

A modified negative pressure wound therapy for the treatment of refractory wounds

A preliminary study

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Abstract

Negative pressure wound therapy (NPWT) is an important therapy for the management of refractory wounds. The aim of this retrospective preliminary study was to introduce a modified NPWT (m-NPWT) and compared the efficacy of it with conventional NPWT (c-NPWT) in the management of refractory wounds.

A total of 127 patients with refractory wounds receiving the NPWT from January 2010 to October 2017 in our hospital were retrospectively reviewed. The demographics and clinical data were collected from medical records and compared between m-NPWT group and c-NPWT group.

There were 65 patients in c-NPWT group and 62 patients in m-NPWT group. No significant difference was observed between 2 groups in antimicrobial use ($P = .51$), hospitalization time ($P = .24$), wound-healing rate ($P = .44$) or complication rate ($P = .59$). However, patients in m-NPWT group had shorter wound-healing time (24.82 vs 27.66 days, $P < .01$), less debridement times (1.23 vs 2.08, $P < .01$), less total cost (3743.93 vs 6344.33 yuan, $P < .01$) and higher satisfaction rate (56/62 vs 44/65, $P = .02$) compared to those in c-NPWT group.

The m-NPWT technique was an efficient and safe alternative therapy for refractory wounds.

Abbreviations: c-NPWT = conventional NPWT, m-NPWT = modified NPWT, NPWT = negative pressure wound therapy.

Keywords: modified negative pressure wound therapy, refractory wounds, total cost., wound-healing time

1. Introduction

Refractory wounds refer to wounds unresponsive to initial therapy or persist despite appropriate care, which heavily affect the quality of patient's life and increase the financial burden on the health care system.^[1,2] It is estimated that nearly 7 million

Americans suffer from refractory wounds and around \$25 billion is cost on this disease annually.^[1] There are a variety of potential causes for the development of refractory wounds, such as vascular insufficiency, bacterial presence in wounds, lack of growth factors for healing, and so on.^[3,4] Cell failure has been proved to play an important role in the occurrence of refractory wounds, and the ability to migrate and respond to growth factors of keratinocytes adjacent to refractory wounds has been diminished, which facilitates the occurrence of refractory wounds.^[3,5] In clinical practice, the management of refractory wounds needs multidisciplinary therapies, including surgery, dressing change, anti-infection medicine and the control of primary diseases.^[6-8] However, although these therapies may cure most of refractory wounds, patients have to face the relevant problems along with the treatment, such as long disease course, painful experience and huge financial burden.^[9,10]

Negative pressure wound therapy (NPWT) is originally developed for the requirement of plastic and reconstructive surgery.^[11,12] NPWT is the delivery of intermittent or continuous sub-atmospheric pressure by a specialized pump, which is connected to a resilient and open-celled solid foam. The solid foam is covered with a semipermeable membrane to keep a closed environment, and the wound exudate is collected by a canister connected to the pump.^[13] NPWT has been widely used in the treatment of various acute or chronic complex wounds for its satisfactory efficacy and simple methods.^[14-21] Nevertheless, along with the satisfactory results of NPWT, this technique brings up some other matters, including the infection, hardening of solid foam and difficulty of removal.^[20,22] Therefore, how to further improve the efficacy and decrease the complication rate of NPWT has become an important clinical issue. Here, we

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All data and materials used in this study are stored in the medical record room of Hebei General Hospital.

This study has been approved by the Institutional Review Board of Hebei General Hospital, and all included patients have signed the informed consent.

The authors have no conflicts of interests to disclose.

The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

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performed this preliminary study to introduce a modified NPWT (m-NPWT) and compare the efficacy of it with conventional NPWT (c-NPWT) in the management of refractory wounds.

