CHAPTER 1

1.1. Introduction

One of the aims of the Polish Surgeons’ Society, the Section of Videosurgery of the Polish Surgeons’ Society, the Section of Hernia Treatment of the Polish Surgeons’ Society and the Polish Coloproctology Club is creating and implementing into clinical practice recommendations and guidelines for dealing with patients having various surgical problems, including parastomal hernias. The purpose of these guidelines and recommendations is not only to ensure a high standard of patient care, but also to influence the quality of specialist training, development of new materials used in repair surgery and reporting rate of complications as well as to aid in ongoing improvement of personnel qualifications. Basing scientific research on the guidelines may have a significant impact on the development in this field, through indicating areas where implementing recommendations are necessary.

The guidelines are a consensus pertaining to clinical practice, based on available, up-to-day scientific research and daily surgical practice, and they are meant to help in critical assessment of therapeutic methods with reference to specific clinical cases, and to suggest the best possible algorithm of dealing with the patients.

The guidelines were created in order to:

– improve the quality and efficiency of medical services;
– reduce differences in the treatment process: the clinical practice must be based on the
EBM rather than opinions of experts or surgeons’ own beliefs;
– making the treatment process more transparent (what may be expected from whom and when).

The guidelines for treatment of patients with parastomal hernia were created and proposed by the Polish Surgeons’ Society and remain its intellectual property.

1.2. Motivation

In 2009, the European Hernia Society published guidelines for management of patients with inguinal hernia. This event was preceded by attempts to introduce recommendations in national societies, including those in Poland. Introduction of these guidelines had a significant impact on the quality of care and treatment outcomes. To date, attempts to introduce similar guidelines for parastomal hernias have proved unsuccessful. Some of the already published papers can serve as a basis for the new guidelines. The work group was established. Eminent specialists in procedural fields, who deal with stoma patients’ problems in their daily practice, were invited to participate in creation of the Polish Recommendations.

1.3. Aim

These guidelines, compiled together with recommendations in the form of a paper, are meant to serve as an aid in surgeons’ daily clinical practice. The guidelines were based on the results and an analysis of available clinical studies, and conclusions drawn therefrom are aimed at improving the level of services received by the patient. The recommendations included in these guidelines are meant to be a “manual” of sorts explaining how to manage patients with diagnosed parastomal hernias. Moreover, the present authors believe these guidelines will form a basis for implementation of local protocols, and thus have a positive impact on the education process of surgical residents. A decrease in the rate of complications may be another potential health-related benefit, possibly leading to reducing chronic pain and the recurrence rate.

1.4. Definition

Parastomal hernia is a protrusion of the contents of the abdominal cavity, or only of the preperitoneal fat, through a defect in the abdominal wall to the hernial sac. The stoma opening can be treated as a defect in the abdominal wall. This situation leads to such symptoms as pain and discomfort. Impaired passage of the intestinal content is also a frequent condition, leading to subobstruction and impaired emptying of the intestinal content into the stoma pouch. In a certain percentage of cases, it becomes impossible to return the hernial sac contents to the free peritoneal cavity (irreducible hernia). Where the hernia orifice is narrow, there is a risk of incarceration and in some cases strangulation. This may lead to life- and health-threatening complications, such as: intestinal wall necrosis or perforation of the intestine, and in the most serious cases may lead to the patient’s death because of septic shock. Some classifications of parastomal hernias (Devlin, type IV and Rubin, type II) distinguish also so-called prolapse of the stoma through mucosa eversion or formation of interstitial pseudohernia (between the mucosa and serosa of the stoma terminal segment). These conditions, however, are not proper hernias, since in the proper form there is no dilatation of the stoma opening in the fascia. Because of a different way of preparation, they are not included in the following report.

1.5. Patient population

The target population is the group of patients with any type of stoma (temporary, permanent, ileostomy, colostomy, urostomy) treated in Poland.

1.6. Problem description and preliminary questions

At the very beginning, the work group defined and formulated the most important questions, the answers to which were to form a basis for the guidelines:

a. What are the indications for treatment of patients with parastomal hernia? Do all patients require surgical treatment?
b. Is there a classification of parastomal hernias? Is there a chance to unify the classifications available in the literature?

c. Which surgical technique can be the “golden standard” of treatment (with consideration of such factors as relapse rate, percentage of chronic pain, complication rate, quality of life and procedure cost)?

d. Which mesh is suitable?

e. What are the most common complications and how should they be dealt with?

f. What type of antibiotic and antithrombotic prevention should be used?

1.7. The process and method of guidelines creation

The Study Group was established during the Congress of the Polish Surgeons’ Society in 2010. After two months, a meeting was held to distribute specific topics between the members, recall the EBM guidelines and create a schedule of work. During the meeting, available databases were searched, i.e. Cochrane, Embase, Medline and Pubmed. Towards the end of 2011, during a conference in Gdansk, which was entirely dedicated to the problem of parastomal hernias, a meeting of the work group was held. During that meeting, sections prepared by individual members were revised in order to unify the style. A consensus was reached as regards the content and quality of the paper.

Between December 2011 and March 2012, comments were gathered from all researchers. Responsibility for gathering and editing of the final version rested upon Dr Śmietański and Dr Bury. In April 2012, a meeting was held, during which each chapter was presented by the responsible author and discussed. The final form of the manuscript was achieved and accepted by all members of the Study Group. After this meeting, a decision was made to publish the manuscript in the “Polski Przegląd Chirurgiczny” journal.

1.8. Study group

While organising the research groups, member candidates meeting the following criteria were sought:

a. Extensive clinical experience and scientific achievements as regards stomas and/or gastrointestinal surgery and/or herniology.

b. Members recruited form the biggest possible number of sites.

c. Members from universities and other institutions.

d. Members, who are recognised experts in various surgical techniques pertaining to gastrointestinal surgery and hernia treatment.

e. Considerable experience in epidemiological and/or scientific research.

1.9. Right holder and legal status

These guidelines are property of the Polish Surgeons’ Society.

Legally speaking, the guidelines are not a legal act and cannot determine interpretation of law and standards of conduct described in different legal acts issued by authorised bodies of the Republic of Poland. They are, in fact, a collection of instructions and suggestions as well as a compilation of information from the international literature, and as such, they can contribute to ongoing improvement in the quality of medical services. Now it needs to be emphasised that there are different levels of “strength of scientific evidence”. The highest level is the 1A class of evidence, the strength of which results from meta-analyses and systematic reviews of scientific studies. The lowest strength of evidence, 4D, describes single expert opinions. This results in creation of recommendations of different classes. Given the fact that the guidelines pertain to the average patient, deviations from the guidelines in the treatment process are acceptable in exceptional situations, based on the surgeons’ individual experiences.

More importantly, one needs to be aware that cases of failure to follow the guidelines and acting against them should be thoroughly explained and justified in the patient’s medical record.

1.10. Data acquisition and processing

All papers available in the international literature by June 2011 were collected in elec-
Polish guidelines for treatment of patients with parastomal hernia

Electronic form and then printed. All members of the group were given identical sets of literature stored on labelled USB flash drives. Special emphasis was placed on finding all papers with level 1A or 1B strength of evidence. In controversial cases, a consensus was drawn, and conclusions and recommendations were formulated. Each time, in line with the EBM guidelines, two experts assessed the level of articles used to formulate a given conclusion. Moreover, an independent opinion of an anonymous member was discussed. Where no doubts were expressed, the recommendation was eventually accepted. In case of literature characterised by level 2C strength of evidence or lower, the recommendation strength may be subject to large deviations.

Strength of evidence:

<table>
<thead>
<tr>
<th>Recommendation class (strength)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Scientific data or a generally accepted opinion indicate that a given diagnostic or therapeutic procedure is beneficial, useful and efficient</td>
</tr>
<tr>
<td>II</td>
<td>Scientific data or opinions regarding usefulness or efficiency of a given diagnostic or therapeutic procedure are not in agreement</td>
</tr>
<tr>
<td>IIa</td>
<td>Scientific data or opinions support usefulness or efficiency</td>
</tr>
<tr>
<td>IIb</td>
<td>Usefulness or efficiency are supported by scientific data or opinions to a lesser extent</td>
</tr>
<tr>
<td>III</td>
<td>Scientific data or a generally accepted opinion suggest that a given diagnostic or therapeutic procedure is neither useful nor efficient, and in some cases may be harmful</td>
</tr>
</tbody>
</table>

Degree of data credibility

<table>
<thead>
<tr>
<th>Data credibility</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Data from numerous randomised studies or meta-analyses</td>
</tr>
<tr>
<td>B</td>
<td>Data from one randomised study or from large studies without randomisation</td>
</tr>
<tr>
<td>C</td>
<td>Established expert opinion or data from small studies, retrospective studies or registries</td>
</tr>
<tr>
<td>D</td>
<td>Single expert opinions</td>
</tr>
</tbody>
</table>

**CHAPTER 2**

**DEFINITION AND CLASSIFICATION OF PARASTOMAL HERNIAS**

**Definition**

Parastomal hernia is a protrusion of the contents of the abdominal cavity, or only of the preperitoneal fat, through a defect in the abdominal wall to the hernial sac. The stoma opening should be treated as a defect in the abdominal wall. This situation leads to such symptoms as pain and discomfort. Impaired passage of the intestinal content is also a frequent condition, leading to subobstruction and impaired emptying of the intestinal content into the stoma pouch. In a certain percentage of cases, it becomes impossible to return the hernial sac contents to the free peritoneal cavity (irreducible hernia). Where the hernia orifice is narrow, there is a risk of incarceration and in some cases strangulation. This may lead to life- and health-threatening complications, such as: intestinal wall necrosis or perforation of the intestine, and in the most serious cases may lead to the patient’s death because of septic shock. Some classifications of parastomal hernias (Devlin, type IV and Rubin, type II) distinguish also so-called prolapse of the stoma through mucosa eversion or formation of interstitial pseudohernia (between the mucosa and serosa of the stoma terminal segment). These conditions, however, are not proper hernias, since in the proper form there is no dilatation of the stoma opening in the fascia. Because of a different way of preparation, they are not included in the following report.

Are the existing classifications of parastomal hernias useful and have they been used in practice?

