POLISH CONSENSUS STATEMENT ON THE PROTECTIVE STOMA

MAREK SZCZEPKOWSKI, TOMASZ BANASIEWICZ, PIOTR KROKOWICZ, ADAM DZIKI, GRZEGORZ WALLNER, Michał DREWS, ROMAN HERMAN, ZBIGNIEW LORENC, PIOTR RICHTER, KRZYSZTOF BIELECKI, WIESŁAW TARNOWSKI, JAN KRUSZEWSKI, JÓZEF KŁADNY, STANISŁAW GŁUSZEK, WOJCIECH ZEGARSKI, WOJCIECH KIELAN, KRZYSZTOF PAŚNIK, MAREK JACKOWSKI, MARIUSZ WYLEŻOŁ, ZORAN STOJCEV, ALICJA PRZYWOZKA

Department of General and Colorectal Surgery, Bielański Hospital in Warsaw
Department of Rehabilitation, J. Piłsudski University of Physical Education in Warsaw
Z Katedry i Kliniki Chirurgii Ogólnej, Endokrynologicznej i Onkologii Gastroenterologicznej Department of General and Endocrinological Surgery and Gastroenterological Oncology, Medical University in Poznań, H. Święcicki Teaching Hospital in Poznań
Department of General and Colorectal Surgery, K. Marcinkowski Medical University in Poznań
Department of General and Colorectal Surgery, Military Medical Academy University Teaching Hospital, Central Veterans’ Hospital in Łódź
2nd Department of General, Gastroenterological and Gastrointestinal Tumour Surgery, Medical University in Lublin, Independent Public Teaching Hospital No 1 in Lublin
Department of Oncological Surgery, Oncology Centre, M. Skłodowska-Curie Institute in Cracow
Department of General and Colorectal Surgery and Multi-Organ Trauma with Surgical Nursing Unit, Silesian Medical University, Provincial Specialist Hospital No 5 in Sosnowiec
3rd Department of General Surgery, Jagiellonian University Collegium Medicum in Cracow
Department of General Surgery, Solec Hospital in Warsaw
Department of General, Oncological and Gastrointestinal Surgery, Medical Centre of Postgraduate Education in Warsaw
Department of Oncological Surgery, Gdańsk Centre of Oncology, Polish Red Cross Maritime Hospital in Gdańsk
Department of General and Oncological Surgery, Pomeranian Medical University, Independent Public Teaching Hospital No 2 in Szczecin
Department of General, Oncological and Endocrinological Surgery, Provincial Hospital Complex in Kielce
Department of Oncological Surgery, Professor F. Łukaszczyk Oncological Centre in Bydgoszcz
Department of General and Oncological Surgery, University Teaching Hospital in Wrocław
Department of General, Oncological and Chest Surgery, Central Teaching Hospital of the Ministry of National Defence, Military Medical Institute in Warsaw
Department of General, Gastroenterological and Oncological Surgery, L. Rydygier Collegium Medicum in Bydgoszcz, L. Rydygier Provincial Complex Hospital in Toruń
Department of Surgery, Military Institute of Aviation Medicine in Warsaw
Department of General, Oncological and Vascular Surgery, Provincial Specialist Hospital in Słupsk

The coordinator of the working group:

MAREK SZCZEPKOWSKI
INTRODUCTION

One of the objectives of the Polish Coloproctology Club (PCC) is the development and the introduction into the clinical practice of recommendations and guidelines on treating patients with different surgical colon-related problems, also those affected by the rectal cancer, that need to undergo a low anterior resection of the rectum. Definition of the clinical situation, which requires the protection of the anastomosis by means of a protective stoma, is a highly important and current problem.

The guidelines on proceeding have been presented as a clinical consensus statement based on available, current scientific research and everyday surgical practice, represented by a group of experts. These recommendations are aimed at providing help in critical assessment of therapeutic methods related to a given clinical case and indicating the best possible algorithm of proceeding. The authors have striven to create a comprehensive approach while searching for research that could enable the development of uniform guidelines.

The consensus statement is aimed at:

- the improvement of quality of medical services and their effectiveness,
- the development of therapeutic standards based on the so-called Evidence Based Medicine,
- the development of good medical practices.

The consensus statement of experts of the Polish Coloproctology Club has been presented in the form of recommendations within a publication, and its objective is to assist surgeons in their everyday clinical practice. The consensus statement has been based on the results and analysis of available clinical research, including meta-analyses, retrospective and prospective studies and literature reviews. The aim of recommendations contained in the consensus statement is to collect and order the available literature and also unify individual experts’ opinions, which ultimately should greatly impact the improvement of results of treatment of rectal cancer in Poland – decrease the mortality, the percentage of complications and also improve patients’ life quality. The standardisation of protocols, which are an important source of knowledge for doctors in the process of speciality training, is also an essential issue.

