Comparison of improvised negative pressure wound therapy and conventional wound dressing in abdominal wounds dehiscence after surgery

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ABSTRACT

Introduction: Negative pressure wound therapy (NPWT) is an effective novel technique of wound dressing resulting in faster wound healing. The technology is not widely adopted, partly due to the high price of industrially made products and limited awareness of their effectiveness. Some hospitals in resource-limited settings have developed an improvised gauze-based NPWT (iNPWT) to attain a similar effect. Several published case reports have shown good outcomes with these improvised prototypes. This study aimed to compare the effectiveness and safety profiles of these approaches in patients with gapped abdominal wounds post-surgery.

Method: This was a hospital-based, non-randomized study that involved eighty participants (aged ≥18 years) with abdominal wounds dehiscence (gapping) from two central Tanzania regional referral hospitals. Patients voluntarily chose to be treated by either iNPWT or CWD. The iNPWT was applied using the Chariker-Jeter technique and dressings were changed at 48-hour intervals before secondary closure. The primary efficacy endpoint was time until wound closure achieved by secondary suture within 42 days of follow-up and was compared between groups by Kaplan-Meier curve and statistical significance was confirmed by log-rank test.

Results: The median time for wound closure was shorter with iNPWT than with CWD (difference: 7 days, $p<0.001$). At the end of the follow-up period, all wounds dehiscence treated with iNPWT were closed while four wounds in CWD were not closed, including those of three patients who died before 42 days. Most participants in the CWD arm experienced pain more than those treated with iNPWT. There was no statistically significant difference in the occurrence of other adverse events.

Conclusion: iNPWT is a safe and effective wound dressing technique in a resource-limited setting to promote swift patient recovery.

Keywords: negative-pressure, wound dehiscence, resource-limited, Tanzania

Introduction

Caring for complicated abdominal wounds is one of the most challenging tasks in the surgical field. Impairment of abdominal wound healing might show up as either spontaneous dehiscence (gapping) or the requirement for reopening.[1] Surgical site infections, along with patient-related variables such as malnourishment, advanced age, and alcohol misuse, frequently result in impaired abdominal wound healing.[2,3]

Abdominal wound dehiscences must be regularly treated until adequately granulated before secondary suturing. Available techniques for abdominal wound dressing include conventional wound dressing (CWD) and negative pressure wound therapy (NPWT). CWD is a simple treatment for wound treatment. It involves daily dressing changes with gauze, lint, plasters, bandages and the application of antimicrobial cream protecting the wound from contamination.[2] Surgical site infection has been the most common (77.5%) reported complication faced with CWD.[3] NPWT applies sub-atmospheric pressure to the system on a continuous or sporadic basis.[4] NPWT was first reported by Argenta and colleagues in 1997 and was shown to remove chronic oedema, boost local blood flow, stimulate the creation of granulation tissue, and decrease wound depth in chronic wounds. It accelerates wound healing and has proven very promising and beneficial in managing difficult-to-heal wounds.[5] The technique may be used on acute, sub-acute and chronic wounds. NPWT is also linked to a lower rate of delayed primary closure and an increased clearance of bacteria.[6] Research indicates that NPWT does not raise the risk of death or intestinal fistulation in individuals with an exposed abdomen.[7]

A standard commercially available vacuum-assisted closure system consists of a portable vacuum machine, suction canister and adhesive dressing packages, which need to be changed three times a week, and cost around 94 US dollars per day.[7] These appliances are not readily available in most parts of the country including Dodoma and Iringa regional hospitals. Hospitals in resource-limited settings have developed a less expensive, gauze-based NPWT, known as the Chariker-Jeter technique.[8,9] Multiple layers of gauze are applied over the wound with a nasogastric tube (NG tube) sandwiched in the gauze layers connected to a regular suction machine. Cling film was applied over the gauzes to provide air tightness. Locally assembled gauze-based NPWT combined with comprehensive surgical assessment, exploration, and meticulous debridement, further facilitates wound healing.[10] The effectiveness of industrially-made NPWT is well documented in the literature[4,10] while the studies on improvised NPWT (iNPWT) are based on case reports.[4,5] The authors are unaware of any studies to evaluate the effectiveness of iNPWT on infected/gapped abdominal wounds. This study aimed to compare the effectiveness and safety profile of iNPWT and CWD in treating gapped abdominal wounds, to provide information which is crucial to both patients and clinicians in resource-limited settings.