Do the classifications include guidelines for choosing the appropriate surgical method, where there are indications for surgical treatment?

Conclusions

Level 3

The existing classifications offer no unambiguous instructions concerning the choice of a method and surgical approach.

Only the Bielański Hospital classification is based on a physical examination of the patient.

Level 4

There is a consensus that a standardised method of hernia description is needed in order to compare treatment outcomes and create further recommendations.

Recommendations

D Parastomal hernia descriptions used must be based on classifications.

During the patient’s physical examination, the use of Bielański Hospital classification is recommended.

It is recommended to use the radiological classification in a CT examination description.
Classifications of parastomal hernias are based on three basic assessment tools: physical examination, perioperative assessment or additional imaging examinations. Depending on the type of hernia and the content of the hernial sac, authors distinguish 4 to 5 types of hernias. These types describe different degrees of pathology of the stoma: from proper hernias (with presence of the hernial sac and its content) to conditions involving hernia recurrences – both subcutaneous or through the stoma itself. Only the classification described by Szczepkowski includes in the assessed parameters coexistence and size of hernias in the postoperative scar after a vertical incision.

The existing classifications of parastomal hernias, except for the one described by Szczepkowski, have low clinical usefulness. This is evidenced by the fact that so far they have not been used in any paper presenting outcomes of parastomal hernia surgical treatment. The above classifications by Rubin and Devlin contain categories that in fact are not parastomal hernias, which leads to lack of clarity.

In the classifications by Devlin, Moreno-Matias and Seo, it is impossible to determine the hernia type based on a clinical examination. Moreover, the classifications do not include guidelines for choosing the appropriate surgical method, where there are indications for surgical treatment. The classification by Moreno-Matias and Seo was assessed according to symptoms reported by the patient (2, 3). Over 70% of type 0 hernias were not associated with any symptoms, while all type III hernias were symptomatic. It is also supported by Seo’s observation (2). Szczepkowski’s classification allowed differentiation of symptoms and indications for treatment in individual groups. Diagnostic imaging seems a valuable addition to Szczepkowski’s classification. It contributes to better identification of the pathology, allowing better planning of the procedure. The most common indications for surgery in type I hernias were incarcerations and passage disorders. In type II, indications concerning local conditions were most common. In types III and IV, the most

<table>
<thead>
<tr>
<th>Author</th>
<th>Type of classification</th>
<th>Basis of classification</th>
<th>Number of hernia types</th>
<th>Clinical validation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Devlin (1983)</td>
<td>perioperative</td>
<td>USG</td>
<td>4</td>
<td>yes</td>
</tr>
<tr>
<td>Rubin (1993)</td>
<td>perioperative</td>
<td></td>
<td>4</td>
<td>no</td>
</tr>
<tr>
<td>Moreno-Matias (2007)</td>
<td>radiological</td>
<td>CT</td>
<td>5 (0, Ia, Ib, II i III)</td>
<td>yes</td>
</tr>
<tr>
<td>Seo (2011)</td>
<td>radiological</td>
<td>CT</td>
<td>5</td>
<td>yes</td>
</tr>
<tr>
<td>Szczepkowski (2011)</td>
<td>clinical physical examination</td>
<td></td>
<td>4</td>
<td>yes</td>
</tr>
</tbody>
</table>

Table 2. Hernia types in different classifications

<table>
<thead>
<tr>
<th>Author</th>
<th>Type of classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Devlin (1983):</td>
<td>Type I – interstitial hernia;</td>
</tr>
<tr>
<td></td>
<td>Type II – subcutaneous hernia;</td>
</tr>
<tr>
<td></td>
<td>Type III – intrastomal hernia;</td>
</tr>
<tr>
<td></td>
<td>Type IV – peristomal hernia associated with stoma prolapse.</td>
</tr>
<tr>
<td>Rubin (1993)</td>
<td>Type I – true parastomal hernia:</td>
</tr>
<tr>
<td></td>
<td>I a – interstitial,</td>
</tr>
<tr>
<td></td>
<td>I b – subcutaneous;</td>
</tr>
<tr>
<td></td>
<td>Type II – intrastomal hernia;</td>
</tr>
<tr>
<td></td>
<td>Type III – so-called subcutaneous prolapse of the stoma;</td>
</tr>
<tr>
<td></td>
<td>Type IV – classical pseudohernia, associated with denervation and debility of muscles in this area.</td>
</tr>
<tr>
<td>Moreno-Matias (2007) i Seo (2011)</td>
<td>Type 0 – peritoneum follows the intestine, forming a hernial sac;</td>
</tr>
<tr>
<td></td>
<td>Type Ia – the intestine (hernial loop) fills up the sac, gate &lt; 5 cm;</td>
</tr>
<tr>
<td></td>
<td>Type Ib – the intestine (hernial loop) fills up the sac, gate &gt; 5 cm;</td>
</tr>
<tr>
<td></td>
<td>Type II – the sac contains the greater omentum;</td>
</tr>
<tr>
<td></td>
<td>Type III – the sac contains other intestinal loops.</td>
</tr>
<tr>
<td>Szczepkowski (2011)</td>
<td>Type I – isolated, small parastomal hernia;</td>
</tr>
<tr>
<td></td>
<td>Type II – parastomal hernia with concomitant hernia in a vertical incision scar (without significant abdominal deformation);</td>
</tr>
<tr>
<td></td>
<td>Type III – isolated, large parastomal hernia (deformation of the anterior abdominal wall);</td>
</tr>
<tr>
<td></td>
<td>Type IV – large parastomal hernia with concomitant hernia in a vertical incision scar (significant abdominal deformation).</td>
</tr>
</tbody>
</table>
frequent indication were very large sizes of the hernias (1).

Hernia classifications fail to give an unambiguous answer to the question concerning the choice of a surgical method. Inasmuch as Szczerpkowski confirmed the necessity to perform additional procedures (abdominal wall plastic surgery, segmental colon resection, fixation of the intestine in case of concomitant relapse or translocation of the site of the stoma skin opening), in the cited study only open methods were used. It seems that the level of procedure complication and the necessity to expand a surgical procedure increase with the condition type, irrespective of classification.

CHAPTER 3
EPIDEMIOLOGY OF PARASTOMAL HERNIAS

Conclusions
Level 4
Lack of registers renders reliable epidemiological assessment impossible.
Significant underestimation prevents any negotiations with the payer.
Recommendations
D It is recommended to keep registries of parastomal hernia surgeries.
It is recommended to use a unified classification and definition of parastomal hernia.
Parastomal hernia is a common complication of stoma forming surgeries. Lack of large randomised studies, low reporting rate and lack of registries, both in Poland and worldwide, prevent epidemiological assessment.
The present authors note significant variation in the reported incidence rate of parastomal hernias, ranging from 5% to even 50% (4). This might be explained by differences in diagnostic protocols (the use of CT, USG, MRI or only of a physical examination) and in definitions used by the authors (3, 5). Data from the USA, reported by SAGES (Society of American Gastrointestinal and Endoscopic Surgeons) reveal that every year 87,000 ileostomies and 135,000 colostomies are formed. Half of them are definitive stomas. From 20,000 to 35,000 of these patients (30-50%) will develop parastomal hernia. European data from British databases indicate necessity to form nearly 20,000 stomas every year. The estimated incidence of parastomal hernia among all patients in the database (over 115,000 patients) is nearly 50% (6, 7). The percentage of patients that will require surgery is estimated to be 30% (8). Prolongation of intestinal stoma patients’ survival results in an increase in the number of complications, especially of parastomal hernias. Cheung reports that after 20 years from stoma formation hernia develops in nearly 77% of the patients (9). Rulier in his study observes that parastomal hernia is more frequent after colostomy-forming surgeries than after ileostomy-forming surgeries (10). This paper confirms data (comparing colostomies and loop ileostomies) from a randomised trial performed by Gooszen in 1998 (10, 11). In 2003, Carne published a paper demonstrating that the percentage of hernias after terminal ileostomy formation is significantly higher than after loop ileostomy formation (6.7% vs 1.3%) (12).

Lian’s meta-analysis of 2011 proved beyond doubt that the percentage of parastomal hernias is higher when the stoma creation is performed with transperitoneal route than when it is performed using the extraperitoneal technique (p = 0.002) (13).

Shabbir in his paper points to the fact that best result are achieved with loop ileostomy formation (14). It needs to be mentioned, however, that this stems from the temporary nature of this approach rather than from its actual advantage.

No data in the available literature demonstrate any advantage of stoma formation through the rectus abdominis muscle over a method of creating the stoma outside of that muscle (15, 16). On the other hand, a meta-analysis performed by Carne in 2003 showed that only 4 of 24 papers demonstrated a lower percentage of hernias after creating a stoma through the rectus abdominis muscle (12).

A separate clinical problem pertains to patients with prior repair surgery of parastomal hernia. In a group of patients after repair surgery involving translocation of the stoma without the use of a mesh, the mean complication rate was 24.3% (in some papers it was reported to be as high as 76%). By contrast, a group in which the mesh was used demonstrated complication rate of approx. 3% (17, 18). Abdominal hernia formation in the site of stoma reversal surgery is seen on average in one in three patients (5). Special emphasis
needs to be placed on complication risk after repair surgery depending on the method used. Basic suturing is characterised by complication risk ranging from 55% to 100%, stoma translocation as the only method is associated with complication risk of approx. 75%, in case of surgeries involving a mesh the risk is between 0% and 33%, while with minimally invasive methods values up to 48% are achieved (4, 12, 14, 19, 20).

Since there are no credible literature data, it is difficult to estimate the percentage of hernia formation after laparoscopic stoma formation surgery. The overall number of described patients who underwent this type of surgery is below 300, which makes it impossible to draw any conclusions in line with the EBM (21).

There are no precise data pertaining to Poland. The only available data come from Szczepkowski’s 2009 paper. Most of the data seem to be underestimated. The author reports that in Poland 5 to 6 thousand stomas are formed every year. The most frequent cause are neoplastic diseases of the colon (76.6%), followed by complicated diverticular diseases (20.3%), inflammatory intestinal diseases (below 1%) and other causes, not amounting to more than 2% (22). Overall, in Poland there are at least 20,000 living with a stoma of any kind. Most procedures are lifesaving surgeries (52%) and in most cases they are colostomy-forming surgeries (88.7%) (22).

