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The negative pressure wound therapy may salvage the infected mesh following open incisional hernia repair

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ABSTRACT

Background: s: Incisional hernias may occur in 10–25% of patients undergoing laparotomy. In cases of a surgical site infection (SSI) after incisional hernia repair (IHR) secondary operative intervention with mesh removal are often needed. There is only minimal data available in the literature regarding the treatment of a wound infection with negative pressure wound therapy (NPWT). Conducting the study at hand, we aimed to provide more evidence on this topic.

Methods: From April to June 2020 a monocentric retrospective study has been performed. Patients who underwent NPWT due to a SSI with mesh involvement following open IHR from 2007 to 2020 were included. The primary endpoint was the mesh removal rate in the end of NPWT. Main secondary endpoints were the duration of NPWT and the amount of NPWT procedures.

Results: The data of 30 patients were extracted. The average age was 65.9 years (9.9). A total of 13 individuals were male and 17 females. The BMI was on average 31.1 kg/m^2 (4.9). All patients received a polypropylene mesh. The average duration of NPWT was 31.3 days (22.1). The first wound revision with initiation of a NPWT was conducted on average 31.1 days (34.0) after IHR. The average amount of NPWT procedures was 8.3 (7.2). In 5 of 30 patients (16.6%) the mesh was removed (Open sublay group n = 4 (36.34%) vs. open onlay group n = 1 (5.26%), p = 0.047).

Conclusion: In cases of SSI following IHR the NPWT may facilitate mesh selvage. Further trials with a larger sample size are mandatory to confirm our hypothesis.

1. Introduction

Incisional hernias (IH) are a common complication after abdominal surgery and occur in approximately 10–25% of patients undergoing laparotomy. Up to 30% of these hernias leads to symptoms and often require hernia repair [1–3].

Next to various surgical approaches who has been successfully implemented into IH surgery routine, the open onlay and open sublay techniques remain sufficient approaches to treat these hernias [4]. As one of a main complication a SSIs may occur in up to 30% of cases [4]. Furthermore, the SSI can also lead to mesh infection with an incidence of 1–2% [1–3,5].

Risk factors for SSI with mesh infection include steroid use, smoking, old age, obesity, diabetes and malnutrition [3]. It is a severe complication because it often leads to comorbidities and a prolonged hospital stay. The conservative non-operative treatment includes antibiotic administration and percutaneous or surgical drainage [3,6]. In a recent retrospective analysis by Warren et al., in 2020 (n = 213) a mesh salvage rate of only 18.8% was stated, when local wound care was performed alone [7]. Hence, the mesh removal has often been described as part of a sufficient treatment for mesh infections [8]. In these cases, the IH is treated without a mesh and a relapse can often be expected.

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A sufficient strategy to salvage mesh removal may consist of the negative pressure wound therapy (NPWT) but scientific data are limited. Hence, we aimed to analyze our data to reveal more evidence on that topic.

2. Methods

The study occurred at the Helios hospital Berlin-Buch (Germany) between April and June 2020. The data of patients who were operated on due to an IHR from 2007 to June 2020 were analyzed. The study was approved by the Ethics Committee of the 'Ärztekammer Berlin' (Medical Association Berlin) in Mai 2020 (Eth-09/20) and conducted in accordance with the ethical standards of the Helsinki Declaration 1975.

The study was registered with the German clinical trial registry DRKS (DRKS00022170). No funding has been received.

The study is based on the patients' data available from their files. The time of their hospital stay has been analyzed. We did not perform a systematic follow-up.

The manuscript was written according to the STROCSS guidelines [9].

2.1. Surgical approach

The open incisional hernia repair in sublay and onlay technique were performed according to the described techniques by Chevrel [10] and by Rives [11]. All patients received an antibiotic single shot with cefuroxim (1.5 g). Drain tubes were routinely inserted. These approaches were chosen in cases of a hernia gap >7 cm.