Method

This was a non-randomized clinical trial conducted at Iringa and Dodoma Regional Referral Hospitals from April 2023 to June 2024, comparing improvised negative pressure wound therapy (iNPWT) with CWD for gapped abdominal wounds. The study involved 80 patients, with 40 receiving the iNPWT intervention and 40 unmatched CWD controls. In order to calculate the required sample size we used a study by Ondieki et al,[11] which found a mean of 8.1 days to complete wound closure, with a standard deviation of 2.4 days. Using the formula:

$$n = (Z_{\alpha/2}+Z_{\beta})^2 * 2 * \sigma^2 / d^2$$

where $Z_{\alpha/2}$ is 1.96 for 95% confidence, Z_{β} is 0.84 for 80% power, σ is the standard deviation (2.4 days) and d is the desired detectable difference (1.6 days), we calculated 36 per group, which we increased to 40 to allow for any loss to follow-up.

The study involved patients who had primary abdominal surgery for any reason, who subsequently experienced spontaneous gapping, suture removal (due to infection) or post-surgical abdominal wounds which were not possible to close primarily without fascial dehiscence, and who presented within 48 hours of this event. Those with unexcised necrotic tissues/eschar that was incompletely removed and those who had an exposed anastomotic site/intestines/blood vessels within or directly surrounding the wound that could not be adequately covered, were excluded from the study. After being informed about the various wound treatment modalities, the patients made an informed decision. Those who chose either of the two treatment modalities were included in the study after giving verbal consent. Recruitment continued until 40 patients were included in each group.

In both treatment arms, wounds were prepared by removing necrotic tissues and irrigating with normal saline. Wound areas were measured using the imitoMeasure® Android application. Participants in the treatment arm were treated with an iNPWT using the Chariker-Jeter technique. A fenestrated nasogastric tube was positioned between five layers of non-adhesive gauze that were applied to the wound. To guarantee airtightness, cling film was used to cover the entire dressing. After that, the tube was attached to a suction device. Initially, a steady negative pressure of 125 mm Hg was maintained until the wounds were cleaned.[12] Once the cleaning was done (after reduction of exudates), the pressure was reduced to a minimum of 50 mm Hg. Because of the noises generated by the suction machine, it ran for four hours, followed by a four-hour rest period, and this cycle was repeated. The dressing was changed after every 48 hours. In the control group, the traditional dressing was used; three layers of non-adhesive gauze were placed over the wound after it was cleaned and topical antiseptic or antibiotic applied. The dressing was changed daily, and the dressing materials were held in place with adhesive tape. Participants in both groups were evaluated during the 42-day follow-up period[10] for fever (defined as any temperature above 36.5°C), the presence of necrotic tissue, pain experienced during dressing (using verbal rating scale), wound area and other adverse events.

Participants' demographic data, treatment outcome parameters, and adverse effects were gathered using a data collection sheet. SPSS version 26 was used to code, clean, and analyse the data. Kaplan-Meier curves were used to illustrate the time to wound closure, and the log-rank test was used to compare the two interventions. Descriptive data were presented in proportions and means. To evaluate the factors associated with the time until wound closure, Cox proportional hazards regression analysis was employed. The relationship between the type of intervention and the incidence of adverse events was evaluated using chi-squared tests. A p-value of <0.05 was considered to be statistically significant.

Results

The study enrolled 80 patients between 21 April 2023 and 15 June 2024 from the two study sites. Sixty percent of study participants were female, and they were split equally between the treatment groups. The median baseline wound areas in the iNPWT and CWD arms were 97.4cm^2 and 96.6cm^2, respectively, but the interquartile range was much larger for the CWD arm (240cm^2) than for iNPWT (110cm^2) (Figure 1). HIV was equally prevalent in the treatment groups, but more were obese or underweight in the iNPWT group (14 versus 3). More participants in the CWD arm (8) than in the iNPWT arm (1) were alcohol drinkers (Table 1).