CHAPTER 4
DIAGNOSTIC IMAGING

Principles of optimal diagnostic approach in parastomal hernia (PH)

Parastomal hernia is a sac-like bulge formed by the peritoneum protruding through the stoma opening, present in approximately half of the patients with a terminal stoma (5, 23). Clinical assessment is complicated and unreliable, especially in obese people. Planning of the optimal therapeutic approach is conditioned upon assessment of the hernial sac contents and abdominal wall condition.

1. There are no unambiguous diagnostic indications for people with a stoma. No results of prospective studies are available concerning complication rate and a properly adjusted diagnostic approach. Available data pertain mostly to retrospective analyses of clinical observations, where it is impossible to maintain unified study methodology. The risk of developing complications increases with time, but it is highest during the first five years after stoma forming surgery. No differences were demonstrated between the risk of complications seen in ileostomy and terminal colostomy. Much fewer complications were reported in patients with a double-barrel stoma, but this stems from the temporary nature of this treatment option.

Level 2

In case of overt parastomal hernia (PH) clinical assessment is insufficient. Clinically overt parastomal hernia is diagnosed in several to less than twenty per cent of patients. Imaging examinations reveal a much higher percentage of diagnosed PH. Gastrointestinal X-ray may be performed during the passage procedure after oral administration of contrast agent. No specific modifications of the routinely used procedure are needed.

X-ray herniography is performed after introducing contrast into the intestinal lumen through the stoma opening – this method allows assessment of the intestine condition with accuracy reaching 90% (sensitivity: 96%, specificity: 86%) in detecting and differentiating various pathological changes (adhesions, ulceration, stenoses, relapses of neoplasm or Crohn’s disease, perforations, fistula and hernias).

Ultrasonography is an efficient method of stoma assessment, but dependent upon the operator’s experience and quality of the equipment used (the highest efficiency is achieved with transintestinal 3D ultrasonography (24). In everyday practice ultrasound resolution varies significantly, which makes its importance limited.

Computer tomography (CT) is a reference method. One part of the examination should be performed during the Valsalva manoeuvre or in the prone position, over a ring protecting the stoma opening, after optional trans-stomal administration of contrast agent into the intestine.
MRI is indicated only in case of diagnostic doubts where significant clinical conditions are present. The examination protocol should include the DWI sequence (b: 0,500).

Recommendations

Level C

It is recommended to perform a survey computer tomography scan 12 months after the surgery, and subsequently every two years. The examination should be combined with follow-up of the underlying disease.

- Two-phase CT (after intravenous administration of contrast agent during the Valsalva manoeuvre and/or after administration of contrast agent through the stoma).
- USG (expert level) every 3 months in the first year, then annually.
- In case of diagnostic doubts and negative results of CT/USG, classical herniography or CT herniography.

Diagnostic imaging

Every diagnostic imaging technique may be useful in assessing parastomal hernia in certain clinical circumstances.

There are no unambiguous guidelines based on the published prospective studies or so-called golden standard, there are, however, reasons for CT performed using the methodology described below to be recognised as such a standard.

Ultrasonography

Indications for a USG examination:

- hernia diagnostics,
- differentiation from other parastomal lesions.

Ultrasonography technique:

- transabdominal scan is performed using a linear array transducer, while transintestinal scan (performed through the stoma opening) – using a rotational transducer, most preferably with 3D acquisition (a small stoma opening, making it impossible to enter a transducer, is a limitation);
- the patient should be in the supine position;
- in order to visualise the hernia, the patient should perform the Valsalva manoeuvre;
- in case of difficulties in visualising the hernia, the examination may be performed with the patient standing or sitting;
- preparation for a USG examination is not necessary.

Assessment of the ultrasound image should be classified in line with the guidelines used in interpreting the CT results (reference method) – see below.

Computer tomography

Computer tomography is a reference method used to assess abdominal cavity organs, characterised by the highest accuracy (sensitivity and specificity) in detecting pathological structures in this area.

Indications for a CT scan:

- complications of hernia incarceration (ischaemia, necrosis, obstruction);
- assessment of the condition of the abdominal wall surrounding the stoma.

CT scan technique:

Preparation for the examination involves the following steps:

- gastrointestinal tract passage using 1 litre of 0.5-1% aqueous solution of contrast agent performed 1.5 h before the examination, with administering of 200 ml of the solution every 15 minutes;
- administering directly before the examination 0.5-1% aqueous solution of contrast agent into the stoma (in the maximum volume possible to be introduced into the stoma opening).

The examination is performed in two phases, before and after intravenous administration of contrast agent in a volume depending on the patient’s body mass (the standard protocol of two-phase abdominal-pelvic examination). During the second phase, the patient, in addition to pulling the air into the lungs, performs the Valsalva manoeuvre in order to increase the abdominal cavity pressure and better visualise any hernia they might have. Acquired images are assessed by a radiologist, who classifies the image of the abdominal wall surrounding the stoma, using the scale proposed by Moreno-Matias et al. (3).

Type 0: the peritoneum does not form a hernial sac.
Type 1: the peritoneum forms a hernial sac containing only the stomal loop (Type 1a – the sac is less than 5 cm in diameter; Type 1b – the sac is more than 5 cm in diameter).

Type 2: the hernial sac contains the greater omentum.

Type 3: the hernial sac contains an intestinal loop other than the stomal loop.

MRI

MRI has limited application in diagnosing parastomal hernias (artifacts caused by respiratory and peristalsis) and can be an option only in case of contraindications for using ionising radiation.

Where proliferative processes are suspected (mishap, relapse), the DWI sequence (b=0, 500) in the transverse and sagittal plane is recommended. The examination requires no preparation. The DWI sequence is an equivalent of PET in this clinical situation. Technically acceptable MRI examination is characterised by accuracy over 90% in detecting and assessing progression of proliferative changes and inflammatory complications.

Differential diagnosis

– Hernia with the greater omentum.
– Hernia with an intestinal loop other than the stomal loop.
– Soft tissue tumour.
– Abscess.
– Oedema of different origin.

CHAPTER 5
RISK FACTORS FOR PARASTOMAL HERNIA

Are there any independent factors known to cause parastomal hernia?

What is the impact of surgical technique on complication rate?

Conclusions

Level 2

The circumference of the abdomen over 100 cm, Crohn’s disease and age over 60 years are independent patient-related risk factors.

Recommendations

B The use of a prophylactic mesh is recommended, at least in some patients with an increased risk of hernia formation.

Parastomal hernia is the most frequent late complication of stoma forming surgery. Clinical manifestation ranges from an ordinary, insignificant aesthetic problem to incarceration and necessity of emergency surgical intervention. Based on data from the international literature, only 30% of patients with parastomal hernia will undergo a surgery. It stems from the fact that hernia repair surgery is associated with a high failure rate.

In light of the available literature, risk factors for parastomal hernia can be divided into three main groups. The first group are patient-related factors, the second group – surgical technique-related factors, while the third group consists of broadly understood factors related to peri- and postoperative care. They are summarised in tab. 1.

In multivariate analysis, such factors as obesity (BMI > 30), diabetes, malnutrition or obstructive lung diseases are associated with a higher rate of complications after stoma formation, including stoma stenosis, stoma necrosis, or abscess in the site of stoma formation, but only such factors as the abdominal circumference above 100 cm or age over 60 years are associated with a higher risk of parastomal hernia (25, 26, 27).

A prospective analysis performed by De Raet in a group of 41 patients after a surgery due to neoplastic disease (abdominoperineal resection of the rectum) demonstrated that only the abdominal circumference above 100 cm is an independent risk factor for parastomal hernia.

Table 1. Risk factors for parastomal hernia

<table>
<thead>
<tr>
<th>Patient-related</th>
<th>Circumference of the abdomen over 100 cm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Age over 60 years</td>
</tr>
<tr>
<td></td>
<td>Crohn’s disease</td>
</tr>
<tr>
<td>Surgical technique</td>
<td>Stoma created in the large intestine</td>
</tr>
<tr>
<td>Perioperative care</td>
<td>Infection complicating the surgery (surgical site infection, SSI)</td>
</tr>
<tr>
<td></td>
<td>Long survival after stoma formation</td>
</tr>
</tbody>
</table>
cm is a factor for parastomal hernia formation. This complication was seen in 75% of patients with this factor (28).

In case of colostomy formation in patients treated for Crohn’s disease much more perioperative complications are observed, including hernias. This correlation is not seen among patients with ulcerative colitis (29-33).

As regards factors related to surgical technique, in stomas formed in the colon, the incidence of parastomal hernia was significantly higher than in ileostomies. The opening through which the stoma is conducted is an important factor. There are many papers, whose authors recommend an opening not larger than 3 cm for colostomy and no larger than 2.5 cm for ileostomy (12, 34-37). Carne in his study did not confirm a decrease in parastomal hernia incidence rate in case of using minimally invasive techniques; it needs to be emphasised, however, that the study group was not very numerous and did not allow drawing precise conclusions (21).

As far as postoperative care is concerned, there are many different factors potentially leading to weakening of the abdominal wall, hence promoting parastomal hernia development. Unfortunately, the available literature lacks papers specifically confirming the effect of such factors on parastomal hernia development. However, we are aware that, from a purely theoretical point of view, they undoubtedly promote such a situation, but further research is necessary to confirm these speculations.

Given the literature data stating that, in most cases, parastomal hernias develop within two years after stoma formation, it becomes obvious that prolongation of patient survival increases the risk of parastomal hernia development (38).

CHAPTER 6
INDICATIONS FOR PROCEDURE

When should parastomal hernia be operated?

Conclusions
Level 4

Medical indications for an emergency procedure include stoma incarceration, obstruction of the gastrointestinal tract and/or necrosis of the terminal segment of the intestinal loop.

Indications for an elective procedure include defecation disorders associated with discomfort and pain conditions, difficulties in adjustment of stoma equipment, and at times cosmetic defect.

Recommendations
D In cases of incarceration, obstruction and/or necrosis of the terminal loop segment, an emergency surgery should be performed.

Surgery should be considered in cases of discomfort, difficulties in applying stoma equipment or due to (cosmetic) discomfort of the patient.

