RESEARCH ARTICLE

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The Innovation of Artrihpi Irrigation Wound Cleansing for Decreasing Bacterial Load in The Treatment Diabetic Foot Ulcers: Randomized Controlled Trial

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Irrigation is an important step in the treatment diabetic foot ulcers particularly for avoiding infection spread. In the previous study, the irrigation using artrhipi was effective for diabetic foot ulcers, it based on wound recovery score. This study aims to investigate the effectiveness of artrihpi based on the load of the bacteria. Randomized controlled trial (RCT) with a parallel design and double-blind was used as the method. Twenty-two respondents with diabetic foot ulcers in hospital participated in this study. After randomizing step, the respondents were treated by using artrihpi (with pressure 10-15psi) or spuit 12 cc with needle number 22 (with pressure 13 psi). Before and after the wound care, the wound had to swab for analyzing of an amount the bacterial.Wilcoxon and Mann-Whitney were used for analyzing the bacterial load. The result of this study shows there was statistical difference between the load of bacteria pre and post the irrigation in both intervention group (p value: 0,041) and control group (p-value: 0,006). There was no statistical different between intervention and control group (p-value: 0,25). The differences amount of bacterial before and after irrigation in the intervention group was more than the control group. This study recommends the wound irrigation using artrihpi as one of nursing intervention toward diabetic foot ulcers.

Keywords: diabetic foot ulcers, bacterial load, irrigation, artrihpi

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1. INTRODUCTION

Uncontroling glucose in patients with Diabetes Mellitus (DM) could cause the complication. One of long term complication in a patient with DM was diabetic foot ulcers. Previous studies have indicated that diabetic patients estimated up to 15–25% lifetime risk for developing a diabetic foot ulcers.[1,2]. Some clinical research's finding in Indonesia reported that prevalence of diabetic foot ulcer was around 17,3% to 32,9% from the percentage of hospitalized patiens[3].

The diabetic foot ulcers could cause the infection. The bacteria colonized on the wound then infected it. If the amount of the bacteria more than 10^5 germs/gram could inhibit the wound recovery process[4]. In a serious stage of untreated diabetic foot ulcers, it becomes gangrene then amputation and also mortality would be the impact[5]. Diabetic foot ulcers caused 85% of amputation in a patient with DM[6].

Good infection treatment is the important step to avoid the complication of infection in diabetic foot ulcers. An effort for preventing the infection its self by optimising the wound cleansing[7]. The wound cleansing aims to clean necrotic tissue, through out and decreasing amount of bacteria, exclude purulent exudation and maintain sanitation of the wound[8]. Conformity of wound cleansing technic can support the wound recovery process effectively. The common wound cleansing technics are swabbing, showering, bathing and irrigation[9].

The effective technic in wound cleansing for decreasing the bacteria is irrigation with pressure. Based on American College of Surgeon, there is high-pressure irrigation (35-70 psi), and low pressure (1-15 psi)[10]. High-pressure irrigation is common in an acute wound. If the high pressure used in the chronic wound it destroys granulation and uncomfortable for the patient. Generally, high-pressure irrigation pushes the bacteria into depth compartment, then increase the risk of infection. Agency for Health Care Policy and Research (AHCPR) released guideline for effective and safe pressure irrigation by using 4-15 psi. The pressure more than 15 psi can cause trauma and push the bacteria, meanwhile, the pressure below 4 psi could not release pathogen and slimes around the wound are[a11]. Wound cleansing with irrigation using syringes and needles that produce 13 psi pressure proved to be more effective for reducing infections and inflammation than using the bulb syringe. Wound irrigation pressures of 10 and 15 psi is better than 1-5 psi[12].

