ORIGINAL RESEARCH

The Effectiveness of the 15 Psi Irrigation Technique in Wound Cleansing to Reduce the Number of Bacteria on Patients with Diabetic Foot Ulcers

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Abstract

The increasing population of diabetic patients leads to the increasing number of diabetic foot ulcer (DFU) cases. To avoid the expansion of the infection, the wound cleansing is conducted through the irrigation and pressure methods. The aim of this research was to identify the effectiveness of wound cleansing using 0.9% normal saline technique with the pressure of 15 Psi in reducing the number of bacteria. This research used the randomized control trial method with a double blind design which had been approved by the ethnical committee of Muhammadiyah University of Jakarta with the ethnical committee number 261/PMK-UMJ/IV/2017. There were as many as 31 samples in each group collected through consecutive sampling technique with randomization. It had been found that there was a significant difference in the number of bacteria before and after wound cleansing. Thus, it could be concluded that from the statistical test and clinical test, wound cleansing with normal 0.9% saline technique with the pressure of 15 Psi could decrease the number of bacteria in diabetic foot ulcers. Wound cleansing with 0.9% normal saline irrigation technique pressurized at 15 Psi was recommended as a safe wound cleansing method for diabetic foot ulcers.

Keywords: Bacteria; diabetic foot ulcers; pressure irrigation; wound cleansing

Introduction

The increasing population of DM (Diabetes Mellitus) patients will have an impact on the increasing incidence of diabetic foot ulcers (DFU) as chronic complications of DM. According to Clayton & Elasy (2009), one of the long-term complications of diabetes mellitus is the complication of foot ulcers (15%-25%). This is in line with a research finding stating that the incidence of diabetic foot ulcers in Indonesia occurs among about 15% of people with diabetes mellitus, and it has caused most of the 80% of diabetic patients hospitalized. Critical infected diabetic foot ulcers will increase mortality rate. The mortality rate caused by DFU (Diabetic Foot Ulcers) in Indonesia is 32% from the total number of DM patients, and 15-30% of the total number has led to amputation. Furthermore, Soewondo, Ferrario, & Tahapary (2013) states, "National survey data suggests that in 2007, the prevalence of diabetes was 5.7% where more than 70% of the cases were undiagnosed. This estimate hides large intracountry variation. The data available on direct costs were very limited, and there were no data on indirect costs. The most commonly-identified complication was diabetic neuropathy".

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If diabetic foot ulcers do not receive proper treatments, it will cause an infection. It is the contamination of bacterial colonies that can interfere the wound healing process. The bacteria will colonize within the wound and continue to multiply excessively. The wound will be infected. If the number of bacteria exceeds 10⁵ bacteria/gram of tissue, it means that the wound is infected, and if the number of bacteria reaches 10⁶, it will cause wound healing delay. If diabetic foot ulcer infection is not cured seriously, it will be gangrene which can lead to amputation or even death when it develops into a systemic infection (American Diabetes Association, 2013). According to Clayton and Elasy (2009), diabetic foot ulcers have caused 85% cases of amputation among patients with diabetes mellitus. Management of diabetic ulcers is needed to make sure that the ulcer healing phase can be well facilitated. There are principles of diabetic foot ulcer management, namely metabolic control, vascular control, infection control, wound control, and pressure control (Blakely, 2016).

Good infection control is an important step in treating diabetic ulcers to avoid the spread of infection. One of the efforts to prevent the spread of infection is to perform optimal wound cleansing (Cutting, 2010). The purpose of wound cleansing is to clean necrotic tissue, remove and reduce the number of bacteria, remove purulent exudates, and maintain the cleanliness of skin tissue around the wound (Carville, 2007). The right and proper wound cleansing techniques will repair the damaged tissue and speed up its recovery. Wound cleansing techniques which are often performed are swabbing, irrigation, and bathing. Irrigation and bathing are the most commonly used techniques, and many researches support these techniques. The advantages of these techniques are that with an enough pressure, they can lift the colony of bacteria, reduce the occurrence of trauma, and prevent cross-infection. The traditional method of swabbing (wiping) technique is not recommended because it causes germs to be distributed throughout the wound area, creates new tissue damages, and compromises healing (Fernandez et al: 2001).

