroenterologist. Gastroscopy, barium swallow test, and/or a CT were performed. All patients were discussed at a multidisciplinary team meeting with the surgeon, a dedicated gastroenterologist, and a radiologist. Oesophageal manometry was performed if there was suspicion of motility disorders after multidisciplinary consultation. The use of the polypropylene strips was part of the standard care, and patients were informed about the use of prosthetic strips. Recurrent PEH was only included when the first operation was performed without PSRC before 2013 or when patients were referred from another hospital.

The medical records of each patient were retrospectively reviewed to assess patient characteristics (sex, age at surgery, BMI, and ASA classification). Hernia characteristics (type of hiatal hernia), surgical characteristics (operation time, length of stay [LOS], type of mesh, and number of strips used), intraoperative complications, and postoperative outcomes (recurrence, dysphagia, and return of proton pump inhibitor [PPI] use) were assessed during follow-up appointments.

Surgical Procedure

All procedures were performed using a standardized laparoscopic technique under general anaesthesia. Antibiotic prophylaxis was given 30 minutes before skin incision (cefazolin 1 g and metronidazole 500 mg). The first step was dissection and reposi-

Fig. 1. Polypropylene strips created from a standard polypropylene mesh (Prolene).
Crural Repair

Polypropylene strips of 3 cm in length and 1 cm in width were cut from a standard polypropylene mesh (Prolene; Ethicon Inc., Somerville, NJ, USA) or a polypropylene mesh with coating to prevent adhesion formation (C.R. Bard, Murray Hill, NJ, USA) (Fig. 1). The posterior crural repair was performed with woven non-absorbable sutures (Ethibond; Ethicon Inc., Somerville, NJ, USA). First, the suture was brought through the strip (Fig. 2a) and then through the left crural pillar (Fig. 2b), the right pillar (Fig. 2c), and back through the strip again (Fig. 2d). A knot pusher was used to get tactile feedback of the tension of the reinforcement, making sure the strips are stitched tension free to the crural pillars. The number of strips used was determined intraoperatively by strip-by-strip approximation. This enabled the surgeon to perform the repair for all 3 types of PEH. The most ventral sutures were tied without using a strip to avoid direct contact with the oesophagus. Normally, one suture was used for the ventral side. If the ventral hiatus was deemed too wide still, another suture was used to approximate the defect. In addition, a 270° posterior Toupet fundoplication was performed to avoid reflux and to reinforce the posterior crural repair.

The fundoplication was created by placing two sutures between the wrap and suturing this against the strips and the crural pillars, achieving a firm attachment (Fig. 3a). The middle section of the fundoplication was sutured to the right side of the oesophagus (Fig. 3b), and the left side of the fundoplication stitches was stitched to the left side of the oesophagus, with exception of the most cranial suture, which was placed to the left side of the diaphragm (Fig. 3c). By fixating the fundoplication on to the polypropylene strips, friction was avoided between the polypropylene strips and the oesophagus (Fig. 3d).

Outcomes

Because of the difference in patient outcomes and surgical risks between the PEH repair and recurrent PEH repair, these two groups were analysed separately. The primary outcome was
perioperative complications categorized according to the Clavien-Dindo classification for surgical complications [13]. When the intraoperative and postoperative complications were comparable to other studies reported in the literature and not related to the use of mesh, the PSRC technique was considered a safe procedure.

Secondary outcomes were LOS (in days), operation time (in minutes), persistent dysphagia (defined as dysphagia for solids lasting >1 year), return to PPI use, and recurrences. A recurrence was defined as a symptomatic herniation of the stomach or other abdominal organs in the mediastinum or the presence of a new PEH as diagnosed by gastroscopy or a radiological modality (i.e., barium swallow test or CT). Symptoms or signs that led to radiological or gastroscopic investigation were no resolution of preoperative symptoms, progressive retrosternal pain, dysphagia, reflux, and return of symptoms after heavy coughing.

**Follow-Up**

Patients were seen two and six weeks after the operation. No routine barium swallow test, gastroscopy, pH monitoring, or manometry was done. When patients did not develop new symptoms and were satisfied, they were discharged from further follow-up.

