

Incisional Negative-Pressure Wound Therapy for Perineal Wounds After Abdominoperineal Resection for Rectal Cancer, a Pilot Study

Maxime J.M. van der Valk,^{1,2,*} Eelco J.R. de Graaf,¹
Pascal G. Doornebosch,¹ and Maarten Vermaas¹

¹Department of Surgery, IJsselland Hospital, Capelle aan de IJssel, The Netherlands.

²Department of Surgery, Leiden Universitair Medisch Centrum, Leiden, The Netherlands.

Presented at the European Society of Coloproctology, 11th Scientific and Annual Meeting as a poster presentation, September 28–30, Milan, Italy.

Objective: Abdominoperineal resection (APR) is associated with high incidence of surgical wound infections. The use of incisional negative-pressure wound therapy (iNPWT) is known to reduce wound infections for several surgical indications. The aim of this pilot study was to investigate the potential of a new portable negative-pressure therapy device on perineal wound healing in patients undergoing APR.

Approach: A new single-use incisional negative-pressure therapy device was applied in 10 patients. A negative pressure of -80 mmHg was continued for 7 days postsurgery. Incidence of wound complications and time to wound healing were compared with a historical control group of 10 patients undergoing APR in 2014, treated with conventional wound care.

Results: Patient characteristics were comparable in both groups. Mean 1.6 dressings were used per patient. A wound complication was diagnosed in seven patients versus six in the control group. Wound infections were diagnosed median 11.5 days after surgery, compared with 10.5 days in the control group. Duration of wound healing was shorter in the study group (median 8.5 weeks vs. 13 weeks).

Innovation: This is the first study to report on the use of this iNPWT device for patients who underwent APR for rectal cancer.

Conclusion: In this study, iNPWT did not reduce wound complications. Wound infections occurred slightly later and seemed to have a less severe clinical course. After treatment with iNPWT, the duration of wound healing was shorter.

Keywords: incisional negative-pressure wound therapy, abdominoperineal resection, rectal cancer



Maxime J.M. van der Valk, MD

Submitted for publication June 28, 2017.
Accepted in revised form August 13, 2017.

*Correspondence: Department of Surgery,
IJsselland Hospital, Prins Constantijnweg 2, Capelle a/d IJssel 2906 ZC, The Netherlands
(e-mail: mvandervalk@lumc.nl).

INTRODUCTION

SURGICAL RESECTION OF the rectum for rectal cancer via abdominoperineal resection (APR) is associated with high rates of perineal wound complications, reported to be 14–80%.¹ This may be caused by the large cavity in the pelvis that exists after resection, where blood and fluid can accumulate

and accelerated bacterial growth can occur subsequently. Furthermore, neoadjuvant treatment for rectal cancer is a known risk factor for perineal wound complications.² Other patient-related risk factors for perineal wound complications include diabetes mellitus, malnutrition in cancer patients, obesity, smoking,

hypertension, and hypercholesterolemia.^{3–5} Perineal wound infections are known to lead to decreased postsurgical quality of life, prolonged hospital stay, intensive wound care, and sometimes, even require reconstructive surgery.⁶

Clinical problem addressed

Perineal wound complications after APR for rectal cancer occur frequently and are known to have a prolonged impact on postoperative recovery and quality of life. The use of negative-pressure wound therapy (NPWT) to support wound healing has been described for many indications, including acute and chronic wounds.⁷ Over the last two decades, there has been an increase in development of commercially available negative-pressure devices, including devices that can be applied to closed incisions to prevent wound complications, so-called incisional NPWT (iNPWT).

The aim of this study was to evaluate the potential of a new portable NPWT device in reducing wound complications and accelerating wound healing for patients undergoing APR for rectal cancer.

MATERIALS AND METHODS

This is a single center prospective feasibility study conducted between January 1st and December 31st 2015 at IJsselland Hospital, The Netherlands. The use of the disposable PICO™-device was evaluated in 10 patients undergoing laparoscopic APR for rectal cancer. Patients undergoing extralevator APR or treated with a perineal subcutaneous drain were excluded. Primary endpoint was the incidence of wound complications. Secondary endpoints were wound complication severity score assessed with the Clavien–Dindo classification (CD)⁸ and time to wound healing, defined as time to complete closure of the wound. Outcomes were compared with a historical control group of patients undergoing APR in 2014 and treated with conventional wound care.