Indications for surgery are present in approx. 20-30% of patients diagnosed with parastomal hernia. According to Evans, if parastomal hernia develops in 30% patients with terminal colostomy, then in presence of indications for surgery, only 4-6% of the patients will undergo surgery for hernia (39).

This data are estimated, and indications for surgery have never been fully documented. There are no confirmed data pertaining to natural development of parastomal hernias, and studies concerning conservative treatment and its comparison with surgical treatment were not included in clinical trials (watchful waiting strategy).

Except for emergency cases, where indications for surgery do not result from the presence of hernia, but from clinical consequences of obstruction and/or necrosis, these relative indications are disputable.

The generally accepted view that discomfort, both pain-related and cosmetic, as well as difficulties in applying stoma pouches can be considered such indications, is not supported by studies. With the existing data concerning the number of complications after surgeries and recurrence rate of hernia in the stoma area, the value of this recommendation is very low. Most authors refers this view to opinions cited from 3 sources, where they are presented only as the authors’ beliefs (12, 40, 41).
CHAPTER 7
TREATMENT OF PARASTOMAL HERNIAS

7.1. Parastomal hernia preparation – open methods

1. What is the efficiency of the methods of fascial repair and stoma translocation as compared to open methods involving a synthetic implant and laparoscopic methods?

2. What is the best method of surgical treatment of parastomal hernias?

3. Where should the implant be located, and what type should it be?

Conclusions

Level 1
Biological materials are well tolerated and are not associated with an increased rate of infectious complications. Biological materials result in a high recurrence rate of approx. 15%.

Level 2
The use of an implant in parastomal hernia preparation results in a lower recurrence rate.

Level 3
Synthetic materials are well tolerated and characterised by an acceptable rate of infectious complications and seromas. Biological materials were not reported to be better in terms of lower susceptibility to infections. The number of complications with the sublay method is lower than with the onlay method. Translocation of the stoma to the opposite site helps in preparation of large hernias.

Recommendations

B The use of implants in parastomal hernia surgeries is recommended in all patients undergoing elective procedures.

C The use of a synthetic or biological implant for specific applications cannot be recommended due to lack of differences in implantation outcomes (they are equivalent).

When choosing the implantation method, the sublay method should be considered a better option when the recurrence rate is the primary criterion of choice.

The use of a big mesh and stabilisation of the anterior abdominal wall are recommended in case of complex defects.

Where necessary, stoma relocation might be recommended to aid repair of extensive defects on the side where the stoma was originally located.

The available surgical methods of parastomal hernia treatment may be divided into three main groups: stoma translocation, surgeries using the patients’ native tissues, and surgeries using synthetic materials.

Stoma translocation. Stoma translocation is one of the easiest ways to solve the problem of parastomal hernia, but at the same time associated with a significant failure rate. This method results in fact in recreation of conditions that have already led to development of parastomal hernia. There are only a few papers demonstrating outcomes of treatment using this method, pertaining only to 91 patients. The recurrence rate reaches 76% (36% on average) (9, 15, 42-46). After translocation of the stoma to the same side of the abdomen, recurrences are seen in 86% of cases, and after translocation to the opposite site – in 57%. Another problem is the possibility of hernia recurrence in the site where the previous stoma was located. The estimated risk of this complication is approx. 50%.

Fascial repair. Surgeries using the patient’s native tissues have equally unsatisfactory outcomes as stoma translocation procedures. As regards surgical technique, these procedures involve simple suture closure of the hernial defect within the fascia with prior reduction of the hernial sac or incision of the sac after inspection of its contents. The results of using this method are also highly unsatisfactory. The recurrence rate ranges from 46% to even 100% (9, 15, 43, 46, 47). Comparison of results achieved with stoma translocation and fascial repair reveals 33% and 76% of recurrences, respectively (43).

Repair using synthetic material. The use of synthetic materials allowed significant decrease in recurrence rate, which, according to different sources, ranges from several to less than twenty percent (12). However, there is no surgical method generally accepted as the standard one. The proposed methods differ in two basic aspects: the approach type (i.e. direct approach, laparoscopic approach and extrap-
eritoneal approach) and choice of anatomical space where the mesh is inserted (onlay, sublay, intraperitoneal).

The table summarises the number of complications and recurrences for different approach types.

**Number of papers and patient group sizes.** Since 1977, in the international literature there have only been several dozen papers presenting outcomes of parastomal hernia surgeries using synthetic implants. They are mostly casuistic papers describing one, at most several patients. There are only a few papers describing experiences with several dozen patients, and they include multicentre studies.

**Extraperitoneal onlay methods.** These methods involve implanting the mesh on top of the musculofascial layer. Steele, in 58 cases of using a heavy-weight polypropylene mesh inserted through an incision around the stoma, noted 28% of recurrences, although the size of the mesh and margin extending below the hernial gate was not disclosed (48). Venditti observed no recurrences in a follow-up period lasting for up to 3 years, when using a mesh in which a rhombus-shaped opening was cut (49). However, only 9 patients were included in the observations. Similarly, Kald reported 1 recurrence after using a light-weight mesh in a group of 5 patients (50). Attempts at using a biological mesh (Permacol) resulted in a 28% recurrence rate, with prostheses both in the onlay and in the inlay positions (51). These results indicate lack of usefulness of this approach. Luning, through comparing patients from the available papers on the use of implants in the onlay position, also confirms safety of this method. The overall recurrence rate in the collective group of 116 patients was approx. 25%, yet a low rate of infectious complications (4.3%), fistulas (3.45%) and stoma erosion (1.72%) was noted. Mesh removal for the above reasons was performed only in less than 2% of patients (17).

**Extraperitoneal sublay methods.** In the literature, there are over 100 cases described of patients with implants located in the retrorectus or preperitoneal positions. Generally, two approaches can be distinguished in this method: through an incision around the stoma and through one located next to the stoma (medial and lateral), or through a vertical incision. The recurrence rate with an incision in the stoma area is 0% (0/10 patients) (52), 8% (53) to 13% (36). In spite of lack of comparative studies, the recurrence rate seems to be lower than with the onlay method.

In the approach through a vertical incision a large mesh was used. This mesh additionally covers the midline, allowing stabilisation of the anterior abdominal wall and preparation of any additional incisional hernias. Kasperk used this method in 7 patients, and reported no recurrences (54), as did Egun in 10 operated patients (55). The concept of stabilising the anterior abdominal wall is the equivalent of the laparoscopic sandwich method proposed by Berger. The results do not differ from ones obtained with the open method (56).

In cases of complex defects of the abdominal wall and hernia recurrences, Rosen proposed using a method involving separation of musculofascial compartments accompanied by moving of the flaps (component separation technique) at the stoma site and relocating the intestine to the opposite site. In 12 described cases no recurrences were noted, nevertheless it needs to be emphasised that in this study 33% of complications were observed, including one death in the postoperative period, renal insufficiency and aortic bypass graft thrombosis (57). Similarly, in a group of 34 patients with concomitant incisional hernia, Szczepkowski noted less than 10% of recurrences, yet the postoperative complication rate was not given (58).

**Intraperitoneal methods.** Placement of an anti-adhesive mesh from the midline open approach was described in several papers. The biggest group is reported by van Sprundel, where an ePTFE implant was used. Among 16 operated patients one recurrence was noted,
but also 3 cases of intestinal obstruction and perforation, requiring implant removal (59). This high infection rate may be caused by the implant type. However, using a biological implant (Surgisis) did not cause any significant reduction in the complication rate. Eblis noted 20% of complications (among 12 patients) and 10% of recurrences60, while the overall complication and recurrence rate for biological meshes was 26.2 and 15.7%, respectively (61).

7.2. Parastomal hernia preparation – laparoscopic methods

Is the use of the laparoscopic methods a valuable alternative for the open methods, and if so, in what cases?

Conclusions

Level 3

The Sugarbaker’s and sandwich techniques result in good procedure outcomes and low recurrence rates.

The key-hole technique results in a high recurrence rate.

The laparoscopic approach makes it possible to operate both small and large parastomal hernias.

No data are available concerning treatment of concomitant abdominal hernias in the published series of patients.

Level 4

Experts believe that the sandwich and Sugarbaker’s techniques are more valuable than the key-hole technique.

Recommendations

C Laparoscopic techniques should be considered in all cases of elective parastomal hernia surgeries.

C The key-hole technique should not be recommended due to a high recurrence rate.

Laparoscopic methods in treating parastomal hernias find increasingly wider application. The theoretical basis for the development of laparoscopy was founded by the first results published by Sugarbaker, who successfully inserted an implant in the intraperitoneal position (1985) (62). There are three conceptions of laparoscopic preparation of parastomal hernias: Sugarbaker’s technique, key-technique and sandwich technique.

Sugarbaker’s technique, laparoscopic modification

After preparation of the hernial sac contents, a flat mesh is placed on a hernia orifice with a 5 cm margin left (range from 3 to 7 cm), and subsequently attached to the abdominal wall using a stapler. The terminal end of the intestine is driven inside the sac over the mesh and into the peritoneum at the lateral surface of the abdominal wall. The intestine, from the place it is sutured to the abdominal wall, goes through a tunnel created from the outside by the skin and subcutaneous tissue together with the hernia sac, and down through the implant. Several series of patients were described where this technique was used. Pastor (2009), among 12 operated patients, observed 33% of direct postoperative complications and 33% of recurrences after the mean time of 10 months after the surgery (63). Mancini (2007), among 24 patients, noted only one recurrence after the mean time of 19 months of follow-up (64). Craft performed 12 procedures, and observed no recurrences in the period of 12 months (65). Other papers describe also several additional cases (series of <5 patients) with positive outcomes.

