Prophylactic Mesh Placement for Preventing Parastomal Hernia in Patients Receiving a Bricker Ileal Conduit at Örebro University Hospital

UNIVERSITY OF GOTHENBURG
Prophylactic Mesh Placement for Preventing Parastomal Hernia in Patients Receiving a Bricker Ileal Conduit at Örebro University Hospital

Master Thesis in Medicine

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Programme in Medicine

Gothenburg, Sweden 2014
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ABSTRACT

Master thesis in medicine, Programme in Medicine, Sahlgrenska Academy, Gothenburg, Sweden

Title:

Prophylactic Mesh Placement for Preventing Parastomal Hernia in Patients Receiving a Bricker Ileal Conduit

Author, Year: Oskar Fagerström, 2014

Institution: School of Health and Medical Sciences, Department of Urology, University of Örebro, Örebro, Sweden

Background:

Parastomal herniation is a common complication occurring after construction of stomas and may require additional medical resources and affects the patient’s quality of life. Surgical techniques for repairing parastomal hernias show less than ideal results with high recurrence rates and morbidity. Studies regarding stomas in colorectal surgery have shown a decreased incidence of parastomal hernia using a prophylactic mesh net reinforcement of the abdominal wall at the primary stoma operation. The pathophysiological mechanisms for occurrence of parastomal hernia in urinary diversions such as the Bricker ileal conduit are likely similar and therefore allow for similar prophylactic measures but up to this date there are no studies on the subject.
**Aims:**

The primary aim of this project is to compare the frequency of parastomal hernia in patients receiving a Bricker ileal conduit at the urology department of Örebro University Hospital with or without the placement of a prophylactic mesh.

As a secondary aim the rate of stoma related complications in patients receiving prophylactic mesh will be reviewed.

**Method:**

A retrospective review of urological, surgical and emergency medical records for 40 consecutive patients who did not receive prophylactic mesh reinforcement and 42 consecutive patients who did receive mesh reinforcement of the abdominal wall during primary Bricker conduit construction was conducted. Appurtenant radiological records were also reviewed. Statistical comparative and descriptive analyses were performed on collected data using IBM SPSS.

**Results:**

A total of 82 patients’ medical records were reviewed. 40 patients did not receive prophylactic mesh implantation and 42 had the implantation, retaining two homogenous groups with no significant demographic differences (table 1). 19 (23%) patients developed parastomal hernias in a mean time of 16 months without any significant difference in frequency between the mesh and no-mesh group. There were no significant frequencies of mesh related complications, namely wound infection (1 patient), stomal necrosis (1 patient) or stomal stenosis (3 patients). The patients who developed parastomal hernias were found to have a significantly higher BMI than those who did not.
Conclusion:

This master thesis project failed to identify prophylactic mesh placement as a method of reducing the frequency of parastomal hernias in patients with Bricker ileal conduits. High BMI was identified as a significant risk factor for hernia development.

Due to the low power of this study no applicable conclusions can be made. Nevertheless it highlights the need for further, larger and prospective randomized studies of the subject.

Keywords: Parastomal hernia, prophylactic mesh, Bricker ileal conduit, urostomy, parastomal complications

BACKGROUND

For patients with severe bladder or urinary tract disease, or following removal of the bladder usually due to invasive bladder cancer, the normal flow of urine must be rerouted. This is achieved through the construction of a urinary diversion. There are several ways to surgically create a urinary diversion of which a majority requires the formation of a stoma, an opening which connects part of the body cavity to the outside environment. Constructing a urinary diversion is a major surgery and data from The Swedish Urinary Bladder Cancer Registry show that a majority of patients having radical cystectomy and urinary diversion have not insignificant co-morbidities [1].

For patients undergoing radical cystectomy in Sweden, the Bricker ileal conduit was the most commonly used urinary diversion at 83% in 2011 [1]. In a review of outcomes and complications with urinary diversion after radical cystectomy, Lee et. Al. found ileal conduits to be “the fastest, easiest, least complication-prone and most commonly performed urinary diversion” [2].
The ileal conduit