2. Materials and methods

2.1. Study design

This retrospective study was proved by the Institutional Review Board of our hospital and all included patients have signed the informed consent. Consecutive patients with refractory wounds, who received c-NPWT or m-NPWT from January 2010 to October 2017 at our hospital, were included into this study. The demographics and clinical data were collected from medical records, including gender, age, body mass index, cause, preoperative course of disease, antimicrobial use, wound-healing time, hospitalization time, debridement times, total cost, wound-healing rate, patient's satisfaction rate, and complications.

2.2. Surgical technique

All patients received the routine debridement to clear the necrotic, infected or scar tissues in refractory wounds, and then, NPWT was used to drain the drainage liquid and promote the wound healing.

In c-NPWT group, the c-NPWT consisted of a solid foam, a semipermeable membrane, 2 drainage tubes, and a negative-pressure device (Wuhan NPWT Medical Science& Technology Co., Ltd) (Fig. 1). The solid foam with 2 drainage tubes was cut according to the shape of the wound. Then, a semipermeable membrane was pasted over the solid foam to form a sealed environment, and 2 drainage tubes were connected to a mini-

pump, which was typically set at 450 mm Hg. The c-NPWT was generally replaced every 5 to 7 days, and the final removal of c-NPWT was performed according to wound condition and growth of granulation tissues.

In m-NPWT group, the m-NPWT consisted of 2 drainage tubes, a semipermeable membrane (Mepore Film, Sweden, Menek) and some medical gauze (Fig. 2). The first drainage tube, also named internal tube, was placed at the deep part of the wound via a 2 cm incision by the side of the wound to drain the wound liquid. Then, the wound was sutured and covered by the medical gauze to absorb the wound exudate. The next step was to place the second tube, also named external tube, into the medical gauze. And then, we pasted a semipermeable membrane over the medical gauze and external tube to form the sealed environment. Both tubes were connected to the 400 mm Hg negative pressure provided by our hospital. Dressing change was conducted when 50% or more of medical gauze was saturated by the wound exudate, otherwise, dressing change was performed every 3 days. Besides, the internal tube was normally removed when the 24-hour drainage fluid was less than 5 mL for 3 days. On the contrary, if the 24-hour drainage fluid was larger than 15 mL or tissue necrosis occurred within 1 week after the debridement, the repeated debridement would be performed. The external tube and negative-pressure device were removed when there was no drainage fluid in the external tube.

2.3. Outcome measures

The following variables were compared between 2 groups: antimicrobial use, wound-healing time, hospitalization time, debridement times, total cost, wound-healing rate, satisfaction