A new portable iNPWT device

The PICO system (Smith & Nephew, London, United Kingdom) is a disposable NPWT device, designed for open and closed surgical incisions. The PICO pump generates a preset negative pressure of -80 mmHg and is designed for 7-day use. This device is portable, ultralight, and canister-free. The PICO system was shown to be effective in reducing wound healing problems in small series of various specialties: orthopedic surgery, cardiothoracic surgery, and plastic reconstruction.^{9–12} The work-mechanism of the PICO-NPWT is different from other NPWT systems, as it is canister-free,

but it is similar with regard to fluid evacuation, tissue contraction, and changes in blood flow.¹³

Surgical procedure

All patients underwent elective laparoscopic APR for distal rectal cancer. Patients received one dose of antibiotic prophylaxis before surgery. The pelvic floor defect was reconstructed primarily or using biologic mesh. For closure of the perineal incisions both absorbable and nonabsorbable stitches could be used. Immediately after closure of the perineal incision, an iNPWT device was applied, in presence of a trained delegate of Smith & Nephew and a surgeon (Fig. 1).

A negative pressure of -80 mmHg was applied with an intentional duration of 7 days. In female patients a “bridge” between perineal wound and posterior vagina wall was constructed using foam strips to ensure an airtight seal. During postoperative hospital admission, all patients were assessed daily by staff surgeon and specialized nurses. In case of vacuum failure, leakage, or dressing saturation, the dressing was changed. In case of repeated device failure, iNPWT was aborted. Hospital admission was not prolonged for study-related assessments or interventions.

Outcomes

The data of both groups were collected using digital and paper patient records. For statistical analysis of comparison of two means, a two-sided unpaired T-test was used. For comparison of two medians, a Kruskal–Wallis test was used.

RESULTS

Patient characteristics of the study group and the control group were comparable (Table 1). In five



Figure 1. Application of the PICO™ pump directly after surgery.



Figure 2. Incisional negative-pressure wound therapy device before and directly after removal at 7 days postsurgery.

patients, the perineal incision was closed using nonabsorbable transcutaneous sutures, and in the other patients, absorbable intradermal sutures were used. In the control group, eight patients were treated with a postoperative intra-abdominal drain, and in four patients, a perineal drain was applied. No biological mesh was used. In seven patients, the perineal incision was closed with absorbable intradermal sutures; nonabsorbable transcutaneous sutures were used in three patients.

iNPWT device

Application of the PICO pump was performed under supervision of a trained delegate from Smith & Nephew directly after closure of the perineal incision. Overall, there were no complaints of pain or discomfort related to the device. Mean time to change of the first dressing was 5.4 days. Six pa-

tients completed the 7 days iNPWT with one dressing (Fig. 2), two patients required a second dressing because of saturation. In two patients, a third dressing was necessary, and in one of these patients, NPWT was aborted because of repeated vacuum failure. In one other female patient, wound therapy was stopped because an airtight seal could not be achieved after removal of the urinary catheter. Mean duration of iNPWT was 6.7 days (range 4–8 days). In two patients, iNPWT was continued for 8 days.

Wound complications

A wound complication was diagnosed in 7 out of 10 patients, all classified as CD-grade 1 (Table 2). No reinterventions were performed. Wound infections were diagnosed at median 11.5 days postsurgery (mean 12.6 days, range 5–21 days postsurgery). For one patient, hospital admission was prolonged for adequate wound care, and two patients were readmitted for bedside wound opening, after which they were discharged shortly. Median time to wound healing was 8.5 weeks (mean 10.4, range 0–34).

In the control group, a wound complication was diagnosed in six patients, of which five were clas-

Table 1. Patient characteristics

	Group A (10)	Group B (10)	p
Age mean (range)	65.4 (51–83)	66.6 (45–79)	0.082 ^a
Gender M: F	6:4	6:4	
ASA med (range)	2 (1–3)	1.5 (1–4)	0.129 ^b
Charlson index med (range)	4.5 (3–6)	5 (2–7)	0.53 ^a
BMI mean	26.46	26.05	0.85 ^a
Smoking	20%	10%	
Cardiovascular comorbidity	50%	30%	
Neoadjuvant therapy	40% CRT	30% RT 20% CRT	
T-stage			
pT0	0	1	
pT1	2	1	
pT2	8	3	
pT3	0	5	
pT4	0	0	
Inflammatory disease	20% Crohn's disease		

^aTwo-sided unpaired T-test.

^bKruskal-Wallis Test.

