THE EFFECT OF OZONE BAGGING THERAPY ON WOUND HEALING IN DIABETIC ULCER PATIENTS
(In the Working Area of the Kedungdung Health Center, Bangkalan Regency)

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ABSTRACT
Diabetes mellitus with diabetic ulcers can cause complications, namely susceptibility to infection, pulmonary tuberculosis, and infections of the feet. Chronic complications include diabetic feet with the risk of foot ulcers (diabetic ulcers) and resulting in amputation, these diabetic feet can develop into gangrene. This study aims to analyze the effect of wound healing on diabetic ulcer patients who are given ozone bagging therapy.

The research design used a quasi-experimental design with pre-test and post-test with control group design. Population 30 respondents. The number of samples taken is 26 respondents. The sampling technique used is probability sampling with the Simple Random Sampling technique. The data collection technique used a questionnaire sheet. Statistical test using Man-Whitney test with (a=0.05). This research has been carried out Ethical clearance tested by the KEPK STIKes Ngudia Husada Madura. The results showed that based on the Man-Whitney statistical test with test results (p=0.021) < (a = 0.05). So it can be concluded that there were differences in wound healing in diabetic ulcer patients in the control group (without ozone bagging therapy) and the treatment group (with ozone bagging therapy).

It is suggested that this research can be used as a reference regarding wound healing in diabetic ulcer patients who are given ozone bagging therapy and can motivate patients with diabetes mellitus in controlling blood sugar levels, as well as serve as information about one way that can be done in controlling blood sugar levels daily.

INTRODUCTION
Diabetes is a complex, chronic illness requiring continuous medical care with multifactorial risk-reduction strategies beyond glycemic control. Ongoing diabetes self-management education and support are critical to preventing acute complications and reducing the risk of long-term...
complications. Significant evidence exists that supports a range of interventions to improve diabetes outcomes. (ADA, 2022). Diabetes mellitus with diabetic ulcers can cause complications, namely susceptibility to infection, pulmonary tuberculosis and infections of the feet. Chronic complications include diabetic feet with the risk of foot ulcers (diabetic ulcers) and resulting in amputation, these diabetic feet can develop into gangrene. Gangrene wound is one of the chronic complications of diabetes mellitus which is the most feared by every diabetic patient (Widodo, Susilo, & Kurniawan, 2017).

The prevalence of diabetic ulcer patients in the United States is 15-20%, the risk of amputation is 15-46 higher than non-diabetic patients (Rahimah, 2019). The prevalence of diabetic ulcers in Indonesia is around 15%, the amputation rate is 30%, in addition the 1-year mortality rate after amputation is 14.8%. This is supported by data (Riskesdas, 2018) that the increase in the number of diabetic ulcer sufferers in Indonesia can be seen from the increase in prevalence of 11%). In the working area of the Kedungdung Health Center in 2019 27 people were found with diabetic ulcers from January to December 2019, and in 2020 found 43 people with diabetic ulcers from January to December 2020 and in 2021 found 48 people with diabetic ulcers starting from January - November 2021.

The cause of diabetic ulcers is caused by damage to various body systems, especially nerves and blood vessels. One of the consequences of diabetes is neuropathy (nerve damage) in the feet which increases the incidence of diabetic ulcers. Some of the negative impacts that arise are physically the patient's immune system decreases which will slow down the wound healing process. Psychologically the patient will feel hopeless with his situation, the patient is not cooperative with the treatment therapy given so that it will prolong the treatment period (Selano et al., 2021)

Efforts in treating diabetic ulcers are by early detection of patients who are at risk for diabetic foot complications, steps are needed that can reduce or even prevent amputation for diabetic disease, such as assessments that are followed by strict regulations for diabetes, providing education to patients about treatment feet, use of proper footwear, oxygen therapy treatment, use of collagen materials, recombinant growth factors, physical therapy and others (Widodo, Susilo, & Kurniawan, 2017).

Complementary therapy is often referred to as adjuvant therapy or complementary therapy is currently busy being discussed. One of them is ozone therapy. Ozone therapy is a type of complementary medicine based on the regulation of the Indonesian Minister of Health, Number: 1109/Menkes/Per/2007 (Widodo, Susilo, & Kurniawan, 2017).

The medical effects of ozone have been known since the 19th century (Widodo, Susilo, & Kurniawan, 2017). Ozone bagging therapy has been proven to be an infection control, anti-microbial and more effective for healing diabetic foot ulcers compared to moist wound care alone (Temu & Sujianto 2020). Chronic wound conditions and wounds that are difficult to heal can be treated with ozone therapy, which is a gas naturally present in the earth's atmosphere with a pungent odor, easily soluble in water and ten times stronger than oxygen. Ozone (O3) is a chemical compound consisting of three components. Oxygen atoms that can quickly decompose into oxygen and single oxygen atoms act as strong oxidants to kill microorganisms (Zeng & Lu, 2018).