Patients were instructed to contact the hospital if new symptoms emerged. A barium swallow test was performed in patients who experienced lasting symptoms after the 6-week follow-up appointment. If this barium swallow test showed a normal anatomy, another appointment was made after three months. In case of persistent symptoms after three months, the patient was referred to a multidisciplinary consultation team, and a gastroscopy and/or CT scan was performed. If no clear pathology was found, an additional oesophageal motility and pH monitoring investigation was performed.

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**Fig. 3.** Fundoplication as a natural barrier for the oesophagus. The caudal right side of the fundoplication being sutured to the crural pillars and the strips (a), the middle section of the fundoplication was sutured to the right side of the oesophagus (b), the most cranial suture of the left side of the fundoplication was sutured to the left side of the diaphragm (c), and fundoplication acting as a natural barrier (d).
Statistical Analysis

Statistical analysis was performed with SPSS software version 26 (IBM SPSS Statistics for Mac version 26; IBM Corporation, Armonk, NY, USA). Continuous variables are presented as median and interquartile range or median. Discrete variables are presented as absolute numbers and percentages.

Results

A total of 380 patients underwent laparoscopic hiatal hernia surgery between 2013 and 2020. One hundred seventy patients were excluded because they had a type I hiatal hernia, eight patients who had a redo after PSRC, and two patients had a Morgagni-type hernia. Another 40 patients were excluded because they did not receive PSRC, and two patients were excluded because they received bio-absorbable strips, leaving 158 patients for review (Fig. 4). Patient characteristics are shown in Table 1. The most prevalent type of paraesophageal hernia was a type 4 hernia in 79 patients (50.0%). Median follow-up was seven months with an interquartile range of 17.5 months.

Surgical Characteristics

Almost 50% of the surgeries took place at the start of 2018. Mean operation time was 159 min (SD 39.0 min), and mean LOS was 4.4 days (SD 2.9 days), shown in Table 2. In most procedures, 3 strips were used for reinforcing the cruroplasty (40.8%), and a Prolene mesh was used most often to construct the strips (96.6%). Two conversions (1.4%) to an open procedure occurred: one conversion because of a lesion to the oesophagus and one conversion because of severe adhesions in the upper abdomen.

Perioperative Complications

Three intraoperative complications occurred during the PSRC surgeries, including a lesion of the oesophagus which required a conversion to an open procedure and
primary closure (Table 3). All patients recovered without further sequelae.

There were three patients with a grade 4 complication and seven patients with a grade 3 complication (Table 3). All patients fully recovered. The grade 1 and grade 2 complications included antibiotic and heparin treatments, requirement of additional analgesia, and obstipation.

Postoperative Symptoms

The postoperative symptoms, recurrence rate, return to PPI use, and dysphagia are shown in Table 4. Twenty-eight patients reported recurrence-like symptoms (Fig. 4). These patients were seen at the outpatient clinic and underwent radiological and/or endoscopic investigation. Twenty-five (15.8%) of the patients reported PPI use after the operation, and four patients reported having persistent dysphagia (2.5%).

Symptomatic Recurrences

Thirteen patients developed a symptomatic recurrence (8.2%). Seven recurrences occurred in the PEH type 4 group (4.8%), 5 in the type 3 group (3.3%), and 1 (0.6%) in the redo group (type 4). Symptoms leading to investigation consisted of epigastric discomfort, reflux complaints, dyspnoea, and dysphagia.

Four patients received four strips, another four patients three strips, three patients two strips, one patient five strips, and one patient one strip. Six patients were diagnosed by a CT scan, another six with a barium swallow test, and one patient during gastroscopy. Mean time to discovery of the recurrence was 22.3 months.

Discussion

This retrospective cohort study evaluated perioperative complications and short-term recurrence of the PSRC technique in PEH surgery and showed a low rate of intraoperative complications (1.9%), as well as low symptomatic recurrence rate (8.2%). Intraoperative complications occurring during primary PEH mesh-reinforced cruroplasty have been reported to be 7.3% and 4.8% in the