One effective wound cleansing method to reduce infection is using irrigation performed simultaneously with pressure. According to the American College of Surgeon, high pressure irrigation is 35-70 psi, and low pressure irrigation is 1-15 psi. High pressure irrigation is often applied in acute wounds, while low pressure irrigation is applied in chronic wounds. In chronic wounds, high-pressure irrigation can damage granulation and discomfort in patients (Joanna Briggs Institute, 2008). In all wounds, high pressure irrigation can also induce bacteria into deeper compartments, thereby causing an increased risk of infection. The Agency for Health Care Policy and Research (AHCPR) has issued guidelines for effective and safe irrigation pressure that is 4-15 psi. Higher pressures than 15 psi can cause trauma to the wound and push the bacteria deeper, while lower pressures than 4 psi have been proven to be unable to remove surface pathogens and impurities (Gabriel, 2015).

The description above suggests that wound cleansing using pressure is an important measure to be performed by nurses in wound care so that the infection in the wound will not spread, and the amputation can be prevented. In this study, the researchers want to find out the effectiveness of wound cleansing using 0.9% normal saline irrigation technique pressurized at 15 Psi in decreasing the number of bacteria in diabetic foot ulcers in Kitamura wound care clinic, Pontianak.

Method

This research employed the randomized controlled trials method with a double blind design. There were 31 respondents in each group taken by a consecutive sampling technique with the inclusion criteria of DM type II, age ≥ 35 years, and wound Grade 3-4 (Wagner scale).

The researchers determined that each group consisted of 31 samples. The randomization method used a random allocation technique of simple randomization by making 62 envelopes. The determination of the intervention group and the control group was carried out using online computer system randomization conducted by the researchers' assistant through www.sealedenvelope.com with the seed number of 76172576789207. It was determined that the treatment groups were 2 (two), the block sizes were 6 (six), and the list length was 62 (sixty two). The samples were decided based on the inclusive and exclusive criteria. The inclusive criteria included (1) DM Type II Client, (2) male and female patients with chronic diabetic foot ulcers infected with grade 3-4 (Wagner Scale), (3) outpatients coming and treated at the Kitamura clinic, Pontianak, (4) application of antibiotics of the same type, (5) the age of patients ≥ 35 years, and (6) willingness to be a respondent during the period of the research. As for the exclusive criteria, they covered (1) patients having dangerous disease complications, and (2) patients who died before the period of the research was completed.

The researchers conducted informed consent, filled out the characteristics of the respondents, and performed a temporary blood sugar examination. Next, the researchers took the bacteria and clean the wound when the wound bandage was opened then the researchers' assistant took the bacteria before and after the wound cleansing among the patients with diabetic foot ulcers (DFU) using a special cotton bud by swabbing it from the top of the wound to the bottom (pre and post bacterial taking must be in the same place and manner). It was then inserted into the *aquades* liquid tube, and into the bacterial counter. The bacteria counter used was DEPIM (DiElectro Phoretic Impedance Measurement) produced by Panasonic Japan. This was a method that uses a microelectrode chip in which the bacteria in the liquid are captured by dielectrophoresis (DEP). The impedance change was measured and converted to bacterial concentration per ml of sample (cfu/ml). Based on the manual of the product, the total number of bacteria will be visible on it after ± 10 seconds with cfu/ml (cfu=colony forming units) as the unit of measurement. Bacterial counting was performed every time the wound care was conducted with the treatment schedules of 2 (two) days for 3 (three) treatments.

Wound cleansing was applied after wound bandage was opened and bacterial taking was done. After that, the wound was irrigated using 0.9% normal saline irrigation technique with the pressure of 15 Psi (pressure obtained using 50 ml syringe and 20 G needle at ± 10 ml/sec) in the intervention group and the standard clinical wound care in the control group. It was then rewashed with gauze with mixed wound soap and subsequently irrigated using 0.9% normal saline irrigation technique with the pressure of 15 Psi in the intervention group and with the standard wound care in the control group. The irrigation technique used a bottle holed at the bottom.