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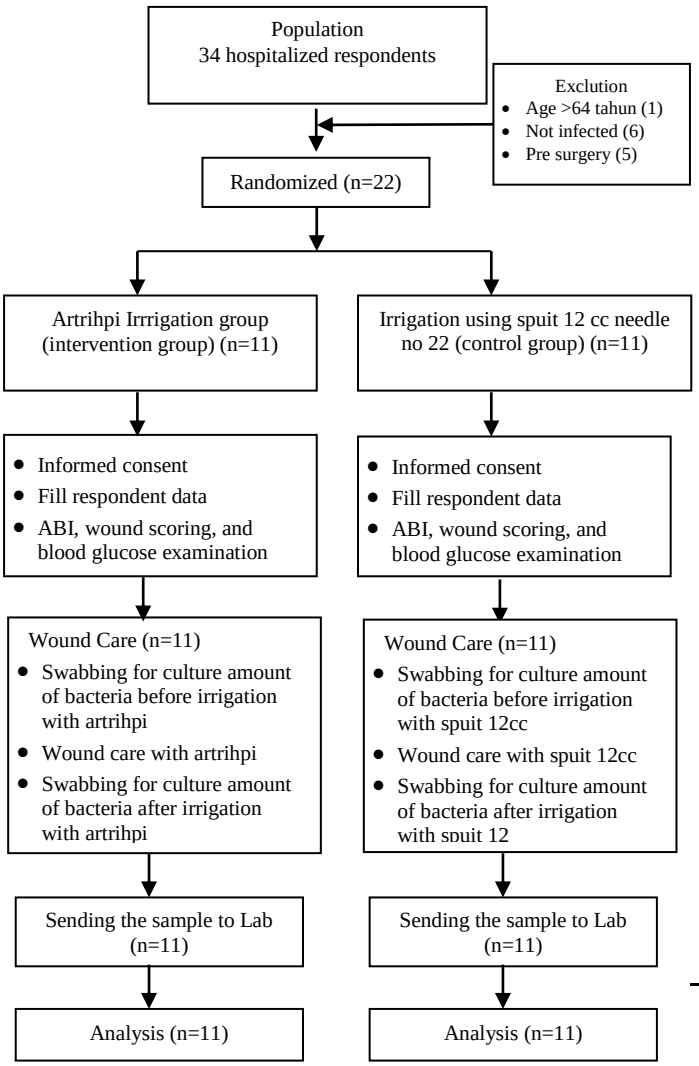


Figure 1. frame work of research

2. EXPERIMENTAL DETAILS

This research was a *randomized controlled trial* (RCT) study, with parallel design. Masking in this research that the respondents didn't know whether during wound care as a group of intervention or control. Blinding in this study used double-blind, the respondents and evaluators are equally unaware whether given intervention by artrihpi irrigation or 12 cc syringe. Evaluator in this research is a laboratory evaluator of bacterial culture test.

There were 22 respondents, with inclusion criteria: DM type 2, age $\leq$ 64- year-old, infected ulcus diabetic in grade 2,3 based on a clinical classification of *Infectious Disease Society of America* (IDSA). Exclusion criteria: the respondent received chemotherapy or radiation and the respondent with surgical debridement.

The respondents who fill the inclusion and exclusion criteria were blocked randomized. Giving Informed consent before wound care, ABI (ankle-brachial index), wound scoring, and blood glucose examination. After that wound care was given by using irrigation artrihpi in the intervention group and using spuit 12 cc with needle number 22 as the control group. Before and after the wound care, the wound had to swab for analyzing of an amount the bacteria.

The Wilcoxon test was used as statistic analysis to investigate the difference amount of the bacteria before and after the irrigation in the intervention group and the control group with the significance value of $p<0,05$. Mann Whitney Test to determine difference amount of bacteria between intervention and control group and also to analyze the difference between each group before and after the irrigation with the significance value of $p<0,05$. The procedure of research can be seen in figure 1.

This study was allowed by Ethic Commission of Faculty of Nursing, Universitas Indonesia (ethic number: 127/H2.F12.D/HKP.02.04/2014) and Ethic Commission of the hospital. The researcher has implemented the principles of ethic in this study process.

3. RESULTS AND DISCUSSION

a. The Demographic Characteristic of The Respondents

Mean range of blood glucose was 202,27 mg/dl with standard deviation 32,48 mg/dl. The lowest and highest range of blood glucose respected was 144 mg/dl and 266 mg/dl. Ankle Brachial Index (ABI) of the subjects in this study was 1,01 with standard deviation 0,07 g/dl. The lowest and highest score of ABI were 0,85 and 1,08. Mean of respondents wound score was 47,55 with standard deviation 5,33. The lowest and highest wound score are respectively 35 and 53. Mean of irrigation pressure score in the intervention group was 13 psi with standard deviation 1,6 psi. The lowest and highest score of irrigation pressure were respected 10 psi and 15 psi. In control group, the pressure of irrigation reached means to score at 13,36 psi with standard deviation 6,68 psi. The lowest was 3 psi and the highest was 26 psi, it can be seen in table 1.