The ileal conduit, or Bricker ileal conduit, is a urologic surgical procedure for creating a permanent urinary diversion. A 12-18 cm segment of small bowel from ileum is isolated, length depending on the physical characteristics of the patient as to prevent a short ileal segment leading to stretching of the stoma or the mesentery, causing stretching of the vessels impairing the blood supply, while still limiting the length as to retain as much bowel as possible. Corresponding mesentery is incised and spared to allow for appropriate blood flow to the detached ileal segment. The procedure of incising the mesentery must be carefully performed as to prevent vascular damage as well as openings in the mesentery allowing for possible internal herniation. Following this the ureters are isolated from their retro-peritoneal location and the left one is brought over to the right-side intra-peritoneal space. Here the ureters are anastomosed to the proximal end of the ileal segment to allow for the bowels peristaltic movement to be directed towards the cutaneous stoma. Catheters, placed in each ureter and removed a few days postoperatively, allow healing of the uretero-ileal anastomosis. To finalize the procedure, the distal end of the ileal segment is exteriorized by making a small circular incision in the wall of the abdomen at a preoperatively marked location. The stoma is often placed to the right for the mesentery to not stretch or twist and to ease managing the stoma for right-handed patients. [3-5]

Bricker ileal conduit is an incontinent urinary diversion which implies that the conduit requires an external collecting bag for the urine. This bag is connected to the stoma with an adhesive plate individually fitted to each stoma. Patients are taught how to apply materials and care for their stoma.
**Parastomal complications**

As with every surgical procedure creating urinary diversion is associated with a risk of developing complications. Despite the ileal conduit being described as the least complication-prone urinary diversion procedure after radical cystectomy [2] conduit complications are far from uncommon with complication rates described as high as 66% depending on the length of follow up [6].

Complications related to the site of the stoma after urinary diversions are a substantial problem with incidence numbers as high as 62% [2, 7] although incidence numbers vary greatly in the literature. Incidence numbers this high makes stomal complications one of the most frequent conduit related problem encountered in urinary diversions [2]. The stomal complications include retraction and obstruction of the stoma, stomal stenosis, stomal necrosis, prolapse and formation of parastomal hernias [7].

Due to the high incidence of complications in association with incontinent urinary diversions the World Health Organization recommend it mandatory to offer lifelong follow-up with stomal therapists and surveillance of function in the upper urinary tract [8].

**Parastomal herniation**

A hernia can be described as a “protrusion of tissue, structure, or part of an organ through the bone, muscular tissue or the membrane by which it is normally contained” [9] and may emerge spontaneously or as a complication of surgery.

Consensus on the definition of parastomal herniation is lacking, in an article from 2010[10] Jänes suggests both a radiological and clinical definition. Clinically parastomal hernia is defined as any protrusion in the vicinity of the stoma. The radiological parastomal hernia is
defined as any intra-abdominal content protruding beyond the peritoneum or the presence of a hernia sac.

The parastomal protrusion or hernia sac may contain fat, bowel forming the stoma, omentum and/or an intestinal bowel loop not part of forming the stoma [11, 12]. Although parastomal hernias are usually asymptomatic different rare complications may occur as a result of the herniation causing intestinal obstruction and strangulation [13]. Less dramatic complications such as abdominal discomfort and poorly fitting stoma appliances occur with a higher frequency [13-15].

A large retrospective review study of the Indiana University database with patients who had undergone radical cystectomy and ileal conduit diversion showed an incidence of parastomal hernias at 29% [16]. This is much lower than the incidence of 48 % found by Donahue [12] in a study describing prevalence and risk factors for the development of parastomal hernias after radical cystectomy. In a review of parastomal hernia incidence from 2003 [17] the incidence was found to be lower in ileostomies when compared to colostomies, indicating that the type of stoma influences the rate of hernias.

Independent risk factors have been identified that increase the risk of developing a parastomal hernia. Such risk factors include, but do not seem limited to; prior laparotomy, severe obesity and increasing age [12, 16, 18]. Surgical technique, placement of stoma opening and size of the stoma aperture may also affect the outcome of parastomal hernias [16].

**Methods of Treatment for Parastomal Hernia**

When faced with a parastomal hernia several treatment options are available. As most parastomal hernias are asymptomatic this allows for a conservative approach adapting stoma appliances. Indications for surgical repair include ill-fitting appliances, cosmetic, abdominal
pain/discomfort, intestinal obstruction and strangulation [19, 20]. Most surgery can be performed electively.

The surgical principles for repairing a parastomal hernia are: direct suture of the peristomal fascia, suture and closure together with prosthetic mesh net and relocation of the stoma site. Direct suture of the peristomal fascia has an estimated recurrence rate of 69% making it ill-fit for parastomal hernia reparation [19] while the recurrence rate of prosthetic mesh repair is estimated around 39% [20].

Beside the still high recurrence rates, there is also a complication rate as high as 65 % [20] indicating that parastomal hernia reparation surgery has inherent difficulties which should be considered in concert with the patient [7, 19, 20].

**Prophylactic Mesh Application to Prevent Parastomal Herniation**

With the high recurrence rate and poor results with reparative surgery new strategies need to be implemented to prevent parastomal herniation.

