Efficacy of Portable Vacuum Dressing in Chronic Wound Care: A Prospective Randomized Control Trial

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Background: *Chronic wound is a common clinical condition and often cause treatment problems. This is because chronic wound usually require extended treatment period, which result in high hospital cost. The treatment of chronic wound depends on the type of wound, the cause of wound, and the physical status of patient. Vacuum dressing has become a standard treatment of chronic wound. However, in most hospitals, vacuum dressing is only used for in-patients thus, keeping the patients in hospital for this treatment. The problems with this are the long hospital stay, the high cost, and the unavailability of bed for other patients. This problem led us to develop a new treatment to help chronic wound patient. The potential solution was the use of a portable vacuum machine for out-patient. If the efficacy of the portable vacuum machine was comparable to the wall vacuum then the benefit could be transferred to out-patient.*

Material and Method: *A Randomized control trial of two groups of patients, conventional vacuum dressing (n = 15) and portable vacuum dressing (n = 15), was done. Rate of wound healing was measured every three days and compared to represent efficacy between the two groups of patients.*

Results: *Thirty chronic wound patients were assigned randomly to a group of 15 for treatment with conventional wall vacuum dressing and another group of 15 for treatment with our portable vacuum dressing. Demographic data was similar in both groups (sex, age and underlying cause). Wound area was recorded at the start of the treatment on day 0 and recorded at day 3, 6, 9 and 12. It was then calculated into percentage of wound healing. Rate of wound healing was 1.57%/day in conventional group and 1.59%/day in portable group. There is no clinical difference between groups ($p > 0.05$).*

Conclusion: *Our portable vacuum dressing method had no clinical difference from conventional wall vacuum dressing with respect to the rate of wound healing.*

Keywords: *Portable vacuum, Chronic wound, Randomized control trial*

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In 1997, Argenta and Morykwas[1-3] introduced negative pressure therapy to enhance wound healing. Since then, it has been used in a variety of conditions to promote healing and reduce the size of wounds. Although the exact mechanisms of action of treatment with topical negative pressure is still not clear, the mechanical force of negative pressure on wounds has been shown to improve local blood flow by changing the micro vascular blood flow dynamics, reduce interstitial edema by removal of fluid exudates, stimulate the formation of granulation tissue, reduce the bacterial colonization, provide closure of wounds by reverse tissue expansion, help retract the edges of the wound, maintain the moist wound environment with better wound healing, and possibly affect the cellular activity and angiogenesis of the wound[4-10].

In Thailand, chronic wound is a common condition and often caused treatment problems. This is because chronic wound usually require extended treatment period, which result in high hospital cost. The treatment of chronic wound depends on the type of wound, the cause of wound, and the physical status of patient.

Vacuum dressing has many research supports. Phramongkutklao hospital try to use vacuum dressing to treat patients with serious chronic wound but this can only be used for patients who stay at the hospital. The problem with patients who have to stay at the hospital for this treatment is the extended hospital stay

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Fig. 1 Portable vacuum machine

Fig. 2 Testing of Portable vacuum machine

Fig. 3 Male 67 years old have chronic wound over right heel was treat with portable vacuum dressing

Fig. 4 Male 56 years old have surgical wound dehiscence was treat with portable vacuum dressing

Fig. 5 Ambulatory vacuum dressing with portable vacuum

leads to high cost. It can also lead to bed shortage for other patients.

This problem leads us to develop portable vacuum machine to help chronic wound patients. The portable vacuum machine was selected because it is easy to use and can be applied to out-patients. This study evaluated the efficiency difference between the

portable vacuum machine and wall vacuum with the hope to transfer the benefit to out-patients.

Material and Method

This was a prospective, randomized double-blind study comparing efficacy of conventional wall vacuum dressing and portable vacuum dressing. This study was done between January 2007 and May 2008

Healthy adults (19 to 76 years old) who had chronic wound were included in this study. The criteria for exclusion were age under 10 years old, patient not agree to use vacuum dressing, infected wound and area of wound that makes vacuum dressing not applicable.

Patients who met the entry criteria were randomly assigned to be treated with portable vacuum dressing (n = 15) or wall vacuum dressing (n = 15). Vacuum dressing was done by placing NG tube No. 18 inside a sterile sponge and sealed it with adhesive tape. It was then applied on vacuum with negative pressure. Negative vacuum pressure was set at -80 mmHg in both groups.

Baseline of the wound being studied was taken on Day 0 by measuring the size of the wound and taking photograph. This was repeated every three days.

Statistical analysis

Data were statistically analyzed using descriptive statistics such as frequency, percentage, and mean $\pm$ standard deviation (SD). The Chi-square test was used for categorical variable for comparing demographic data. Data analysis focused on the rate or wound healing. P-value of less than 0.05 was considered statistically significant different.

Ethical aspects

The ethics committee for each site of the study approved the trial at each site and all patients provided written informed consent before participation.

All the patients were informed about potential risks and benefits of the medicine under study and they were allowed full liberty to withdraw from the present study at any moment, without any loss of medical attention.