Table 1. Distribution of Blood Glucose and Irrigation pressure (N=22)

Variable	Mean	Median	Standard Deviasi (SD)	Min-Maks
Blood Glucose	202,2	207,5	32,48	144-266
ABI	1,01	1,04	0,07	0,85-1,08
Wound Score	47,55	48,5	5,33	30-53
Irrigation pressure of Intervention Group	13,0	13,0	1,61	10-15
Irrigation Pressure of Control Group	13,37	13,0	6,68	3-26

In this study, we found that the average blood glucose was hyperglycemia. The results of this study are similar to the research in M. Djamil Padang Hospital that many respondents found hyperglycemia in diabetic foot ulcer patients with blood glucose levels 316 + 77.6 mg / dl[13]. Hyperglycemia can cause leukocytes to become abnormal. It made the bacteria were difficult to destroy by an intra-cell bacterial phagocytic system[14]. High glucose levels also make diabetes patients have a five times greater chance of infection than non-diabetic. Because neutrophil chemotaxis, phagocytosis, intracellular killing mechanisms, and serum opsonic activity are impaired in a diabetic. High levels of glucose in chronic wound fluid will stimulate the production of succinate in gram-negative bacteria, which then will damage the function of host cells and make the host more susceptible to infection. Succinate production by Klebsiella pneumonia was also enhanced by the presence of glucose[15].

The result of this study found 72,7% were female respondents, 27,3% had a smoking history. The respondent who consuming systemic antibiotic and topical (54,5%) more than the respondent who consumes the antibiotic only. It can be seen in table 2.

Table 2. Distribution of antibiotic and smoking history (N=22)

Characteristics	Frequency	Percentage
Gender		
Male	6	27,3
Female	16	72,7
Smoking history		
Yes	6	27,3
No	16	72,7
Antibiotic		
Systemic	10	45,5
Systemic and topical	12	54,5

The results of this study showed more female than men. This study is similar with research Arifin Achmad Riau Hospital that is 56,42% respondent of diabetic ulcer of woman[16]. This result is also in line with research in Shahid Beheshti Hospital and Shahid Yahyanejiad Iran got 66% of respondents who were exposed to diabetic ulcer was female[17]. A number of female patients experienced DM with ulcers in the age range of more than 45 years due to women entering the menopause. Women who have entered menopause will decrease estrogen production resulting in decreased elasticity of blood vessels which will lead to atherosclerosis and hypertension. Atherosclerosis will lead to blocked blood flow, in addition to high blood pressure will damage blood vessels and cause lesions in the endothelium which will subsequently occur macroangiopathy and tissue hypoxia that will momentum diabetic ulcers[18].

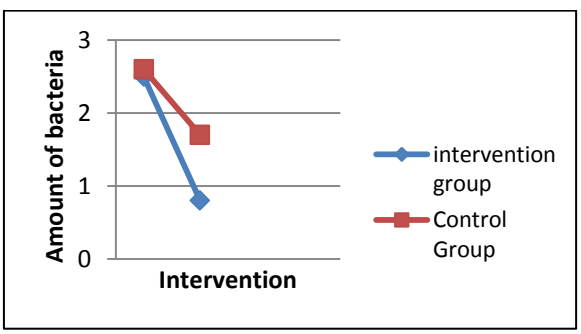
Based on the research results found that 6 of 22 people have a history of smoking (27.3%). Respondents who had a smoking history in this study were found in all-male respondents, of whom 6 were male. The number of respondents who smoked on diabetic ulcers was similar in Western Sydney against 195 respondents, 14.5% of respondents were smokers and 42.6% of respondents had a smoking history[19]. Smoking habits caused by nicotine contained in the cigarette will be able to cause endothelial damage and then attachment and platelet aggregation which subsequently occurs leakage so that lipoprotein lipase will slow the clearance of blood lipids and facilitate the onset of atherosclerosis.