The Wilcoxon test was employed to prove the hypothesis that there was a difference in the number of bacteria before and after the wound irrigation treatment in the intervention and the control groups. Meanwhile, the Mann Whitney Test was performed to prove the hypothesis that there was a difference in the number of germs before and after the wound irrigation treatment in the intervention and the

control groups. All the data were analyzed using SPSS. This research was released by Muhammadiyah University of Jakarta with the ethnical committee number 261/PMK-UMJ/IV/2017.

Figure 1: Research Plot

Table 1. The Distribution of the Respondents by Age, Nutritional Status, Length of Wound, Wound Condition, and Blood Sugar Level

Variable	Intervention group				Control group			
	mean	standard deviation	min-max	95% CI	mean	standard deviation	min-max	95% CI
Age	53.74	9.59	32-74	50.22; 57.26	54.74	9.28	41-73	51.34; 58.15
Nutritional Status	103.82	11.99	85-138	99.42; 108.22	107.29	15.16	85-157	101.73; 112.85
Length of Wound	24.81	19.8	3 -90	17.54; 32.07	21.97	33.53	2-180	9.67; 34.27
Wound Condition	8.87	2.3	3-13	8.03; 8.72	9.74	2.22	4 -14	8.93; 10.56
Blood Sugar Level	260.19	137.87	81-599	209.62; 310.77	251.13	148.08	61-537	196.81; 305.45

Results

The research findings show that the average age of respondents in the intervention group and the control groups were almost the same. They were 53.74 in intervention group and 54.74 in control group. The average nutritional status for the intervention group was 103.82 and 107.29 in control group. For the intervention group, the average length of the wound was 24.81 days and in control group was 21.97 days. The. The average respondents' wound condition for the intervention group was 8.87 mungs and the average respondents' wound condition for the control group was 9.74 mungs. For the intervention group, the average blood sugar level was 260.19 mmHg and for the control group, the average blood sugar level was 251.13 mmHg. The results show that as many as 90.3% and 77.4% of the respondents of the intervention and the control groups respectively used antibiotics.

Graph 1. The Average Number of Germs before and after the Treatment in the Intervention and Control Groups at Kitamura Clinic, Pontianak

In both the intervention and the control groups, the majority of the respondents have experienced the decrease in the number of bacteria after the treatment (Graph 1). However, on average, the decrease was greater in the control group, that is from 34276752.61 (before the treatment) to 9574752.61 (after the treatment). As for the intervention group, the decrease was from 30766741.87 to 7953215.13 (Table 2).

Table 2. The Difference in the Average Number of Bacteria in Diabetic Foot Ulcers before and after Wound Cleansing Using 0.9% Normal Saline Irrigation Technique with the Pressure of 15 psi

	n	Average $\pm$ SD	Median (min-max)	p
The number of bacteria before treatment	31	30766741.87 $\pm$ 2.06	26033333 (3865333-76466667)	<0.001
The number of bacteria after treatment	31	7953215.13 $\pm$ 1.01	4660000 (290333-55166667)	

Table 2 shows a p-value of <0.001. It means that there is a significant difference between the average number of bacteria in the diabetic foot ulcers before and after wound cleansing using 0.9% normal saline irrigation technique with the pressure of 15 psi. The average number of germs before the treatment in the intervention group was 30766741.87 CFU/ml and that after the treatment was 7953215.13 CFU/ml.

Table 3. The Difference in the Average Number of Bacteria in Diabetic Foot Ulcers Before and After the Standard Wound Cleansing at Kitamura Clinic, Pontianak.

	n	Average $\pm$ SD	Median (min-max)	p
The number of bacteria before treatment	31	34761966.55 $\pm$ 2.37	24190000 (6543333-88566667)	<0.001
The number of bacteria after treatment	31	9574742.61 $\pm$ 2.19	8430000 (1013000-93933333)	

Table 3 shows a p-value of <0.001, which means that there is a significant difference between the average number of bacteria in the diabetic foot ulcers before and after the standard wound care was applied in Kitamura clinic. The average number of germs before the treatment in the intervention group was 34761966.55 CFU/ml and that after the treatment was 9574742.61 CFU/ml.

