COMPARISON OF THE EFFECTIVENESS OF THE TREATMENT USING STANDARD METHODS AND NEGATIVE PRESSURE WOUND THERAPY (NPWT) IN PATIENTS TREATED WITH OPEN ABDOMEN TECHNIQUE

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Open abdomen technique is a surgical treatment in which the fascia and skin are left open in order to reduce the value of the intra-abdominal pressure. According to the World Society of the Abdominal Compartment Syndrome (WSACS) normal values of the intra-abdominal pressure are between 5 and 7 mm Hg. Intra-abdominal hypertension occurs when the pressure value is equal to or exceeds 12 mm Hg.

The aim of the study was to compare the results of the open abdomen treatment using standard methods and negative pressure wound therapy.

Material and methods. The study was in the form of a retrospective analysis of the documentation of the patients treated with open abdomen technique. The study included 37 patients treated in the Department of General and Endocrine Surgery and Gastroenterological Oncology and in the Department of Anesthesiology and Intensive Care of the Medical Sciences since 2009-2012. Patients were divided into two groups: group 1 (n = 20) was treated with standard surgical procedures (laparostomy, repeated peritoneal cavity lavage) and group 2 (n =17) was treated using negative pressure wound therapy (NPWT).

The analysed clinical data included the period of hospitalization and clinical outcome (survival vs death), the occurrence of enteroatmospheric fistulae, cyclical determination of the quantitative C-reactive protein levels.

Results. The number of deaths during hospitalization in the group treated with NPWT was lower than in the group treated with standard methods (3 vs 9). The number of fistulae during hospitalization in the group treated with NPWT dropped as compared to the group treated using standard procedures (18% vs 70%). The decrease in the CRP levels was recorded in the group treated with NPWT and its increase – in the group treated with standard methods.

Conclusions. The use of NPWT in patients requiring open abdomen treatment is reasonable due to the positive results with respect to survival rates and the decrease in the number of gastrointestinal fistulae. It is necessary to train the physicians in using this type of therapy in the form of workshops and in the clinical setting.

Key words: C-reactive protein, negative pressure wound therapy, open abdomen
Open abdomen management (OAM) was presented for the first time by Oglivie in 1940 (1). The classification of open abdomen includes four grades:

Grade 1A. Clean open abdomen with no adherence between bowel loops and abdominal wall.

Grade 1B. Contaminated open abdomen with no adherence between bowel loops and abdominal wall.

Grade 2A. Clean open abdomen developing adherence/fixed conglomerates of bowel loops.

Grade 2B. Contaminated open abdomen developing adherence/fixed conglomerates of bowel loops.

Grade 3. Open abdomen complicated by fistula formation.

Grade 4. Open abdomen with adherence and fixed conglomerates of bowel loops, impossible to close surgically, with or without fistulae.

Open abdomen technique is described as an intentional surgical procedure consisting in leaving the fascia and skin open in order to lower the intra-abdominal pressure. According to WSACS (World Society of the Abdominal Compartment Syndrome) normal values of the pressure in the abdominal cavity are between 5 and 7 mm Hg. Intra-abdominal hypertension occurs when the pressure is equal to or higher than 12 mm Hg (2).

Grade I 12-15 mm Hg.

Grade II 16-20 mm Hg.

Grade III 21-25 mm Hg.

Grade IV > 25 mm Hg.

When the intra-abdominal pressure exceeds 20 mm Hg with the accompanying drop in perfusion pressure in abdominal cavity below 60 mm Hg and a failure of at least one organ, the Abdominal Compartment Syndrome (ACS) is diagnosed (3, 4).

The strategy in case of intra-abdominal hypertension syndrome includes:

- intensive medical supervision of the patient,
- maintaining normal perfusion of abdominal and pelvic organs,
- lowering the intra-abdominal pressure using non-surgical methods,
  - normovolemic resuscitation when the intra-abdominal pressure value is between 10 and 14 mm Hg,
  - hypovolemic resuscitation when the intra-abdominal pressure value is between 15 and 24 mm Hg,
- abdominal cavity decompression by creating a controlled laparostomy, that is using the open abdomen techniques, when the pressure exceeds 25 mm Hg.