ASA, American Society of Anesthesiologists physical status classification; CRT, chemo-radiotherapy; RT, radiotherapy;

Table 2. Presence of wound complications in both groups

	Group A (10)	Group B (10)	p
Wound complications	70% infection	40% infection	
Diagnosis (days)	Median 11.5 Mean 12.6	Median 10.5 Mean 10	0.94 ^a
Time to wound closure	Median 8.5 Mean 10.4	Median 13 Mean 11.4	0.87 ^a
CD-classification	100% Grade 1	83.3% Grade 1 16.7% Grade 3B	
Intervention	None	1 surgical intervention	

^aKruskal-Wallis test.

CD-classification, Clavien–Dindo classification.⁸

sified CD grade 1. One patient required surgical reintervention under general anesthesia (CD-grade 3B). Two other patients were readmitted for bedside wound opening. Wound complications were diagnosed median 10.5 days after surgery (mean 10 days, range 5–14 days). Median time to wound closure was 13 weeks (mean 11.4 weeks, range 0–24).

DISCUSSION

Patients undergoing APR for rectal cancer remain at high risk of developing wound complications not only due to surgical aspects but also the combination of patient-related risk factors and preoperative chemo–radiation treatment, as is illustrated by this study; 45% of all patients underwent radiotherapy. While previously conducted studies have shown a beneficial effect for conventional NPWT in case of wound complications, it is known that NPWT on perineal incisions can be painful, discourage postoperative mobilization, and especially in woman, it may be difficult to maintain an airtight seal.¹

The new iNPWT device, PICO, is light, portable, and canister-free, and therefore has the potential to be very patient friendly. The use of PICO on laparotomy incisions in patients with Crohn's disease undergoing abdominal surgery was previously studied in Italy, where the authors report a decrease in wound infections as well as hospital stay in patients treated with PICO.^{14,15} These studies suggest that PICO can be effective in decreasing wound complications, even in a high-risk population. There are two previously conducted studies that report on the use of iNPWT for perineal incisions after APR.^{16,17} In these studies a continuous negative pressure of –125 mmHg was applied for 5 days on primarily closed perineal incisions, leading to a reduction in postsurgical wound complications. Also, the use of variable NPWT was suggested previously.¹⁸ Although there is no evidence from clinical studies yet, porcine wound studies show that variable NPWT increased the amount of granulation tissue.

The aim of this study was to investigate the potential of the PICO device to reduce wound complications in patients undergoing APR for rectal cancer. Because of the small sample size of this pilot study, it was not within our expectation to find statistical significant differences.

When compared with a historical control group, no decrease in wound complications was found in the present study. However, wound infections did seem to occur later in patients treated with iNPWT

KEY FINDINGS

- iNPWT with the PICO pump was well tolerated.
- iNPWT did not reduce the incidence of perineal wound complications, but use of iNPWT seemed to result in a reduction of the wound healing time.
- Perineal wound infections after iNPWT seemed to have a shorter and less severe clinical course.

and appeared to have a favorable clinical course. There were no complaints about device usability and comfort; this is in line with the previously conducted studies.^{11,14}

In other studies on the effect of iNPWT for perineal incisions after APR, a negative pressure of –125 mmHg was applied.^{16,17} Possibly the negative pressure of –80 mmHg that was applied in this study is not sufficient in relationship to the depth and size of the cavity that exist after APR, while it can be effective for other abdominal surgical indications.¹⁴ As iNPWT may facilitate faster superficial wound healing, this possibly counteracts drainage of the exudate in higher tissue levels, causing fluid stasis that subsequently will lead to wound complications. This may explain the slightly later onset of wound infection in the study group. It is possible that the use of wide interrupted sutures facilitates drainage of blood and exudate from the pelvis better than a running suture, which was used in half of our study population. This is the first report on the use of iNPWT for perineal incisions with a canister-free device. The comparison between canister- and canister-free iNPWT should be addressed in future studies. Other recommendations for future research include the role of variable pressure of iNPWT and the effect of interrupted versus running sutures.

INNOVATION

Patients undergoing APR for rectal cancer remain at high risk of developing wound complications. Although present study is too small to draw major conclusions, iNPWT failed to show an evident reduction in wound infection rate. However, it seemed that patients treated with iNPWT had a shorter and less severe course of wound complications. The use of iNPWT seemed to accelerate wound healing. This pilot study may serve as a basis for further research into iNPWT following APR, as the results of this study suggest that there may be a beneficial effect on the course of perineal wound healing.

AUTHOR DISCLOSURE AND GHOSTWRITING

No competing financial interests exist. The content of this article was expressly written by the authors listed. No ghostwriters were used to write this article.