All patients treated with iNPWT had their wounds closed by the twenty-second day; however, one patient passed away a day after the wound was closed because of a coexisting medical condition. By the end of 42 days of follow-up, 36 patients (90%) in the CWD arm had their wounds closed. One patient showed no signs of wound closure by the end of the study period, and three patients passed away prior to the wound closure. The iNPWT and CWD arms had median times to wound closure of 15 days (IQR 9 days) and 22 days (IQR 17 days), respectively (difference of 7 days, log-rank test p<0.001) (Fig 2 and 3).

In both the unadjusted and adjusted Cox proportional hazard analyses, the type of intervention was statistically

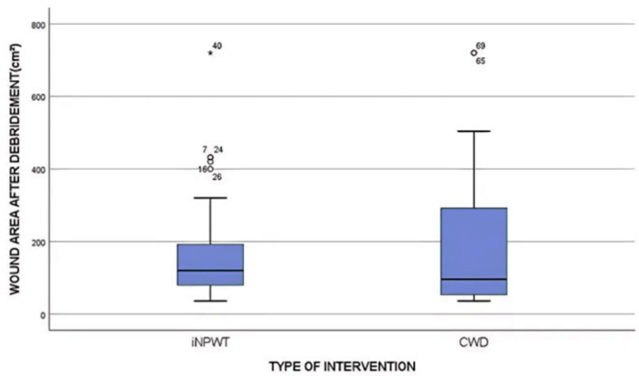

*Figure 1. Distribution of wound area after debridement for iNPWT and CWD patients (box plot showing median, lower and upper quartiles, lower and upper adjacent values and outliers). * Indicates outlier more than 3 IQR above upper quartile.*

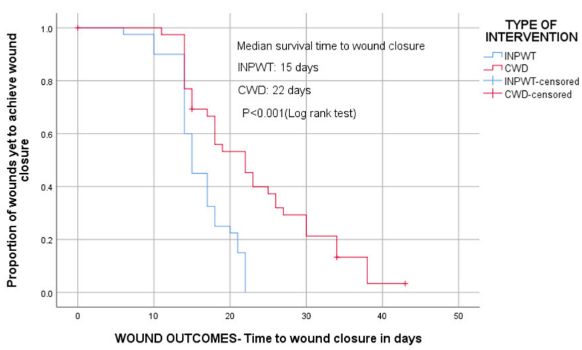

Figure 2. Kaplan-Meier curves showing the time to wound closure by wound dressing techniques. The log-rank test indicated a significant difference in time to wound closure between the two intervention groups.

Table 1. Distribution of participants based on age, sex, education, residence, and occupation concerning the type of intervention (iNPWT and CWT). n=80

Demographic Data	Categories	iNPWT n (%)	CWD n (%)	Total n (%)
Hospital	DRRH	28 (35)	23 (29)	51 (64)
	IRRH	12 (15)	17 (21)	29 (36)
Age (years) Mean (SD)		30.5 (9.7)	28.5 (10.4)	29.5 (10.0)
Sex	Male	16 (20)	16 (20)	32 (40)
	Female	24 (30)	24 (30)	48 (60)
Residence	Rural	22 (28)	20 (25)	42 (53)
	Urban	18 (23)	20 (25)	38 (48)
Education	No formal education	8 (10)	8 (10)	16 (20)
	Primary education	17 (21)	18 (23)	35 (44)
	Secondary education	8 (10)	11 (14)	19 (24)
	Higher education	7 (9)	3 (4)	10 (13)
Occupation	Peasant	18 (23)	18 (23)	36 (45)
	Self-employed	15 (19)	18 (23)	33 (41)
	Employed	2 (3)	3 (4)	5 (6)
	Student	5 (6)	1 (1)	6 (8)
Type of Surgery	Caesarean Section	15 (19)	18 (23)	33 (41)
	Ileostomy/colostomy	4 (5)	4 (5)	8 (10)
	Hysterectomy	9 (11)	3 (4)	12 (15)
	Graham patch	1 (1)	1 (1)	2 (3)
	Other laparotomies	11 (14)	14 (18)	25 (31)
Baseline Wound Size (cm^2) Mean (SD)		97.4 (11.1)	96.6 (78.5)	96.9(73)
BMI Kg/m^2	Normal weight	18 (23)	31 (39)	49 (61)
	Underweight	6 (8)	1 (1)	7 (9)
	Overweight	8 (10)	6 (8)	14 (18)
	Obesity	8 (10)	2 (3)	10 (13)
Alcohol	Yes	1 (1)	8 (10)	9 (11)
	No	39 (49)	32 (40)	71 (89)
Smoking	Current smoker	0 (0)	9 (11)	9(11)
	Former smoker	6 (8)	5 (6)	11(14)
	Never smoked	34 (43)	26 (33)	60 (75)
HIV	Positive	1 (1)	1 (1)	2 (3)
	Negative	39 (49)	39 (49)	78 (98)