When the pressure is higher than 35 mm Hg all the patients require immediate decompression due to the risk of a cardiac arrest (5).

In case of leaving the abdominal cavity “open” (laparostomy, open abdomen management), it is necessary to use one of the methods of temporary closure of the abdominal wall.

Another stage of the open abdomen treatment is a definitive closure of fascia. The optimal time of abdominal wall closure is a period of 5 to 7 days. This protects against substantial retraction of wound edges by abdominal muscles (2).

Indications to employ the open abdomen method are successively broadening, starting with the management of severe sepsis of abdominal origin to a standard procedure within trauma surgery called „damage control” (DCS damage control surgery).

Treating patients with the use of open abdomen technique is a great therapeutic challenge. The treatment is usually an interdisciplinary procedure and the main role is played by the surgery team, along with an essential assistance with anaesthesiologists, internal medicine specialists and microbiologists. The group of patients with open abdomen in whom additionally gastrointestinal fistulae occurred, is especially difficult to treat. The occurrence of fistulae significantly increases the risk of death, prolongs the duration of treatment and makes its distant results worse. The treatment of gastrointestinal fistulae requires large individualisation of treatment and an experience from the staff managing the treatment.

The number of patients in Poland treated with the use of an open-abdomen technique is difficult to determine. In a DRG system, which is used for settlements with the National Health Fund, there is no code for open abdomen procedure. However, based on the data taken from the DRG statistics it is possible to assess the number of patients in case of which the open-abdomen technique could be used. Acute pancreatitis and gastrointestinal fistulae are the most common indications for open abdomen treatment.

According to the DRG system statistics the general number of hospitalised patients who were diagnosed with AP in 2013 equals to
Out of this group 123 patients underwent major abdominal procedures (laparotomy). In 2012 those numbers are respectively 26,880 of treated patients diagnosed with AP, out of which 148 persons underwent major abdominal procedures. Thus the number of patients with AP undergoing major abdominal procedures equals to 120-150 cases a year. Open abdomen techniques could be of use in those cases.

In case of persons operated due to intestinal fistulae – according to DRG statistics, 351 patients with such diagnosis were operated in 2013, 310 patients in 2012 and 313 patients in 2011. Patients with intestinal fistulae constitute another group of approximately 300-350 cases per year, in which group the open abdomen technique may prove useful. Patients with extensive wound dehiscences status post various types of injuries or complications after major vascular surgeries.

The analysis of these two groups of patients form a general concept concerning the situation in Poland, however, it does not exhaust all the possibilities with respect to open abdomen treatment, which can also be used in other cases, in patients with different diagnoses.

The aim of the study was to compare the results of open abdomen treatment using standard treatment and NPWT. The analysis also included patients in which the enteroatmospheric fistulae occurred at the start of the treatment or in the course of the therapy.

MATERIAL AND METHODS

The study was in the form of a retrospective analysis of the documentation of the patients treated with open abdomen technique. The study initially included 51 patients treated in the Department of General and Endocrine Surgery and Gastroenterological Oncology and in the Department of Anesthesiology and Intensive Care of the Poznan University of Medical Sciences in the years 2009-2012.

Inclusion criteria

Initial inclusion criteria included:
- acute pancreatitis treated with open abdomen technique,
- extensive eventration,
- wound dehiscence,
- occurrence of the enteroatmospheric fistulae in patients hospitalised between 2009-2012.

Exclusion criteria

Then 14 persons were excluded from this group, each for one of the following reasons:
- they died within 48 hours from the admission/start of the therapy,
- there were other, severe risk factors for death or complications in their case, such as head injury, massive gastrointestinal haemorrhage, recent myocardial infarction.

Ultimately 37 patients were included in the study and they were divided into two groups. Group 1 (n = 20) was treated with standard surgical procedures (standard changes of dressing, stay sutures, abdominal zip sutured to the skin, repeated peritoneal cavity lavage). Group 2 (n =17) was treated using negative pressure wound therapy (NPWT). In 13 cases the Viviano (Hartmann, Germany) equipment was used and in case of 4 = V.A.C. (KCI, USA). Figures 2 through 5 show and example of treatment by means of vacuum therapy.