Atherosclerosis results in an insufficiency vascular so that blood flow to the dorsal artery of pedis, popliteal, and tibialis will also decrease[20,21].

Based on the research, 10 respondents (45.5%) had given systemic antibiotics and 10 systemic and topical antibiotics were given (54.5%). Types of systemic antibiotics given are metronidazole, ceftriaxone, and bactacym, whereas the topical antibiotic used is metronidazole.

b. Bacterial Amount Before and After The Experiment in Intervention and Control group

Mean of bacterial amount pre experimental in the intervention group was $2,5x10^7$ CFU/ml and post-experimental was $0,83x10^7$ CFU/ml, meanwhile, in control group, the mean of bacterial pre and post experiment orderly were $2,7x10^7$ CFU/ml and $1,7x10^7$ CFU/ml. Amounts of bacteria in the intervention group were decreased a lot. It can be seen in picture 1 and table 2.



Picture 1
Mean of bacterial in intervention and control group pre and post-experiment.

Based on the result of this study, the amount of bacterial in both group showed that infection happened in the wound. It also stated by Australian Wound Management Association that amount of bacterial could cause infection in an amount of 10^5 microorganisms/gr in tissue[22] and based on a study of Robson dan Heggers found that acute and chronic infection reach amount of bacterial 10^5 CFU/g in tissue.

Table 3
Difference between bacterial amount before and after the experiment in Intervention and Control group (N=22)

Group	Variable	N	Mean	SD	MD (95%CI)	Z	p-value
Intervention	Pre	11	$2,5x10^7$	$2,5x10^7$	$0,79x10^7$;	-2,045	0,041*
	Post	11	$0,83x10^7$	$1,4x10^7$	$2,5x10^7$		
Control	Pre	11	$2,7x10^7$	$2,9x10^7$	$0,27x10^7$;	-2,756	0,006*
	Post	11	$1,7x10^7$	$2,06x10^7$	$1,6x10^7$		

*statistical difference α 0.05 with Wilcoxon

Table 4
Difference bacterial amount post experiment and difference amount in both group (N=22)

Variable	Group	N	Mean	SD	MD (95%CI)	Z	p-value
Amount of bacterial post experiment	Intervention	11	$0,83x10^7$	$1,4x10^7$	$-2,5x10^7$;	-1,149	0,250
	Control	11	$1,7x10^7$	$2,05x10^7$	$0,67x10^7$		
Difference amount	Intervention	11	$1,6x10^7$	$1,2x10^7$	$-0,29x10^7$;	-1,149	0,250
	Control	11	$0,92x10^7$	$097x10^7$	$1,7x10^7$		

In an amount of 10^6 CFU/ml would significantly delay the wound recovery time, it happened in diabetic foot ulcers[23]. The amount of bacterial in diabetic foot ulcers influence the wound recovery time. The ulcus diabetic contaminated by more than 10^6 then the recovery time of the wound would be 0,055 cm/week, in the wound that had germs $10^5 – 10^6$, the recovery time of the wound was 0,15 cm/week, and for the wound free of bacterial the recovery time of wound was 0,2 cm/week[24].

Table 3 shows there was a difference between bacterial amount before and after the experiment in both groups (*p; 0,041* for the intervention group and *p: 0,06* for the control group). Meanwhile the as statistical difference amount of bacterial in control group pre-post experiment was more than intervention group, then univariate analysis shows that the difference amounts of bacterial pre-post-experiment in intervention group ($1{,}6x10^7$ CFU/ml) was higher than control group ($0{,}92x10^7$ CFU/ml)and amounts of bacterial post experiment in intervention group ($0{,}83x10^7$ CFU/ml) was lower than control group ($1{,}7x10^7$ CFU/ml).

Table 4 shows that there was no difference between intervention and control group in terms of the amount bacteria post experiment and the difference amount of bacterial pre-post experimental. It can be seen from the p-value of both group post experiment 0,250 and also for p-value at difference amount of both group was p-value 0,250.