The most frequent indications for performing a protective stoma are low anterior rectosigmoid as well as anal-sigmoid anastomoses after the low anterior resection of the rectum, mainly due to the adenocarcinoma of the rectum. Other clinical situations that require the performance of a stoma are as follows: a total reconstructive proctocolectomy with a J-pouch, a recto-vaginal fistula, a recto-vesical fistula or an anal stricture during or after radiotherapy. This consensus statement has focused exclusively on the issue of the protective stoma after the anterior resection of the rectum.

The issues related to the protective stoma have been discussed on numerous occasions for years. For a long time, a popular belief was that the protective stoma only decreased the symptoms of patients who experienced leakages. However, this conviction was changed after the publication of the meta-analysis by Pata et al., who clearly demonstrated in their paper that the protective stoma not only prevented the unfavourable results of a leakage at the moment of its occurrence, but first and foremost it decreased the percentage of clinically manifested leakages. It was observed that the introduction of the protective stoma
greatly decreased the number of urgent repeated surgeries due to leakages, which significantly impacted the reduction of the percentage of complications and the mortality coefficient (1).

In Polish and global literature, there are no uniform recommendations on treating patients who require an anastomosis protection by means of a diverting stoma after the anterior resection, and the available research is quite fragmentary and inconsistent. Despite numerous attempts, to this day it has not been possible to propose comprehensive and concise guidelines. In the last two years, two extremely interesting debates on the protective stoma have taken place in Poland: the first of them was the Interactive Round Table Conference (debate moderator: M. Szczepkowski) during the 9th Symposium of the PCC (Poznań 2012) as well as the debate entitled “Protective stoma – the discussion on the Polish Consensus Statement” during the 3rd Polish Nationwide Symposium “Advances in Colorectal Surgery” (debate moderator: M. Szczepkowski) (Warsaw 2014), during which the PCC recommendations concerning the discussed problems were proposed. These events initiated increasingly frequent discussions on that subject. Polish surgeons expressed the need to present the Polish Consensus in this area more and more frequently. Renowned specialists in the area of general surgery, colorectal surgery and oncological surgery, members of the Polish Coloproctology Club were invited to work on Polish Recommendations. The research group was set up in 2014 upon the initiative of Marek Szczepkowski, the President of Polish Coloproctology Club, who also became the coordinator of the research group. In June 2014, a survey was developed, which was later completed by each member of the research group. The survey consisted of 3 questions, corresponding to the most important clinical issues.

Question 1. The importance of criteria of performing a protective stoma

Each member of the research group was to assess, using the point-based scale of between 0 and 5 points (0 – an unimportant factor, 5 – a very important factor), 19 risk factors of an anastomotic leakage listed below.

The presented criteria are as follows:
1) being a male,
2) age > 60,
3) obesity,
4) low anastomosis – in the distance < 3 cm from the anal pectin,
5) the need of blood transfusion during the surgery,
6) anaemia < 8 g/dl,
7) hypoalbuminaemia < 3.5 g/dl,
8) neoadjuvant therapy,
9) coexistence of vascular diseases,
10) therapy with steroids,
11) immunosuppression,
12) stimulants – cigarettes, alcohol,
13) TME (Total Mesorectal Excision),
14) positive result of anastomosis tightness test and/or incomplete stapler rings,
15) surgery duration > 4 hours,
16) significant inter-surgical difficulties (m.in. a very narrow pelvis, technical difficulties),
17) emaciation – BMI < 19,
18) ASA III or IV,
19) a centre performing fewer than 20 anterior resections annually/surgeon performing fewer than 10 anterior resections annually.

Question 2. Is ileostomy or colostomy better as a protective stoma?

Each member of the research group was to decide which procedure performs the function of a protective stoma in a better way.

Question 3. Which name is more adequate?

Each member of the research group was to decide which name is best: a protective stoma, a covering stoma or a diverting stoma?

The results of the survey were collected and processed in July 2014. Then, in compliance with the Evidence Based Medicine guidelines, global literature from the last few years, available in databases such as Cochrane, Pubmed, or Embase, was analysed. The whole result was confronted with an experts’ opinion. The consensus statement on the protective stoma was developed and proposed by the Polish Coloproctology Club, and it remains its intellectual property.
Questions

At the very beginning, the working group defined and asked the most important questions, which should be answered by the Polish Consensus, concerning the issue discussed herein:

1. What are the definitions of the anastomotic leakage and the low anastomosis?
2. Is the question of a protective stoma a significant problem?
3. Can a protective stoma improve surgical treatment results?
4. Should a covering stoma be performed?
5. What is the risk of occurrence of an anastomotic leakage after the low anterior resection of the rectum and what is the significance of specific factors (listed from those with the greatest clinical significance to least clinically significant ones)?
6. Does ileostomy or colostomy perform the function of a protective stoma better?
7. When should a protective stoma be closed?
8. Which name is the most appropriate: a protective stoma, a covering stoma or a diverting stoma?

1. DEFINITIONS

a. Anastomotic leakage

The discussion on the protective stoma resulted from the problem which is quite essential from the clinical point of view, i.e. anastomotic leakage. An anastomotic leakage is one of the most serious complications after colorectal surgeries; it can lead to the need to repeat the surgery, it can prolong hospitalisation time, and it can increase mortality coefficient (2).