ABOUT THE AUTHORS

Maxime van der Valk, MD, PhD-Student, has worked on this study during her surgical residency

at IJsselland hospital, under direct supervision of **Maarten Vermaas, MD, PhD**. She is now working as a PhD-candidate at Leids University Medical Center. **Eelco de Graaf, MD, PhD, Pascal Doornebosch, MD, PhD**, and **Maarten Vermaas, MD, PhD**, are dedicated gastrointestinal surgeons at IJsselland hospital. All authors were closely involved in execution of this study and preparations of the article.

REFERENCES

- Wiatrek RL, Thomas JS, Papaconstantinou HT. Perineal wound complications after abdominoperineal resection. *Clin Colon Rectal Surg* 2008;21:76–85.
- Bullard KM, Trudel JL, Baxter NN, Rothenberger DA. Primary perineal wound closure after preoperative radiotherapy and abdominoperineal resection has a high incidence of wound failure. *Dis Colon Rectum* 2005;48:438–443.
- Christian CK, Kwaan MR, Betensky RA, Breen EM, Zinner MJ, Bleday R. Risk factors for perineal wound complications following abdominoperineal resection. *Diseases of the colon and rectum* 2005;48:43–48.
- Artioukh DY, Smith RA, Gokul K. Risk factors for impaired healing of the perineal wound after abdominoperineal resection of rectum for carcinoma. *Colorectal disease: the official journal of the Association of Coloproctology of Great Britain and Ireland* 2007;9:362–367.
- Althumairi AA, Canner JK, Gearhart SL, Safar B, Sacks J, Efron JE. Predictors of perineal wound complications and prolonged time to perineal wound healing after abdominoperineal resection. *World J Surg* 2016; 40:1755–1762.
- Vermaas M, Ferenschild FT, Hofer SO, Verhoef C, Eggermont AM, de Wilt JH. Primary and secondary reconstruction after surgery of the irradiated pelvis using a gracilis muscle flap transposition. *Eur J Surg Oncol* 2005;31:1000–1005.
- Hyldeg N, Birke-Sorensen H, Kruse M, et al. Meta-analysis of negative-pressure wound therapy for closed surgical incisions. *Br J Surg* 2016;103:477–486.
- Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 2004;240:205–213.
- Colli A, Camara ML. First experience with a new negative pressure incision management system on surgical incisions after cardiac surgery in high risk patients. *J Cardiothorac Surg* 2011;6:160.
- Horch RE. Incisional negative pressure wound therapy for high-risk wounds. *J Wound Care* 2015; 24(4 Suppl):21–28.
- Hurd T, Trueman P, Rossington A. Use of a portable, single-use negative pressure wound therapy device in home care patients with low to moderately exuding wounds: a case series. *Ostomy Wound Manage* 2014;60:30–36.
- Hudson DA, Adams KG, Van Huyssteen A, Martin R, Huddleston EM. Simplified negative pressure wound therapy: clinical evaluation of an ultraportable, no-canister system. *Int Wound J* 2015;12:195–201.
- Malmsjo M, Huddleston E, Martin R. Biological effects of a disposable, canisterless negative pressure wound therapy system. *Eplasty* 2014;14:e15.
- Pellino G, Sciaudone G, Candilio G, Campitiello F, Selvaggi F, Canonico S. Effects of a new pocket device for negative pressure wound therapy on surgical wounds of patients affected with Crohn's disease: a pilot trial. *Surg Innov* 2014;21:204–212.
- Selvaggi F, Pellino G, Sciaudone G, et al. New advances in negative pressure wound therapy (NPWT) for surgical wounds of patients affected with Crohn's disease. *Surg Technol Int* 2014;24:83–89.
- Chadi SA, Kidane B, Britto K, Brackstone M, Ott MC. Incisional negative pressure wound therapy decreases the frequency of postoperative perineal surgical site infections: a cohort study. *Dis Colon Rectum* 2014;57:999–1006.
- Sumrien H, Newman P, Burt C, et al. The use of a negative pressure wound management system in perineal wound closure after extralevator abdominoperineal excision (ELAPE) for low rectal cancer. *Tech Coloproctol* 2016;20:627–631.
- Borgquist O, Ingemansson R, Malmsjo M. Individualizing the use of negative pressure wound therapy for optimal wound healing: a focused review of the literature. *Ostomy Wound Manage* 2011;57:44–54.

Abbreviations and Acronyms

APR = abdominoperineal resection
 CD = Clavien–Dindo classification
 iNPWT = incisional NPWT
 NPWT = negative-pressure wound therapy