As a standard approach at our hospital, when a SSI with mesh infection occurs, wound debridement with NPWT was initiated. In cases of a systemic inflammatory response with detection of a bacteraemia antibiotic agents were administrated according to an antibiogram. The pressure dressing was changed after 72 h. Based on surgeons experience, in cases of a macroscopic mesh inbuilt failure, the mesh was removed.

2.2. Inclusion criteria

Patients who underwent NPWT due to a wound infection with mesh involvement (mesh located inside or next to the wound infection) following open IHR were included.

2.3. Exclusion criteria

Individuals with a SSI following incisional hernia repair, who did not receive the NPWT, were excluded.

2.4. Aims

Primary endpoint: mesh removal rate after finalized NPWT.

Secondary endpoints: Amount of NPWT procedures, duration of hospital stay, Clavien-Dindo-Classification [12] until finalization of NPWT; Mesh removal rate (if available in patients file).

2.5. Database

In April 2020, an MS Excel data sheet was provided. This data was imported into R (ver. 3.6.1), and multiple plausibility checks were performed. In Mai 2020 inconsistencies of the data were resolved.

3. Results

3.1. Baseline characteristics

The data of 30 patients were analyzed. The average age was 65.9 years (9.9). A total of 13 individuals were male and 17 females, 2 patients had an ASA-Score I, 13 an ASA-Score II and 15 an ASA-Score of III. The BMI was on average 31.1 kg/m^2 (4.9). The baseline characteristics are shown in Table 1.

3.2. Perioperative data

Overall, 19 patients were operated on in open onlay and 11 patients in open sublay technique. In 13 cases a component separation took place. 18 patients suffered from a primary IHR and 12 individuals from a secondary IHR. The operating time was on average 122.6 min (51.1). Table 2 depicts these perioperative data.

3.3. Primary endpoint

In 5 of 30 patients (16.6%) the mesh was removed. In three cases the removal was conducted within the first year after IHR (Average postoperative day (POD): 36.5 (46.3). In one case the mesh was removed on the 430 POD.

3.4. Secondary endpoints

The average duration of NPWT was 31.3 days (22.1). The first wound revision with initiation of a NPWT was conducted on average 31.1 days (34.0) after IHR. The average amount of NPWT procedures was 8.3 (7.2; average pressure 72.9 mmHg (7.2)). In all cases a suture wound closure was conducted in the end of NPWT. The cumulative length of hospital stay was 47.2 days (28.11). The CDC was revealed during the hospital stay. A total of 27 patients had a CDC grade III (due to their wound infection). Three individuals had a CDC grade IV (2x catheter sepsis with multiorgan failure, 1x respiratory insufficiency; Table 3).

3.5. Univariate analysis on NPWT following open onlay and sublay IHR

A total of 11 patients underwent open Sublay IHR. The average age was 67.27 (SD 8.27) years. Male were 5 and female 6. No patient had an ASA score of I, 8 an ASA score of II and 3 an ASA score of III. The BMI was on average 32.29 (SD 5.34) kg/m^2. In three cases the Sublay IHR was performed due to a relapse. The operating time was on average 139.36 (SD 47.23) minutes (Table 4). The average duration of NPWT was 31.27 (SD 28.40) days. On average the first wound revision was 35.55 (SD 49.60) after surgery. The average amount of NPWT procedures was 10.64 (SD 10.74) days. The average pressure was 72 (SD 11.35) mmHg. In 4 cases (36.34%) the mesh was removed. The mesh was removed on average 10 (SD 8.66) days after IHR. The average length of hospital stay was 43 (SD 28.33) days (Table 5).