The lack of uniform definition of leakage is one of the most important problems that can be encountered in the literature. When analysing the literature, Bruce et al. demonstrated that there were 56 definitions of leakage after the surgical anastomosis of the digestive tract in 97 studies. The variation of clinical and radiological symptoms constituted the criterion. The authors expressed the opinion that there was no single, generally applicable definition of leakage (3). Such diversity of definitions results in varied percentage of recorded leakages depending on the study. However, if we try to unify the term, we will see that leakage has been defined most frequently as the deviation in a clinical or radiological examination, or in protoscopy, which indicates that there are intestinal contents escaping from the intestinal lumen at the site of the performed surgical anastomosis (4, 5).

Depending on the characteristics, three leakage types (A, B or C) have been defined (6).
1. Asymptomatic leakage or leakage discovered in a radiological examination, which can be discovered only if routine imaging examinations are performed after the surgery. Its existence does not require additional treatment.
2. Leakage with slight intensification of clinical symptoms. It does not require surgical treatment, it is enough to introduce conservative treatment, such as antibiotic therapy, drainage or infusions.
3. Full-blown leakage which requires relaparotomy and the performance of a protective stoma or an end stoma.

Classification according to Caulfield et al., which is based on the presence of deviations in clinical examination and radiological symptoms of leakage (7), is yet another proposed division.

Class I – Free liquid in the pelvis or in the presacral area in the CT scan, lack of contrast extravasation and no presence of abscesses.
Class II – Post-surgical abscess, lack of contrast extravasation in the CT scan:
   a) with an abscess in the anastomosis area,
   b) with an intra-abdominal abscess located far from the anastomosis.
Class III – Restricted contrast extravasation in the presacral area in the CT scan.
Class IV – Diffuse contrast extravasation in the CT scan.

Additionally, there is also leakage division based on the time of its occurrence. A group of symptoms which appear on average 8 days after the surgery is referred to as an early leakage, while leakage that appears 22 days after the surgery, i.e. most often when the patient has been discharged from the hospital (8), is referred to as a late leakage.

b. Low anterior resection

Previously, tumours of the rectum located between 7 and 8 cm from the anal canal edgew-
ere treated using an abdominoperineal or abdominosacral amputation of the rectum. Thanks to the development of technologies, such as staplers, it is possible to perform a sphincter-preserving surgery. Low anterior resection is a surgery of this type. There is no unambiguous definition of this surgery in the literature. In the 1990s, during a conference in Washington, English, American and Australian surgeons tried to provide a definition which stated that low anterior resection was a surgery consisting in the resection of the rectum together with the total excision of the perirectal tissue – the mesorectum – up to the level of the levators (9). It is the so-called TME (Total Mesorectal Excision) surgery. However, the authors define the height at which the resection of the rectum is performed in a different manner, and the distance is calculated from the edge of the anal canal, the edge of the anal pecten, the peritoneal pouch or other levels, which introduces many ambiguities in the literature. Anterior resections can be divided into a low anterior resection of the rectum and an ultra-low anterior resection of the rectum. According to some experts, a surgery resulting in the performance of anastomosis at the height of 5 cm (10), 6 cm (11), and according to other even of 8 cm (12) above the anal pecten, or located below the peritoneal pouch or other levels, which introduces many ambiguities in the literature. Anterior resections can be divided into a low anterior resection of the rectum and an ultra-low anterior resection of the rectum. According to some experts, a surgery resulting in the performance of anastomosis at the height of 5 cm (10), 6 cm (11), and according to other even of 8 cm (12) above the anal pecten, or located below the peritoneal pouch (13), depending on the literature, is a low anterior resection of the rectum. However, most often the low anterior resection is defined as a resection at the height of 3 cm above the anal pecten (14), and the ultra-low anterior resection is defined as resection located at the height of 2 cm above the anal pecten (14, 15).

2. IS THE ANASTOMOTIC LEAKAGE A SIGNIFICANT PROBLEM?

The frequency of leakage differs, depending on the study, which is mainly due to different criteria of inclusion of the diseased persons into the study. The meta-analysis by Cong et al. concerns 50 research studies covering 24 thousand patients; however, it contains 40 research studies, out of which the half concern fewer than 10 patients with leakage after the low anterior resection. On the other hand, the meta-analysis by Tan et al. based on 21 studies with the participation of 11.5 thousand patients compares the percentage of anastomotic leakage after low anterior resection of the rectum. In both meta-analyses, the percentage of leakage rate was quite high, and, on average, it was app. 8%; however, in some studies it even reached 26.2%. In the meta-analysis by Pata et al., the percentage of clinically manifested leakages was 17% in 358 patients from four randomised studies and 9.6% in 4,059 patients from 39 observational studies (1)

Some smaller meta-analyses, such as by Hüser et al., based on the literature from 1966–2007, analyse numerous studies with groups of the diseased ranging between 70 and 2,729 patients (16).