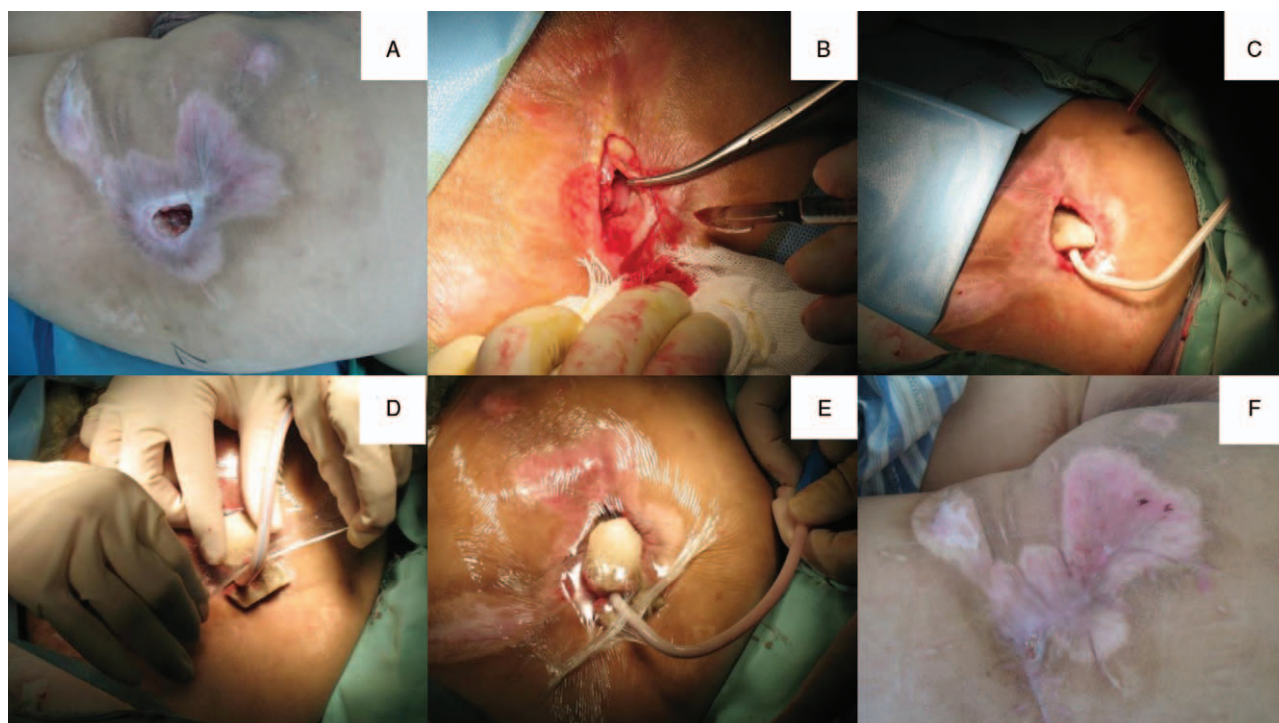


Figure 1. A 67-year-old female patient had a pressure sore around the left hip receiving c-NPWT. A, the pressure sore around the left hip; B, the debridement to remove the necrotic tissue; C, the implantation of the solid foam with a drainage tube; D, sealing the wound with a semipermeable membrane; E, checking the leakproofness and connecting the negative-pressure device; F, the healed wound.