In the early 90’s Morris-Stiff and Hughes performed a small study [21] using non-absorbable heavyweight mesh placed intra-abdominal for repairing paraileal and colostomy hernias with depressing results not only showing a high rate of recurrence but also 57% of patients with dense bowel adhesions to the mesh and mesh-related abscesses. However, more recent studies have shown more promising results. A review of surgical techniques for parastomal hernia repair done in 2012 [19] shows a number of new techniques using a light-weight mesh, placed extra-peritoneal, associated with notable lowering of recurrence rates and low overall rate of mesh infection. A review by the World Health Organization [8]on urinary diversion describes the use of mesh material for repair of parastomal hernia as having yielded good results with evidence level 3 meaning good-quality retrospective case-control studies or case series.

Nevertheless there is a concern among surgeons about the use of prosthetics in surgical fields
that can be seen as contaminated as well as about placing prosthetics in an intraperitoneal position[21, 22]).

Jänes et. Al. [23] and Serra-Aracil [24] have performed randomized prospective studies on the use of prosthetic mesh to prevent parastomal herniation in association with patients undergoing permanent colostomy, hypothesizing that addition of light-weight mesh in an extra-peritoneal position at the primary operation would reduce the incidence of parastomal hernias while still being well tolerated. As mentioned, this technique has previously been used for the reparation of already existing hernias.

**Comment on Previous Literature on the Subject**

Although there are several articles and studies on the subject of risk factors, incidence and repair of parastomal hernias in both colorectal surgery and urology depicting high incidence, poor results of reparative surgery and advocating preventive measures, the knowledge and study of prophylactic mesh implantation is lacking. In 2010 a systematic review and meta-analysis of randomized controlled trials in prevention of parastomal herniation [22] found that mesh reinforcement reduce the incidence of parastomal herniation without increased morbidity and seemingly less parastomal hernias requiring surgical repair. Two [23, 24] out of the three [23-25] randomized controlled trials referred to in this article have studied permanent colostomies while the last one studied loop-ileostomies and had a study population of only 20 patients.

In a review from 2013 [18] looking at the evidence regarding treating and preventing parastomal hernias A. Hotouras concludes that “Despite limited evidence, routine prophylactic mesh reinforcement of the stoma trephine should be offered to all patients undergoing permanent stoma formation”.

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Up until now there are no studies of prophylactic mesh implantation to prevent parastomal hernia in patients receiving ileal urinary diversions although the technique is already used clinically.

**Clinical Basis for this Master Thesis**

In September 2010 the Department of Urology at Örebro University Hospital started using prophylactic mesh for the prevention of parastomal herniation in patients undergoing ureteroileocutaneous urinary diversion, a Bricker Ileal conduit. As part of a clinical evaluation the records of 40 consecutive patients operated before and 42 after the implementation of this method were reviewed.

**AIM**

The primary aim of this project is to compare the frequency of parastomal hernia in patients receiving a Bricker ileal conduit at Örebro University Hospital with or without the placement of a prophylactic mesh.

As a secondary aim the rate of stoma related complications in patients receiving prophylactic mesh will be reviewed.

**MATERIAL AND METHOD**

This master thesis project was conducted as a retrospective review of medical records for patients who received a Bricker ileal conduit at the Department of Urology at Örebro University Hospital.

**Literature Search and Collection**

To increase fundamental knowledge on the subject a review of literature was conducted. The review included study of relevant surgical techniques and basic anatomy as well as going
through available PubMed articles. Search terms used in different combinations were; urostomy, ileal conduit, parastomal hernia, stomal complications, prophylactic mesh. Related articles and sources were also reviewed. The search did not include articles in other languages than English.

**Population and Data Collection**

Starting with the first patient who received a prophylactic mesh implantation, all patients who underwent a construction of a Bricker ileal conduit diversion at the Department of Urology at Örebro University Hospital up until the start of a randomized trial investigating parastomal mesh placement, were obtained from the hospital database resulting in 50 eligible patients. The patients were identified with the ICD10 code for ureteroenterocutaneostomí,” KBJ 10” starting from the day the first prophylactic mesh implantation was performed. In the same way, 50 consecutive patients who underwent a Bricker ileal conduit diversion prior to the start of prophylactic mesh implantation were identified and used as a control group for comparison.

The first patient in the study population received a Bricker ileal conduit in June 2009 and the last patient included received a Bricker ileal conduit in March 2012. There were no patients excluded, but due to a technical error 13 duplicates were found when going through the selected patients resulting in a study population of 87 patients. Another 5 patients whom underwent follow-up at another department were later excluded due to hospital not sharing medical records in time for review.