Based on the phenomenon above, the researcher is interested in conducting a study entitled "The Effect of Ozone Bagging Therapy on Wound Healing in Diabetic Ulcer
Patients in the Work Area of the Kedungdung Health Center, Bangkalan Regency

MATERIALS AND METHODS

The research design used in this study used a quasi-experiment with pre-test and post-test with control group design. This type of research is used to analyze the effect of ozone bagging therapy on the healing process of diabetic foot ulcers in clients with diabetes mellitus. The independent variable in this study was ozone bagging and the dependent variable in this study was diabetic wound healing.

The sampling technique used in this research is probability sampling with simple random sampling. The number of respondents used in this study were 26 respondents.

The data collection tool used in this study was an observation sheet for wound assessment of the Leg Ulcer Measurement Tool (LUMT). Statistical tests in this study include data normality test, paired test with paired T-test and test between groups of independent T-test.

THE RESULT OF STUDY

The Effect of Wound Healing on Diabetic Ulcer Patients in the Treatment Group Before and After Ozone Bagging Therapy was Given in the Working Area of the Kedungdung Health Center, Bangkalan Regency

Table 1 Frequency distribution of the effect of wound healing on diabetic ulcer patients in the treatment group before and after being given ozone bagging therapy in the Work Area of the Kedungdung Health Center, Bangkalan Regency

| No. Respondent | Pretest Score | Category | Posttest Score | Category |
|----------------|---------------|----------|----------------|----------|
| 1              | 40            | Grade II | 16             | Grade I  |
| 2              | 47            | Grade II | 23             | Grade II |
| 3              | 35            | Grade II | 17             | Grade I  |
| 4              | 37            | Grade II | 21             | Grade II |
| 5              | 45            | Grade II | 19             | Grade I  |
| 6              | 48            | Grade II | 30             | Grade II |
| 7              | 37            | Grade II | 18             | Grade I  |
| 8              | 37            | Grade II | 20             | Grade II |
| 9              | 41            | Grade II | 19             | Grade I  |
| 10             | 41            | Grade II | 19             | Grade I  |
| 11             | 38            | Grade II | 17             | Grade I  |
| 12             | 33            | Grade II | 16             | Grade I  |
| 13             | 37            | Grade II | 19             | Grade I  |

Mean (rate rate) 42.77 20.69
Std. Deviation 5.069 3.903
P-Value 0.001

Source: Primary data December-January 2022

Based on table 1 of the 13 respondents in the treatment group after being given ozone bagging therapy, it was found that the mean value for the pretest was 42.77 and the posttest was 20.69.

From the results of statistical analysis using paired t-test, p-value is 0.000, so it can be concluded that there are differences in wound healing in diabetic ulcer patients in the treatment group before and after being given ozone bagging therapy in the Kedungdung Health Center, Bangkalan Regency.

The Effect of Wound Healing on Diabetic Ulcer Patients in the Control Group Before and After Without Ozone Bagging Therapy Working Area of Kedungdung Public Health Center, Bangkalan Regency

Table 2 Frequency distribution of the effect of wound healing on diabetic ulcer patients in the control group before and after without ozone bagging therapy in the Kedungdung Health Center, Bangkalan Regency

| No. Respondent | Pretest Score | Category | Posttest Score | Category |
|----------------|---------------|----------|----------------|----------|
| 1              | 40            | Grade II | 16             | Grade I  |
| 2              | 47            | Grade II | 23             | Grade II |
| 3              | 35            | Grade II | 17             | Grade I  |
| 4              | 37            | Grade II | 21             | Grade II |
| 5              | 45            | Grade II | 19             | Grade I  |
| 6              | 48            | Grade II | 30             | Grade II |
| 7              | 37            | Grade II | 18             | Grade I  |
| 8              | 37            | Grade II | 20             | Grade II |
| 9              | 41            | Grade II | 19             | Grade I  |
| 10             | 41            | Grade II | 19             | Grade I  |
| 11             | 38            | Grade II | 17             | Grade I  |
| 12             | 33            | Grade II | 16             | Grade I  |
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Based on table 1 of the 13 respondents in the treatment group after being given ozone bagging therapy, it was found that the mean value for the pretest was 42.77 and the posttest was 20.69.

