



## Combination of modern dressing and bagging ozone therapy for speed up the process of wound healing of grade II diabetic ulcer patients

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### Abstract

This study aims to determine a way to cure diabetic ulcer appropriately using a combination of modern dressing methods and ozone bagging therapy. The study was carried out experimentally with nonequivalent control group pretest and posttest design. Research subjects in the samples amounted to 25 respondents with grade II diabetic ulcer in the inflammatory phase who visited Pontianak Wound Care Clinic from November 2017 to March 2018. The research subjects were divided into 2 groups, namely the control group of 11 respondents and the intervention group numbered 14 respondents. The control group received wound care with modern antibacterial dressings namely *Calcium Alginate*, *Cutimed Sorbact*, *Aquacell*, *Dalethyne*, and *Powder Iodosorp*, while in the intervention group received the same wound care with modern dressing plus ozone bagging therapy with a concentration of 60-100µg / ml for 15 minutes. A combination of modern dressings and ozone bagging therapy had an effect on the wound healing process ( $p = 0.018$ ), and also had a significant effect on the number of bacterial colonies ( $p = 0.006$ ) so as to accelerate the healing process of grade II diabetic ulcer in the inflammatory phase, so it could be applied in providing care nursing diabetic ulcer patients.

**Keywords:** diabetic ulcer, modern dressing, ozone bagging, wound healing

### 1. Introduction

Diabetic ulcer is an open wound in the skin layer into the dermis. This complication can occur due to hyperglycemia and neuropathy which results in various changes to the skin and muscles, resulting in an imbalance in the distribution of pressure on the soles of the feet and furthermore will facilitate ulceration <sup>[1]</sup>. In diabetic ulcer patients, 50% will experience infection due to high blood glucose because it is a fertile bacterial growth medium <sup>[3]</sup>. The bacteria found in ulcers are a combination of aerobic and anaerobic bacteria, the bacteria that most often cause infection are gram-positive aerobics (especially *S.aureus*), sometimes also caused by gram-negative bacteria such as *Pseudomonas Enterococcus aeuruginosa*. DM patients who are accompanied by diabetic ulcer complications, require holistic management of diabetic ulcer wounds, one of them is wound control and infection control <sup>[5]</sup>.

Wound control is an effort in the form of regular removal of infected and necrotic tissue <sup>[6]</sup>. The principle of wound care is to create optimal conditions by using modern dressings, creating moist conditions that accelerate wound healing <sup>[7]</sup>. In diabetics, infection of the wound is relatively difficult to overcome because of damage to blood vessels to the site of injury, this occurs due to high blood glucose levels in the body due to diabetes, this condition is worsened by the presence of hypertension, hyperlipidemia, and smoking habits commonly referred to as peripheral artery disease (PAP) <sup>[8]</sup>. The presence of ischemia due to peripheral artery insufficiency causes oxygenation in the wound area which makes healing process

more difficult, because antibiotics given by oral therapy, oxygen, food substances, immune devices are difficult to reach the site of the wound. This situation will inhibit the healing process, making the wound experience an inflammatory phase that extends. If this condition is not immediately addressed, it will endanger the lives of sufferers because of the risk of experiencing systemic infection and amputation to be an alternative solution, in addition to increasing the burden of time and maintenance costs <sup>[9]</sup>.

Ozone bagging therapy is one of the complementary therapeutic devices in the management of diabetic ulcers, because it has an effect on wound healing, which releases new oxygen that has been shown to have bactericidal abilities and stimulates antioxidant enzymes <sup>[10]</sup>. In bacteria, ozone disrupts the integrity of bacterial cell capsules through oxidation of phospholipids and lipoproteins. Ozone can also penetrate bacterial cell capsules directly affecting cytoplasmic integrity and interfere with some levels of metabolic complexity, which can kill bacteria directly <sup>[11]</sup>.