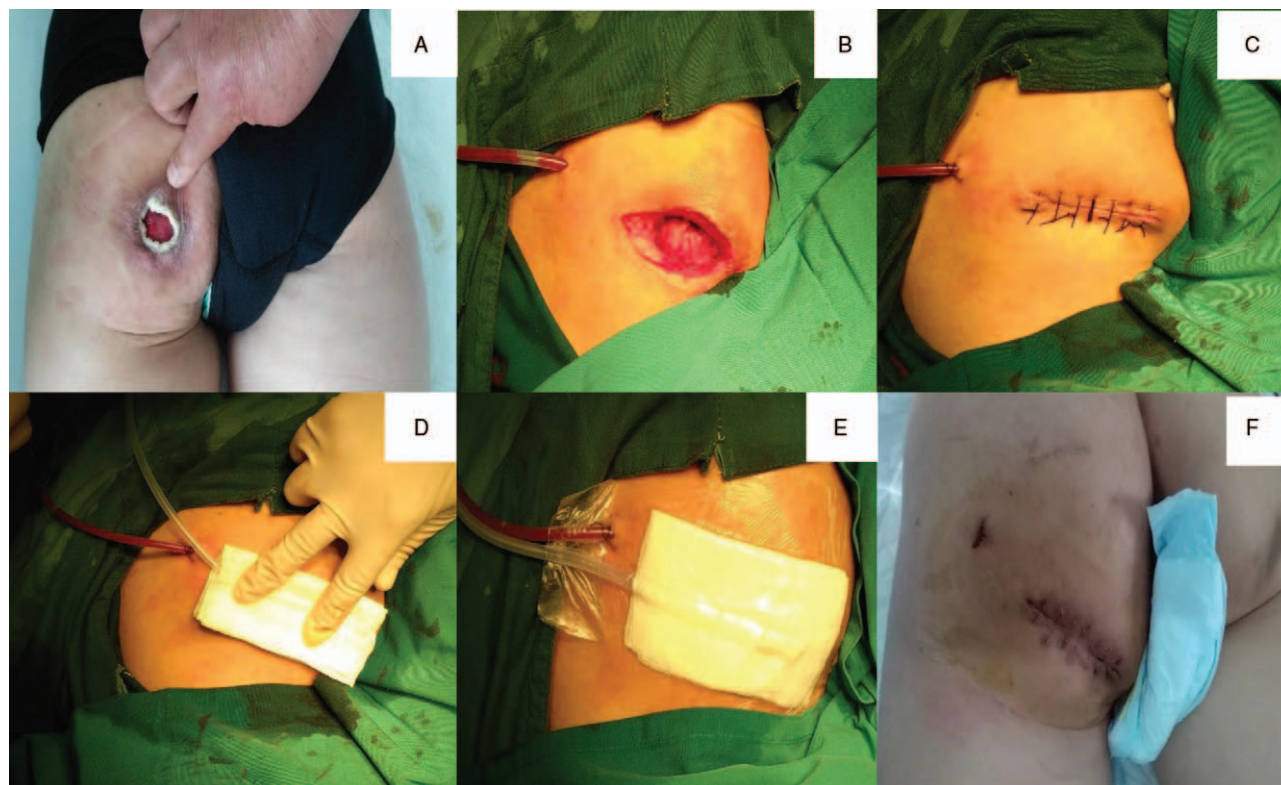


Figure 2. A 65-year-old female patient had a pressure sore on the left haunch receiving m-NPWT. A, the pressure sore on the left haunch; B, the debridement to remove the necrotic tissue and the implantation of the internal drainage tube; C, suturing the wound; D, the medical gauze and the external drainage tube outside the wound; E, forming the sealed environment with a semipermeable membrane and connecting the negative pressure provided by the hospital; F, the healed wound.

rate, and complications. Especially, the patient's satisfaction rate was used to evaluate the patient's subjective response to these 2 techniques (excellent, good, fair, and poor).

2.4. Statistical analysis

All analyses in this study were conducted using SPSS 22.0 (IBM Inc., Armonk, NY). The continuous data between the c-NPWT and m-NPWT groups were compared by independent sample *t* test for normal distribution or Mann–Whitney *U* test for abnormal distribution. The categorical variables between m-NPWT and c-NPWT groups were compared using Chi-squared test. All results were presented in the form of “mean ± standard deviation”. All *P* values were 2 sided and the difference was considered significant when *P* < .05.

3. Results

The demographics of included patients are listed in Table 1. A total of 127 patients (63 males and 64 females) were included into this study. These patients had a mean age of 64.82 (range, 30–85) years old and a mean body mass index of 23.35 ± 4.73 kg/m². Besides, as for the cause of refractory wounds, 59 patients suffered from refractory wounds for the pressure sores, 30 patients for the infection after surgery, 24 patients for the diabetic foot and 14 patients for the radiotherapy prior to surgery. The mean preoperative course of disease was 7.47 months, ranging from 1.20 to 16.80 months. There were 65 patients in c-NPWT

group and 62 patients in m-NPWT group (Table 2). There was no obvious difference between c-NPWT group and m-NPWT group in terms of gender (*P* = .43), age (*P* = .75), BMI (*P* = .85), cause of refractory wounds (*P* = .89) or preoperative course of disease (*P* = .16).

The comparison of clinical outcomes between 2 groups was showed in Table 3. As for the time of antimicrobial use, there was no obvious difference between 2 groups in total treatment time (*P* = .51), intravenous treatment time (*P* = .24) or oral treatment after intravenous treatment (*P* = .57). Similarly, no distinct difference between 2 groups was found in hospitalization time (*P* = .24) or wound-healing rate (*P* = .44). However, shorter wound-healing time (24.82 ± 3.53 vs 27.66 ± 4.48 days, *P* < .01),

Table 1

Demographics of included patients.

