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Research Article

Retrospective Cohort Study: Negative Pressure Wound Treatment for Surgical Site Infection After Radical Cystectomy

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Abstract

Objectives: The negative pressure wound therapy (NPWT) is a well-established advanced for treatment surgical site infections (SSI) such as wound suppuration, postoperative peritonitis or open abdominal. How-ever, the evidence base for use for complications in oncological surgery is very limited. Therefore, in this study assessed the 30-days results of NPWT in treatment SSI in oncological surgery.

Methods: This is a retrospective cohort study which was performed in accordance with the STROBE protocol. The study included data of 446 patients who were underwent to radical cystectomy with uroderivation (RC) at the Oncourology department between January 2012 and December 2021. For next analysis 62 cases of SSI were allocated with completely data. These cases were separated into two groups: group A (n=36) of standard SSI's management and group B (n=26) of NPWT-dressing with VivanoTec® S042 device in constant negative pressure mode (85-110 mmHg). All calculations were performed with MS Excel and StatPlus:mac (2022).

Results: SSIs were identified in 57 men (91.93%) and 5 cases in women (8.07%). The age, BMI in both groups did not differ. There was a statistically significant increase in CRP at the time of detection of SSI in group D - 233.72±139.67 mg/ml (p=0.011). It was confirmed by the severity of the process according to the APACHE scale and correlation analysis (r=0.318, p=0.011). The mortality rate dur-ing hospitalization did not differ between groups. When conducting a one-way analysis of variance in groups A and B, no convincing data were obtained on the effect of NPWT on mortality (F=2.68 p=0.106).

Conclusion: The NPWT dressing does not negatively affect on incidence of postoperative mortality, intestinal fis-tulas or lateralization of wound edges. The method showed identical results in comparison with the standard method, despite the inclusion cases with more severe inflammatory processes (90% of pa-tients with APACHEII scale > 20 points).

Keywords: Radical cystectomy, surgical site infection, peritonitis, negative pressure wound dressing, open ab-dominal

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The main treatment for muscle invasive bladder cancer and non-muscle-invasive with a high risk of progression –remains RC with lymphadenectomy.[1] According to some locoregional obser-vation studies RC is still associated with high incidence of postoperative complications, regardless of the type of access.[2-4] One of the most common of them remains SSIs with an incidence from 0.6% to 46%.[5]

It is recognized that effective SSI's management requires a comprehensive assessment of both the patient and the wound to determine the optimal treatment plan.[6] The standard of treatment for SSI is the elimination of the infection's source, necrectomy and debridement of wounds or abdominal cavity as necessary and definitely an adequate antimicrobial therapy. Negative pressure wound therapy (NPWT) is a tool commonly used to assist in preparing larger at-risk wounds for delayed closure es-pecially for open abdominal. The use of negative pressure in case of a complicated surgical wound or widespread purulent peritonitis makes it possible to influence several links in the pathogenesis of the infectious-inflammatory process at once.[6]

The NPWT dressings simplifies hospital care, reduces the pain and traumatic factors of daily dressings: according to SF-36 questionnaire noted an increase in physical condition - by 27%, general health indicators - by 17%, relief of physical pain more often - by 11%.[7] In one meta-analysis was identified wound healing time was shorter in the NPWT group (p=0.0001), better wound healing rates (OR 5.80 p<.0001), but the same time NPWT-dressing provoked significantly longer hospital stays [MD –3.77d, p=.02] and medical costs of treatment (MD 732.78$ p<.00001).[8] However, despite the demonstrated effectiveness, the widespread of NPWT dressings is associated with chal-lenges: absent evidence of the optimal level for negative pressure, a number of authors indicate an in-creased risk of enteral fistulas or demedialisation of the wound's edges, at last, no data were demon-strating the safety such approach in oncology surgery. Therefore, conducting this study on the basis of a large oncology surgical center will provide valuable the 30-days results of NPWT for surgical complications after RC.

Methods

This is a retrospective cohort study which was performed in accordance with the STROBE protocol. The study included data of 446 patients who were underwent to radical cystectomy with uroderivation (RC) at the Oncourology department between January 2012 and December 2021. The sample was continuous. General features of the patients are presented in Table 1.

Eligibility criteria: Confirmed muscle invasive bladder cancer and non-muscle-invasive with a high risk of progression; ages from 18 to 85 years old; completed RC with different type of uroderi-vation (any types were allowed); SSI have to occurred within 30- days after RC; allowed treatment – necrectomy and/or debridement of wounds or abdominal cavity, laparotomy, open abdominal, relepa-rostomy or NPWT-dressing; completely data. For next analysis 62 cases of SSI were allocated.