### 2. Methods

This research has been done by experimental research with nonequivalent control group design. Research subjects in the population amounted to 25 respondents with grade II diabetic ulcer in the inflammatory phase who visited the Pontianak "KITAMURA" Pontianak Wound Care Clinic from November 2017 to March 2018. The research subjects were divided into 2 groups, namely the control group of 11 respondents and the intervention group numbered 14

respondents. The control group received wound care with modern antibacterial dressings namely Calcium Alginate, Cutimed Sorbact, Aquacell, Dalethyne, and Powder Iodosorp, while in the intervention group received the same wound care with modern dressing plus ozone bagging therapy with a concentration of 60-100 µg / ml for 15 minutes. Measurement of bacterial colonies and wound healing scores were carried out every 3 days until day 13. The bacterial colonies were measured by swab method and calculated using a colonic counter, while wound healing scores with Bates-Jensen Wound Assessment Tool (BWAT) instrument. Bacterial colonies with results above 100 CFU / ml showed that the wound was still infected, and BWAT score above 33 showed that the wound was still in the inflammatory phase.

**3. Result and discussion**

**3.1 Characteristics of respondents in control groups and intervention groups**

The results showed that in control group and intervention group, the age of the respondents was in the age range of the elderly. In a control group there were 6 (54.5%) male respondents and 5 (45.5%) female respondents, while in the intervention group male and female respondents totaled 7 (50%) respondents respectively. Most respondents did not have exercise habits (92%) and did not smoke (68%). For ABPI values, it is known that 80% of respondents experienced mild occlusion (0.7-0.9). The detail of respondents characteristic can be seen on the table below.

**Table 1**

	Control Group (n=11)		Intervention Group (n=14)		Total		p	
	n	%	N	%	N	%		
Age(mean ± SD)	58.55±7.090		61.50±9.338				0.461	
Min-Max	49-69		40-73		40-73			
Gender	Male	6	54.5	7	50	13	52	0.746
	Women	5	45.5	7	50	12	48	
Habit Exercise	Yes	-	-	2	35.7	2	8	0.005
	No	11	100	12	64.3	23	92	
Smoking Habit	Yes	3	27.3	5	35.7	8	32	0.388
	No	8	72.7	9	64.3	17	68	
Score ABPI(mean ± SD)	0.845±0.82		0.871±1.2				0.397	
Min-Max	0.7-1.0		0.6-1.1		0.6-1.1			
Normal	1	9.1	3	21.4	4	16		
Light Occlusion	10	90.1	10	71.4	20	80		
Medium Occlusion	-	-	1	7.1	1	4		

**3.2 Bates-Jensen Wound Assessment Tool Score in Control Groups and Intervention Groups Based on Injury Size**

The results of the study based on observations for 13 days showed the average BWAT score in the control group and the intervention group consisting of 4 categories based on the size of the wound. The size of the wound <4cm<sup>2</sup> is 31.00 in the control group, had a higher BWAT score compared to the intervention group with the same size, namely 26.00. Whereas in the 4- <16 cm<sup>2</sup> wound size the average BWAT score in the control group was 35.00 and in the intervention group 34.00. The wound size 16-36 cm<sup>2</sup> have average BWAT score in the control group about 37.67 and in the intervention group is

36.00. And the last, for wound size 36-80 cm<sup>2</sup> in the control group is 40.00 while in the intervention group is 42.00. The ulcer enters the healing process if it has an inflammatory phase process, proliferation phase, and maturation phase. The wound healing process is not only limited to the regeneration process that is local, but also greatly influenced by endogenous factors (age, vascularization status, metabolic conditions, immunology, drug use) 7. In this study all patients received Cefixime antibiotic therapy and anti-hyperglycemic drugs to control blood glucose levels. The detailed about assessment tool score in control based on injury size can be seen on the table below

**Table 2**

	Wound Size	Pre Test	Post Test I	Post Test II	Post Test III	Post Test IV	Pre Test – Post Test IV
Control Group (n=11)	<4 cm <sup>2</sup>	31.00	31.00	30.00	28.00	25.00	6
	4 - <16 cm <sup>2</sup>	35.00	34.80	34.40	32.20	30.00	5
	16 - 36 cm <sup>2</sup>	37.67	36.67	35.00	32.33	30.00	7.67
	36 - 80 cm <sup>2</sup>	40.00	40.00	40.00	37.00	34.00	6
Intervention Group (n=14)	<4 cm <sup>2</sup>	26.00	25.00	24.00	21.00	19.00	7
	4 - <16 cm <sup>2</sup>	34.00	33.25	31.62	29.12	25.88	8.12
	16 - 36 cm <sup>2</sup>	36.00	37.00	36.00	33.33	32.33	3.67
	36 - 80 cm <sup>2</sup>	42.00	41.50	39.00	36.00	34.50	7.5

Decreasing number of BWAT score illustrate the wound healing process in the control group , had significant decrease with initial wound size 16-36 cm<sup>2</sup>, namely from 37.67 at the time of pre-test to 30.00 when measuring post-test to IV.