The percentage of leakage varies depending on the fact whether a patient subject to the anterior resection of the rectum has had a protective stoma performed or not. In the randomised study by Matthiesen et al., the leakage percentage in 234 patients was assessed to be 19.2% (45 patients out of 234). In patients with a protective stoma, this percentage was 10.3% (12 out of 116) and 28% (33 out of 118) in patients without a stoma (OR 3.4; 95% CI 1.6–6.9; p < 0.001) (17).

The frequency of leakage also varies depending on its degree and the surgery as a result of which it occurred.

In their meta-analysis, Cong et al. defined the frequency of occurrence of A type leakage (not manifested clinically) as 2.57% after the low resection, 1.14% after the low anterior resection and 7.41% after the ultra-low anterior resection of the rectum. In the case of B-type leakage, the respective values were as follows: 2.37%, 3.75% and 5.26%, while in the C-type leakage they totalled 5.4%, 4.7% and 1.81% (6). It seems that the percentage of leak-
age is the highest in the case of the ultra-low anterior resection; however, the data from the meta-analysis are still ambiguous.

In Poland, there are no available epidemiological data on the leakage and protective stomas. The only available data on the epidemiology of intestinal stomas come from the Polish-nationwide epidemiological study from 2009 (18). The author of the paper states that approximately 5–6 thousand stomas are performed in Poland each year. The tumour of the colon (76.6%), complicated diverticular diseases (20.3%) and intestinitis (below 1%) are the most frequent reasons. Other reasons constitute no more than 2%. There is a total of 20,000 patients with intestinal stomas living in Poland (ileostomy or colostomy). Unfortunately, there are no data stating how many of these stomas correspond to protective stomas in patients after the anterior resection of the rectum. It seems, however, that the number of stomas in Poland, and especially the number of protective stomas, keeps increasing.

3. CAN A PROTECTIVE STOMA IMPROVE SURGICAL TREATMENT RESULTS?

The objective of the guidelines is to define whether the performance of protective stomas has scientific justification in the perspective of the improvement of surgical treatment results. In literature, the evolution of surgeons’ views on that subject can be observed. The meta-analysis by Pata et al., conducted between 1997 and 2004, under which 4,000 patients were examined, was a very important work which somehow changed the approach to the performance of protective stomas. This paper and discussion which has lasted from its publication until today changed the approach to a protective ileostomy after TME. The authors of the paper proved that the a priori performance of an ileostomy decreased the percentage of leakage after TME, apart from decreasing leakage-related symptoms.

The tendency towards the performance of protective stomas, especially an ileostomy, can also be observed in the global literature. In a Danish study with the character of a national audit, the frequency of performance of protective stomas in the period between 1996 and 1999 as well as in 2010 was compared. The increase of the frequency of protective stoma performance was observed in the examined group: it increased from 57% to 70% (p<0.001), which resulted in the decrease of the 30-day mortality from 4% to 1% (19).

The paper by Pata et al.: lists significant advantages resulting from the performance of a protective stoma. They indicated the decrease of the percentage of repeated surgeries due to anastomotic leakage – 11.8% in patients with stomas compared to 88.6% in patients without stomas, (OR 0.028 95% CI 0.001-0.14) in prospective studies and 48.4% in patients with a stoma compared to 84% in patients without a stoma, (OR 0.18 95% CI 0.09-0.36) in retrospective studies. Leakage-related mortality in patients with a stoma was 0%, while in patients without a stoma it was 4.5% in prospective studies and it totalled 7.2% in patients with a stoma and 7.7 in patients without a stoma in retrospective studies.

On the other hand, in the meta-analysis by Tan et al., the need of repeated surgery due to leakage in the group without a stoma was greater both in the randomised studies with RR-0.29 (95% CI 0.16–0.53) p<0.001 and in the non-randomised studies with RR0.28 (95% CI 0.23–0.35) (p<0.001). In the randomised studies, there were no differences in the frequency of perioperative mortality, while in the case of non-randomised studies it was significantly higher in the group without a stoma with RR0.42 (95% CI 0.28-0.61) (p<0.001).

Other available studies also confirm the benefits of performing a protective stoma surgery. In the national study by the American Academy of Surgery with 6,337 patients, 991 (16%) out of which had a protective stoma performed, it was observed that the percentage of repeated surgery was significantly lower – it decreased from 6.9% to 4.5% (20). Another large-scale, multi-centre Swedish study indicates that the percentage of clinically manifested leakage in patients with a stoma was 9.7%, compared to 11.6% (p=0.002) in patients without a stoma (21). The studies confirm the justifiability of a protective stoma especially in the case of very low anastomoses. It has been proved that the percentage of leakage in patients with a stoma is lower (0.8%) than in patients without a stoma (5.1%).

On the basis of 6 randomised control studies, it has been confirmed that a protective stoma significantly decreases the risk of anastomotic leakage [RR 0.33; 95% CI (0.21, 0.53)]
Conclusions

A protective stoma significantly improves surgical treatment results. It decreases the negative effects of the anastomotic leakage, it reduces the leakage percentage and the number of repeated surgeries due to leakage, and it also reduces hospitalisation time.