Key-hole technique

After preparing the hernia sac, inside the peritoneum, from the medial side, a small round or oval mesh is placed, with an opening created for the stoma. After fastening the mesh, its slit branches are attached together using a suture (or sutures), which makes the mesh enclose the stoma. The double crow technique with a Protac stapler was used, and in some papers the mesh was fastened using transabdominal sutures. In papers by Craft and Muysoms, the authors decided not to use this technique because of a high recurrence rate, and operated the subsequent patients using the Sugarbaker’s technique (65, 66). Safadi observed 44% of recurrences among 9 operated patients in 24 months (67). Similarly, Mizrahi noted 46% of recurrences in the mean follow-up time of 30 months. A multicentre study conducted in the Netherlands also demonstrated a 37% recurrence rate in the mean time of 36 months (68).
Good results were noted by Wara, who observed only 2 recurrences among 72 operated patients after the mean time of 3 years. In case of this patient group, however, the technique was modified: no opening was cut in the implant, but instead it was slit radially in its central part, which allowed forming a few triangular flaps surrounding the stomal loop (69).

Sandwich technique

This technique, described by Berger in 2007, combines the aforementioned techniques. Two meshes — one used in the key-hole technique and one flat, forming a tunnel for the intestinal loop — are placed inside the peritoneum. The flat mesh forms a large surface and, with its medial side, covers the vertical incision wound after laparotomy, thus offering potential prevention or preparation of incisional hernia. The recurrence rate in the two reported series (47 and 66 patients) was approx. 2% in the period of 2 years. In the reported procedures Berger used PVDF (polyvinylidene fluoride) implants.

Conclusions drawn from the published papers

In the literature published to date, there are no randomised studies comparing open and laparoscopic techniques as well as individual laparoscopic techniques with one another. Authors using two techniques, that is the key-hole and Sugarbaker’s technique, in every case rejected the former due to a high recurrence rate observed (Draft, Muysoms). Other authors were also sceptical about outcomes achieved with this method (Hansson, Safadi, Mizrahi). It needs to be noted that laparoscopic procedures were also performed in patients with extensive hernias, the area of which reached 400 cm² (Berger, Hansson, Draft), but the remaining authors did not include epidemiology in their papers. Therefore, the results are not referred to the described recurrences in the context of the hernia size. Hence, it is impossible to draw conclusions concerning the usefulness of laparoscopic method in specific patients groups and hernia sizes. Emergency surgeries were also excluded from the studies (Berger), no indications for surgery, expect for the hernia itself, were demonstrated, and all surgeries were performed in the elective setting. Among the complications characteristic of abdominal hernia laparoscopic surgeries and associated with not removing the hernial sac, seromas were a rarely described condition (Pastor 1/25, Berger 1/47 (infection), Hansson 0/55; Wara 7/72).

CHAPTER 8
BIOMATERIALS

What materials can be used in preparation of parastomal hernias?

Is using biological implants more beneficial than using synthetic implants?

Conclusions

Level 1

The use of an implant in parastomal hernia preparation results in a lower recurrence rate.

No increased infection risk was demonstrated in parastomal hernia surgeries compared with abdominal hernia surgeries.

Level 3

Synthetic materials are well tolerated and characterised by a low rate of infectious complications and seromas, both with open and laparoscopic methods.

Biological materials are well tolerated and are not associated with an increased rate of infectious complications.

Biological materials were not reported to be better in terms of lower susceptibility to infections.

Recommendations

A The use of implants in parastomal hernia surgeries is recommended in all patients undergoing elective procedures.

C The use of a synthetic or biological implant for specific applications cannot be recommended due to lack of differences in implantation outcomes (they are equivalent).

In open and laparoscopic procedures many synthetic and biological materials were used. Table 1 lists papers describing the use of different synthetic materials.

Both in the open and laparoscopic techniques synthetic implants were used, made of different types of polymers. In the group of
patients operated using the key-hole technique a higher recurrence rate was observed; no analyses were performed, however, to assess whether recurrences resulted from the method itself or from increased shrinkage of the ePTFE mesh observed in animal models (70). No increased infection rate was observed in the group using synthetic materials, irrespective of their type. Craft reports a 10% infection rate in patients operated using an ePTFE implant, but in other papers this rate does not exceed 2% (65, 67, 69). There are no available randomised studies or meta-analyses concerning comparison of the individual material types.

In the past few years, attempts have also been described to use biological implants in parastomal hernias preparation. The table below summarises the biggest series of patients with implanted collagen prostheses of different origin.

It needs to be noted that contaminated surgical field is an indication for these prostheses, but in the described series the implants were used in the elective setting. Small patient groups make it impossible to draw conclusions regarding the efficiency of the procedure; however, the results demonstrate that the material used did not resolve the problem of infections and recurrences. There are no data that would justify using biological prostheses as the routine method of parastomal hernia surgery.

### CHAPTER 9
PERIOPERATIVE ANTIBIOTIC TREATMENT AND THROMBOEMBOLIC PREVENTION IN PARASTOMAL HERNIAS

**Is it necessary to use antithrombotic and antibiotic prevention during plastic surgery of inguinal hernias?**

Parastomal hernia is the most common distant complication of stoma formation. Repair surgery is associated with a low risk of surgical site infection. The recommended method of repair involves using a mesh, which may promote development of infection of the implanted foreign body and persistent infection.

Nevertheless, the problem of antibacterial and thromboembolic prevention is not widely described in the literature.

**Conclusions**

**Level 1**

All patients should receive basic prevention in the form of LMWH or NFH; the use of stockings of compression-class II may be considered.

**Level 2**

Parastomal hernia repair surgery is associated with a low risk of surgical site infection (SSI). The use of generally accepted procedures in a given department should be sufficient.
Parastomal hernia surgery is associated with a moderate risk of thromboembolic complications.

Recommendations

A Antithrombotic prevention typical for patients of the moderate risk group.
B Standard perioperative antibiotic prevention is sufficient.

9.1. Perioperative antibiotic treatment

Based on the analysed material, we can conclude that the problem of surgical wound infections, despite a high infection risk, is not a serious problem in the postoperative period. It is an issue of minor importance, easily manageable with intravenous antibiotics, drainage or suction drainage. Infections of the implanted material occur rarely, in isolated cases mesh removal was necessary. The only exception is a study by P.de Ruiter and A.B. Bjinen (36), in which out of 46 patients who underwent parastomal hernia surgery (mean follow-up period of 5 years), 4.3% had early infections, 2.3% late infections, and in 10 cases the prosthesis was definitely removed.

Antibiotics used in perioperative prevention found in the literature include second-generation cephalosporins (e.g. cefuroxime) in a single dose or 3 doses perioperatively, third-generation cephalosporins (e.g. 1 g cefotaxime directly before the surgery and 2 subsequent doses after the surgery in 8-hour intervals), amoxicillin with gentamicin, cefuroxime with metronidazole in a single dose and doxycycline in combination with metronidazole (36, 53, 54, 69, 71-81).

Scarcity of information about the method and dose of antibiotic treatment in the studied papers makes it impossible to analyse treatment efficiency in a credible way, therefore the present authors do not attempt to suggest inferiority of any of the prevention schemes.

As seen in the above example, there is no single accepted method of efficient antibacterial prophylaxis, therefore the present authors suggest that the perioperative prophylactic scheme used in a given site should not be changed.

9.2. Antithrombotic prevention

In the analysed material there are virtually no mentions of thromboembolic complications. There are also few data concerning the type of prevention used. Analogically as in the case of perioperative antibiotic treatment, we conclude that these incidents were occasional and unrelated to the underlying disease, nor were they assumed complications of the surgery.

Among several types of prophylaxis named in the papers, the standard low molecular weight heparin prevention was mentioned, including the use of compression stockings or repeated pneumatic compression.

Due to lack of thromboembolic events reported in the analysed literature, we conclude that parastomal hernia surgery is not associated with an increased risk of such complications, and patients can receive standard prevention, with optional modification, depending on the patient’s clinical condition and concomitant diseases.

Patients operated due to parastomal hernia can be assigned to the group at a moderate risk of VTE, as is the case with patients operated due to other types of abdominal hernias, such as inguinal hernias or postoperative hernias, and prevention should take into account other aggravating factors. In line with the Polish guidelines regarding prevention and treatment of venous thromboembolism, the moderate risk groups includes patients undergoing general surgery lasting over 30 minutes. Concomitant diseases, such as malignant neoplasm, can change the qualification to high risk, and some of the stoma patients are operated due to neoplastic disease. A large group of patients is comprised of elderly people, which is a risk factor for DVT in itself.

According to the report “Polskie wytyczne profilaktyki i leczenia żylnej choroby zakrzepowo-zatorowej” (22) (Polish guidelines regarding prevention and treatment of venous thromboembolism) patients at moderate risk of VTE should receive LMWH in an adequate prophylactic dose recommended by the manufacturer, with the first dose given 12 h before or 6 h after the surgery, or NFH (non-fractionated heparin) 5000 UI SC every 12 h, with the first dose given 1–2 h before the surgery. In case of high-risk patients one of the following options is recommended: NFH 5000 UI SC every 8 h, with the first dose given 1–2 h before the surgery or LMWH in an adequate prophylactic dose recommended by the manufacturer, with the first dose given 12 h before or 6 h after the surgery.
Since patients operated for parastomal hernia belong to the moderate or high-risk group, they should all receive basic prevention in the form of LMWH or NFH, and optionally elastic stockings or repeated pneumatic compression of the lower limbs might be used, especially in patients who, for different reasons, cannot be immobilised early.