Results

Thirty chronic wound patients were studied and were assigned randomly. Fifteen patients received treatment with conventional wall vacuum dressing and another 15 patients received treatment with our portable vacuum dressing. There were seven males and eight females in the conventional wall vacuum dressing group and eight males and seven females in the portable vacuum dressing group. The mean age was 49.2 years old (20 to 75) in the conventional group and it was 48.8 (19 to 76) in the portable vacuum group. Distribution of the underlying cause of the wounds was similar in both groups (Table 1).

The wound area was recorded at beginning of the treatment as day 0 and recorded at Day 3, 6, 9, and 12 (Table 2, 3). It was then calculated into percentage of wound healing (Table 4, 5). Rate of wound healing was 1.57%/day in conventional group and 1.59%/day in portable group. There was no

Table 1. Patient demographics data

Characteristics	Conventional vacuum group (n = 15)	Portable vacuum group (n = 15)
Average age $\pm$ SD (yr)	49.2 $\pm$ 17.28	48.8 $\pm$ 17.01
Gender, no of subjects (%)		
Male	7 (46.7%)	8 (53.3%)
Female	8 (53.3%)	7 (46.7%)
Underlying, No. of subjects (%)		
Burn	2 (13.3%)	2 (13.3%)
D M	4 (26.7%)	3 (20.%)
Renal disease	0	1 (6.7%)
Infected wound	3 (20.%)	2 (13.3%)
Trauma	3 (20.%)	3 (20%)
Pressure sore	2 (13.3%)	2 (13.3%)
Surgical wound dehiscence	1 (6.7%)	1 (6.7%)
Venous ulcer	0	1 (6.7%)
Total	15 (100%)	15 (100%)

clinical difference of healing between groups ($p > 0.05$) (Table 6).

Discussion

Despite the unclear mechanisms of the negative pressure therapy, increasing local blood flow, reduction of tissue edema and bacterial contamination are thought to play a major role. The result of the present study presented a cheaper and safe alternative to the conventional vacuum dressing.

Globally, the peoples are living longer with more complex systemic pathology. Furthermore, they are subjected to more extensive surgical procedures. In addition, the number of patients with chronic no healing wounds complications continue to increase, stressing the available resources resulting from

Table 2. Data of conventional wall vacuum dressing group

Case	Sex	Age	Underlying disease	Area (cm^2)				
				D_0	D_3	D_6	D_9	D_{12}
1	Female	70	DM	8.64	8.00	7.28	6.60	6.05
2	Male	38	Trauma	49.02	47.43	45.87	44.23	42.50
3	Female	59	Wound infection	61.92	59.90	57.70	55.69	53.75
4	Female	64	DM	40.04	38.05	36.36	35.28	33.79
5	Male	54	Wound dehiscence	57.72	55.38	53.18	50.63	48.52
6	Female	20	Wound infection	27.60	26.31	24.71	23.23	21.86
7	Male	75	Pressure sore	9.28	8.59	7.95	7.30	6.48
8	Male	20	Trauma S/P fasciotomy	72.15	68.26	65.73	63.15	60.64
9	Female	47	Burn	62.16	60.94	58.59	56.34	54.39
10	Male	52	Pressure sore	16.53	15.26	14.16	13.02	12.17
11	Female	53	DM	90.78	88.68	85.69	84.03	81.92
12	Male	48	Wound infection	98.49	95.50	92.75	89.22	88.05
13	Male	52	DM	14.88	14.01	12.86	12.00	11.40
14	Female	23	Trauma	24.00	22.84	21.52	20.55	19.65
15	Female	63	Burn	8.58	8.28	7.53	6.88	6.22

Table 3. Data of portable vacuum dressing group

Case	Sex	Age	Underlying disease	Area (cm^2)				
				D_0	D_3	D_6	D_9	D_{12}
1	Male	65	Burn	48.72	47.11	45.44	44.04	42.59
2	Female	43	DM	11.02	10.35	9.72	9.03	8.39
3	Female	55	DM	60.27	57.32	55.11	53.28	51.25
4	Male	67	Renal disease	52.25	50.06	48.26	46.39	45.15
5	Female	48	Wound infection	138.84	135.39	131.07	128.91	125.20
6	Male	23	Trauma	38.86	37.68	35.9	34.65	33.29
7	Female	76	Wound infection	7.84	6.69	6.21	5.45	4.89
8	Male	19	Trauma S/P fasciotomy	108.81	103.43	99.32	96.24	92.82
9	Female	45	Burn	63.19	61.06	59.15	57.38	55.48
10	Male	54	Venous ulcer	17.28	16.61	15.5	14.52	13.61
11	Male	56	Wound dehiscence	9.5	8.81	8.1	7.47	6.86
12	Female	45	DM	24.36	23.26	20.96	19.71	18.76
13	Male	52	Pressure sore	17.28	16.07	15.3	14.30	13.38
14	Male	21	Trauma	87.22	84.18	81.95	79.34	76.86
15	Female	63	Pressure sore	21.42	21.14	18.65	17.20	15.67