Analysed parameters

Clinical data included the period of hospitalization and clinical outcome (survival vs death), the occurrence of enteroatmospheric fistulae at the beginning and at the end. Data were collected on the basis of clinical research forms and orders of the Department of Anesthesiology and Intensive Care and the Department of General and Endocrine Surgery and Gastroenterological Oncology (Recovery Ward, Clinical Wards).

Determination of C-reactive protein (CRP)

Quantitative level of C-reactive protein was determined on the determined on the day of admittance (0), 7th, 14th, 21st, 28th, 35th and 42nd day of treatment (+) 2 days. The determination was performed with the use of Cobes 6000 analyser, with a latex particle-enhanced im-
munoturbidimetric method, reference range was 0.01-4 mg/l.

Safety of the therapy

The safety of NPWT therapy and the occurrence of side effects potentially associated with NPWT were analysed as well. The analysis also covered the occurrence of the intestinal fistulae that were formed during the treatment.

Statistical analysis

The results of the analysed factors were presented with the use of median and mean± standard deviation (mean ± SD). The patients were divided for the purpose of the statistical analysis into two groups: standard wound treatment (20 patients) and NPWT therapy (17 patients). The Shapiro-Wilk test, Kolmogorov-Smirnov test and Lilliefors test were performed. The normality of the groups was declared when the p-value was greater than 0.05.

On the basis of the obtained results of the normality tests, the comparison of the C-reactive protein (CRP) values was performed on 0, 7, 14, 21, 28 and 35 day of hospitalization with the use of tests for two independent groups – Mann-Whitney U test (when there was no normality of distribution) and t-Student test (when the normality of distribution was declared). The results of the p value lower than 0.05 were recognised as statistically significant. All the analyses were performed with the use of STATISTICA 10 program created by StatSoft.

RESULTS

Table 1 shows the comparison of clinical data and results of the treatment between the groups. The average hospitalization time was 43 days in the group treated with the use of standard methods and 40 days in the group treated with NPWT, and no statistically significant difference was found. The average age and BMI in both groups also did not statistically significantly differ. On the other hand, the number of deaths during hospitalization was significantly lower in the group treated with NPWT (3 deaths, 18%) as compared to the group treated with the use of standard therapy (9 deaths, 45%). In both groups the number of recorded fistulae was initially high – 71% in NPWT group and 65% in the group treated with standard methods respectively. The number of fistulae during hospitalization dropped to 18% in NPWT group as compared to the group of patients treated with the use of standard methods, where the increase to 70% after the end of treatment was recorded.

The results with respect to the CRP levels are presented in tab. 2 and with the use of diagram (tab. 2, fig. 1). The CRP level at the start of the treatment was comparable in both groups (50.5 vs 52.9, p>0.05). In the course of the therapy the CRP level decreased in the group treated with NPWT – a decrease from the average value of 52.9 mg/dl to 48.4 mg/dl (35 day), and in the group treated with standard methods the CRP level increased signifi-
cantly from 50.5 mg/dl to 82.5 md/dl on a 35th day. Statistically significant differences in the average CRP values were also recorded on day 14, 21 and 35 (p<0.05) in favour of the group treated with NPWT (tab. 2).

Safety of the therapy and the occurrence of side effects

In patients treated with the use of negative pressure the occurrence of allergic skin reaction was recorded (redness, rash, itchiness). In all cases the foil used was substituted with a foil produced by another manufacturer, and the allergic reaction was resolving. This event has been defined as the one definitely connected with the used therapy (“definite relationship”). In one of the patients a haemorrhage after the change of dressing has been recorded. The negative pressure wound therapy was suspended for 1 hour and the bleeding wound edges were approximated. When the NPWT was continued a haemorrhage was recorded again. A negative pressure dressing was removed, electrocoagulation of wound edges was performed and a negative pressure dressing was put on again. There were no signs of another haemorrhage. This event was defined as the one possibly connected with the therapy applied (“possible relationship”).