4. SHOULD A STOMA BE PERFORMED?

Many studies based on the Evidence Based Medicine (EBM) confirm the justifiability of performing a protective stoma after the low anterior resection of the rectum in the case of low anastomoses (22).

Also a number of studies confirm the justifiability of a protective stoma performance. It should be remembered, however, that a stoma, and especially an ileostomy increases the risk of both early complications (including, among others, metabolic or surgical disturbances) as well as late complications during its closure (23).

It should be underlined that despite its benefits the protective stoma, and especially the surgery of its closure can be related to a high risk of complications. In their study with the participation of 89 patients, Mangual-Ballester et al. observed post-surgical complications in as many as 45.9% patients (24).

The most serious complications in this patient group included:
- post-surgical bowel obstruction – 32.6%,
- diarrhoea – 6%,
- surgical wound infection – 6%,
- intestinal-dermal fistula – 4.5%,
- bleeding into the digestive tract – 3.4%,
- anastomotic leakage – 1.12%.

In their study, Kye et al. observed metabolic complications in 21% of patients after the performance of a protective stoma, and 9.6% of complications after its closure; they especially affected older persons, especially those who were more than 65 years old (25). On the other hand, Messaris et al. state that as many as 16.9% patients with a protective ileostomy needed to be re-admitted to hospital due to dehydration (26). Acute renal insufficiency [OR 2.4; 95% CI (1.2, 4.6); p < 0.05] (20) was another serious described complication.

5. WHICH ARE THE RISK FACTORS OF AN ANASTOMOTIC LEAKAGE OCCURRENCE AFTER THE LOW ANTERIOR RESECTION OF THE RECTUM?

The group of experts of the Polish Coloproctology Club agrees that a protective stoma should not be performed in the case of all patients, but only in a carefully selected group of persons with the so-called “high risk anastomosis”. The criteria used for patient selection are the subject of many discussions in expert organisations all over the world, and such discussions focus on the importance of specific risk factors, which have the greatest impact on the occurrence of anastomotic leakage.

The most important anastomotic leakage factors described in the studies from between 2010 and 2014 were selected and analysed on the basis of global literature. Risk factors with statistical significance p < 0.05 were considered to bestatistically significant. These factors include:

- being a male (27),
- diabetes (28),
- age > 57 (29),
- obesity (30),
- tumour size >5 cm (28),
- tumour location > 5 cm from the anal pectin (28, 29, 31, 40),
- anastomosis distance >3 cm from the anal edge (27, 29, 40),
- blood transfusions (32, 33),
- loss >200 ml of blood (27, 33),
- haemoglobin concentration before the surgery <8 g/dl (32),
- albumin level <3.5 g/l (28, 32),
- hypotension (32),
- neoadjuvant therapy (29, 30, 34),
- vascular diseases (33),
- therapy with steroids (35),
- immunosuppression (30),
- cigarette smoking (30, 36),
- alcohol (30),
- geographical factors – Europe (6),
- performed ileostomy (37).

Some of these factors are quite unexpected. For example, the geographical factor indicates that the frequency of leakage has greater sta-
tistical significance for the inhabitants of Europe when compared with the inhabitants of Asia and the United States. Indication of a protective ileostomy as a risk factor of anastomotic leakage (the study by Reilly et al.) was one of the most interesting statements. However, this statement is quite paradoxical, since the leakage in the studied group was established on the basis of radiological examinations in the early post-surgical period, so probably the presence of other risk factors was the reason for the performance of an ileostomy. Therefore, the performance of an ileostomy in these patients was necessary, since it prevented the occurrence of unfavourable leakage results.

Some studies suggest that only the patient’s age of more than 60 is an independent factor of leakage occurrence ($p = 0.004$) – retrospective analysis of a group of 108 patients.

The distance of the anastomosis from the anal pectin is one of the most significant risk factors which has been confirmed by the analysis of literature. In 2011, the authors of a Polish study analysed 884 patients with a tumour of the rectum, out of which nearly 72% were subject to a sphincter-preserving surgery. The distance of anastomoses $\leq 6$ cm from the anal edge significantly impacted the increase of leakage percentage. It was established that in the case of anastomoses of this type a protective stoma decreased the risk of leakage from 20.5% to 6.3%.

On the other hand, another study assessing the impact of the height of anastomosis recommends that a stoma should be performed already in the case of an anastomosis in the distance of 5 cm from the anal edge. It is especially recommended in the case of very low anastomoses at the distance of 2 cm from the anal edge.

Risk factors obliging a surgeon to perform a protective stoma are a subject of discussion of surgical societies all over the world. The American Society of Colorectal Surgeons (the ASCRS) also conducted a survey among its members, concerning their opinion on the role of a protective stoma in low and high anastomoses. On the basis of the acquired results (505 completed surveys) given by the members, the majority of which had had over 20 years of experience in colorectal surgery, it was established that the most important risk factors upon the correct performance of anastomosis after a low anterior resection of the rectum were as follows:

- radiation of the pelvis in medical history,
- hypoalbuminemia,
- malnutrition,
- therapy with steroids,
- immunosuppression.