Whereas in the intervention group had a significant decrease (8.12) with an initial size of 16-36 cm<sup>2</sup> that is from 36.00 at the time of pretest to 32.33 when measuring posttest IV. During the 5 times of observation in 13 days, both the control

group and the intervention group remained in category of regenerating and the wound was still in the inflammatory phase.

**3.3 Bates-jensen wound asessment tool (bwat) score in control groups and intervention groups based on modern types of dressings used in wound care**

Bandage replacement is done with the concept of moist balance and applying advance dressing (modern dressing). Wound care with modern dressings must still pay attention to three stages, namely washing the wound, removing dead tissue, and choosing dressing, besides also having to consider the costs incurred [12]. In this study, modern dressings used are dressings that have antibacterial properties and have maximum exudate absorption, such as Aquacel Ag Foam Dressing, these dressings provide broad spectrum antimicrobial activity continuously during the dressing period.

In an in vitro study, ionic silver is active against various strains of bacteria resistant to antibiotics including methicillin-resistant *Stapilococcus aureus* (MRSA) and vancomycin-resistant Enterococcus (VRE), this dressing is also capable of killing *Pseudomonas aeruginosa* and various other aerobic and anaerobic bacteria [7]. In addition to Aqua cell, Calcium-Sodium Alginate Dressing is used in wound care in studies because it has > 50% granulation tissue, this dressing is used for this type of wound with the production of active exudates. Cutimed sorbat is also the dressing used in this study, reminding of the injuries experienced by many respondents who have tunneling which is a source of bacteria. With this dressing, the bacteria on the wound are irreversibly bonded to the dressing when they come into contact with hydrophobic fibers of Cutimed sorbact in a humid environment, after the bacteria is bound to the dressing, the bacteria will not escape the dressing [7].

**Table 3**

	Modern Dressing	Pre Test	Post Test I	Post Test II	Post Test III	Post Test IV	Pretest Post Test IV
	Calcium-Alginat	36.00	35.00	34.00	32.33	29.67	6.33
	Cutimed Sorbact	35.75	35.75	34.50	32.25	29.50	6.25
	Aquacell	40.00	40.00	40.00	37.00	34.00	6
	Dalethyne	33.00	32.67	32.33	29.33	27.67	5.33
	Powder Iodosorp	-	-	-	-	-	-
Intervention Group (n=14)	Aquacell	36.00	35.00	32.00	29.00	26.00	10
	Dalethyne	32.00	31.50	30.00	26.50	24.50	7.5
	Calcium-Alginat	35.50	35.00	33.75	30.75	28.25	7.25
	Cutimed Sorbact	38.35	38.50	37.25	34.00	31.50	6.80
	Powder Iodosorp	31.67	31.00	29.00	28.33	26.00	5.67

For the control group experienced, had a significant decrease in wounds using Calcium-Alginate dressing, from the mean value at pretest 36.00 to 29.67 at posttest IV. Whereas in the intervention group had a significant decrease in BWAT scores occurred in wounds using modern Aqua cell dressings, the

average value of 36.00 became 26.00 at posttest IV. Although for 5 times observation of injury remains in the regeneration category but the scores for the 13 items run into a reduction, this showed that both the control group and wound development intervention entered the granulation phase.

**3.3.1 Analysis of differences in number of bacterial colonies between control groups and intervention groups**

**Table 4**

Variable		Mean ± SD	Different (IK95%)	*P
Total Plate Count	Group			
	Pre Test	Control 422.91 ± 251.366	-158.45 (- 87.932-1.036)	0.167
	Intervention 581.36 ± 292.432			
Post Test I	Control	530.27 ± 254.695	-49.09 (46.896-148.727)	0.613
	Intervention	579.36 ± 223.055		
Post Test II	Control	562.55 ± 193.091	97.69 (-45.507-240.884)	0.172
	Intervention	464.86 ± 153.430		
Post Test III	Control	485.00 ± 191.594	68.29 (-69.657-206.229)	0.316
	Intervention	416.71 ± 142.209		
Post Test IV	Control	505.73 ± 172.069	183.52 (57.556-309.470)	0.006
	Intervention	322.21 ± 132.778		

General linear test model p = 0.125. \* Post hoc analysis.