The ileal conduits were all performed at the Department of Urology at Örebro University Hospital and all patients had at least one follow-up appointment at the department. Roughly half (54%) of the patients then continued their follow-up at Örebro University Hospital while
the rest were followed up by five other surgical/urological departments from which the patients had been referred.

Basic information such as sex, age, BMI, operative indication, date of primary ileal conduit operation and follow-up time was collected from the patient medical files as well as from the Swedish Cystectomy register. Using a predetermined protocol a review of each individual journal was completed and data stored anonymously in a excel document.

The review was limited to information found in surgical and emergency medical records. For the patients who had their follow-up at other departments copies of surgical and emergency medical files as well as x-ray files were obtained from the specific hospital.

Due to the hospital switching to a different computerized system for medical files the record of every patient who underwent surgery before November 2010 had to be obtained from the hospital archives for review.

Complications were divided into two groups; those occurring within 90 days and those occurring after 90 days. Complications searched for were; wound infection, distal stomal
necrosis and stomal stenosis as these complications were seen as potentially attributed to the mesh placement. Other complications, including intestinal obstruction, incarceration and strangulation, were also scanned for and compared between the mesh and no mesh group as to identify eventual differences in occurrence. Complications were identified by the diagnosis of the attending doctor. Parastomal hernias were noted concerning number of hernias and time of debut as well as number of relapsing hernias. Primary parastomal hernias were also divided between those managed with conservative treatment and those requiring surgical treatment.

Total follow-up time was the time from the date of the primary surgery until the last noted clinical meeting with a surgeon in the patients’ medical files.

The resulting demographics for the total study population are shown in table 1.

**Table 1** Demographic presentation of the total study population. *IQR* = InterQuartile Range

<table>
<thead>
<tr>
<th></th>
<th>Total (n=82)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>49 (60)</td>
</tr>
<tr>
<td>Female</td>
<td>33 (40)</td>
</tr>
<tr>
<td><strong>Median Age (IQR)</strong></td>
<td>68 (63.0-73.8)</td>
</tr>
<tr>
<td><strong>Median BMI (IQR)</strong></td>
<td>25.7 (23.9-28.4)</td>
</tr>
<tr>
<td><strong>Mean Follow-up (Months)</strong></td>
<td>23.2</td>
</tr>
<tr>
<td><strong>Parastomal Hernia (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>19 (23.2)</td>
</tr>
<tr>
<td>No</td>
<td>68 (76.8)</td>
</tr>
<tr>
<td><strong>Indication for Urostomy (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Benign</td>
<td>24 (29.3)</td>
</tr>
<tr>
<td>Malign</td>
<td>58 (70.7)</td>
</tr>
<tr>
<td><strong>Prophylactic Mesh (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>42 (51.2)</td>
</tr>
<tr>
<td>No</td>
<td>40 (48.8)</td>
</tr>
</tbody>
</table>
The Prophylactic Mesh Placement

All patients in the mesh group received a light-weight mesh placed in a sublay position, meaning that the mesh net was placed preperitoneally behind the rectus muscle. The mesh placement was performed as part of the primary construction of the Bricker ileal conduit.

A total of three patients supposedly belonging to the group of patients receiving prophylactic mesh placement were found to not have received a mesh due to two patients with very short expected survival and perioperative difficulties, and one who already had an ileostomy.

Identifying Parastomal Hernias

To identify patients with parastomal hernias the student reviewed all available medical records from urological and/or surgical follow-up as well as emergency medical records. A parastomal hernia was identified by the diagnosis of the attending doctor, written in the medical records. All patients with suspected parastomal hernias had received a computerized tomography (CT) in supine position and appurtenant records were reviewed. For patients who had been diagnosed with clinical parastomal hernia without mentioning of the hernia in available radiological records CT-examinations were reevaluated by radiologists.

The majority of the “non-hernia” population had CTs as part of routine follow-up, and to increase the likelihood of finding parastomal hernias appurtenant radiological records were reviewed. Not all radiological examinations reviewed were abdominal CTs but there were also intravenous pyelograms (IVP) which were a part of the patients routine follow-up. A total of 3 patients did not receive a follow-up CT due to one patient with benign indication and two who passed away early. None of these patients had clinical signs of parastomal hernia.
Identifying Stomal Complications

Complications were identified by the diagnosis of the attending doctor and the time of debut was set as the same date the diagnosis was set, assuming there were no obvious starting dates noted.