The factors such as a surgery performed under emergency duty procedure, the contamination with the intestinal contents, blood loss during the surgery or long surgery duration were also quoted; however, they were less important in the experts’ opinion.

The two conferences specified above were an important element of discussion. During these conferences, Polish experts, apart from significant indications for the performance of a protective stoma indicated above, also took into account important additional criteria, such as:

- TME (Total Mesorectal Excision),
- positive result of anastomosis tightness test and/or incomplete stapler rings,
- surgery duration exceeding 4 hours,
- significant inter-surgical difficulties (such as: a very narrow pelvis, technical difficulties),
- emaciation – BMI <19,
- ASA III or IV burden,
- centre performing fewer than 20 anterior resections annually/surgeon performing fewer than 10 anterior resections annually.

On the basis of available current literature and their own experience, a group of experts from the PCC specified the most important indications for the performance of the diverting stoma. Each of 20 experts was to assess specific indications using the point-based scale of between 0 and 5 points (0 – an unimportant factor, 5 – a factor with high clinical importance). The results have been presented in tab. 1.

The most important of the indications listed above are those which have been assessed by the experts as 4 and 5 using the point-based scale. Therefore, the most important indications according to Polish experts are as follows:

- positive result of anastomosis tightness test and/or incomplete stapler rings – 19 experts,
- low anastomosis – the distance $<3$ cm from the anal pectin – 18 experts,
- emaciation – BMI <19 – 14 experts,
Table 1. The importance of protective stoma performance criteria according to the PCC experts

<table>
<thead>
<tr>
<th>Ref. No.</th>
<th>Criteria</th>
<th>The number of experts indicating a given criterion (scale from 0 to 5 points)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Being a male</td>
<td>0 1 4 4 8 3 0</td>
</tr>
<tr>
<td>2</td>
<td>Age &gt; 60</td>
<td>3 1 6 4 4 2</td>
</tr>
<tr>
<td>3</td>
<td>Obesity (BMI &gt;30)</td>
<td>0 1 3 7 4 5</td>
</tr>
<tr>
<td>4</td>
<td>Low anastomosis-the distance &lt;3cm from the anal pecten</td>
<td>0 0 0 2 5 13</td>
</tr>
<tr>
<td>5</td>
<td>The need of blood transfusion during the surgery</td>
<td>1 4 1 6 3 5</td>
</tr>
<tr>
<td>6</td>
<td>Anaemia &lt;8 g/dl</td>
<td>1 3 0 5 6 5</td>
</tr>
<tr>
<td>7</td>
<td>Hypoalbuminemia &lt;3.5 g/dl</td>
<td>0 2 3 3 6 6</td>
</tr>
<tr>
<td>8</td>
<td>Neoadjuvant therapy</td>
<td>0 1 2 4 4 9</td>
</tr>
<tr>
<td>9</td>
<td>Coexistence of vascular diseases</td>
<td>2 4 2 5 5 2</td>
</tr>
<tr>
<td>10</td>
<td>Therapy with steroids</td>
<td>0 2 3 4 6 5</td>
</tr>
<tr>
<td>11</td>
<td>Immunosuppression</td>
<td>0 0 2 5 8 5</td>
</tr>
<tr>
<td>12</td>
<td>Stimulants – cigarettes, alcohol</td>
<td>4 4 6 3 2 1</td>
</tr>
<tr>
<td>13</td>
<td>TME (Total Mesorectal Excision)</td>
<td>3 3 4 5 4 1</td>
</tr>
<tr>
<td>14</td>
<td>Positive result of anastomosis tightness test and/or incomplete stapler rings</td>
<td>0 0 0 1 3 16</td>
</tr>
<tr>
<td>15</td>
<td>Surgery duration &gt;4 h</td>
<td>1 4 1 6 3 5</td>
</tr>
<tr>
<td>16</td>
<td>Significant inter-surgical difficulties (including a very narrow pelvis, technical difficulties)</td>
<td>0 2 2 3 6 7</td>
</tr>
<tr>
<td>17</td>
<td>Emaciation (BMI &lt;19)</td>
<td>1 1 1 3 6 8</td>
</tr>
<tr>
<td>18</td>
<td>ASA III or IV</td>
<td>1 2 2 2 5 8</td>
</tr>
<tr>
<td>19</td>
<td>A centre performing fewer than 20 anterior resections annually/ a surgeon performing fewer than 10 anterior resections annually</td>
<td>0 0 3 5 7 5</td>
</tr>
</tbody>
</table>

- neoadjuvant therapy –13 experts,
- immunosuppression– 13 experts,
- ASA III or IV – 13 experts,
- significant inter-surgical difficulties (including a very narrow pelvis, technical difficulties) – 13 experts.