CHAPTER 10
INDICATIONS IN THE PERIOPERATIVE PERIOD (FOR PATIENTS AFTER STOMA FORMATION AND AFTER PARASTOMAL HERNIA REPAIR SURGERY)

Conclusions
Level 2
The use of a hernia truss or supporting underwear without an opening for the stoma, for at least 3 months.
Level 3
Necessity of constant care in stoma clinics.
Recommendations
B Modification of lifestyle, quitting smoking, supporting underwear or equipment in every patient after repair surgery.
Postoperative recommendations for patients after stoma forming surgeries are meant to eliminate or limit the risk of postoperative complications, especially of parastomal hernia formation or recurrence. Due to the nature of complications and the time they develop, indications for the postoperative period relate to either the early or the late period after the repair procedure.
Postoperative indications for the patients must pertain to two areas – indications typical for abdominal hernia operations (using supporting trusses, avoiding forceful physical activity, dietary restrictions) and typical for the stoma (caring for the skin around the stoma, minimising the risk of wound infection).
Thompson recommends the use of a postoperative abdominal truss or underwear supporting the abdominal wall (82). At the same time, patients should be given clear instructions regarding the use of these products. The postoperative abdominal truss or supporting underwear should be applied for the first time immediately after the surgery, before the patient is woken. Subsequently, in the postoperative period after discharge, the patient should use these products daily for approximately three months. The truss should be applied immediately after waking up, before the patient leaves the bed. The supporting truss should be removed before going to sleep, since during the night immobilisation and rise in the intraabdominal pressure increase venous stasis in the lib, possibly leading to thrombotic changes in the veins. During the night’s rest the abdominal wall becomes relaxed, and the pressure applied to the stoma area decreases. Removal of the abdominal truss is also necessary before all actions performed at the stoma, such as pouch replacement or stoma cleaning. Reapplication and adjustment of the truss also should be performed after a short rest in the supine position, for the reasons described above. After three months from the surgery, supporting trusses should be used only during forceful physical activity or lifting heavier weights. These measures should be continued for one year after the surgery (83).
Using abdominal trusses and supporting underwear with factory-cut opening for the stoma should be avoided. This may cause bulging of the stoma through this opening and increase the risk of complications. Pressure applied to the abdominal wall should be evenly distributed over the whole surface covered by the truss or underwear (82).
Another way to decrease the risk of parastomal hernia development is implementation of a prevention programme developed by Thompson and Trainor (84).
Analysis assessing care of 300 patients after stoma formation surgeries revealed that implementation of the prevention programme caused a statistically significant decrease in the number of parastomal hernias from 28% to 15% (p < 0.025), where patients were merely familiarised with the principles of the plan, and to 10%, where patients complied with the principles (p < 0.01). Based on this study results, the authors distinguished three basic components of prevention. The patients need to be made aware of the risk associated with the possibility of hernia development; abdominal physical exercise is recommended to strengthen the abdominal muscles as well as afore-mentioned simultaneous use of trusses and supporting underwear while lifting heavier weights for up to one year after the surgery.
Additional recommendations include abstention from forceful physical activity and lifting heavier weights for at least three months after the surgery and maintaining a proper erect posture (avoidance of excessive bending of the trunk; bending legs rather than leaning down in order to lift objects from low places). In situations causing a sudden increase in the intraabdominal pressure (e.g. during coughing, vomiting), for several months after the surgery the patient needs to hold the abdominal wall surrounding the stoma with an open hand (84).

Exercises proposed by Thompson as part of the prevention programme involve physical activity leading to strengthening of the abdominal wall muscles, especially of the rectus abdominis muscle, without simultaneous increase of the intraabdominal pressure (82). Three exercises were described. They are all performed while lying on the back on a flat surface, with slightly bent, elevated knees, with the feet resting on the surface. The first exercise involves pushing the pelvis slightly upwards with simultaneous detachment of the buttocks from the surface. The second exercise involves keeping the knees together, and rotating them alternately to the sides. The third one involves pulling the trunk forward with the shoulder blades detaching from the surface (so-called crunches). Exercises should be commenced after the wound heals. Each exercise should be repeated 10 times a day, for at least three months after the surgery. Patients should additionally be encouraged to engage in moderate physical activity (strolling, bicycle riding).

Obesity is a risk factor for parastomal hernia, since – through stretching the muscles – it decreases muscular fitness (85). Obesity promotes development of surgical site infections, which is another proved factor for hernia development (86, 87). According to Weisbren, obesity as defined as percentage of the adipose tissue in the body causes a fivefold increase in the number of surgical site infections (p < 0.03) (88). At the same time, postoperative body mass increase might contribute to stoma prolapse (19). Therefore Thompson recommends that in the postoperative period the body mass index (BMI) should be reduced and then maintained in the range of 20-25 kg/m² (84).

Difficulties with maintaining the proper skin condition around the stoma are observed in 80% of such patients. Every third visit in a stoma clinic is regarding skin problems. Healing disorders affecting the skin around the stoma significantly affect the patients’ quality of life, since it makes the use of stoma equipment difficult, or even impossible. That is why the patient adaptation to the presence of the stoma depends mainly upon maintaining good skin condition around the stoma (89). The most frequent complication is inflammation of the skin around the stoma caused by chemical irritation by the faeces or urine. This leads to stoma leakage. Attention should be paid to avoiding mechanical irritation of the skin around the stoma. Everyday replacement of the stoma equipment glued onto the skin is necessary.

<table>
<thead>
<tr>
<th>Abdominal wall support</th>
<th>use abdominal trusses (or underwear supporting the abdominal wall) for at least three months after the surgery \ remove the truss for the night’s rest \ after three months use the trusses only during lifting heavier weights \ avoid using trusses with an opening for the stoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body mass</td>
<td>maintain the body mass index (BMI) in the range of 20-25 kg/m²</td>
</tr>
<tr>
<td>Physical exercise</td>
<td>avoid lifting heavier weights for at least three months after the surgery, \ avoid forceful physical activity for at least three months after the surgery, \ immediately after wound healing, begin a specially designed cycle of mild exercises aimed at strengthening the abdominal muscles, \ avoid coughing and vomiting, and where they cannot be avoided, hold the stoma area with an open hand, \ maintain a proper, erect posture (avoid excessive bending of the trunk and leaning down)</td>
</tr>
<tr>
<td>Caring of the skin around the stoma</td>
<td>take care of tight application of the stoma equipment, \ avoid too frequent removal of the rings used to attach pouches</td>
</tr>
<tr>
<td>Diet</td>
<td>avoid constipations and diarrhoea, \ use a balanced, high-fiber diet (20–35 g of fiber/day)</td>
</tr>
<tr>
<td>Tobacco smoking</td>
<td>quit smoking</td>
</tr>
</tbody>
</table>
evitably leads to epidermic damage, and subsequently to skin inflammation with all its consequences. This phenomenon is not observed, if the stoma equipment glued onto the skin is replaced twice a week. That is why one should avoid too frequent replacement of the adhesive ring applied to the skin surface (90). In order to maintain proper skin condition around the stoma, its leakage should be prevented (it is necessary to use well-adjusted rings as well as pastes in order to seal and even out the surface). In case of development of a bacterial or fungal infection, adequate topically acting agents should be used (antibacterial creams, antifungal powders).

Eating of foods potentially leading to constipation or diarrhoea should be avoided. Difficulties in defecation may lead to an increase in the abdominal pressure and contribute to development of complications. That is why, in case of difficulties in defecation, mildly acting laxatives are recommended, which is especially important for patients with stoma stenosis (19). On the other hand, sustained diarrhoea may cause chemical damage of the skin around the stoma, making it difficult to use stoma equipment. That is why a balanced, high-fibre diet is recommended, with daily fibre consumption of at least 20 to 35 g (91).

Sørensen’s studies revealed that smoking tobacco increases the risk of postoperative hernia fourfold (92). Additionally, it leads to exacerbation of changes in chronic obstructive lung disease. Cough resulting from these changes causes a sudden, uncontrolled increase in the intraabdominal pressure, which adversely affects the stoma (93). For this reason it is recommended that patients undergoing stoma formation surgeries should quit smoking.

An important role in the postoperative care is played by stoma nurses, through sharing their knowledge with the patients and developing support programmes for persons with parastomal hernias. All prophylactic recommendations presented in this section (tab. 1) should be supervised by this personnel. Introduction of proper habits and stoma care lies within the competence of stoma nurses, since the patients seeking help are much more likely to consult them than the surgeon. That is why it is important to introduce measures aimed at streamlining the work of stoma clinics (19).

CHAPTER 11
COMPLICATIONS OF PARASTOMAL HERNIA TREATMENT

What local complications might occur during parastomal hernia repair surgery, and what complications can develop in the postoperative period?

Which of the complications are the most serious clinical problem?

What is the parastomal hernia recurrence rate and what are the risk factors for this complication?

Conclusions
Level 2
The use of an implant in parastomal hernia surgery results in a lower recurrence rate. No increased infection risk was demonstrated in parastomal hernia surgeries compared with abdominal hernia repair. The most serious clinical problem are surgical site infections and intestinal fistula in the stoma channel. The recurrence rate ranges from 0 to 100%, while in groups comprising at least 25–30 patients it is 0–29%. Recurrences were most frequent in case of the laparoscopic key-hole technique.

Level 3
Synthetic materials are well tolerated and characterised by a low rate of infectious complications and seromas, both with open and laparoscopic methods. Laparoscopic methods result in a higher rate of infectious complications (SSI). Biological materials are well tolerated and are not associated with an increased rate of infectious complications. No superiority of biological materials was demonstrated in terms of smaller susceptibility to infections. Intestinal damage is not an indication for conversion or decision of not implanting a mesh.

Recommendations
B The use of implants in parastomal hernia surgeries is recommended in all patients undergoing elective procedures.
B If the infection rate is taken into account, laparoscopic methods should be used.
C Due to a high recurrence rate, the key-hole technique is not recommended.
C While managing seromas, conservative should be always considered.
Polish guidelines for treatment of patients with parastomal hernia

C Small intestinal damage managed preoperatively should not result in a decision of not using the implant.

Surgical complications associated with parastomal hernia repair are a very serious, still not entirely resolved clinical problem. These complications can occur both during the repair surgery (perioperatively) and in the postoperative period.

11.1. Perioperative complications

11.1.1. Surgical field contamination

Outcomes of parastomal hernia treatment using other methods clearly demonstrate than only the use of meshes allows obtaining a satisfactory late outcome, measured mainly as acceptably low complication rate. However, the use of synthetic material near the intestinal stoma may raise doubts. Additionally, repair surgery may also involve intestine resection, causing even higher risk of surgical field contamination. Papers concerning the use of meshes in a potentially contaminated surgical field in case of incarcerated inguinal hernia surgeries and postoperative hernia surgeries, also involving intestine resection, or of parastomal hernia surgeries, demonstrating the risk of infection and surgery failure is not high (approx. 4-7%) (62, 67, 94). The use of a mesh during surgery involving opening of the colonic lumen requires special care and caution. According to the authors, mechanical preparation of the intestine seems to be of special importance (Berger, Hansson, Janes, Sugarbaker); most available papers, however, do not refer to this issue and there is no unambiguous evidence for usefulness of this solution, as is the case with other colon surgeries (94).