Statistical Methods

To determine relevant differences between those who received prophylactic mesh and those who did not, as well as between those who developed hernia and those who did not, the groups were compared using Statistical Package for the Social Sciences (IBM SPSS Statistics 22, SPSS) to perform statistical descriptive and comparative analyses. The comparison of mean values and p-values for statistical significance were calculated using the independent T-test as the data followed normal distribution. For comparing categorical variables such as sex (Male or Female), herniation (Yes or No), operative indication (Malign or Benign) and prophylactic mesh application (Yes or No) the Chi-square or Fishers Exact test was used.

The same procedure was performed to compare the population that developed herniation and the population that did not develop hernias. A statistically significance was indicated when p-values reached ≤0.05.

The calculations in SPSS were performed under the supervision of a statistician with PhD in medicine.

ETHICS

This master thesis project was performed as an evaluation of a clinical procedure for the local urological department and did not need ethical review.
RESULTS

Of the initial 100 patient records selected for review 13 were excluded due to duplicates and 5 were excluded due to records from other clinics not being available, resulting in a total of 82 patient records reviewed. Out of these 82 patients, 42 had received prophylactic mesh placement at the primary stoma operation. There were no statistically significant differences observed between the two groups in regard to sex, age, BMI, mean follow-up time or indication for urostomy.

A comparison between the demographics of the total study population, mesh population and control population can be found in Table 2.

<table>
<thead>
<tr>
<th></th>
<th>Total (n=82)</th>
<th>No mesh (n=40)</th>
<th>Mesh (n=42)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>49 (60)</td>
<td>25</td>
<td>24</td>
<td>0.621</td>
</tr>
<tr>
<td>Female</td>
<td>33 (40)</td>
<td>15</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Median Age (IQR)</td>
<td>68 (63.0-73.8)</td>
<td>68 (60.0-73.0)</td>
<td>67.5 (63.5-74.0)</td>
<td>0.738</td>
</tr>
<tr>
<td>Median BMI (IQR)</td>
<td>25.7 (23.9-28.4)</td>
<td>25.7 (24.0-28.0)</td>
<td>25.6 (23.6-28.8)</td>
<td>0.782</td>
</tr>
<tr>
<td>Mean Follow-up (months)</td>
<td>23.2</td>
<td>26.6</td>
<td>20</td>
<td>0.068</td>
</tr>
<tr>
<td>Indication for Urostomy (%)</td>
<td></td>
<td></td>
<td></td>
<td>0.072</td>
</tr>
<tr>
<td>Benign</td>
<td>24 (29.3)</td>
<td>8</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Malign</td>
<td>58 (70.7)</td>
<td>32</td>
<td>26</td>
<td></td>
</tr>
</tbody>
</table>

*IQR = InterQuartile Range

* P-value referring to significant/non-significant differences between mesh and no mesh populations where p<0.05 is seen as significant.

P1 → P-value refers to the relationship male vs. female in mesh and no mesh population.
Five stomacomplications were identified. Two out of these five complications were found in patients who had received prophylactic mesh at the primary stoma operation. Three of the complications were identified in the control group who had not received a mesh. Of the complications noted two occurred within the first 90 days and were seen as early complications while the remaining three complications occurred after 90 days and were seen as late complications.

Stomacomplications for the prophylactic mesh group and no-mesh group are presented in table 3.

### Table 3. Comparison of complications between mesh and no-mesh groups.

<table>
<thead>
<tr>
<th></th>
<th>Early complications</th>
<th>Late complications</th>
<th>Infection</th>
<th>Necrosis</th>
<th>Stenosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesh</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>No Mesh</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

After a review of all 82 included patients’ medical records a total of 19 (23%) parastomal hernias were identified. 10/40 (25%) of the patients who did not receive a prophylactic mesh implantation developed a parastomal hernia in a mean time of 16.6 months. 5 (50%) of these parastomal hernias required surgery.

9/42 (21%) of the patients who received a prophylactic mesh implantation developed a parastomal hernia, which was both clinically and verified by radiology, in a mean time of 16.2 months. 1 (11%) of these parastomal hernias required surgery. There were no significant differences between the group receiving prophylactic mesh implantation and the group that did not, but there was a trend towards parastomal hernias in patients without mesh being more prone to require surgery once they had developed a hernia ($p$-value = 0.141). The trend was
even stronger when comparing the risk of having hernia surgery in the mesh and no-mesh group (p-value=0.105)

Hernia frequency, time to hernia and No. of hernias requiring surgery in each group are presented in table 4.

Table 4. Describing hernia frequency, mean time to hernia and hernias requiring surgery in the no-mesh and mesh group respectively.