Table 2. Cox proportional hazards model indicating the factors associated with time to wound closure

Predictor	HR	[95% CI]	p-value	AHR	AHR [95%CI]	p-value
Type of intervention						
CWD		Ref				
iNPWT	2.717	1.595-4.629	<0.001	2.294	1.184-3.982	0.012
Age groups						
<30		Ref				
30-40	1.433	0.843-2.437	0.183	1.554	0.835-2.893	0.164
>40	1.101	0.535-2.267	0.793	0.644	0.279-1.486	0.302
Type of surgery						
Other laparotomy		Ref				
Caesarean section	0.824	0.484-1.402	0.475	0.613	0.275-1.368	0.232
Ileostomy/colostomy	0.864	0.368-2.031	0.738	0.509	0.140-1.851	0.305
Graham patch	1.007	0.134-7.545	0.995	0.797	0.089-7.102	0.839
Hysterectomy	1.736	0.849-3.550	0.131	1.447	0.404-5.186	0.571
Sex						
Male		Ref				
Female	1.104	0.693-1.759	0.677	0.974	0.557-1.704	0.928
Smoking						
Never smoked		Ref				
Current smoker	0.825	0.450-1.512	0.533	0.410	0.067-2.502	0.334
Former smoker	0.803	0.343-1.878	0.613	0.785	0.174-3.538	0.753
Alcohol						
Yes		Ref				
No	0.447	0.210-0.950	0.036	0.691	0.193-2.478	0.571
BMI						
Normal weight		Ref				
Underweight	2.743	1.182-6.368	0.041	2.102	0.186-2.243	0.102
Overweight	0.796	0.429-1.477	0.469	0.735	0.453-3.789	0.389
Obesity	2.175	1.072-4.414	0.031	1.829	0.311-2.115	0.128

significantly associated with time to wound closure (AHR = 2.294, 95% CI: 1.184-3.982, p = 0.012) (Table 2).

Table 3 shows there were no significant differences between the arms in the occurrences of fever, pus, or death. Pain, however, was more severe in the CWD arm. In neither arm were there any other adverse effects.

Discussion

This study demonstrated significant superiority in reducing the time until wound closure in iNPWT compared to CWD. The benefits of iNPWT have been demonstrated in other studies on different wound types, and this study extended those results to abdominal wounds.[13-15] There was a higher rate of wound closure in the iNPWT arm, and all wounds in iNPWT were secondarily sutured within the study duration. In the CWD arm, the rate of wound closure was slower, and one participant did not achieve wound closure in the follow-up time. It has been reported that iNPWT offers benefits in granulation tissue