All cases were divided into two groups: group A (n=36) of standard SSI's management (necrectomy and/or debridement of wounds or abdominal cavity, laparotomy, open abdominal, releparostomy) and group B (n=26) with NPWT-dressing.

Vacuum treatment of wounds under negative pressure was used using the ATMOS S 042 NPWT VivanoTec device (Hartmann, Germany). The range of negative pressure in con-

Table 1. General features of patients

	Group A (NPWT-) 36	Group B (NPWT+) 26	p
Superficial SSI, abs (%)	7 (11.29)	5 (8.07)	1.000
Profundal SSI, abs (%)	29 (46.77)	21 (33.37)	
Gender, men, abs (%)	33 (92)	24 (92)	1.000
Age M±SD	63.47±10.58	67.61±10.38	0.130
BMI M±SD	26.12±3.73	25.71±3.48	0.665
Smoking, abs (%)	17 (47.2)	12 (46.15)	0.765
Radiation therapy*, abs (%)	4 (11.11)	0	0.132
Therapy*, abs (%)	8 (22.22)	9 (34.61)	0.388
ASA scale assessment, abs (%)			
ASA 1	6 (16.81)	4 (15.31)	0.227
ASA 2	19 (52.63)	15 (57.69)	
ASA 3	11 (30.56)	7 (27.0)	

*Radiation therapy before surgery for the bladder cancer; Chemo (immuno) therapy like as neoadjuvant chemotherapy or immunotherapy (during clinical trials).

stant mode was from 85 to 110 mmHg. All NPWT-dressings consist of constant elements: a porous and hypoal-lergenic polyurethane sponge (the size of the sponge is determined by the volume of the wound de-fect), an adhesive transparent film and a non-collapsing drainage tube connected to a vacuum and exu-date container. For superficial SSI, after filling the wound defect with a sponge, the wound was her-metically sealed with a transparent adhesive film and a drainage tube was connected to a vacuum sys-tem to collect exudate (see Fig. 1A). In case of an intra-abdominal vacuum was used a special "ab-dominal kit " which included a non-adhesive porous film as a protective layer between the sponge and intestine, omentum, liver, vessels or nerves. (see Fig. 1B). NPWT dressings were changed for a peri-od from 1–2 to 4 days depending on demand. Planned revision of wounds was carried out under an-esthesia and it could be supplemented with staged necrectomy.

Staging was performed using the TNM AJCC version 7 system. The physical status of pa-tients before RC was assessed with ASA scale (American Society of Anesthesiologists).[9] The se-verity of the patient's condition at SSI's time was assessed with APACHE II scale.[10] Additionally, indicators were analyzed: length of hospitalization, frequency of changing NPWT, C-reactive protein and leukocyte index in dynamic.

Statistical Analysis

All calculations were performed with MS Excel and StatPlus:mac (2022). The threshold criterion for statistical significance is $p<0.05$. Quantitative and qualitative data were assessed with parametric and non-parametric statistics: Man-Whitney test, t-test, chi-square test (χ^2), Pearson correlation, one-way analysis of variance. In order to prevent the systematic errors (this is retrospective analysis) the study protocol was written according to STROBE checklist, assessment the adequacy and methodology of data analysis is carried out on The Newcastle-Ottawa Scale.[11, 12]

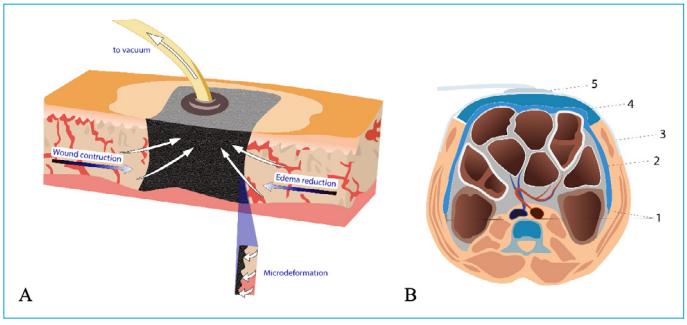

Figure 1. (a) sagittal section: mechanism of the negative pressure in the wound. **(b)** intra-abdominal NPWT-dressing: 1 - Told line; 2-non-adhesive porous film; 3-adhesive sealing film; 4- polypropylene hydrophilic sponge; 5-portable system with double lumen tube.

Results

The basis of the work were 62 cases of SSIs which were identified within 30 days after surgi-cal treatment. Detailed characteristics of the patients are presented in Table 1. It was revealed 10 cases of superficial SSI, which affected only the skin, subcutaneous fat at the site of surgical access; and 52 cases of profundal SSIs that affected deep soft tissues and/or internal organs.