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>No mesh (n=40)</th>
<th>Mesh (n=42)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parastomal Hernia (%)</td>
<td>0.702</td>
<td>19 (23.2)</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td>10</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>68</td>
<td>30</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td>Mean time to hernia (month)</td>
<td>16.4</td>
<td>16.6</td>
<td>16.2</td>
<td>0.955</td>
</tr>
<tr>
<td>Hernia req. Surg./treat.</td>
<td>6 (31.6)</td>
<td>5</td>
<td>1</td>
<td>0.141</td>
</tr>
<tr>
<td>No. of patients requiring</td>
<td></td>
<td>5 (12.5%)</td>
<td>1 (2.4%)</td>
<td>0.105</td>
</tr>
<tr>
<td>surgery</td>
<td>6 (7.3%)</td>
<td>5 (12.5%)</td>
<td>1 (2.4%)</td>
<td></td>
</tr>
</tbody>
</table>

The patients whom developed parastomal hernias had a significantly higher BMI (29,2) than the patients that did not (25,5), p= 0.003. There was also a significant difference in mean follow-up time. The patients who developed parastomal hernia had a mean follow-up time of 34,4 months while those who did not develop hernia had a follow-up time of 19,8 months, p< 0.001.

A trend towards female overrepresentation in patients presenting with parastomal hernias was seen at a p-value of 0.209.

The characteristics of the group that developed parastomal hernia compared to the group of those who did not can be seen in table 5.
Table 5. Comparison of the characteristics of those who developed parastomal hernia and those who did not.

<table>
<thead>
<tr>
<th></th>
<th>Hernia</th>
<th>No Hernia</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td>0,209</td>
</tr>
<tr>
<td>Male</td>
<td>9</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>10</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td><strong>Median Age (IQR)</strong></td>
<td>67 (63,0-73,0)</td>
<td>(63,0-74,0)</td>
<td>0,689</td>
</tr>
<tr>
<td><strong>Median BMI (IQR)</strong></td>
<td>27,0 (25,6-32,5)</td>
<td>25,00 (23,2-27,1)</td>
<td>0,003</td>
</tr>
<tr>
<td><strong>Mean Follow-up (months)</strong></td>
<td>34,4</td>
<td>19,8</td>
<td>≤0,001</td>
</tr>
<tr>
<td><strong>Indication for Urostomy</strong></td>
<td></td>
<td></td>
<td>0,801</td>
</tr>
<tr>
<td>Benign</td>
<td>6</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Malign</td>
<td>13</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td><strong>Prophylactic Mesh (%)</strong></td>
<td></td>
<td></td>
<td>0,702</td>
</tr>
<tr>
<td>Yes</td>
<td>9 (21,4)</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>10 (25%)</td>
<td>30</td>
<td></td>
</tr>
</tbody>
</table>

**DISCUSSION**

The frequency of parastomal hernia among the included patients was 23%, a number concurrent with studies of both end ileostomies containing bowel excrement[17] and urostomies [7] but notably lower than the parastomal hernia incidences presented by the no mesh groups in previous studies on prophylactic mesh placement[23-25]. Beyond that, a total of 5 (6%) possibly stoma associated complications were found which is approximately the same frequency as found by Serra-Aracil et. al.[24]. Statistical analyses of the material did not succeed in identifying any significant differences in hernia frequency or complication rate between the patients who received prophylactic mesh implantation and those who did not. There was however a trend towards patients operated without prophylactic mesh being more prone to require surgery for their parastomal hernia. Five out of six hernias that required surgery were located in the no-mesh group resulting in a p-value of 0,141. If confirmed by
other studies this tendency could prove valuable as patients with a mean age of 66 years and not insignificant comorbidity would be well served by every method that reduces risk of further surgical procedures.

It is important to remember that the patients receiving prophylactic mesh in this study were the first ones going through this type of implantation at the department. The possibly lower expected rate of parastomal hernia together with the learning curve of the departments’ surgeons must be considered when comparing this study to other studies describing notable decreases in parastomal hernia frequency by using mesh.

A comparison between the group of patients who developed parastomal hernia and those who did not showed a significantly higher BMI in the patients with hernia. This finding reflects the same correlation between high BMI and stomal morbidity found in previous studies of parastomal hernia [16, 26].