Table 4. Percentage of wound healing in conventional wall vacuum dressing group

Case	Percentage of healing			
	D_{0-3}	D_{0-6}	D_{0-9}	D_{0-12}
1	7.4	15.7	23.6	29.5
2	3.2	6.4	9.8	14.2
3	3.3	6.8	10.1	13.0
4	5.0	9.2	11.9	15.6
5	4.0	7.9	12.3	15.9
6	4.7	10.5	15.8	22.8
7	7.4	14.3	21.3	30.0
8	5.4	8.9	12.5	15.9
9	2.0	5.8	9.4	12.5
10	7.7	14.3	21.2	26.0
11	2.3	5.6	7.4	9.8
12	3.0	5.8	9.4	10.6
13	5.8	13.6	19.4	23.4
14	4.8	10.3	14.4	18.0
15	3.5	12.2	19.8	27.5
Average±SD	4.6±1.84	9.82±3.5	14.5±5.2	18.8±7.1

Table 5. Percentage of wound healing in portable vacuum dressing group

Case	Percentage of healing			
	D_{0-3}	D_{0-6}	D_{0-9}	D_{0-12}
1	3.3	6.7	9.6	12.6
2	6.1	11.8	18.1	23.8
3	4.9	8.6	11.6	15.0
4	4.2	7.6	11.2	13.6
5	2.5	5.6	7.2	9.8
6	3	7.6	10.8	14.3
7	14.7	20.8	30	38.0
8	4.9	8.7	11.6	14.7
9	3.4	6.4	9.2	12.0
10	3.9	10.3	16	21.0
11	7.3	14.7	21.4	27.8
12	4.5	14	19.1	23.0
13	7	11.5	17.2	22.6
14	3.5	6	9	11.9
15	1.3	12.9	19.7	26.8
Average±SD	4.95±3.13	10.2±4.15	14.8±6.26	19.1±7.79

Table 6. Rate of wound healing

	Conventional vacuum dressing	Portable vacuum dressing	
Rate of healing (%/day)	1.57	1.59	$p > 0.05$

prolong hospitalization. Additionally, many require repeated operative procedures. The negative pressure therapy technique help shorten the hospital stay. In addition, they may be treated at home, reducing hospital stay and lowering the cost. In many occasions, patients with chronic wound who are unable to undergo surgical procedures can be efficiently treated with vacuum dressing to complete closure, at less expense and with less pain and suffering.

Patients undergoing portable vacuum dressing can be sent home until wound closure is achieved, which decreases the length of hospital stay. Furthermore, the portable vacuum machine can be placed by a home care nurse.

Conclusion

The present study found that there was no clinical difference between the rate of wound healing from a conventional wall vacuum treatment or from a portable vacuum treatment

Based on the findings from the present study, we believe that we can apply the portable vacuum machine to ambulatory care, which will lower hospital cost, reduce hospital stay, increase turnover rate of new admission, and increase patient satisfaction

Potential conflicts of interest

None.

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การศึกษาประสิทธิผลของเครื่องดูดสุญญากาศชนิดพกพาในผู้ป่วยแผลเรื้อรัง: โครงการวิจัยสุ่มแบบก้าวหน้า

ชาติชาย พฤกษาพงษ์

วัตถุประสงค์*: เพื่อศึกษาประสิทธิผลของเครื่องดูดสุญญากาศชนิดพกพา เปรียบเทียบกับการดูดสุญญากาศชนิดดั้งเดิม (แบบต่อจากผนัง) เกี่ยวกับอัตราการหายของแผล*

วัสดุและวิธีการ*: ผู้ป่วยที่ได้รับการวินิจฉัยว่าเป็นแผลเรื้อรัง จะถูกสุ่มแบ่งออกเป็น 2 กลุ่ม กลุ่มละ 15 คน โดยกลุ่มแรกได้รับการรักษาแผลด้วย เครื่องดูดสุญญากาศชนิดดั้งเดิม และกลุ่มที่ 2 จะได้รับการรักษาด้วยดูดเครื่องสุญญากาศชนิดพกพาและเปรียบเทียบประสิทธิภาพโดยดูอัตราการหายของแผล*

ผลการศึกษา*: ทำการประเมินอัตราการหายของแผลของผู้ป่วยทั้ง 2 กลุ่ม ในวันที่ 3, 6, 9 และ 12 หลังจากเริ่มรักษา ผลการเปรียบเทียบพบว่าอัตราการหายของแผลในกลุ่มที่ใช้เครื่องดูดสุญญากาศชนิดดั้งเดิมคิดเป็นร้อยละ 1.57 ต่อวัน ส่วนกลุ่มที่ใช้เครื่องดูดสุญญากาศชนิดพกพามีอัตราการหายคิดเป็นร้อยละ 1.59 ต่อวัน ($p < 0.05$)*

สรุป*: ประสิทธิผลการรักษาในแง่ของอัตราการหายของแผลจากเครื่องดูดสุญญากาศ ชนิดพกพาไม่แตกต่างกันเมื่อเทียบกับการดูดสุญญากาศชนิดดั้งเดิม*