11.1.2. Perioperative bleeding

Perioperative bleeding is rarely a serious problem during parastomal hernia surgery, irrespective of the approach used. This issue is not mentioned in the literature at all.

11.1.3. Intestinal damage caused during surgery

This complication occurs relatively rarely and pertains mostly to loops formed by the small intestine constituting the contents of the hernial sac. Most frequently this kind of damage, when spotted, requires immediate repair without significant consequences. However, this is the case only in open surgeries, since in laparoscopic procedures such damage can be overlooked. In papers presenting outcomes of laparoscopic surgeries the complication rate is usually relatively low, but there are cases of intestinal damage and fistula formation reported. The number of cases of intestinal damage reported in papers ranges from approx. 2% (94, 95) to even 10–20%. In Hansson’s study intestinal damage rate was 10.9%, in case of primary hernias and even 20% in case of recurrent hernias (96).

11.2. Early perioperative complications

11.2.1. Surgical site infection

It is the most clinically significant and serious complication occurring in the early postoperative period. Data found in the literature reveal that surgical site infection occurs in 0 to 40% of cases. Analysis of individual reports reveals that this rate decreases with increase in the size of the group presented. However, comparison of individual patient series reported in the literature is very difficult due to lack of uniformity (different surgical methods, different approaches, no classification used, etc.). Using the laparoscopic approach can be also associated with a lower incidence of surgical site infection (62).

It is also worth noting that infections occur relatively rarely in the space where the mesh is located, and usually wound site infections affect the subcutaneous tissue. Unfortunately, in the literature there are no analyses regarding this issue. Studies conducted by Szczepkowski reveal that risk factors of surgical site infection include the following: sloppy surgical technique, lack of preoperative mechanical preparation of the intestine, surgery using so-called “open” technique, procedure time over 2 hours, overweight and failure to perform tight closure of the stoma at the beginning of the surgery (using a Foley’s catheter to close the stoma).

11.2.2. Seromas

Similarly as in abdominal hernia treatment, development of seromas is observed. The number of seromas with laparoscopic methods ranges from 8% (94, 95) to even 35% (67). Large
volume, symptomatic seromas require aspiration. In Berger’s study 12% of seromas were aspirated, and in Moreno–Eege’s study similar numbers of seromas requiring aspiration were found (10–14%).

11.2.3. Other rare complications

The remaining complications occurring in the early postoperative period, such as stoma oedema or postoperative obstruction are usually successfully managed with conservative treatment. Prolonged leakage of serous matter from the space surrounding the mesh makes it necessary to maintain drains placed in this area. It is largely associated with the surface of the mesh used in the surgery. It is usually used for 3–5 days.

11.3. Late complications

11.3.1. Stoma stenosis

Stoma stenosis occurs usually several months after the surgery and in most cases it is a consequence of ischaemic and necrotic changes in the stoma. Incidence of this complication ranges from 0 to 26%, and depends mostly on the cause of stoma formation (if the reason for stoma formation was inflammatory disease, the probability of stoma stenosis is higher) and surgical technique. Szczepkowski states that the incidence of stoma stenosis of 6% was mainly a consequence of ischaemic changes in the early postoperative period. Stenosis of the stoma channel at the mesh level. When symptoms of difficulties in intestinal passage are present, reoperation should be considered involving cutting out a part of the mesh, but it needs to be noted that such a surgery is associated with a high risk of complications. There are no scientific data describing such measures.

11.3.2. Intestinal fistula in the stoma channel

A key element of surgical technique is the manner of driving the intestine – through or next to the mesh. If an excessively large opening is created, hernia recurrence might occur, and if the opening is too small, the side of the mesh might damage the intestinal wall. Such damage can happen also through a different mechanism (97), involving movement of the mesh in relation to the stoma intestine during the patient’s verticalisation in the immediate postoperative period. This effect is called the “delayed guillotine effect”. An argument supporting this mechanism is the fact that it does not occur immediately after the surgery, which would be expected if the intestine was constricted from the surgery. Such complications are rarely the object of separate papers. Aldridge presents a case of colon perforation caused by a mesh after recurrent parastomal hernia surgery. The perforation with concomitant abscess in the site of mesh placement required segmental colon resection, translocation of the stoma to the opposite site of the abdomen and mesh removal (98). Two complications of this kind described in another paper were managed without the need to remove the mesh, with maintaining the general aim of the primary surgery (97).

11.3.3. Hernia recurrence

The complication rate after parastomal hernia treatment is significantly lower when the mesh is used, although in papers presenting treatment outcomes, we find the recurrence rate ranging from 0 to 100%. After rejecting casuistic reports and short case series, the recurrence rate ranges from 4% to 41.7%. After surgeries performed with the mesh placed in the sublay position were included, the recurrence rate ranges from 0 to 29%. The highest recurrence rate was reported for the laparoscopic key-hole technique (68). In a patient series treated by the author this rate was approx. 10% (58). The recurrence rate cannot be treated as the only factor of a given surgical method’s efficiency; it seems, however, to be one of the most important factors affecting assessment of a given method, especially with a long follow-up period. The currently available literature data are insufficient to perform such comparative analysis. The literature contains no analyses regarding the relationships between parastomal hernia complication rate, BMI and other patient-related factors.

Treatment of complications after parastomal hernia repair surgeries is a difficult procedure, associated with a high risk of complications, including life-threatening ones. They should be performed in sites with sufficient clinical experience in this regard.
CHAPTER 12
COSTS OF PARASTOMAL HERNIA TREATMENT (COST-EFFECTIVENESS ANALYSIS)

Conclusions
Level 1
The most effective way of managing parastomal hernia is stoma removal.
Repair of a hernia with a mesh should be recommended as treatment of choice.

Level 2
Modification of lifestyle, quitting smoking and physical exercise improve the cost-effectiveness of the stoma-supporting equipment.
The use of biological and synthetic implants proved successful in parastomal hernia treatment.

Level 3
Hybrid operation as an alternative; RCT needed.

Recommendations
A Implant use is recommended in case of parastomal hernia repair surgery, improving the cost-effectiveness of the procedure.
B The laparoscopic approach should be used in order to reduce distant costs.
C Cost-analysis should be performed in order to present the results to the payer.
The most effective way of managing parastomal hernia is stoma removal. In such cases, however, the patient is at risk of developing incisional hernia (99). If the stoma is a definitive solution, the only options are conservative or surgical treatment. Conservative treatment using supporting devices in the most common solution used by patients. Surgical treatment is performed only in isolated cases due to a high recurrence rate after classical repair surgeries. Surgeries are performed in case of obstruction, incarceration or discharge caused by stoma leakage. Relative indications for the surgery include persistent pain conditions and cosmetic reasons.

Thompson, in a presented cost-effectiveness analysis of parastomal hernia treatment, distinguished three possible options (100, 101):
1) lack of treatment,
2) conservative treatment aimed at preventing hernia development or the use of hernia-supporting devices,
3) surgical treatment,
Costs should be understood not only as direct financial expenses associated with the treatment, but also as social consequences, not limited only to the patient.
Ad 1. Costs resulting from lack of hernia treatment include social aspects (with drawal from previous roles, loss of potential benefits), psychological aspects (feelings of shame, sadness), physical aspects (discomfort, pulling sensation, nausea, spinal pains, skin damage, leaks, incarceration of the hernia sac content) as well as financial aspects (necessity to buy additional, larger clothes, expenses for keeping the underwear clean, costs of visits to doctors, stoma care products – tab. 1) (20).

Patients usually report 1–3 leaks a week before they seek specialist help (102). One leak a week is an additional cost of approx. 45.00 PLN needed to fully replace devices and accessories. Annually this amounts to 2,250–6,750 PLN of additional expenses associated only with caring for the skin around the parastomal hernia.

Lack of surgical treatment is not associated with any benefits, except for rare cases of patients, who prefer to assume the so-called "sick role".

Table 1. The cost of basic devices and accessories required for caring for the stoma (price list of 2011).

<table>
<thead>
<tr>
<th>Device name</th>
<th>Gross cost (PLN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>One-piece, closed-end pouch with a window</td>
<td>8,97 – 12,95</td>
</tr>
<tr>
<td>One-piece, open-end pouch with a clamp</td>
<td>12,11 – 16,05</td>
</tr>
<tr>
<td>Urostomy pouch</td>
<td>13,08 – 14,26</td>
</tr>
<tr>
<td>Cleaning wipes (1 piece)</td>
<td>0,71</td>
</tr>
<tr>
<td>Remover with skin caring properties (180 ml)</td>
<td>34,99</td>
</tr>
<tr>
<td>Anti-chafing cream (60 ml)</td>
<td>35,18</td>
</tr>
<tr>
<td>Paste, tube (60 g)</td>
<td>50,03</td>
</tr>
<tr>
<td>Baseplate (15x15)</td>
<td>28,84</td>
</tr>
<tr>
<td>Tape (10 strips, 6 g each)</td>
<td>53,40</td>
</tr>
</tbody>
</table>
Ad 2. Thompson also performed a comparison of parastomal hernia development in two groups of patients (82, 83). The first group included retrospective analysis of hernia development in patients who were not subjected to any preventive measures. The second – analysed prospectively – group consisted of patients who during discharge were given instructions to avoid heavy weights for 3 months. After this time, patients began moderate abdominal exercises and were encouraged to use trusses supporting the abdominal wall during lifting. The analysis performed demonstrated a statistically significantly higher incidence of hernia in the first group (33 vs. 15%; n = 300).

The costs of conservative treatment include the necessity to buy an abdominal truss having an opening for the stoma, but its wear rate makes it possible to efficiently use one truss only for approx. 3 months. (100.00 PLN each, according to a price list of 2011; thus the annual cost is 400.00 PLN). The Polish National Health Fund (Narodowy Fundusz Zdrowia, NFZ) refunds one piece in 2 years. There are also more advanced and expensive options involving the use of underwear supporting the abdominal wall (291.00–322.00 PLN). One should also add costs associated with missing work due to frequent visits in the stoma clinic or the time dedicated by the patient to perform exercise. Costs associated with caring for the skin surrounding the stoma are discussed above.