Variables	Results
Gender (n) (male/female)	63/64
Age (yr) (mean, range)	64.82 (30–85)
BMI (kg/m ²) (mean ± SD)	23.35 ± 4.73
Causes (n/%)	
Pressure sores	59/46.45
Infection after surgery	30/23.62
Diabetic foot	24/18.90
Radiotherapy before surgery	14/11.03
Preoperative course of disease (mo) (mean, range)	7.47 (1.20–16.80)

BMI = body mass index, SD = standard deviation.

Table 2
Comparison of demographics between 2 groups.

Variables	c-NPWT Group (n=65)	m-NPWT Group (n=62)	P value
Gender (n)			
Male	30	33	.43
Female	35	29	
Age (yr) (mean, range)	65.11 (30–84)	64.52 (45–85)	.75
BMI (kg/m ²) (mean ± SD)	23.43 ± 4.50	23.27 ± 4.98	.85
Causes (n)			
Pressure sores	30	29	
Infection after surgery	17	13	.89
Diabetic foot	11	13	
Radiotherapy before surgery	7	7	
Preoperative course of disease (mo) (mean, range)	7.87 (1.20–15.00)	7.04 (1.30–16.80)	.16

BMI = body mass index, c-NPWT = conventional negative pressure wound therapy, m-NPWT = modified negative pressure wound therapy, SD = standard deviation.

less debridement times (1.23 ± 0.58 vs 2.08 ± 0.59 , $P < .01$) and less total cost (3743.93 ± 746.23 vs 6344.33 ± 617.20 yuan, $P < .01$) were observed in patients receiving m-NPWT when compared to patients receiving c-NPWT. Moreover, higher satisfaction (excellent or good) rate was detected in m-NPWT group compared to c-NPWT group ($56/62$ vs $44/65$, $P = .02$). With regard to complications, comparable complication rate was detected between c-NPWT group and m-NPWT group ($P = .59$). Six patients in m-NPWT group and 7 patients in c-NPWT group suffered from postoperative complications. In c-NPWT group, leakage occurred in 3 patients, localized infection occurred in 3 patients and extreme pain occurred in 4 patients. In m-NPWT group, 3 patients suffered from the leakage, 2 patients suffered from the localized infection and 1 patient suffered from the extreme pain.

Table 3
Comparison of clinical outcomes between 2 groups.

Variables	c-NPWT Group (n=65)	m-NPWT Group (n=62)	P value
Antimicrobial use (d)			
Intravenous treatment	27.52 ± 6.21	26.40 ± 4.26	.24
Oral after intravenous	14.61 ± 4.13	15.01 ± 3.68	.57
Total treatment time	42.14 ± 6.65	41.42 ± 5.46	.51
Wound-healing time (d)	27.66 ± 4.48	24.82 ± 3.53	$< .01^{\S}$
Hospitalization time (d)	31.92 ± 6.73	30.58 ± 6.15	.24
Debridement times (n)	2.08 ± 0.59	1.23 ± 0.58	$< .01^{\S}$
Total cost (yuan)	6344.33 ± 617.20	3743.93 ± 746.23	$< .01^{\S}$
Wound healing (n)			
Yes	61	60	
No	4	2	.44
Patients' satisfaction (n)			
Excellent	10	17	
Good	34	39	
Fair	15	4	.02 [§]
Poor	6	2	
Complications (n)			
Leakage	3	3	
Localized infection	3	2	
Pain	4	1	.59
No	55	56	

c-NPWT = conventional negative pressure wound therapy, m-NPWT = modified negative pressure wound therapy.

[§] $P < .05$ indicating the significant difference between 2 groups.