From the results of statistical analysis using paired t-test, p-value is 0.000, so it can be concluded that there are differences in wound healing in diabetic ulcer patients in the treatment group before and after being given ozone bagging therapy in the Kedungdung Health Center, Bangkalan Regency.
Based on table 2 of the 13 respondents in the control group without ozone bagging therapy, it was found that the mean value for the pretest was 42.08 and the posttest was 26.85.

From the results of statistical tests using the paired t test, the p-value is 0.040. So it can be concluded that there are differences in wound healing in diabetic ulcer patients in the control group before and after without ozone bagging therapy in the Work Area of the Kedungdung Health Center, Bangkalan Regency.

**Differences in Wound Healing in Diabetic Ulcer Patients in the Treatment Group and Control Group and the Working Area of the Kedungdung Health Center, Bangkalan Regency**

Table 3 Differences in wound healing in diabetic ulcer patients in the treatment group and the control group in the Kedungdung Health Center Work Area, Bangkalan Regency

Based on table 3 of the 13 respondents of diabetic ulcer patients in the control group and the treatment group, the mean value of the post-test treatment group was 20.69 and the post-test control group was 26.85.

After the Mann Whitney test was carried out, the p-value was 0.021. So it can be concluded that there are differences in wound healing in diabetic ulcer patients in the control group and the treatment group in the Kedungdung Public Health Center, Bangkalan Regency.

**DISCUSSION**

The Effect of Wound Healing on Diabetic Ulcer Patients in the Treatment Group Before and After Ozone Bagging Therapy Was Given

After the test, it was concluded that there was a difference in the effect of wound healing on diabetic ulcer patients in the treatment group and after being given ozone bagging therapy in the Kedungdung Health Center, Bangkalan Regency.

Based on research according to Bakri (2011) this method of Ozone Bagging Therapy uses a specially made plastic bag that is placed around the area to be treated.
An ozone/oxygen mixture is pumped into the bag and the mixture is absorbed into the body through the skin. In ozone therapy it is especially recommended for treating ulcers, gangrene, fungal infections, burns and slow healing wounds.

Ozone is claimed as a potential alternative to be used as an agent that helps wound healing in addition to existing conventional therapies. Until now, the use of ozone either systemically in the form of autohemotherapy or topically has been applied to assist wound healing such as burns, gunshot wounds, infected wounds, diabetic gangrene ulcers, pressure ulcers, postoperative wounds etc. Ozone therapy for wounds is generally given topically as an antimicrobial (Widodo, Susilo, & Kurniawan, 2017).

Based on research conducted by Megawati et al., (2015) with the title The Effectiveness of Modified Modern Dressing and Ozone Therapy on Wound Healing in Patients with Pressure Ulcers at Wocare Clinic Bogor stated that the results of statistical tests using the Independent t-Test test showed that "The use of modified modern dressings and ozone therapy is more effective in wound healing compared to the use of modern dressings alone in patients with pressure ulcers.

Ozone is claimed as a potential alternative to be used as an agent that helps wound healing in addition to existing conventional therapies. Ozone therapy for wounds is generally administered topically as an antimicrobial. Ozone bagging therapy in non-conventional or topical therapy is very effective in wound healing in diabetic ulcers. The effect of ozone on bacteria is to disrupt the integrity of the bacterial cell capsule through oxidation, resulting in cell regeneration. Foot ulcers in diabetic patients should receive treatment for several reasons, for example to reduce the risk of infection and amputation, improve function and quality of life.

Effect of Wound Healing on Diabetic Ulcer Patients in the Control Group Before and After Without Ozone Bagging Therapy

After the test, it was concluded that there was a difference in the effect of wound healing on diabetic ulcer patients in the control group before and after without ozone bagging therapy in the Kedungdung Health Center, Bangkalan Regency.

In patients with diabetes mellitus, if blood glucose levels are not controlled, chronic complications will occur, namely neuropathy, causing changes in nerve tissue due to accumulation of sorbitol and fructose, resulting in loss of axons, decreased speed of induction, paresthesias, decreased muscle reflexes, muscle atrophy, excessive sweating, dry skin, and lost taste. If patients with diabetes mellitus are not careful, trauma can occur which will cause lesions and become diabetic foot ulcers (Waspadji, 2006). The size of the area of diabetic foot ulcers that diabetic ulcer patients have depends on how the wound is obtained. The causes of foot ulcers are different for each diabetic ulcer patient. These causes include being scalded by hot water, exposed to stones or gravel, using inappropriate footwear, being exposed to sharp objects while working, exfoliating warts, being exposed to animal claws, abrasions, and so on. The wound is not realized by diabetic ulcer patients because of the decreased sensation of feeling in the wound due to high sugar levels and infection (Usiska et al., 2015).