The overwhelming majority were men 57 (91.93%), only 5 women (8.07%). The average age and BMI did not differ between A/B groups. About ½ of the patients in the following groups were smokers and correlation established between the depth of SSI and patient's smoking status ($r=0.319$, $p=0.006$) which was confirmed by the univariate analysis ($F=2.65$ $p= 0.040$). According to the ASA scale assessment was noted that patients with severe systemic diseases accounted for **⅓** of all included patients at RC step.

At first all 62 patients were performed RC with lymphadenectomy and different types uroderi-vation by one surgeon N.: heterotopic in the Bricker or Mainz-I volume in 47 cases (75.8%), ortho-topic derivation of J -pouch - 11 cases (17.74%), ureteroctuaneostomy in 1 case and 3 cases (4.83%) were completed by nephrostomy drains. RC was performed with minimally invasive approach in 85.48% (52/62) with intracorporeal uroderivation for 58 patients. Laparotomy access was used only in 2012 in 10 cases (14.52%) at the stage of development of endoscopic surgery in our institution. There were no significant differences in the duration of the operation between A/B groups ($p=0.272$), however, the volume of intraoperative blood loss in group B was higher 291.15±394.86 ml vs 210.41±227.90 ml. According to correlation analysis established a moderate inverse relationship between the type of uroderivation and depth of SSI: intracorporeal orthotopic derivation was associat-ed with the risk of developing deep surgical infection ($r=-0.328$, $p=0.009$). The data of APACHE II scale was significantly different between groups: group B with NPWT-dressings the high scores on the APACHE2 scale were statistically significantly more likely to be encountered, which characterizes group B with pronounced impairments of physiological disorders and chronic conditions at the time of SSI diagnosis.

The average length of hospitalization from RC to SSI's development did not differ between the groups (7.74±6.47 days, 0-13 days). The use of negative pressure wound therapy increased the aver-age time from the 1st debridement operation to closure of the laparotomy wound due to periodic changes of NPWT dressings (the maximum number of dressings was 8, the average number of NPWT dressing changes was 3.7), however, there was no differences within

total length of hospitali-zation of a patient with complications between the groups (p=0.529).

There was a statistically significant increase in CRP at the time of detection of SSI in group B 233.72±139.67 mg/ml (p=0.011), which is confirmed by the severity of the process according to the APACHE scale and correlation analysis (r=0.318, p=0.011). The mortality rate during hospitalization did not differ between groups (see Table 2). When conducting a ANOWA analysis of variance in groups it was not revealed convincing data of negative effect of NPWT-dressings on mortality rate (F=2.68 p=0.106).

CRP level was increased at the time of detection of SSI in group B 233.72±139.67 mg/ml (p=0.011), which is confirmed with the severity of condition according to the APACHE scale and correlation analysis (r=0.318, p=0.011). The mortality rate did not differ between groups (see Table 2), figure 2. When conducting a ANOWA analysis of variance in groups it was not revealed convinc-ing data of negative effect of NPWT-dressings on mortality rate (F=2.68 p=0.106).

In group A, at the early postoperative period there was 1 case of intestinal fistula formation and 3 cases at the late period (1 anterior abdominal wall fistula, 2 enterovaginal fistulas), which re-quired additional hospitalization for these patients. In group B none cases of intestinal fistula or

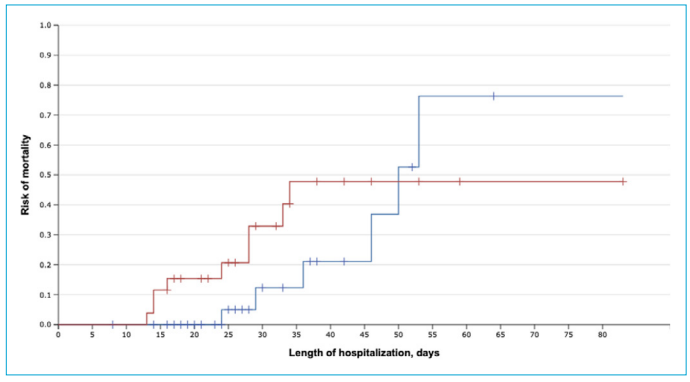

Figure 2. The mortality rate during hospitalization, log rank test (HR0.54, CI95% 0.195-1.495, p=0.231). Read line cases with NPWT-dressing, blue line- conventional wound treatment.

im-possibility of closing the laparotomy wound were identified were revealed, at late postoperative stage- 2 cases of ventral hernia were identified.