**Clinical Relevance**

Not only is parastomal hernia a common complication to stomas in colorectal surgery [14, 18, 23-25], studies show that it is a relatively common complication for urostomies as well [6, 7, 16, 26]. Studies in colorectal surgery [14, 18, 23-25] suggest that the use of a prophylactic mesh at the primary stoma surgery reduces the frequency of parastomal herniation while still being a safe procedure considering risk of complications, including infections. Although the pathophysiological mechanisms of parastomal herniation in urinary diversions is likely similar to that which occurs in stomas containing bowel excrements, at present date (and to our knowledge) there are no studies on the use of prophylactic mesh implantation in urinary diversions.
Methodological Considerations and Strengths and Weaknesses

Being retrospective this study suffers some inherent limitations such as difficulties to identify rare outcomes, e.g. stomal complications, and lack of control over the assessment of relevant outcomes. The later implies a risk of missing relevant data such as known and unknown risk factors due to it not being routinely registered. For example, BMI was found to be significantly higher in the patients that developed parastomal hernias but this BMI was registered at time of operation and there was no knowledge of BMI at time of herniation or follow up. Neither was there any recording of other possible risk factors or preexisting conditions that might or might not be relevant such as a history of hernias.

The median follow-up time did not differ between the mesh and the no-mesh group but differed significantly (p-value=≤0.001) between those who developed hernias and those who did not. Although the mean time until hernia was shorter than both the mean mesh/no-mesh and hernia/no hernia groups mean follow-up time, as well as the mean follow-up time for those who did not develop parastomal hernia, there is a known cumulative risk of parastomal herniation with increasing follow-up time [2, 6]. The significantly higher follow-up time could be caused by patients developing parastomal hernia following a different follow-up regime due to more frequent contact with the departments. In a study of long-term outcome of ileal conduit diversions including 131 patients [6] Madersbacher et. Al. found the median time from surgery to develop stoma related complications to be 54 months. This indicates that this study’s relatively short follow-up time, partly due to early exclusion of patients that died in their disease, might be a significant source of bias. There was also the fact that the last included patients with prophylactic mesh implantation received urinary conduits in 2012 that limited possible follow-up time. However, another study of parastomal hernia incidence found
that only 10% of hernias occurred after the 12 month minimum follow-up [26]. Regardless of which study was closest to the true mean time of herniation, results with lower follow-up time are important in urologic surgery because of the common indication for Bricker deviation being urinary bladder cancer, a diagnosis with a 5-year survival rate as grim as 50% [27] For patients with shortened life-expectancy prolonging the time to herniation could be crucial.

The observational nature of this study limits objectivity but the fact that the parastomal hernia diagnosis was made by doctors unaware of the upcoming study and the mandatory radiological concurrent diagnosis helps abate this weakness. Since the patients with clinical hernia diagnosis, or suspicion thereof, had a CT focusing on finding abdominal wall defects it is possible that radiologist in those cases suffered observational bias leading to a relative under diagnosis of parastomal hernias on CTs not focused on the abdominal wall. Jänes et. Al. have shown [10] that CT in a prone position have a greater correlation with clinical diagnosis of parastomal hernia than conventional CT. It is possible that having the patients receive a CT in prone position would have changed the number of identified hernias but not likely changing the number of hernias with indication for treatment. Within the observational limitations there is also the definition of a parastomal hernia. Although there are definitions for parastomal hernia diagnosis [10], both radiological and clinical, there is no information about what criteria attending doctors used to diagnose the hernias in the study. In an attempt to decrease this effect both a clinical and concurrent radiological diagnosis was required in this study. Further studies should aim to emanate from a consensus on the parastomal hernia diagnosis to avoid this problem.

Concerning the study population the retrospective nature of this study, including all patients consecutively, partly prevented selection bias. The resulting mesh and no-mesh groups had no significant differences when compared demographically. There was a trend towards longer follow-up time in the no-mesh group which occurred naturally since these patients all went
through surgery before prophylactic mesh implantation was implemented. Seeing the study population in a larger perspective it should be noted that the mean age of 66 yrs. is a bit lower than expected (69 yrs.) and the proportion of women is higher (40% vs. expected 26%). The above numbers, taken from the Swedish cystectomy register, relate to patients with urinary bladder cancer but the differences remain even if patients with benign indication in this study are not included in the statistical comparison (67 yrs. vs 69 yrs. and 34% vs 26%). Although it might be preferable not to have different operative indications this study showed no difference in hernia frequency between the malignant and benign group.

The power of this study

Performing a sample-size calculation showed that this study would have required a sample size if 75 patients in the mesh and no-mesh group respectively, resulting in a total study population of 150 patients to acquire sufficient power of >80%.

The calculated power of this study was 6.3% in regards to the development of parastomal herniation. This low power is an obvious disadvantage of this study.

CONCLUSION

This master thesis project failed to identify prophylactic mesh placement as a method of reducing the frequency of parastomal hernias in patients with Bricker ileal conduits. High BMI was identified as a significant risk factor for hernia development.