During the therapy the occurrence of de novo enteroatmospheric fistulae was recorded in 7 patients in total (19%), including 6 patients (30%) treated with standard therapy and in one patient (6%) treated with NPWT.
Negative pressure wound therapy (NPWT) in open abdomen technique

Fig. 2. Patient on the 9th day after laparotomy with resection of the advanced stage of cecal tumor. The dehiscence of the fixation with faecal fistula, stay sutures, leakage of intestinal contents and contaminated serous contents in the lower part of the wound.

Fig. 3. Status post applying NPWT dressing in the central part of the wound, the stoma pouch is maintained due to the high secretion in the lower part of the wound.

Fig. 4. 7 days after the start of NPWT therapy. A significant improvement of the general condition, significant reduction of secretion – the stoma pouch was removed and the whole peritoneal cavity was covered in NPWT dressing.

Fig. 5. 21 days after the start of NPWT therapy. The wound is almost healed, a minor latex drain remains in the lower part of the wound. Minor secretion of serous contents where the drain was placed on the left side, secured with a stoma pouch. End of NPWT treatment.
DISCUSSION

Open abdomen management (OAM) is currently a routine surgical procedure. Decompression of abdominal cavity is a gold standard of the effective and definite treatment of abdominal compartment syndrome. Temporary laparostomy enables to lower the high, life threatening values of intra-abdominal pressure and thus to stabilize the vitals.

The number of indications for this type of treatment is still growing. Currently there are three main indications for performing temporary laparostomy: 1) preventing and treating the intra-abdominal hypertension; 2) controlling severe intra-abdominal sepsis (SIAS); 3) life-saving procedures in traumatic surgery through applying a damage control strategy (DCS damage control surgery). Open abdomen treatment is connected with a high risk of failure. The mortality in this group equals to approximately 30-45%, depending on the cause, general condition of the patient and the experience of the clinic (7).

Among standard methods of treatment, there are repeated laparotomies with peritoneal lavage and with the use of stay or dynamic sutures, or abdominal zip enabling faster and easier opening and closure of abdominal wall in repeated surgical interventions connected with revision, necrectomy and peritoneal cavity lavage. There are also other techniques used, including mainly negative pressure therapy (8). In case of occurrence of intestinal fistulae the surgical techniques are applied, consisting in cutting out the fistula and performing a fixation or a stoma, conservative treatment with securing the intestinal fistulae with the use of stoma equipment, applying new technologies such as silicone plugs (9). The negative pressure wound therapy mentioned above is very effective in the treatment of intestinal fistulae intercurrent with open abdomen, however, a proper technique and experience connected with putting on such dressings is needed (10, 11). Specially prepared abdominal dressings for fistulae treatment enabling proper fistula management are also in use (12).

In the analysed material a significantly lower percentage of deaths of patients treated with NPWT should be noted. In this group only 3 patients died (18%), significantly less than in the group of patients treated with the use of standard methods, where 9 persons died (45%). This confirms the observations of other authors, who noted that using negative pressure therapy in open abdomen treatment has an impact on lowering of the number of deaths and severe complications, enabling to reach more than 80% survivals (13) and increasing the percentage of patients in which it is possible to perform the primary closure of abdominal wall (14). The application of NPWT is also economically justifiable, because it enables to lower the total costs of treatment of the patients with open abdomen (15).

Negative pressure wound therapy has also constituted for several years a recognised method of proceeding with patients in which the enteroatmospheric fistulae appeared. Appropriate use of negative pressure abdominal dressings, and most of all proper securing of the fistulae opening not only causes the improvement of general condition of patients, but also a significant percentage of healed fistulae. In the materials assessed by us the occurrence of intestinal fistulae has been recorded in 13 patients (65%) treated with standard methods and in 12 patients (71%) treated with the use of negative pressure.