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**Table 1. Baseline characteristics for patients with PSRC**

| PSRC          | N = 158 (%) |
|---------------|-------------|
| Sex           |             |
| Male          | 39 (24.7)   |
| Female        | 119 (75.3)  |
| Age, years    | 65 (10.4)   |
| BMI, kg/m²    | 29 (4.3)    |
| ASA classification |        |
| 1             | 9 (5.7)     |
| 2             | 104 (65.8)  |
| 3             | 45 (28.5)   |
| Type of paraesophageal hernia | |
| Type 2        | 11 (7.0)    |
| Type 3        | 57 (36.1)   |
| Type 4        | 79 (50.0)   |
| Redo of paraesophageal hernia | |
| Type 2        | 4           |
| Type 3        | 4           |
| Type 4        | 3           |
| Follow-up, months | 7 (17.5) |

Continuous variables are presented as mean and SD, except for follow-up, which is presented as median with IQR. Discrete variables are presented as absolute number and percentage. ASA, American Society of Anaesthesiologist; PSRC, polypropylene strip-reinforced cruroplasty.

| Type 2, 3, or 4 paraesophageal hernia | N = 147 |
|--------------------------------------|--------|
| Operation time, min                 | 159 (39.0) |
| Strips used for cruroplasty, n       |         |
| 1 strip                              | 22 (15.0) |
| 2 strips                             | 34 (23.1) |
| 3 strips                             | 60 (40.8) |
| 4 strips                             | 26 (17.7) |
| 5 strips                             | 4 (2.7)   |
| Type of mesh for strips used         |         |
| Prolenea                             | 142 (96.6) |
| Ventralightb                         | 2 (1.4)  |
| Seprameshb                           | 3 (2.0)  |
| Conversion to open procedure         | 2 (1.4)  |
| LOS, days                            | 4.4 (2.9) |

**Table 2. Surgical characteristics for patients with PSRC**

| PSRC          | N = 158 (%) |
|---------------|-------------|
| Type 2, 3, or 4 paraesophageal hernia | N = 147 |
| Operation time, min                 | 159 (39.0) |
| Strips used for cruroplasty, n       |         |
| 1 strip                              | 22 (15.0) |
| 2 strips                             | 34 (23.1) |
| 3 strips                             | 60 (40.8) |
| 4 strips                             | 26 (17.7) |
| 5 strips                             | 4 (2.7)   |
| Type of mesh for strips used         |         |
| Prolenea                             | 142 (96.6) |
| Ventralightb                         | 2 (1.4)  |
| Seprameshb                           | 3 (2.0)  |
| Conversion to open procedure         | 2 (1.4)  |
| LOS, days                            | 4.4 (2.9) |

Redo of paraesophageal hernia recurrence     | N = 11 |
| Operation time, min                     | 159 (21.8) |
| Strips used for cruroplasty, n           |         |
| 1 strip                                | 4 (36.7)  |
| 2 strips                               | 7 (63.3)  |
| Type of mesh for strips used            |         |
| Prolenea                               | 10 (90.9) |
| Marlex                                 | 1 (9.1)   |
| LOS, days                              | 3.7 (2.6) |

Continuous variables are presented as mean and SD. Discrete variables are presented as absolute number and percentage. PSRC, polypropylene strip-reinforced cruroplasty; LOS, length of stay. a Prolene; Ethicon Inc., Somerville, NJ, USA. b C.R. Bard, Murray Hill, NJ, USA.
study by Watson et al. [8] and 5.6% in the study by Oor et al. [5]. The intraoperative complication rate of primary suture cruroplasty was reported to be 8.3%, 7.0%, and 18% [5, 6, 8]. The intraoperative complication rate in the primary PEH group was 2/147 (1.3%), and the complications were not related to the PSRC technique itself. This could indicate that the PSRC technique used in this study could be regarded as a safe and feasible operative procedure.

Postoperative complications occurring after prosthetic reinforced cruroplasty are reported to be 11.7% in a study which analysed outcomes from a national database with almost 9,000 patients [14]; however, type of hiatal hernia was not reported. Other similar studies reported incidences of 10–27% [6, 8]. Our study included minor complications including patients who needed additional analgesia or had problems with obstipation. The incidence of a grade 4 complication in our study was low (1.4%).