Diabetic sores or diabetic ulcers contribute significantly to morbidity, both health care costs, and overall quality of life. Proper and routine wound care is very important for patients to achieve better ulcer-related outcomes. Wound care accelerates wound healing by retaining...
tissue moisture which can accelerate tissue granulation. The patient compliance factor in the implementation of wound care is very influential in wound healing, both dietary compliance and compliance in the patient’s presence during wound care, the wound healing process with wound care in ulcer patients, there is a process of moisturizing the tissue which results in the acceleration of granulation in the tissue so that it can reduce the area of the wound, and depth of the wound, as well as speeding up the patient's length of stay (Dimantika et al., 2020).

The process of angiogenesis begins with the normal function of fibroblasts in forming a fibrin network. The role of fibroblasts is very large in the repair process, which is responsible for the preparation of producing protein structure products that will be used during the tissue reconstruction process (Dimantika et al., 2020). The process of changing wound size in diabetic ulcers occurs through the process of wound repair through the process of angiogenesis. The formation of new tissue will be formed if the wound care process is carried out optimally (Usiska, 2015).

Wound care in ulcer patients contributes both to the wound healing process and prevents continued infection, routines that need to be carried out so that complications do not occur in ulcer patients by always keeping the wound clean and always caring for it.

Differences in Wound Healing in Diabetic Ulcer Patients in the Control Group (Without Ozone Bagging Therapy) and the Treatment Group (Given Ozone Bagging Therapy)

After the test, it was concluded that there were differences in wound healing in diabetic ulcer patients in the control group (without ozone bagging therapy) and the treatment group (with ozone bagging therapy) in the Kedungdung Health Center, Bangkalan Regency.

This research is supported by Teuvov et al (2017) that ozone therapy provides a therapeutic effect and is economically effective (Teuvov et al., 2017). Megawati et al (2015) concluded that the use of modified modern dressings and ozone therapy was more effective in wound healing than the use of modern dressings alone. Rosul (2016) in his research proved that ozone therapy with a concentration of 4000 g/mL showed a clinically significant effect on antioxidant protection and reduced length of stay (Rosul & Patskan, 2016). In line with Fathi’s et al (2011) research, ozone therapy increases the healing rate of ulcers and also prevents amputation. None of the respondents involved in this study had an amputation (Fathi, Mawsouf, & Viebahn-Hänsler, 2012).

Agosti's research (2016) showed patients with signs of inflammation for 2 months and had been treated with modern dressings after being modified with ozone therapy within 5 weeks of treatment, the wounds healed (Agosti, 2016). It is supported by research by Rosul (2016) that the use of ozone therapy has clinical effects that have been shown to significantly affect the wound healing phase, as an antioxidant and reduce the length of hospital stay in the treatment of patients with diabetic foot ulcers (Rosul & Patskan, 2016).

Ozone in the right concentration will enter the skin tissue and react with unsaturated fatty acids and water from the stratum corneum which has the potential to form ROS (Reactive Oxygen Species) and lipooligopeptides (LOP) that occur due to oxidative metabolism in the body and are partially absorbed through venous capillaries, and lymphatics. Ozone increases the topic effect and systemic effect, the topic effect when ozone reacts with the tissue will increase Hydrogen Peroxide (H2O2) and
Lipopeptides thereby increasing the antioxidant response. This antioxidant response inhibits the inflammatory response and enhances wound healing mechanisms. In systemic effects, when ozone reacts with platelets, it induces or increases the expression of VEGF, PDGF, TFGbeta1 in the body’s keratinocytes which function to inhibit inflammation and promote wound healing (Rosul & Patskan, 2016).

In this case, it is explained that the control group (without being given ozone bagging therapy) and the treatment group (given ozone bagging therapy) experienced differences in the results of the healing process, where it was proven that the ozone method was more effective than ordinary wound care in wound healing for diabetic ulcer patients. Ozone bagging therapy is very effective in wound healing in diabetic ulcers. The effect of ozone on bacteria is to disrupt the integrity of the bacterial cell capsule through oxidation, so that cell regeneration occurs which can then accelerate the healing of diabetic ulcer wounds.

CONCLUSION

There are differences in wound healing in diabetic ulcer patients in the control group (without ozone bagging therapy) and the treatment group (treated with ozone bagging therapy) in the Kedungdung Health Center, Bangkalan Regency.

REFERENCES

ADA. (2022). Introduction: Standards of Medical Care in Diabetes-2022. *Diabetes Care*, 1. https://doi.org/https://doi.org/10.2337/dc22-Sint

Bakri R., Kamaruzaman H.F., dan Thye S.L. (2011). *Health Technology Assessment Ozone Theraphy an Update*. Medical Development Division, Ministry of Health Malaysia.