The benefits of conservative treatment include an increase in hernia incidence noted by Thompson, from 33 to 15% (82). Additional benefits resulting from lifestyle change include limiting or quitting smoking, and preventing overweight and obesity, which results e.g. from the physical exercise performed by patients. In addition, the patients’ comfort increases as a result of using devices supporting the abdominal wall.

Ad 3. Because of poor outcomes, surgical treatment of parastomal hernias is limited to approx. 15–70% of patients (4, 15). Among the available methods of surgical treatment, the cheapest, but also the least efficient option is local plastic surgery of the hernia (103). Translocation of the stoma opening does not reduce the risk of parastomal hernia recurrence, simultaneously subjecting the patient to the risk of developing postoperative hernia in the previous stoma location (99). A more expensive solution, but at the same time much more efficient, is complex repair, involving supporting of the stoma area with a macroporous synthetic mesh, which reduces the number of recurrences (104). The best outcomes, however, are achieved after using modern materials (including expensive biological meshes), which help reduce infections in the wound area (tab. 2).

The optimal solution proposed currently by many authors is laparoscopic hernia repair with intraperitoneal placement of a mesh with an antiadhesive layer, attached to the abdominal wall using special devices. Benefits of this solution include a significant reduction of recurrence rate and shortening of the time of hospital stay, recovery and returning to work. It seems that refunds of costs associated with parastomal hernia treatment by the payer (NFZ) when using this method should also include expenses for costly synthetic meshes (2,143.26–4,375.98 PLN, depending on the size and manufacturer) and fixing devices (1,134.00–1,749.60 PLN, depending on the type and manufacturer), which is directly balanced by savings associated with care for an untreated stoma (6,750 PLN a year).

The biggest benefits of using synthetic meshes to treat hernias include decrease in

<table>
<thead>
<tr>
<th>Material name (origin)</th>
<th>Gross cost for cm²(USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alloderm (Human dermis)</td>
<td>35,31</td>
</tr>
<tr>
<td>Permacol (Porcine dermis)</td>
<td>18,97</td>
</tr>
<tr>
<td>Surgisis (Porcine SIS)</td>
<td>20,00</td>
</tr>
<tr>
<td>Collamend (Porcine dermis)</td>
<td>18,88</td>
</tr>
<tr>
<td>Peri-guard (Bovine pericardium)</td>
<td>3,91</td>
</tr>
<tr>
<td>Veritas (Bovine pericardium)</td>
<td>22,02</td>
</tr>
<tr>
<td>Polypropylene/e-PTFE/Composite</td>
<td>3,65</td>
</tr>
</tbody>
</table>
Polish guidelines for treatment of patients with parastomal hernia

recurrence rate, elimination of the risk of incarceration or strangulation of the intestine, improvement of respiratory function, reduction of spinal strain and resulting conditions as well as improvement of quality of life. Savings made in expenses for additional skin care products amount to approx. 33,750 PLN during 5 years. It needs to be noted that due to continuous improvement in outcomes of treating colon neoplastic diseases, the expected survival of such patients is continually increasing (105).

Currently, there is increasing attention paid to preventive implantation of synthetic meshes, already during the primary stoma formation procedure. According to Vijayasekar, this allows a significant decrease in parastomal hernia incidence, to approx. 9.5% (106). However, there are no comprehensive studies analysing the cost-effectiveness of such a solution. Janes and Israelsson began a study attempting to analyse these relationships. However, the study was discontinued for ethical reasons, due to very poor outcomes in the group with no prophylactic measures involving the use of a mesh (8).

Poulose, based on the results of a performed analysis, demonstrated that an increase in abdominal hernia recurrence and resulting reduction in the number of repair surgeries by only 1% leads to savings of 32 m dollars in reference only to the costs of the surgical procedure in the United States (in the United States, around 300,000 abdominal wall hernia repair surgeries are performed every year) (107). That is why it seems that the most cost-effective option in case of parastomal hernias is preventing their development during the primary procedure by using hernia meshes.

CHAPTER 13
PARASTOMAL HERNIA PREVENTION

Should implants be used during the primary stoma formation procedure in order to prevent parastomal hernia development?

Conclusions

Level 1

The use of an implant during the primary stoma formation surgery results in a lower parastomal hernia incidence rate.

Level 2

The use of synthetic and collagen implants results in a lower parastomal hernia incidence rate and does not increase the number of perioperative complications caused by the presence of the implant. The efficiency of using biological implant was proved in 12-month follow-up of patients undergoing restoration of gastrointestinal continuity.

Level 3

The use of the Dynamesh IPST implant resulted in a decrease in parastomal hernia incidence.

Recommendations

A The use of an implant is recommended in case of a permanent stoma formation for all patients.

B Synthetic implant use is recommended in case of a permanent stoma.

C The use of the Dynamesh IPST implant should be considered in cases where the implant is used prophylactically, due to optimistic results in preliminary scientific reports.

Given the high confirmed incidence of parastomal hernias (chapter 2), it seems crucial to ask about their prevention through insertion of an implant during the primary stoma formation procedure. In the published series of patients who underwent preventive implant insertion, a much lower hernia incidence rate was demonstrated than in other series, where no implant was used. Hernia was diagnosed in 0–15% of patients who had a mesh implanted. In most studies hernias were not observed, and reported cases occurred after using a flat mesh with an opening (75, 108) or in case of using a small implant (6x6 cm) (106).

In randomised studies groups of patients with and without a prophylactically inserted implant were compared. Synthetic (Janes, Serra-Aracil) (3, 109) and biological (Hammond) (110) implants were used. The results (number of recurrences) are presented in tab. 2. Neither study demonstrated a significantly higher number of infectious complications, lysis of the intestine or seromas, which makes it valid to conclude that both methods – with synthetic and biological implants – are safe. In Hammond’s study, gastrointestinal continuity was restored after 12 months, which allowed thorough assessment.
of the surgical site, but made further observations of the biological implant impossible.

A meta-analysis of these papers published in 2010 by Wijeyekoon confirmed high efficiency of parastomal hernia prevention using an implant (RR 0.23, 95% CI 0.06–0.81; p = 0.02) (18). No statistical differences were also noted in the incidence of postoperative complications. It needs to be noted that infections in the implant group, described in 3 studies, did not require implant removal or cause subsequent hernia development. The type and location of the implant on the anterior abdominal wall was not the object of comparison studies, similarly as results achieved with heavy-weight meshes (polypropylene), composite meshes, light-weight macroporous meshes (polypropylene + polyglecaprone) and biological collagen implants. In addition, the implant size and shape were not the object of comparative studies. It seems, however, that the mesh should be shaped with a margin of at least 5 cm around the stoma – as in classical abdominal hernia surgeries. In one study, specially shaped implant attached laparoscopically inside the peritoneum demonstrated a 100% efficiency, which might prove its usefulness in hernia prevention (95).

**Table 1**

<table>
<thead>
<tr>
<th>Author</th>
<th>Implant/approach</th>
<th>Follow-up period (months)</th>
<th>Number of patients</th>
<th>Percentage of recurrences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marimuthu</td>
<td>6x6 cm PP/open</td>
<td>6-28</td>
<td>18</td>
<td>0</td>
</tr>
<tr>
<td>Vijayasekar</td>
<td>6x6 cm PP/open</td>
<td>9-68</td>
<td>42</td>
<td>10</td>
</tr>
<tr>
<td>Berger</td>
<td>Dynamesh IPST/laparoscopic</td>
<td>2-19</td>
<td>22</td>
<td>0</td>
</tr>
<tr>
<td>Hammond</td>
<td>10x10 cm Permacol /open</td>
<td>6</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Janes</td>
<td>10x10 cm PP/ open</td>
<td>10-45</td>
<td>75</td>
<td>13</td>
</tr>
<tr>
<td>Janson</td>
<td>10x10 cm PP/ open</td>
<td>11-31</td>
<td>20</td>
<td>15</td>
</tr>
</tbody>
</table>

**Table 2**

<table>
<thead>
<tr>
<th>Author</th>
<th>Implant/location</th>
<th>Follow-up period (months)</th>
<th>Number of patients (control group)</th>
<th>Number of patients (implant group)</th>
<th>Recurrences – number/% (control group)</th>
<th>Recurrences – number/% (implant group)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Janes (2009)</td>
<td>PP/infrafascial</td>
<td>60</td>
<td>27</td>
<td>27</td>
<td>20 (74%)</td>
<td>2 (7%)</td>
</tr>
<tr>
<td>Serra-Aracil (2009)</td>
<td>PP/infrafascial</td>
<td>29 (13-49)</td>
<td>27</td>
<td>27</td>
<td>12 (44%)</td>
<td>6 (22,2%)</td>
</tr>
<tr>
<td>Hammond (2008)</td>
<td>Collagen (Permacol)/infrafascial</td>
<td>12</td>
<td>10</td>
<td>10</td>
<td>3 (30%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

**CHAPTER 14**

**ALGORITHM FOR DEALING WITH PATIENTS WITH PARASTOMAL HERNIA**

**CHAPTER 15**

**QUESTIONS FOR THE FUTURE**

In reference to the presented conclusions based on literature, the present authors observe several areas, which should become the object of future organisational works and basis for scientific studies. They include:
1. Creation of a registry of patients operated due to parastomal hernia.
   a. Aim: collection of epidemiological data, including information about the postoperative course, concerning patients treated for parastomal hernia. Keeping the registry will allow, in the first stage, prospective assessment of treatment outcomes, costs and scale of the phenomenon. Maintaining the registry will also allow validation of the parastomal hernia classification.
   b. Realisation: it is subject to the Polish Surgeons’ Society’s decision to create a dedicated database within the National Registry of Hernia Surgeries in Poland (pol. Krajowy Rejestr Operacji Przepuklin w Polsce, KROPP), or to establish a Polish language form within the European Registry of Abdominal Wall Hernias (EuraHS).

2. Creation of study groups in order to perform multicentre trials.
   Objects of future studies:
   a. Comparison of different materials used in parastomal hernia preparation.
   b. Determination of the site of application and comparison of the results of treatment using laparoscopic and open methods.
   c. Assessment based on extensive clinical material, regarding whether it is reasonable to use synthetic implants during stoma formation in order to prevent hernia development.

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Received: 2.12.2012 r.
Adress correspondence: 84-200 Wejherowo, ul. Jagalskiego 10