The result of analysis of the different amount of bacterial pre-post-experiment in intervention group concludes that was a statistical difference between pre and post intervention in both groups. The result of a statistic of post-experiment in both group and the difference an amount of bacteria pre-post-experiment were no difference. However, the univariate analysis the difference of amount germs in intervention group higher than control group pre-post-experiment, and an amount of bacteria in the intervention group post-experiment lower than the control group.

The mean of different amount of bacterial pre-post experiment in intervention group $1{,}6x10^7$ CFU/ml, meanwhile in control group $0{,}92x10^7$ CFU/ml. The mean of bacterial amounts post-experiment in intervention group $0{,}83x10^7$ CFU/ml, and control group $1{,}7x10^7$ CFU/ml. Based on mean data of bacterial amount and statistical conclude that wound washing with irrigation artrihpi in pressure of 10-15 psi, spuit 12 cc and abocet number 22 with pressure 13 psi was effective to decrease bacterial amount in diabetic foot ulcers, with decreasing amount of bacterial in intervention group (with artrihpi) more than control group (spuit 12 cc abocet 22), however there was no difference statistically in decreasing of amount of bacterial between two group, it could be caused by small sample size. This is in line with some studies.

The study investigated an effect of irrigation with the pressure of 1, 5, 10, dan 15 psi for decreasing Staphylococcus aureus and *soil particles* in the contaminated wound. At pressure 1 and 5 could relieve 48,6 % and 50,3 % of contaminants, however, could not prevent from infection. At pressure 10 and 15 psi could relieve 75,7% and 84,8 % contaminants and the average of the wound in this group was low infection[24]. The study of Madden, Eddlich, Schauerharmer investigated the effectiveness of irrigation using 0, 5, 10, and 25 psi for cleaning the Staphylococcus aureus and Escherichia coli contaminated wound of rats. This study found that irrigation using 0,5,10 could decrease bacterial amount, however, could not decrease clinical infection. The clinical infection would happen in amount of bacterial 10^5 /gr tissue, which could result in sign of infection such purulent exudate, odor (bad smell), erythema, color/warm, tenderness, edema, pain, and increasing of leucocyte/white blood cell, and irrigation using 25 psi dominantly got low level of clinical infection[25].

RCT study of JBI (Joanna Brigs Institute) compared irrigation for wound washing with using pressure 13 psi (spuit 12 cc, abocet 22) with pressure 0,5 psi (bulb syringe) in patient who had laceration, depth wound, trauma ulcer and ulcus had found that irrigation using tension 13 psi sold decrease infection with p-value 0.0017[26].

Amounts of bacterial in the intervention group were decreased a lot, regarding irrigation have done in controlling pressure 10-15 psi with gauge pressure as a controller for pressure in arthiphi, whereas in control group using spuit 12 cc and abocet 22 could not deliver constant pressure in 13 psi. The mean pressure of intervention group was 13 psi with standard deviation 1,6 psi. The lowest pressure of irrigation in the intervention group was 10 psi and the highest was 15 psi. In control group, mean of irrigation pressure was 13,36 with standard deviation was 6,68 psi. The lowest pressure in control group was 3 psi and the highest was 26 psi. The irrigation using below 4 psi would be not effective for relieving pathogen in superficial[25].

4. CONCLUSION

The Artrihpi gave effect to decrease an amount of bacterial. There were significant differences between the pre-post experiment in terms of an amount of bacterial pre-post-experiment in the group who had wound care using artrihpi irrigation and spuit 12cc abocet number 22. However, there was no difference amount of bacterial in intervention group and control group and also no significant differences in an amount of the control and the intervention group.

The mean of bacterial amounts before and after intervention in control and intervention group almost in the same number, meanwhile bacterial amount after the research in the intervention group is lower than the control group. The differences amount of bacterial before and after irrigation in the intervention group was more than the control group.

This study has several limitations that are 1) This research only detects a number of aerobic bacteria, so the number of anaerobic bacteria is not identified. However, based on references to previous studies on diabetic foot ulcers, aerobic bacteria were more than anaerobic bacteria, and subjects in this study were found in superficial wounds, whereas anaerobic bacteria were more commonly found in deep wounds; 2) This study only identifies the number of bacteria before and after intervention on one day, so it can not be seen its effectiveness for wound healing up to the reduced or not clinical infection that appears on diabetic foot ulcers.

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