A total of 19 individuals underwent open Onlay IHR. The average age was 65.11 (SD 11.17) years. Male were 8 and female 11. Two patients had an ASA score of I, 5 an ASA score of II and 12 an ASA score of III. The BMI was on average 29.24 (SD 4.32) kg/m^2. In 9 cases the Onlay IHR was performed due to a relapse. The operating time was on average 112.89 (SD 59.62) minutes (Table 4). The average duration of NPWT was 31.37 (SD 19.08) days. On average the first wound revision was

Table 1
Baseline characteristics.

Variable		Study group
		n = 30
Age	*years*	65.9 (9.9)
Gender	*male*	13
	female	17
ASA preoperative	*I*	2
	II	13
	III	15
	IV-V	0
BMI	kg/m2	31.1 (4.9)

ASA = American Society of Anesthesiologists physical status classification; BMI Body Mass Index Continuous measurements are presented as mean (SD).

Table 2
Perioperative data I.

Variable		Study group
		n = 30
Mesh placement	*onlay*	19
	sublay	11
Component separation[a]		13
Primary incisional hernia		18
Relapse		12
Operating time	*minutes*	122.6 (51.1)

Continuous measurements are presented as mean (SD).
[a] TAR transversus abdominis release.

Table 3
Perioperative data II.

Variable		Study group	
		n = 30	
Duration of NPWT therapy	*days*	32.6 (22.3)	
POD of first wound revision	*days*	31.1 (34.0)	
Amount of NPWT procedures	*n*	8.1 (7.1)	
Average pressure	*mmHg*	72.9 (9.9)	
MR	*n*	5 (16.6%)	
MR < 365 POD	*n*	4 (13.3%)	
Average POD of MR	*d*	14	
MR > 365 POD	*n*	1 (3.3%)	
POD of MR	*d*	430	
Cumulative LOS	*days*	47.2 (28.11)	
CDC Grade	*III*	90.0%	(n = 27)
	IV	10.0%	(n = 3)
	V	0%	(n = 0)

CDC Clavien-dindo classification; Continuous measurements are presented as mean (SD); LOS Length of hospital stay; MR Mesh removal; NPWT negative pressure wound therapy POD Postoperative days.

Table 4
Univariate analysis on biometric and perioperative variables following open Onlay and Sublay repair.

Variable		Open Sublay Group	Open Onlay Group	P-Value
		n = 11	n = 19	
Age	*years*	67.27 (SD 8.27)	65.11 (SD 11.17)	0.290 (t)
Gender	*male*	5	8	1.000
	female	6	11	(F)
ASA preoperative	*I*	0	2	0.042
	II	8	5	(F)
	III	3	12	
	IV-V	0	0	
BMI	*kg/m2*	32.29 (SD 5.34)	29.24 (SD 4.32)	0.070 (t)
Primary incisional hernia repair		7	10	0.442 (F)
Operating time	*minutes*	139.36 (SD 47.23)	112.89 (SD 59.62)	0.109 (t)

ASA American Society of Anesthesiologists physical status classification; BMI Body Mass Index Continuous measurements are presented as mean (SD); (F) Fisher-Test; (t) *t*-Test.

28.58 (SD 23.42) after surgery. The average amount of NPWT procedures was 6.95 (SD 4.20) days. The average pressure was 73.44 (SD 9.58) mmHg. In one case the mesh was removed (5.26%). The mesh was removed 116 days after IHR. The average length of hospital stay was 49.63 (SD 29.23) days (Table 5).

In terms of baseline characteristics, no statistical significant differences were revealed between both groups. Regarding mesh removal rate, a statistical significance was detected (Open sublay group n = 4 (36.34%) vs. open onlay group n = 1 (5.26%), p = 0.047).

Table 5
Univariate analysis on NPWT following open Onlay and Sublay repair.