If we established that the opinion of 12 experts (60% of all experts), and not the opinion of 13 experts (65% of all experts), should be the cut-off point, then the number of significant indications would be extended by two other factors: “hypoalbuminemia <3.5 g/dl” and “centre performing fewer than 20 anterior resections annually/ surgeon performing fewer than 10 anterior resections annually”.

The formulation of the need of further intensive research was an important element of discussion. Since today a protective stoma is not questioned as an effective method of decreasing anastomotic leakage percentage, the problem consists in the definition of precise criteria that will help surgeons to make an optimum decision.

Conclusions

A protective stoma should be considered in all patients after the anterior resection of the rectum, and especially in patients with risk factors, such as: low anastomosis, neoadjuvant therapy, immunosuppression, positive result of anastomosis tightness test and/or incomplete stapler rings, emaciation, increased inter-surgical risk of complications assessed according to ASA III/IV scale as well as significant inter-surgical difficulties. Attention should be also paid to other individual risk factors of a specific patient.

6. DOES AN ILEOSTOMY OR A COLOSTOMY BETTER PERFORM THE FUNCTION OF A PROTECTIVE STOMA BETTER?

The studies concerning the protective stoma of the small or large intestine are full of controversies. Some authors suggest that it is impossible to clearly establish the superiority of ileostomy over colostomy, both in terms of its performance and closure (42).

In one of the recent systematic reviews, the authors underline that there is unwillingness to perform a loop ileostomy due to the fears of its leakage and the possibility of faeces entering the distal arm of the loop, termed to be “a surgical folklore”. This paper indicates that the passage of faeces into the distal arm of the intestinal loop was diagnosed on the basis of radiological examinations only in 5% of the patients with a colostomy and the same phenomenon was not observed in any of the patients with a loop ileostomy, which confirms the fact that a correctly performed ileostomy ensures appropriate protection of anastomoses in patients and that it is a more beneficial option than a loop colostomy being a protective stoma (43). It should also be remembered that an appropriate surgical technique applied when performing a protective stoma, especially in the case of ileostomy performance using the “end-loop” technique, prevents the passage of the intestinal content to the distal arm.
El-Hussuna et al. claim that the surgery eliminating the ileostomy is subject to a lower mortality coefficient; however, this surgery entails a high risk of post-surgical complications (e.g. prolonged post-surgical obstruction). It is true that their number is slightly lower than after the elimination of colostomy, but the results are hard to assess and interpret due to lack of homogeneity of studied groups (different criteria of inclusion into the study, different patient characteristics, etc.) (44). The fact that the risk of complications in the case of a protective stoma closure when a surgery is performed by an experienced surgeon is lower seems quite obvious (45).

In the paper by Rondelli et al., the authors prove that a loop ileostomy is related to a lower percentage of post-surgical complications, such as stoma prolapse and septic complications. However, after the elimination of ileostomy, the risk of anastomotic obstruction and dehydration increases (46). A randomised study by Edwards et al. is an argument for the superiority of an ileostomy as a protective stoma. In the study, the authors prove that the frequency of hernias before and after the elimination of a stoma is much higher in the case of patients with a colostomy than with an ileostomy. However, the authors state that both methods give equally satisfactory results in the area of low anastomosis protection (47).

Other authors confirm the results of this study and indicate that an anastomotic leakage after the elimination of a loop ileostomy is much higher than after the liquidation of a loop colostomy – the paper by Oliveira et al. (19.2% vs 3.5%) (48). Some authors state that a loop colostomy should be reserved for the diversion of low anastomoses (49).

Large-scale meta-analyses and literature reviews note that the superiority of an ileostomy in the light of the EBM is relatively low; only the risk of stoma prolapse and the risk of infection in the stoma site seem to be indisputable arguments for the protective ileostomy. Yet another literature review compares the effectiveness of an ileostomy and a colostomy in the view of the following parameters: the time between the performance and the elimination of stoma, the duration of hospitalisation and resulting complications, such as stoma falling inside, peristomal hernia, peristomal fistula, stricture, stomal necrosis, dermatitis in the stoma region, post-surgical obstruction, anastomotic leakage, hernia in the stoma scar and the prolapse of stoma. Among all those parameters only the last factor, i.e. the prolapse of stomawas present statistically more frequently than in the case of a colostomy (50).

In their meta-analysis covering 12 studies, Chen et al. confirmed a significantly lower risk of stoma prolapse and wound infection after the stoma closure in the case of a protective ileostomy (51).

In the survey performed among its members, the American Society of Colorectal Surgeons (ASCRS) obtained the majority opinion that an ileostomy was a better protection when compared with a protective colostomy (31).

It should be stressed that there are no comprehensive papers assessing a global risk of stoma performance (an ileostomy vs. a colostomy) both in the context of the anastomotic leakage and other complications after stoma closure. On the basis of the studies performed to date, it is impossible to define in a clear and ultimate manner the superiority of one type of stoma over another; however, it has been suggested that a protective ileostomy is a better solution.