The results of measurements of bacterial colonies from pretest to posttest IV for each group showed that bacterial colonies were still above normal (> 100 CFU / ml). The results of the multivariate test were confirmed by Estimates Parameters in the GLM test, the p value on the posttest IV that measured on the 13th day obtained p = 0.006 (p <0.05) and the value of the confidence interval (95% CI), so it can be concluded that there

is a significant difference number of bacterial colonies on the wound surface of grade II diabetic ulcer patients between groups on the 13<sup>th</sup> day. Although the number of bacterial colonies for 13 days was still above 100 CFU / mg, but between the control and intervention groups the number of bacterial colonies was decreased.

### 3.3.2 Test results of different bacterial colonies before and after wound care in control groups and total intervention groups

Table 5

Group Control (n=11)				Group Intervention (n=14)			
Measurement	Measurement	Mean Different	p value	Measurement	Measurement	Mean Different	p value
Pre Test	Post IV	-82.818	1.000	Pre Test	Post Test IV	259.143	0.070
Pre Test	Post I	-107.364	1.000	Pre Test	Post I	2.000	1.000
Post Test I	Post II	-32.273	1.000	Post I	Post Test II	114.500	0.029
Post Test II	Post Test III	77.545	1.000	Post Test II	Post Test III	48.143	0.518
Post Test III	Post Test IV	-20.727	1.000	Post Test III	Post Test IV	94.500	0.211

From the table above it can be seen that in the control group from pretest to posttest IV p value > 0.05 which means that there is no significant change in the number of bacterial colonies. Whereas in the intervention group at pretest I to

posttest II p value < 0.05 which means that at the fourth day measurement there was a significant change in the number of bacterial colonies.

### 3.3.3 Differential analysis of BWAT scores between control groups and intervention groups

Table 6

Variabel			Different (IK95%)	*P
BWAT Score	Group	Mean+SD		
Pre Test	Control	35.45±5.768	0.455(-4.5-5.403)	0.851
	Intervention	35.00±6.064		
Post Test I	Control	35.09±5.576	0.448(-4.6-5.521)	0.857
	Intervention	34.64±6.452		
Post Test II	Control	34.27±5.729	1.201(-4.079-6.482)	0.642
	Intervention	33.07±6.765		
Post Test III	Control	31.91±5.991	1.481(-3.989-6.950)	0.581
	Intervention	30.43±6.969		
Post Test IV	Control	29.45±5.520	1.455(-4.322-7.231)	0.607
	Intervention	28.00±7.845		

From the table above it can be seen that, the control and intervention groups from pretest to posttest IV p value < 0.05, it's mean that there is a significant difference in BWAT scores. In the control group, BWAT scores began to change at 7<sup>th</sup> day measurement. Whereas in the intervention group the BWAT score began to changes in the post test I, on the 4<sup>th</sup> day.

#### 4. Conclusion

The combination of modern dressings and ozone bagging therapy has an effect on the wound healing process, with a significant effect on the number of bacterial colonies. The final results in the wound control group < 4 cm<sup>2</sup> significant decrease about 6 points, from 31.00 to 25.00. In the category of 4- < 16 cm<sup>2</sup> wound size decreased five points. Wound size 16-36 cm<sup>2</sup> decreased about 7.67 point from 37.67 to 30.00, and at wound size 36-80 cm<sup>2</sup> only decreased about six points. All wounds began to be in the granulation phase except for wounds with a size of 36-80 cm<sup>2</sup> where the wound was still in the inflammatory phase. For categories based on dressing's materials, wounds dressings using Calcium-Alginate have decreased the wound size more than other dressings. In the intervention group who received wound care with modern dressings and ozone bagging therapy began to change measurements in the second posttest (p = 0.016). The score changes occur mostly in necrotic tissue type items, number of necrotic tissue, type of exudate, number of exudates, and edema. These items are items that indicate the state of

infection or the inflammatory process in the wound, with the reduced score, the wound score representing the growth of granulation and epithelialization also decreases.

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