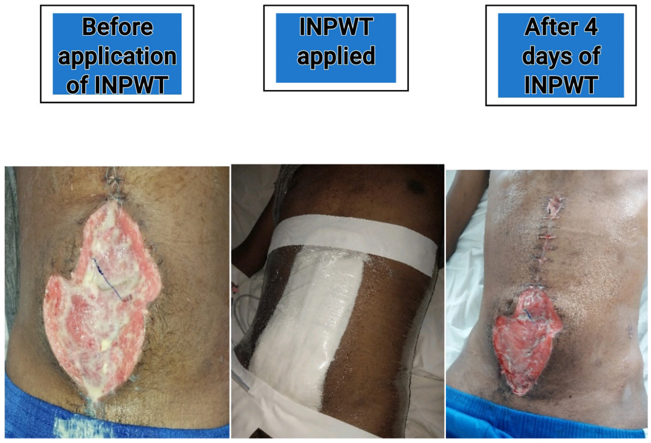

Figure 3. Pre and post-improved negative pressure wound therapy

Table 3. Adverse events including mortality within 42 days, n=80

Variable	All n (%)	iNPWT n (%)	CWD n (%)	p-value
Fever				
Yes	39 (49)	23 (29)	16 (20)	0.117
No	41 (51)	17 (21)	24 (30)	
Pus				
Yes	9 (11)	2 (3)	7 (9)	0.154
No	71 (89)	38 (48)	33 (41)	
Pain				
Mild	20 (25)	20 (25)	0 (0)	
Moderate	32 (40)	20 (25)	12 (15)	<0.001
Severe	28 (35)	0 (0)	28 (35)	
Death				
Yes	3 (4)	0 (0)	3 (4)	0.241
No	77 (96)	40 (50)	37 (46)	

production and exudate clearance, which may enhance a stronger foundation for early wound closure.[5,16]

The patients' self-selection into treatment groups is likely to have been a source of bias as the information given before enrolment could have affected their choice. Furthermore, the fact that three patients in the CWD arm died before their wounds were closed raises the possibility of a patient characteristics imbalance between the treatment groups that the baseline data did not adequately capture. These patients may have had worse outcomes because of more severe comorbidities. In contrast to other studies in this area, our endpoint was the time of secondary suture rather than complete wound healing; an experienced surgeon determined when this should be done, which could have introduced potential observer bias. Also, the non-blinded nature of this study could be a source of bias. Thus, randomized studies should be conducted to strengthen the evidence.

We assumed that iNPWT would be accompanied by a higher incidence of adverse events than CWD as in the German DiaFu-RCT,[15] but this was not the case here. Except for the pain due to dressing changes, which was more severe with CWD, there was no significant difference in the occurrence of adverse events between iNPWT and CWD. These findings led us to believe that iNPWT is as safe as CWD when used for gapped abdominal wounds after surgery. The results were similar to that of the SAWHI study, which revealed no significant difference in the incidence of adverse events between NPWT and CWD arms on abdominal wounds.[10]

The findings were inconsistent with those of a study done in four Australian tertiary hospitals, which showed more signs of infections in conventional wound dressing, 9.7% compared to 7.4% in NPWT. Also, more participants in the NPWT arm (4.0%) developed skin blisters compared to standard wound dressing (2.3%).[13] Unlike these results, a randomized controlled trial by Singh et al[14] revealed less occurrence of complications in the NPWT arm compared to CWD.

The severity of pain due to dressing changes in the CWD arm has been demonstrated in other studies;[15,16] this can be explained by the technical effort of removing debris from the wounds, done automatically by iNPWT. We recommend the use of our approach of iNPWT for gapped abdominal wounds after surgery to reduce the pain associated with CWD during dressing changes. The death of participants in the CWD arm was not related to the dressing technique but rather due to other causes.

During our study planning, no comparative study was found reporting the use of iNPWT in gapped abdominal wounds after surgery, which led to limited information on the duration of follow-up and appropriate definition for wound closure. Recurrence of wound dehiscence and other later complications could not be assessed due to the limited follow-up time of this study.

Conclusion

When compared to CWD for the management of gapped abdominal wounds after surgery, iNPWT significantly reduced the time until wound closure and reported pain with no significant difference in the incidence of other adverse events. iNPWT is a safe and effective wound dressing technique in a resource-limited setting to promote swift patient recovery.

We therefore recommend iNPWT for managing gapped abdominal wounds after surgery, as it is both efficient and safe. We also suggest that randomized trials be conducted to compare iNPWT with CWD for more evidence-based data on this topic.

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Conflict of interest: All authors declare to have no conflict of interest.

Patient's consent: Informed consent was obtained from the patients.

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