Discussion

In accordance with WHO recommendations on intraoperative and postoperative measures for surgical site infection prevention (2016), the main component of SSI's treatment is remaining a surgi-cal control of the source of infection which should be carried out as early as possible towards to pre-vent generalization of infection. It has to include

Table 2. Characteristics of patients at 3 steps: RCE, SSI's detection and discharge-step

	Group A (NPWT-) 36	Group B (NPWT+) 26	p
RC with lymphadenectomy and different types uroderivation			
Bricker-uroderivation, abs (%)	27 (75.0)	19 (73.08)	0.556
Mainz-I type abs (%)	1 (2.77)	0	
J-pouch abs (%)	7 (19.39)	4 (15.40)	
Ureteroctuaneostomy +nephrostomy drains, abs (%)	1 (2.77)	3 (11.54)	
Laparotomy, abs (%)	30 (83.33)	23 (88.46)	0.722
Laparoscopic, abs (%)	6 (16.67)	3 (11.54)	
Operation time, Me±SD, minutes	318.19±112.38	289.38±82.61	0.272
Intraoperative bloodless, M±SD ml	210.41±227.90	291.15±394.86	0.314
The severity of the patients' condition			
APACHE-II scale 0 до 9 points	2/29 (6.90)	1/21(4.76)	0.576
APACHE-II scale 10-19 points	12/29 (41.40)	1/21 (4.76)	0.013
APACHE-II scale 20-29 points	11/29 (37.90)	13/21 (61.91)	0.009
APACHE-II scale >30 points	4/29 (13.80)	6/21 (28.57)	0.037
Length of hospitalization from RC to SSI's develop-ment, Me±SD days	7.63±6.77	7.88±6.16	0.884
Length of hospitalization SSI's development to dis-charge, Me±SD days	6.20±6.59	12.23±13.56	0.024
Total Length of hospitalization M±SD дней	28.08±12.80 (8-64)	30.03±16.27 (13-83)	0.599
CRP at SSI diagnostic step M±SD, мg/ml	155.70±96.59	233.72±139.67	0.018
LII at SSI diagnostic step, M±SD	0.14±0.13	0.17±0.30	0.509
CRP at discharge step, M±SD, мg/ml	91.4±35.64	82.90±53.63	0.485
LII at discharge step M±SD	0.29±0.32	0.48±1.24	0.374
Mortality rate, abs (%)	6 (16.67)	9 (34. 61)	0.137

revision of wounds, removal of necrotic tissue, fibrin and foreign bodies (debridement step), subsequent regular change of dressings if necessary, or until secondary sutures are applied, or until wounds heal by secondary intention.[13] Relatively new in this area is the negative pressure wound therapy.

The pioneers of modern vacuum therapy are considered to be American scientists M. J. Mory-kwas, L. C. Argenta, who in 1997 published data on the treatment of complicated surgical wounds using the method of calibrated negative pressure.[14] The effectiveness of which was due to five factors: 1) continuous clean of the wound and reduction of contamination after debridement; 2) continu-ous removal of exudate into a special container; 3) reduction of interstitial edema; 4) stimulation of the formation of granulation tissue; 5) the final result is a reduction in the size of the wound. Of additional practical significance for surgeons working with an open abdomen are data about the NPWT-role in the prevention of lateralization of wound edges, the formation of ventral hernias and the incidence of intestinal fistulas.

Open abdomen (OA) or laparostomy is a method of managing peritonitis, intra-abdominal in-fection in which the edges of the anterior abdominal wall are deliberately not sutured after debridement (with the possibility of subsequent revision "according to plan" or according to "demand"). The main disadvantage of this technique is due to the rapid onset of wound exhaustion, supercontamination, the appearance of acute visceritis, the formation of external intestinal fistulas and extensive ventral herni-as. At the same time, NPWT dressings preserve of wound centralization, lateralization of wound edg-es and contaminations.

In largest international study Coccolini F. (2017), including 369 cases of SSI in adults and 33 cases in children, a linear correlation was identified between the duration of OA management and the frequency of complications (r=0.326 p<0.0001) and the development of fistulas (r=0.146 p=0.016). However, despite the more frequent use of NPWT dressings (44.2%) as a temporary method of closing the bladder, this method showed the lowest incidence of all adverse events (33%), the inci-dence of intestinal fistulas (13%) and low 30-day case mortality rate (14%).[15]