Dimantika, A., Sugiyarto, & Setyorini, Y. (2020). Perawatan Luka Diabetes Mellitus Menggunakan Teknik Modern Dressing. *Interest: Jurnal Ilmu Kesehatan*, 9(2). Retrieved from https://jurnalinterest.com/index.php/issue/view/11

Fathi, A. M., Mawsouf, M. N., & Viebahn-Hänslser, R. (2012). Ozone Therapy in Diabetic Foot and Chronic, Nonhealing Wounds. *Ozone: Science & Engineering The Journal of the International Ozone Association*, 34(6). Retrieved from https://www.tandfonline.com/doi/abs/10.1080/01919512.2012.718700

Megawati, V. N., Hakimi, M., & Sumaryani, S. (2015). Efektifitas Modifikasi Modern Dressing dan Terapi Ozon terhadap Penyembuhan Luka pada Pasien dengan Pressure Ulcer di Wocare Clinic Bogor. *Hospital Majapahit*, 7(2). Retrieved from http://ejournal.stikesmajapahit.ac.id/index.php/HM/article/view/108

Rahimah, F. (2019). *Hubungan Tingkat Stres Dengan Kualitas Tidur Pada Pasien Dengan Ulkus Diabetikum Di Rumah Sakit TK.III Dr. Reksodiwiryo Padang*. Retrieved from http://scholar.unand.ac.id/52326/

Riskesdas. (2018). *Laporan Hasil Riset Kesehatan Dasar*. Retrieved from abdata.litbang.kemkes.go.id/images/download/laporan/RKD/2018/Laporan_Nasional_RKD2018_FINAL.pdf

Rosul, M. V, & Patskan, B. M. (2016). Ozone Therapy Effectiveness in Patients with Ulcerous Lesions due to diabetes mellitus. *Pubmed*, 1–8. Retrieved from
Selano, M. K., Priyastuti, M. T., & Suhadi. (2021). Peningkatan Sensitivitas Kaki Pada Pasien Diabetes Melitus Yang Mengalami Neuropati Diabetikum Melalui Latihan Senam Ergonomik. *JICE (The Journal of Innovation in Community Empowerment)*, 3(2). Retrieved from https://ejournal.unjaya.ac.id/index.php/jice/article/download/624/521/

Temu, S., & Sujianto, U. (2020). Proses Penyembuhan Ulkus Kaki Diabetik Melalui Terapi Ozon Bagging. *Jurnal Ilmiah Permas: Jurnal Ilmiah STIKES Kendal*, 10(2).

Teuvov, A. A., Baziev, A. M., Lovpache, Z. N., Teunikova, I. S., & Chudopal, S. M. (2017). Ozone Therapy in the Comprehensive Treatment of Diabetic Foot Syndrome. *Biomedical and Pharmacology Journal*, (2). Retrieved from https://biomedpharmajournal.org/vol10no4/ozone-therapy-in-the-comprehensive-treatment-of-diabetic-foot-syndrome/

Usiska, Y. S., Wantiyah, & Nur Widayanti. (2015). *Pengaruh Metode Rawat Luka Modern dengan Terapi Hiperbarik terhadap Proses Penyembuhan Luka Ulkus Diabetik pada Pasien Diabetes Mellitus di Jember Wound Center (JWC) Rumah Sakit Paru Jember*. Retrieved from https://repository.unej.ac.id/bitstream/handle/123456789/65577/102310101066.pdf?sequence=1

Waspadji, S. (2006). *Komplikasi Kronik Diabetes: Mekanisme Terjadinya, Diagnosis, dan Strategi Pengelolaan Dalam: Buku Ajar Ilmu Penyakit Dalam Edisi IV*. Jakarta: Fakultas Kedokteran Universitas Indonesia.

Widodo, T. R., Susilo, C., & Kurniawan, H. (2017). *Pengaruh Terapi Ozone Bagging Terhadap Penyembuhan Luka Pada Pasien Ulkus Diabetikum Di Rumah Luka Nirmala Kecamatan Puger Kabupaten Jember*. Retrieved from http://repository.unmuhjember.ac.id/966/1/Artikel Jurnal.pdf

Zeng, J., & Lu, J. (2018). Mechanisms of Action Involved in Ozone Therapy in Skin Diseases. *Jurnal Ilmiah Permas: Jurnal Ilmiah STIKES Kendal*. Retrieved from https://pubmed.ncbi.nlm.nih.gov/29414657/