At the end of the treatment a statistically significant difference concerning the frequency of occurrence of fistulae in the studied groups of patients has been noted. In patients treated with standard methods the fistulae were noted in 14 patients (70%), in patients treated with NPWT fistulae occurred in 3 cases only (18%). This constitutes a clear confirmation of safety of use of negative pressure wound therapy both in patients with intestinal fistulae and in patients at risk of occurrence of fistulae. It is worth noting that only approximately 10 years ago the negative pressure wound therapy was contraindicated in patients with intestinal fistulae. Constant modernisation of equipment, and most of all introduction of safe foils covering the wall of the intestine and protecting against direct contact with a sponge, improvement of techniques and acquiring experience have led to the situation where the negative pressure wound therapy gives positive results in the treatment of intestinal fistulae and does not increase the risk of their occurrence. Only in one patient during the negative pressure wound therapy the intestinal fistula was formed, and in the group treated with standard therapy this kind of complication appeared in as many as 6 pa-
Negative pressure wound therapy (NPWT) in open abdomen technique

The risk of forming of subsequent fistulae during OA therapy is high and it results from the severe inflammation, severe general condition, septic complications, forming of adhesions and abscesses, and mechanical impact of dressings on the intestinal wall.

In the analysed material, apart from the basic clinical parameters such as number of deaths, hospitalization time, the number of fistulae at the start, in the course of and at the end of the therapy, we also analysed the change in the C-reactive protein level, as this is one of the parameters correlating to the increase of inflammation. C-reactive protein, known since 1930 is a plasma protein participating in the acute-phase reaction. Its material properties include: a short half-life (6-8 hours), fast (up to 6 hours) and significant (up to 500 times) growth after the trigger of activating factor (injury, infection) (16). C-reactive protein is a useful marker in determining and monitoring of the course of acute inflammations in the abdominal cavity, such as appendicitis (17), diverticulitis and its complications (18) or peritonitis in the course of dialysis (19). C-reactive protein level seems to correlate well with the risk of therapy complications (19), but it is not very useful as a marker of distant results of acute inflammations of abdominal cavity (20).

The CRP level in the studied groups was characterised by gradual increase of the mean value in the group treated with standard wound therapy (initially 50.5 mg/dl, after 35 days of treatment – 82.5 mg/dl) and gradual decrease in the group treated with negative pressure wound therapy (initially 52.9 mg/dl, after 35 days of treatment 48.4 mg/dl). After first week of treatment in both groups the increase in CRP level was recorded, which can be connected with severe general condition, repeated laparotomies, escalating inflammation. After 14 days from the start of the therapy the mean value of CRP started to drop significantly in the group of patients treated with negative pressure wound therapy, and it remained high in the group treated with standard therapy. Such tendency was sustained in the following weeks, and in the 3rd and 5th week the differences in the CRP levels were significantly lower in the group treated with NPWT. In the 4th week of treatment no statistical significance of the differences in the CRP levels were noted. The analysed CRP values indicate a substantial impact of the negative pressure wound therapy on the reduction of the systemic inflammatory response in patients treated with NPWT. This fact seems to significantly influence the lower percentage of deaths in the group treated with NPWT, as well as to impact better healing of intestinal fistulae.

Lack of significant differences during hospitalization in both analysed groups should be noted. This gives the impression that despite the improvement in the results of treatment with the use of negative pressure wound therapy, the hospital stay does not shorten. This data should, however, be analyzed comprehensively. An important factor causing the hospitalization time to be long in the group of patients treated with negative pressure wound therapy is a late introduction of this form of treatment. Negative pressure wound therapy was initially seen as a form of treatment of extremely difficult cases that were previously treated for a long time using conservative methods. On the one hand, this extended the total hospitalization time, on the other hand, it often led to the deterioration of the general condition of the patient. The subject of a separate analysis performed in our centre was the assessment of the effects of treatment, hospitalization time and the costs of treatment depending on the introduction of NPWT (15).

In patients in case of which NPWT was introduced not later than on the 5th day of treatment, the effects of the negative pressure wound therapy were significantly better than in the patients in case of which this kind of therapy was introduced later. This is also confirmed by the observations of other authors, clearly emphasising the validity and necessity of fast introduction of NPWT in case of open abdomen (8, 10, 14).

CONCLUSIONS

The use of negative pressure wound therapy becomes more and more popular. On the one hand it is caused by the decreasing costs of treatment, on the other hand, by the easier and more intuitive in handling equipment, which can be adjusted to any type of indications for NPWT. Naturally, a proper training of the doctors in using this type of therapy is necessary, both in the form of workshops (equipment handling, animal models) and in the clinical setting (21).
REFERENCES


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