The group of experts from the Polish Coloproctology Club almost unanimously agreed that it is recommended to perform a protective ileostomy (18 out of 20 experts). However, it should be stressed that this problem requires further research, and the final decision should be made by the operating surgeon (52).

Conclusions

An ileostomy better performs the function of a protective stoma.

7. WHEN SHOULD A PROTECTIVE STOMA BE CLOSED?

According to the assumptions, a protective stoma is a temporary solution; therefore, it is performed with an intention of its closure. Usually, it is recommended to perform the stoma closure surgery after 9–12 weeks from the initial resection surgery of the tumour of the rectum. Unfortunately, the closure is not always possible in the time specified above and often a patient is not subject to a reconstructive surgery. As specified in the literature, the
percentage of unclosed stomas ranges between a few per cent to even 49% in the groups of older persons (53). However, the majority of global experts assess that no stoma closure is effected, for different reasons, even in one out of every five patients who had a protective stoma performed. Independent risk factors, which lead to the permanent maintenance of protective stoma, are as follows: stage IV tumour, complications related to the anastomosis, distant metastases and local relapse (54). Other reasons for the failure to requalify for the surgery are old age >65 years (p< 0.4) and anastomotic leakage (p< 0.1)(55).

It has been suggested that the earlier elimination of a protective stoma is related to an increased percentage of surgical complications. The percentage of serious complications has been assessed as ranging from 0 to 7–9% and the percentage of the so-called “less serious” complications has been assessed as ranging from 4–5 to even 30% (56). However, more and more often such possibility is mentioned, especially if the condition of the patient is good and if there are no risk factors for the occurrence of anastomotic leakage. In the prospective, randomised study by Sung et al., groups of patients in which no leakage symptoms were manifested in radiological examinations were compared, in the early period (after 4 weeks) and in a standard time (9–12 weeks). There were no statistically significant differences in the area of complications such as scarring (p=0.865) or obstruction (p=0.190) after the closure. Some differences existed in relation to the total percentage of other complications (33.3% after the early vs 25% after the standard closure; p = 0.589), the frequency of post-surgical wound infection (6.7% vs 10%; p = 0.727). Mean hospitalisation time was also similar – on average, it was 5 days (3–10) vs. 5 days (3–12) (p = 0.866). This study indicates that the earlier stoma closure is a safe procedure (57).

On the other hand, a Danish multi-centre prospective randomised study (the “EASY” study) indicates the possibility of even earlier protective ileostomy closure, i.e. after 6–13 days from the low anterior resection. In this study, the surgery reconstituting the intestinal passage was performed already after 8–10 days from the initial surgery. The percentage of complications in the studied group (186 patients) was the same as in the control group, and it totalled 15%. However, the complications such as post-surgical wound infections were statistically more frequent in the group of patients with an earlier surgery, and the intestinal obstruction was significantly more frequent in the group that was operated on later (58).

The fact that some authors suggest that a protective stoma should be closed in a situation when anastomotic leakage is discovered by means of radiological examinations in asymptomatic patients seems quite unusual; they claim that sub-clinical leakage often does not lead to complications, and the leakage itself can be self-cured. However, the authors of the study underline that such procedure can only be applied in a group of carefully selected patients (59).

These studies, though significant, need to be continued and confirmed. A standard recommendation is that the surgery of stoma elimination should be performed after 9 weeks, if there are no contraindications in the case of a given patient, at the earliest.

Conclusions

– Optimally, the protective stoma elimination surgery should be performed after 9–12 weeks after the anterior resection surgery.
– Earlier stoma closure can be taken into account in the case of selected patients.
– In the case of each resection, it is necessary to take the possibility of the transformation of a temporary stoma into a permanent stoma into account.

8. WHICH NAME IS THE MOST APPROPRIATE?

In literature, there are many terms for a temporary intestinal stoma. In English literature, the terms, "diverting stoma", "covering stoma" and "protective stoma" are used, and analogous terms can also be found in the Polish language. The group of experts was to select the name which would be the most universal and appropriate and which would facilitate the communication between the specialists. The majority of experts have recommended the
the basis for future scientific research. They include:

1. The creation of a register of patients operated using the TME technique, in which a protective stoma was performed, and the strict clinical supervision of this group.
2. The initiation of studies with the view to further analysis of risk factors of intestinal anastomotic leakage after the anterior resection of the rectum and the discussion on the importance of specific indications of protective stoma.
3. The need to conduct the debates in this area and to analyse current global literature.

Since the experts of the Polish Coloproctology Club are aware that the definition of precise and unequivocal recommendations in this scope is very difficult and often disputable, they are of an opinion that this document, albeit imperfect, can serve as a guideline and can help surgeons who decide about the matters discussed herein, which is often quite difficult. The experts consider that this consensus statement is a substantial support, but the final decision should be made by an operating surgeon on the basis of his own experience and a specific clinical situation.

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Received: 5.08.2014 r.
Adress correspondence: 01-809 Warszawa, ul. Cegłowska 80
e-mail: szczepkowski@hello.pl