Variable		Open Sublay Group	Open Onlay Group	p-value
		n = 11		n = 19
Duration of NPWT therapy	*days*	31.27 (SD 28.40)	31.37 (SD 19.08)	0.496 (t)
POD of first wound revision	*days*	35.55 (SD 49.60)	28.58 (SD 23.42)	0.302 (t)
Amount of NPWT procedures	*n*	10.64 (SD 10.74)	6.95 (SD 4.20)	0.095 (t)
Average pressure	*mmHg*	72 (SD 11.35)	73.44 (SD 9.58)	0.362 (t)
Mesh removal	n	4 (36.34%)	1 (5.26%)	**0.047** (F)
POD of mesh removal	*days*	10 (SD 8.66)	116	[a]
Cumulative LOS	*days*	43 (SD 28.33)	49.63 (29.23)	0.275 (t)
CDC Grade	*III*	11	16	0.279 (F)
	IV	0	3	
	V	0	0	

ASA American Society of Anesthesiologists physical status classification; BMI Body Mass Index Continuous measurements are presented as mean (SD); (F) Fisher test; NPWT negative pressure wound therapy; (t) *t*-Test.
aNo statistical analysis obtainable due to a single variable.

3.6. Biometric and perioperative data of mesh removal group

A total of 5 patients received a mesh removal. In 4 cases an open sublay repair was previously performed. The average age was 63.8 (8.79) years. Two patients were male and three were female. Two patients had an ASA score II and three individuals an ASA score III. The BMI was on average 28.33 kg/m^2. The average operating time was 136.6 (37.5) minutes. The length of hospital stay was on average 46.2 (30.10) days (Table 6).

4. Discussion

Already in 1993, Fleischman et al. published the NPWT for open fractures. The authors stated that this therapeutic approach led to an efficient cleaning and conditioning of the wound, with marked proliferation of granulation tissue. No bone infection did occur among their 15 enrolled patients [13]. These findings were also confirmed in an animal model by Morykwas in 1997 [14].

Table 6
Data on mesh removal group.

Variable		Study group
		n = 5
Age	*years*	63.8 (8.79)
Gender	*male*	2
	female	3
ASA preoperative	*I*	0
	II	2
	III	3
	IV-V	0
BMI	kg/m2	28.33 (6.02)
Mesh placement	*onlay*	1
	sublay	4
Component separation[a]		3
Primary incisional hernia		18
Relapse		1
Operating time	*minutes*	136.6 (37.5)
LOS	days	46.2 (30.10)

ASA = American Society of Anesthesiologists physical status classification; BMI Body Mass Index Continuous measurements are presented as mean (SD); LOS Length of hospital stay.
[a] TAR transversus abdominis release.

Until today the NPWT has been implemented into daily surgical routine. Its use has been described, inter alia, in cases of trunk pressure ulcers and sternal wounds [15–17]. In terms of hernia surgery, Kercher et al. (2002) successfully treated a wound infection with mesh (polytetrafluoroethylene) involvement following ventral hernia repair [18]. The evidence of NPWT for SSI with mesh infection following IHR remains low. Clinical trials with large sample sizes are not existing. To that, current guidelines state only based on a level 5 statement, that SSI following IHR may be treated by NPWT [3]. Many authors recommended the mesh removal in this cases instead [8,19,20].

Using the databases *Pubmed* and *Google Scholar* (search terms: "negative", "pressure", "wound", "therapy", "hernia", "vacuum", assisted") our search yielded 8 relevant publications on that topic [8,21–27]. Case reports were not reviewed. All publications were retrospective analysis. A total of 196 individuals were enrolled. In 36 cases the mesh was removed (18.36%). But unfortunately, data on duration of NPWT, amount of procedures, length of hospital stay were mostly not stated. Hence, we aimed to provide more evidence and analyzed our own data. We enrolled 30 patients, who underwent open IHR in onlay (n = 19) and sublay (n = 11) technique. In only 5 cases the mesh had to be removed (16.66%). Thus, the NPWT may facilitate mesh salvage, when a SSI with mesh infection occurs following IHR. If the mesh is salvaged, the IH naturally remains sufficient treated and the risk for a relapse is reduced. An additional reason for mesh preservation might be the avoidance of mesh removal related complications such as acute bleeding or entero-cutaneous fistula after adjacent vascular or bowl damage [7,28]. To that, Bueno-Lledo et al. (2017) revealed a high complication rate after analyzing 66 patients with a mesh infection following IHR. Three patients suffered from an entero-cutaneous fistula. Even one patient died due to multiorgan failure [29].