In a 2022 Cochrane review, including 14 major studies, the use of NPWT-dressing was halved the risk of developing intestinal fistulas associated with the OA management option: in the group of NPWT 10 cases per 1000 patients, in the group of other methods 50 cases per 1000 patients with fistulas. The NPWT management of open abdomen was reduced the risk of mortality from any cause by 29%: in the group of NPWT 248 cases per 1000 patients, in the group of other methods of abdominal management - 350 cases per 1000 patients.[26] However, none of randomized trials were included there, which would provide a high level of evidence and the possibility of officially including negative pressure vacuum wound treatment in clinical guidelines.[16]

In our study of 26 cases of using NPWT-dressing was not identified cases of intestinal fistula formation in the early and late postoperative period. Secondly, the cases of "frozen abdomen" de-scribed in the literature were also not identified in our series of patients. This fact is probably associat-ed with three mandatory conditions that are implemented during the intra-abdominal installation of a controlled negative pressure system (see Fig. 3). Firstly, at the moment of temporary closure of OA it is necessary to maximally match the edges of the wound and the aponeurosis along the midline with guiding sutures. Secondly, the absorption of exudate through the polypropylene sponge promotes medial traction of the wound edges, causing its progressive closure. Thirdly, to isolate intestinal loops, omentum, large vessels from the absorbent sponge, a non-adhesive film is used which can be inserted into any sloping areas of the abdominal cavity or small pelvis and parietal surface of the liver. This protective coating for internal organs prevents adhesion of internal organs to the parietal peritoneum, sponge or muscles of the anterior abdominal wall and prevents "frozen abdomen" syndrome.

The retrospective study by Wild T., despite the increase in the average hospital day in NPWT dressings group (38.9±27.2 days compared to standard methods 26.6±23.0 days), the authors managed to reduce the level of hospital mortality by 40%: 14% in the NPWT therapy group versus 59% in the main group.[17] In other work of Bleszynski M.S. (2016) was represented large retro-spective series– 211 cases of sec-

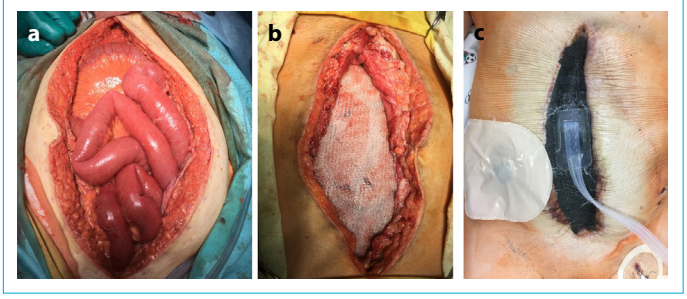

Figure 3. The negative pressure wound therapy in treatment a profundal surgical site infection: 3-d day after radical cystectomy which was complicated ureteral leakage and peritonitis. **(a)** Debridement was performed, the wound was filled with distended a small intestine, there were no fibrin deposits; **(b)** non-adhesive film covers the loops of the small intestine to prevent "frozen abdomen" syndrom; appearance of the wound, **(c)** negative pressure pumping device is connected p=110 mmHg).

ondary peritonitis, including simultaneously 44% of cases of septic shock, managed to reduce the 28-day mortality rate from 38.7% in the general group to 22.8% when using vacuum dressings (p=0.012).[18] According to our results, mortality did not differ between groups: 6 cases (16.67%) were identified in group A and 9 cases (34.61%) in group B (p=0.233) (HR 0.54, CI95% 0.195-1.495, p=0.231) despite of the use of a relatively new method management of SSI in patients with a more severe stage of the inflammatory process (90% of patients in group B had more than 20 points on APACHE2 scale).

The main limitation of the study is its retrospective type, as in many other studies, which is due to the severity of recruitment into a prospective study and the severity of the patients themselves, who are undergoing relief of the infectious process. The second limitation is selection bias, which is caused by the inclusion only cases with complete data for statistical analysis.

Conclusion

Choosing a treatment option for SSI is a complex, resource intensive task for the surgeon. This retrospective analysis was carried out for the first time in a urological oncology hospital. The cur-rent study indicated that NPWT may lead to a lower incidence of SSIs when compared with standard care in high-risk surgical wounds after Radical cystectomy.

The method of negative pressure vacuum treatment proposed in this work has proven to be a safe and effective method that does not increase the length of hospitalization and the incidence of postoperative mortality and allows for early primary musculofascial closure of the abdominal cavity.

Disclosures

Ethics Committee Approval: The study was approved by the Local Ethics Committee.

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

Authorship Contributions: Concept – A.N.K.; Design – M.B.V.; Supervision – A.B.M., A.N.K.; Data collection &/or processing – M.B.V.; Analysis and/or interpretation – M.B.V., A.N.K.; Literature search – M.B.V.; Writing – M.B.V., A.N.K.; Critical review – A.B.M., A.N.K.

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