4. Discussion

NPWT has been proved to promote the healing of refractory wounds by improving the blood circulation, promoting the growth of wound fibroblasts and inducing the wound angiogenesis.^[22–25] However, there are some limitations of NPWT, such as the induration of solid foam, extreme pain during the replacement and high medical expenses.^[22,24] More importantly, the solid foam in the wound is invisible to doctors, which makes it hard to judge the status of solid foam and wound timely. In the current study, we firstly introduced an m-NPWT technique to treat the refractory wounds, and our results showed m-NPWT was superior to c-NPWT in terms of wound-healing time, total cost, debridement times and satisfaction rate. No significant difference between 2 techniques was observed in the antimicrobial use, hospitalization time, wound-healing rate or complication rate. Therefore, m-NPWT was an efficient and safe alternative therapy for refractory wounds. To the best of our knowledge, this novel m-NPWT technique in the management of refractory wounds has not been reported before this study.

In c-NPWT, solid foam was easy to be blocked on account of the huge drainage fluid in the early days, which lowered the efficacy of negative pressure and even increased the risk of deep infection of the wound.^[12,15,26] In m-NPWT, we used the medical gauze, which had a better penetrability than solid foam, to replace the external part of solid foam in c-NPWT. Medical gauze could help us monitor the change of wound exudate and apply the dressing change timely. Besides, the solid foam was normally changed every 5 to 7 days in the form of debridement in operation room in c-NPWT, which was painful and expensive. Nevertheless, the dressing change could be performed using medical gauze and iodophor disinfectant in dressing room every 2 or 3 days in m-NPWT, and the debridement was only conducted when the wound got worse, such as tissue necrosis and deep infection. Therefore, compared to c-NPWT, m-NPWT could significantly decrease the debridement times and elevate the satisfaction rate in treating refractory wounds.

Our findings showed that patients in m-NPWT group had a shorter wound-healing time than those in c-NPWT group. The reduced wound-healing time might benefit by the internal tube used in the m-NPWT technique, which was normally not blocked and promoted the wound healing. Besides, we could monitor the status of the deep wound and adjust the treatment in time by analyzing the volume and color of drainage fluid in the internal tube.

High medial cost is another limitation of NPWT in the management of refractory wounds.^[27,28] We observed a significant reduction of total cost in m-NPWT group, which might profit from the low price of materials used in m-NPWT group. As abovementioned, the m-NPWT consisted of the medical gauze, 2 common medical tubes and negative pressure provided by the hospital, which was significantly cheaper than dedicated solid foam and negative pressure suction device in c-NPWT.

Several complications of NPWT have been reported, including infection, severe pain and bleeding.^[26,29] In the current study, no significant difference was observed in terms of complication rate between m-NPWT group and c-NPWT group. However, patients in m-NPWT group might suffer from less pain during the treatment because there was no medical material in the wound, and the dressing change of medical gauze was almost painless.

Several limitations should be considered when interpreting our results. First, our study is a retrospective single-center study, as a result, selection bias may exist. Second, we only compare the efficacy of m-NPWT with c-NPWT, the other methods used in the treatment of refractory wounds are not compared in this study. Third, it should be noticed that although our results supported the superiority of m-NPWT in the comparison with c-NPWT in treating refractory wounds, the m-NPWT is merely an adjunct therapy, and other means still play important roles in treating refractory wounds, such as antibiotics and dressing change. Fourth, although no restriction has been set on the patient selection, we tended to use the m-NPWT in refractory wounds with dead space, which can better utilize the advantage of the internal tube in draining the wound exudate. Despite these limitations, our study introduces a novel m-NPWT to treat the refractory wounds with good clinical results and safety. Randomized controlled trials with larger sample size and longer follow-up period should be conducted to determine the beneficial attributes of m-NPWT in the management of refractory wounds in future.

5. Conclusions

The m-NPWT was superior to c-NPWT in terms of wound-healing time, total cost, debridement times and satisfaction rate. No significant difference was observed between m-NPWT and c-NPWT in the antimicrobial use, hospitalization time, wound-healing rate or complication rate. Therefore, m-NPWT was an efficient and safe alternative therapy for refractory wounds.

Author contributions

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Statistical analysis: Dong Xing, Zhijie Dong.

Writing – review & editing: Dong Xing, Jingchao Wei, Xuehong Zhen.

Supervision: Wenyi Li.

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