Disadvantages of NPWT are costs and in many cases the need of inpatient treatment. Furthermore, due to pain and discomfort the NPWT was conducted at our hospital under general anesthesia. We revealed an average NPWT duration of 32.6 (22.3) days. Approximately 8 surgical procedures under general anesthesia were performed on average. Hence, for individuals who suffer from higher morbidity the NPWT might be a high cardiovascular load. In addition, the benefit of the NPWT for wound treatment in general remains unclear. In a randomized clinical trial (n = 65) Braakenburg et al. (2006) revealed no significantly faster granulation or wound surface reduction or better bacterial clearance, when a NPWT was performed. The enrolled individuals suffered from acute and chronic wounds [30]. To that, Weed et al. (2004) did not detect a consistent effect of bacterial clearance with NPWT when analyzing 25 patients with wound infections [31].

We performed an univariate analysis between the open sublay and onlay group to investigate the impact of the surgical approach on the mesh removal rate. The baseline characteristics and perioperative data did not differ from each other. But the mesh removal rate was statistical significantly higher among individuals who underwent open sublay repair (Open sublay group n = 4 (36.34%) vs. open onlay group n = 1 (5.26%), p = 0.047; Table 6). This may be explained by the late detection of the SSI with mesh infection in comparison to open onlay repair.

As study limitation the retrospective study design must be stated. Fortunately, SSI with mesh infection following IHR did not frequently occurred at our hospital. Hence, we enrolled only 30 patients. Moreover, we implanted without exception polypropylene (PP) meshes. Of course, the NPWT may lead to lower rate of mesh salvage when other kinds of meshes are used. To that, SSI with mesh infection occurs more frequently when a polytetrafluoroethylene (PTFE) mesh was implanted (Mesh infection rate for PTFE 9.2% vs. 2–4% for PP). In addition, the mesh removal rate was also higher [1–3]. We did not perform a systematic follow-up. This would have been interesting to reveal the long-term recurrence rate. Nevertheless, the NPWT was terminated after sufficient ingrowth the mesh. Hence, maybe a comparable frequency of relapses following elective open incisional hernia can be expected. We define a sufficient ingrowth as a mesh, which is completely covered may granulated tissue. A further study limitation is the small sample size especially in terms of our univariate analysis on mesh removal rate (Open onlay group n = 4 vs. open sublay group n = 1).

5. Conclusions

NPWT is a sufficient approach to treat SSI with mesh infection following open IHR. In most cases the implanted mesh can be salvaged. Further trials with a larger sample size are mandatory to confirm our hypothesis.

Funding

No funding has been received.

Ethical approval

The study was approved by the Ethics Committee of the 'Ärztekammer Berlin' (Medical Association Berlin) in Mai 2020 (Eth-09/20) and conducted in accordance with the ethical standards of the Helsinki Declaration 1975.

Research Registration Unique Identifying Number (UIN)

The study was registered with the German clinical trial registry DRKS (DRKS00022170). No funding has been received.

Author contribution

Fr. Katherina Böttge (co-author):
Contribution to the paper: data analysis, examination and treatment of the patient, writing the paper.
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Dr. med. Christoph Paasch (corresponding author):
Contribution to the paper: author, data collection, data analysis and interpretation, writing the paper, examination and treatment of the patient.

Guarantor

Dr. med. Christoph Paasch.

Disclosure statement

KB, JF, GD, NA, PO, SA, MH and CP declare no conflict of interest.

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Declaration of competing interest

None.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.amsu.2020.12.013.

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