The use of polypropylene strips to reinforce the cruroplasty has been investigated before by Granderath et al. [10]. They reported no intraoperative complications, no symptomatic and radiological recurrences, no mesh-related complications, or other complications in twelve patients six months after surgery. The use of meshes in PEH repair is still controversial, as severe mesh-related complications have been reported (e.g., mesh erosion, infection, and oesophageal stenosis requiring re-interventions) [9]. It is hypothesized that migration of the mesh at the hiatus may occur due to intermittent (coughing and straining) or ongoing (breathing) diaphragmatic contractions and relaxations [9]. Therefore, routine mesh fix-

**Table 3. Perioperative complications after PSRC**

| Type 2, 3, or 4 with PSRC | N = 158 (%) |
|--------------------------|------------|
| Intraoperative complications | 2 (1.3) |
| Bleeding of preperitoneal lipoma | 1 |
| Lesion to the oesophagus | 1 |
| Postoperative complicationsa | 45 (30.6) |
| Grade 1 | 23 (15.6) |
| Grade 2 | 13 (8.8) |
| Pneumonia requiring antibiotics | 9 |
| Pulmonary embolism | 2 |
| Splenic emboli | 1 |
| Delirium | 1 |
| Grade 3a | 5 (3.4) |
| Drainage of subphrenic abscess | 1 |
| Respiratory acidosis | 1 |
| Haematema | 1 |
| Nasogastric tube feeding due to severe dysphagia | 2 |
| Grade 3b | 2 (1.4) |
| Rupture of diaphragm | 1 |
| Respiratory insufficiency | 1 |
| Grade 4 | 2 (1.4) |
| Acute renal failure requiring ICU monitoring | 1 |
| Systematic inflammatory response syndrome | 1 |

| Redo of paraesophageal hernia with PSRC | N = 11 |
| Intraoperative complications | 1 (15.4) |
| Subscapular bleeding of the liver | 1 (9.1) |
| Postoperative complicationsa | 3 (27.3) |
| Grade 1 | 1 (9.1) |
| Grade 2 | 2 (18.2) |
| Pneumonia requiring antibiotics | 1 |
| Blood transfusion after subscapular bleeding of the liver | 1 |

Continuous variables are presented as mean and SD. Discrete variables are presented as absolute number and percentage. PSRC, polypropylene strip-reinforced cruroplasty.

a Graded with the Clavien-Dindo classification of postoperative complications (4).
Paraesophageal Hernia Repair with Strips

Paraesophageal hernia repair with strip reinforcement does not advise to cover the crural defect. The concept of using polypropylene strips for crural reinforcement was small and placed dorsally on the crural pillars. Second, the purpose of placing the strip was to evenly spread tension on the stitched crural pillars. Third, polypropylene causes fibrosis, and this may strengthen the cruroplasty. Fourth, the strips secured a tight connection of the fundoplication with the pillars. The technique that was used in this study prevents erosion of the strips to the gastric wall and oesophagus during movements or traumatic events. Furthermore, peritoneal overgrow on the right crural pillar is seen in patients operated for a recurrence and may prevent contact from the strip with other abdominal viscera. In this study, no mesh-related complications (i.e., oesophageal stenosis, mesh infection, or migration) were observed.

The cost of a Prolene (Ethicon Inc., Somerville, NJ, USA) mesh was EUR 15, in this hospital. The bio-resorbable meshes used in some studies may have a lower risk for mesh-related complications; however, these are expensive. The cost of a Phasix (C.R. Bard, Murray Hill, NJ, USA) mesh was around EUR 500. Furthermore, the long-term follow-up recurrence rates seen in the study by Oelschlager et al. [6] are almost comparable to those with primary suture cruroplasty. In a meta-analysis of randomized controlled trials of Memon et al. [7], a total of 215 patients with prosthetic reinforced cruroplasty in large hiatal hernias were analyzed, and 35 recurrences were objectified (16.3%). One hundred eighty-two patients that underwent primary suture repair were also analyzed, and 50 recurrences (27.4%) were found. In another meta-analysis of Campos et al. [15], no evidence was found that routine mesh reinforcement in laparoscopic repair of giant PEH decreases recurrences, compared to suture repair ($p = 0.12$). Finally, the study by Watson et al. [16] also suggests that mesh reinforcement does not significantly reduce recurrence rates. The short-term recurrence rate found in the present study is low (8.2%). This could be explained due to the fact that no standard postoperative radiological follow-up was scheduled and indicates that some paraesophageal recurrences were asymptomatic or mildly symptomatic not seeking medical attention. However, patients were clearly instructed to see us at the outpatient clinic in case of recurrent symptoms.