Table 4. The Difference in the Average Number of Bacteria in Diabetic Foot Ulcers Before and After and the Deviation of the Intervention and Control Groups

	n	Average $\pm$ SD	Median (min-max)	p
The average number of difference score in the intervention group	31	22813526.81 $\pm$ 1.79	18006667 (2908333-62653333)	0.513
The average number of difference score in the control group	31	24702000 $\pm$ 1.63	210440000 (1843333-58186667)	

Table 4 shows that the difference between the average number of germs for the intervention and for the control groups reveals a p-value of 0.513. It means that there is no difference on the average number of bacteria between wound cleansing using 0.9% normal saline irrigation technique pressurized at 15 Psi and wound cleansing using the standard wound cleansing technique at Kitamura Clinic. The average number of germs before and after the treatment for the control group was higher than that of the intervention group. The average number of germs in the control group was 24702000 CFU/ml and 22813526 CFU/ml for the intervention group.

Discussion

The research finding indicates that the average number of germs before the treatment for the intervention group was 30766741.87 CFU/ml and decreased to 7953215.13 CFU/ml after treatment. As for the control group, the average number of germs before treatment was 34276952.61 CFU/ml and decreased to 9574752.61 CFU/ml after treatment.

Benbow & Stevens (2013) says that the number of bacteria in wounds with more than 105 CFU/ml indicates the occurrence of infection in diabetic foot ulcers. Infection occurs due to the decreasing immune response, micro-angioplasty, and macro-angioplasty. Those cause impaired tissue perfusion in the wound and lengthen the inflammatory phase when interfering with epithelialization, contraction, and collagen deposit. In addition, the ischemic conditions resulting from the decreasing circulation due to a vascular damage also can reduce the ability to fight infectious agents (Frykberg et al., 2006).

Bacteria Colonies above 105 cfu/ml in the respondents were attributable to poor wound cleanliness such as wet and dirty wound dressing. High humidity and dirty wound conditions are good media for bacterial development. The increasing bacterial colonies can be seen from the green color in the bandages, the exudates, and the odors. This condition has caused the wound hard to heal. The decrease of bacteria during the pre-test and post-test for the two groups indicate that both wound cleansing using 0.9% normal saline pressurized at 15 Psi and Kitamura Clinic's standard wound cleansing are able to decrease bacterial colonies.

The Wilcoxon statistic test about the difference in the average number of bacteria in the diabetic foot ulcers before and after wound cleansing using 0.9% normal saline pressurized at 15 Psi show a p-value of $0.000 < 0.05$. It means that there is a significant difference in the average number of bacteria in the diabetic foot ulcers before and after wound cleansing using 0.9% normal saline pressurized at 15 Psi. The results of this study also show that the average number of germs before and after the treatments indicates a significant decrease from 30766741 before the treatment to 7953215 after the treatment. This finding is in line with the results indicated in the previous studies.

A study has shown that there is a greater decrease in the number of bacteria in irrigation with pistons at 20 psi and 7 psi pressures compared to bulb syringe at 0.5 psi (Luedtke-Hoffman & Schafer, 2000). Furthermore, the effectiveness of Artrihpi in the treatment of diabetic ulcers in terms of the number of germs by comparing Artrihpi (10-15 psi), 12 cc syringe irrigation, and needle number 22 G to the number of bacteria shows that Artrihpi has an effect to reduce the number of germs. There is a significant difference in the number of germs found before and after the treatment in the group receiving wound treatment by artillery or 12 cc syringe needle 22. However, there is no significant difference in the number of germs found after the treatment in the intervention and the control groups. Then, there is no significant difference in the number of germs found before and after the treatment in the intervention and the control groups.

The number of germs in the wound treated using 0.9% normal saline irrigation technique pressurized at 15 psi has decreased because the action is carried out with the pressure maintained by the pressure gauge as the pressure controller. This is in accordance with the decision of the Agency for Health Care Policy and Research (AHCPR) to issue guidelines for effective and safe irrigation

pressure that is at 4-15 psi. Pressure greater than 15 psi can cause trauma to the wound and push the bacteria deeper, while pressure lower than 4 psi has proven to be unable to remove surface pathogens and impurities (Gabriel, 2015).