Due to the low power of this study no applicable conclusions can be made. Nevertheless it highlights the need for further, larger and prospective randomized studies of the subject.
POPULÄRVETENSKAPLIG SAMMANFATTNING

Profylaktiskt nät för förebyggande av bråck hos patienter med urostomi

En av fem patienter som genomgår operation med anläggande av urostomi utvecklar stomibråck, en komplikation som kan innebära allt från dagliga problem med skötsel av sin urinavledning till livshotande tillstånd så som tarminklämning. Vid Universitetssjukhuset Örebro har man sedan 2010 använt ett profylaktiskt nät som förstärkning av bukväggen kring stomin i ett försök att förhindra uppkomsten av stomibråck, metoden utvärderas i denna studie.

Den vanligaste anledningen i Sverige för anläggande av urostomi samt, oftast, avlägsnande av urinblåsan är urinblåsecancer men även andra tillstånd så som neurogena blåsrubningar och svår inflammation förekommer. Patienterna i den aktuella studien genomgick operation enligt Bricker-metoden vilket innebär att man kopplar urinledarna till ett isolerat tunntarmssegment. Tarmsegmentet leder urinen vidare genom en öppning i bukväggen, en stomi, till en uppsamlingspåse som fästs på huden kring stomin med en självhäftande platta.

Stomibråck är en relativt vanlig komplikation i anslutning till den konstgjorda bukväggsöppningen. Ett bråck innebär att tarmsegment eller bukfett glider ut bredvid stomin genom bukväggsöppningen ledande till smärta eller att tarmen riskerar täppas till eller tappa sin blodförsörjning (tarmischemi) vilket kan leda till livshotande tillstånd. Utöver akuta tillstånd orsakar stomibråck även sänkt livskvalitét och ökade sjukvårdskostnader i form av undersökningar och behandlingar. När ett stomibråck uppstått kan det behandlas antingen med ett mer konservativt angreppssätt i form av gördel och särskilda omläggningsmaterial eller så kan man förstärka bukväggen kring stomat med olika kirurgiska tekniker. Trots kirurgisk reparation återkommer de parastomala bråcken i så mycket som en tredjedel av fallen.

På grund av den relativt höga förekomsten av stomibråck hos patienter med urostomi och nedslående resultat av reparativ kirurgi finns ett behov av att förhindra tillståndet redan innan det uppkommer. Inom andra kirurgiska specialiteter har man sett lovande resultat med ett förebyggande nät som placeras i bukväggen och fungerar som mekanisk förstärkning.

Vid anläggandet av urostomier sedan 2010 har Urologiska kliniken vid Universitetssjukhuset Örebro använt profylaktiskt nät vid anläggningen av urinavledningar enligt Brickermetoden. Som ett led i en kvalitetsgranskning har 42 patienter med förebyggande nät jämförts i en
studie med 40 patienter som genomgick en cystektomi innan 2010 och därmed ej erhållit något profylaktiskt nät. Patienternas operationsberättelser, post-operativa vård, uppföljningsbesök samt kontrollröntgen granskades med avseende på förekomsten av stomibråck. Samtidigt undersökte man även säkerheten med att placera kroppssfrämmande nätmaterial i anslutning till bukväggsöppningen genom att jämföra antalet stomirelaterade komplikationer i de båda grupperna.

Vad man fann var att frekvensen stomibråck var lika hög i den grupp med patienter som fått ett förebyggande nät inlagt som hos de patienter som ej fått något nät. Totalt utvecklade 19 (23%) av patienterna ett stomi bråck. Man såg ej heller någon skillnad i tid till debut av parastomala bråck eller i frekvensen av stomirelaterade komplikationer. Dock kunde man identifiera en trend i studien där de patienter som utvecklat bråck i icke-nät gruppen i större utsträckning behövde kirurgiska åtgärder av sitt bråck än de som fått ett profylaktiskt nät.

När en jämförelse gjordes mellan de patienter som utvecklat bråck och de som inte utvecklat bråck visade det sig att gruppen med bråck hade ett statistiskt signifikant högre Body Mass Index (BMI) än icke-bråck gruppen.

ACKNOWLEDGEMENTS

The author would like to express his deepest gratitude to,

Dr Tomas Jerlström, Supervisor

For exceptional support and guidance completing this master thesis.

Dr Ralph Peeker, Supervisor

For taking time to supervise and support this masterthesis, acting as a link to Gothenburg University.

Jessica Carlsson, PhD

For help with statistical analyses and calculations.
REFERENCES (EndNote)

5. Novick, A.C., Operative Urology at the cleveland clinic.