One of the complications after laparoscopic PEH repair and especially with use of mesh is persistent dysphagia. This may occur after the use of non-absorbable prosthetics due to fibrosis around the oesophagus [9]. The contact of meshes with the oesophagus should therefore be avoided [9]. However, since the hiatus is a dynamic anatomical structure, complete prevention of mesh contacting the oesophagus is difficult [9, 17]. The short-term incidence of postoperative dysphagia in non-resorbable prosthetic reinforced cruroplasty is reported to be 17.5–23.5% [5, 8, 18]. In a study by Dallemagne et al. [19], the occurrence of persistent dysphagia was approximately in 3% of cases 5 years after surgical treatment of gastro-oesophageal reflux disease by laparoscopy. They did not use prosthetics to reinforce the cruroplasty. The incidence of persistent dysphagia in this study is reported to be 2.0%, which was lower, and with the use of prosthetics. However, no use was made of validated dysphagia questionnaires.

This study has some limitations. No pre- or postoperative validated questionnaires were used to assess the pre- and postoperative symptoms of the patients. Another limitation was the lack of standardized follow-up appointments, including barium swallow studies. Since >50% of the surgeries took place between the end of 2017 and 2020, follow-up duration was limited. This may have led to an underestimation of the recurrence rate. However, one of the reasons the recurrence rate in this study is low could be the multidisciplinary consultation meeting. Comorbidities, preoperative tests, and conservative pharmaceutical treatment were discussed before making the decision to perform surgery. By accomplishing these consultations, a patient population was formed that

**Table 4. Postoperative symptoms after PSRC**

| Type 2, 3, or 4 with PSRC | N = 158 (%) |
|---------------------------|-------------|
| Recurrence                | 12 (8.1)    |
| Type 2                    | 0           |
| Type 3                    | 5 (3.4)     |
| Type 4                    | 7 (4.8)     |
| Return to PPI use         | 21 (14.3)   |
| Persistent dysphagia      | 3 (2.0)     |

**Redo of paraesophageal hernia with PSRC**

| N = 11 |
|--------|
| Recurrence | 1 (9.1) |
| Type 4     | 1 (9.1)  |
| Return to PPI use | 4 (36.4) |
| Persistent dysphagia | 1 (9.1) |

Continuous variables are presented as mean and SD. Discrete variables are presented as absolute number and percentage. PPI, proton pump inhibitor; PSRC, polypropylene strip-reinforced cruroplasty.

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would benefit the most out of this surgery and therefore aimed to minimize the postoperative complaints and complications.

**Conclusion**

The findings from this study show a low incidence of perioperative complications after PEH repair with PSRC. Complications were not related to the PSRC technique itself. The short-term recurrence rate was low, as was dysphagia after surgery, and no mesh-related complications were observed. Longer follow-up is needed to affirm low recurrence rates. The use of small polypropylene strips to reinforce the cruroplasty is a promising concept and a safe and feasible technique.

**Statement of Ethics**

All authors comply that this research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. The local ethics committee reviewed and approved the study protocol (Reference No. NWMO 20-07). Furthermore, the Local Ethics Committee of the Alrijne hospital stated that no informed consent of individual patients was required for the retrospective data collection for this study. All patients under treatment in the Alrijne hospital automatically give informed consent to use their anonymized medical data for research purposes, if standard care is given.

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**Conflict of Interest Statement**

L.M. Van den Dop, MD, G.H.J. De Smet, MD, A. Mamound, MD, J. Lange, MD, PhD, B.P.L. Wijnhoven, MD, PhD, and W.E. Hueting, MD, PhD, have no conflicts of interest of financial ties to disclose.

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**Author Contributions**

Van den Dop was involved in data assembly and writing of the manuscript. De Smet wrote the manuscript. Mamound edited and corrected the manuscript. Lange edited and corrected the manuscript. Wijnhoven edited and corrected the manuscript. Hueting performed surgeries, editing, and correcting of the manuscript.

**Data Availability Statement**

Due to privacy and ethical concerns, the data can not be made publically available.
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