After the analyses of the difference in the average number of bacteria in the diabetic foot ulcers found before and after the standard wound cleansing were conducted at Kitamura clinic, the Wilcoxon statistic test shows a p-value of $0 < 0.001$. There is a significant difference in the number of bacteria in the diabetic foot ulcers found before and after the standard wound cleansing was applied at Kitamura Clinic, Pontianak. The results of this study also show that the average number of germs found before and after the treatment indicate a significant decrease from 34276752.61 before the treatment to 9574752.61 after the treatment. Statistically, the number of bacteria has decreased after the treatment.

Wound Cleansing applied by Kitamura Clinic was performed by making a hole on the bottom of the NaCl 0.9% bottle using scissors, and then the irrigation technique was performed when washing the wound by pressing the body of the bottle. However, the pressure of the bottle discharged during the irrigation could not be identified. Any how, when the jet pressures of the bottle and the pressure of 15 psi were visually compared, the pressure on the washing of the bottle was greater than 15 psi.

A study about a pressure of above 15 psi has been performed by Madden, Eddlich, Schauerharmer (1971) in Luedtke-Hoffman & Schafer (2000). They conducted a research about the effectiveness of irrigation with the pressures of 0.5, 10, and 25 psi to clean wounds in mice contaminated with *Staphylococcus aureus* and *Escherichia coli*. The research finds out that irrigation with the pressures of 0.5 and 10 can reduce the number of germs but not effectively prevent the development of clinical infections. Clinical infection occurs when the number of bacteria or other microorganisms reaches 105 organisms per gram of tissue and when there are signs of infection (such as purulent exudates, odors, erythema, warmth, tenderness, edema, pain, heat, and white blood cell growth). However, on average, the clinical infection in the irrigation with the pressure of 25 is found lower.

The results of the analyses of the difference in the average number of bacteria in the diabetic foot ulcers for the intervention and the control groups before and after the treatment based on Mann Whitney statistic test show a p-value of $0.513 > 0.05$ or there is no significant difference in the average number of bacteria in the diabetic foot ulcers found of wound cleansing using 0.9% normal saline irrigation technique pressurized at 15 Psi and using the standard wound washing at Kitamura Clinic, Pontianak.

The results show that both techniques statistically reveal significant effects of the treatments to remove bacteria in the diabetic foot ulcer wounds. This is indicated by the non-significant difference between the means of the number of bacteria in the diabetic foot ulcers before and after treatments. The difference of the number of bacteria between washing the wound with 0.9% normal saline irrigation technique pressurized at 15 Psi and the standard wound washing at Kitamura Clinic Pontianak can also be attributed to the similar characteristics of the respondents in the intervention and the control groups, such as age, nutritional status, duration of injury, wound conditions, temporary level of blood sugar, antibiotic use, and sex.

However, statistically the decreasing number of bacteria is found greater in the control group. The average number of bacteria found after the treatment in the control group was 24702000 and 22813526 in the intervention group. This is because the pressure used in the standard cleansing at Kitamura Clinic cannot be identified accurately whether it equals or is greater than 15 psi. The Agency for Health Care Policy and Research (AHCPR) has issued guidelines for effective and safe irrigation pressure of 4-15 psi. Pressure more than 15 psi can cause trauma to the wound and push the bacteria deeper. Pressure of more than 15 psi can cause trauma to the wound tissue and cause germs to go deeper so that the age of the germs cannot be dated in the examination.

Conclusion

This research has indicated that the average age of respondents in the intervention group and the control group is almost the same, 53.74 and 54.74 years old. For both the intervention and control groups, the majority of the respondents have experienced the decrease in the number of bacteria after the treatments. However, on average, the decrease has been found greater in the control group, from 34276752.61 before the treatment to 9574752.61 after the treatment. As for the intervention group, the decrease was from 30766741.87 before the treatment to 7953215.13 after the treatment.

Wound cleansing technique using 0.9 % normal saline irrigation pressurized at 15 psi proves to reduce the number of bacteria as indicated by the significant difference in the number of bacteria before and after the treatment in the group receiving 0.9% normal saline irrigation technique pressurized at 15 psi. There is no significant difference in the number of bacteria before and after treatment between the intervention and the control groups.

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