

DIABETIC FOOT SYNDROME AS AN IMPORTANT THERAPEUTIC AND ECONOMIC PROBLEM

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ABSTRACT

Diabetes is becoming a global epidemic and is sometimes called- leprosy of XXI century. Diabetic foot syndrome is one of the most serious and most common issues for this group of patients. The economic costs resulting from the treatment are enormous for patients, their families as well as the whole society. Amputation is not a good solution. Reducing the number of amputations, the necessity to carry out prosthesis does not occur as well as the budget is not burdened with the costs associated with reamputations. HBOT offers many benefits for diabetic foot patients.

Key words: diabetic foot, treatment costs, hyperbaric treatment.

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INTRODUCTION

Diabetes is becoming a global epidemic and is sometimes called- leprosy of XXI century. The number of diabetes cases and their complications with foot ulcers, secondary infections and limb amputations increases therefore budget of health insurance is heavily burdened [1]. 65% of patients with foot ulcers have other symptoms such as neuropathy, deformities, trauma [2].

The economic costs resulting from the treatment are enormous. As the world research form 2011 shows, every 10 seconds there appears 3 new patients, while impaired glucose tolerance is detected in 280 million people [3].

EPIDEMIOLOGY OF DIABETIC FOOT SYNDROME

In Poland, 2 150 000 inhabitants buy antidiabetic drugs or glucometer strips, whereby 30% of people do not know at all that they have diabetes. It means that 2800 000 inhabitants of Poland may have diabetes [4].

In studies concerning young patients with diabetes of type 1 and type 2, ulcers are found in about 1,7- 3,3% patients per year, while in studies involving elderly patients, this percentage is as high as 10%. Nearly 20% of patients have amputation due to diabetes [5].

Diabetic foot syndrome is one of the most serious and most common issues for this group of patients.

In order to better illustrate the scale of the problem in our country, in Table 1 below the data on lower limb amputation in Poland between 2009 and 2012 are presented.

Tab. 1

Numbers according to the categories of people who had amputations in certain years.

	YEAR 2009	YEAR 2010	YEAR 2011	YEAR 2012
All treatments.	7703	7866	7729	8111
Men.	4901	5008	4942	5206
Women.	2802	2858	2787	2905

Table 1 represents the number of people who underwent serious amputations each year, the number of men and the number of women.

Within four years the number of serious amputations increased to 408.

In 2009 amputation 7703 people underwent amputation, whereas in 2012 - respectively 8111. Serious amputations were carried out almost twice as often in men as compared to women. That is demonstrated in Table 2.

Tab. 2

Number of people who had serious amputations.

	YEAR 2009	YEAR 2010	YEAR 2011	YEAR 2012
All treatments.	3731	4137	4254	4598
Men.	2180	2425	2504	2808
Women.	1551	1712	1750	1790

Table 2 lists the number of people who underwent serious non-traumatic amputations for the first time each year in Poland in diabetic patients in the period from 1 January 2009 to 31 December 2012, as well as the number of men, and women.

In 2009, in Poland, in general, 3731 diabetic patients underwent serious amputations for the first time, while in 2012 that number increased to 4598 people.

Thus, within 4 years of observation in 2012 the number of amputations increased to 867 annually, in comparison to 2009. In 2009-2012 the percentage of non-traumatic lower limb amputations of diabetic patients among all serious amputations in Poland is presented in the following way:

The percentage of non-traumatic lower limb amputation in diabetic patients in Poland in 2009-2012.

	Year 2009	Year 2010	Year 2011	Year 2012
Below 50	48,3 %	52,59 %	55,03 %	56,68 %

It should be emphasized that the percentage of carried out serious amputations of diabetic patients according to the age, indicates that 4/5 of serious non-traumatic lower limbs amputations were undergone by the patients above 60. More detailed data are presented in Table 4 [6].

The percentage of non-traumatic lower limb amputation in diabetic patients in Poland in 2009-2012 according to age.

Age	2009	2010	2011	2012
Below 50	3,69%	3,95%	4,02%	4,36%
Between 51 and 60	14,70 %	16,90%	16,80%	17,83%
Above 61	81,61%	79,15%	78,18%	77,81%

An important indicator is the fact that 15% of diabetic patients during their lifetime develop diabetic foot syndrome with ulcers, while the ulcers cancerogenicity is between 50 and 70%. The death toll of patients in the perioperative period after amputation reaches about 10% within a year, within 3 years it increases to 50% whereas within 5 years to 70 % [7].

Treatment of patients with diabetic foot syndrome is complicated and time consuming, moreover, its positive therapeutic result is not easy to achieve. It is due to the complex pathology of that disease. Effective treatment of diabetic foot syndrome requires involvement of mutually cooperating specialists, such as: diabetologist, vascular surgeon, ophthalmologist, neurologist and physiotherapist.

Taking into account the large scale of the phenomenon of the diabetic foot syndrome, one should consider the financial costs generated by this disease. In developed countries, 12-15% of the diabetes treatment costs are generated by diabetic foot syndrome, whereas in developing countries these costs reach 40%.

In developed countries, the direct cost of a single treatment of ulcers is between 7 000 \$ and 10 000 \$. In developed countries, the direct cost of amputation is between 16 200 \$ and 21 000 \$, while with the amount of indirect expenditures the treatment reaches the cost between 43 000 \$ and 64 000 \$ [8].

In the past few years, some countries succeeded in reducing indices of ulceration as well as the very amputations. These countries have introduced:

1. Prevention
2. Interdisciplinary treatment
3. Efficient organization
4. Monitoring
5. Education of patients, their families and guardians
6. Understanding the need for funding.

Taking into account the fact that the phenomenon of type 2 diabetes occurrence in children and youth is growing, one must expect that in the nearest future the number of complications in this group will increase. Here there should be given the example of countries, which focused on that phenomenon and started effective measures to reduce the results of complications caused by diabetes [9].

THE EFFECTIVENESS OF DIABETIC FOOT SYNDROME TREATMENT OF PATIENTS TREATED AT THE HYPERBARIC OXYGEN THERAPY AND WOUND HEALING CENTRE IN BYDGOSZCZ

The Hyperbaric Oxygen Therapy and Wound Healing Centre in Bydgoszcz in the period from 1 January to 31 has treated 84 patients, among them there were 11 patients with diabetic foot syndrome.

Six men and five women with diabetes registered in the HBOT to treat ulcers occurring on feet. Four patients achieved complete healing of wounds and three had a significant improvement in healing. Four patients are currently finishing hyperbaric oxygen therapy.

They also have got improvement in the healing of ulcers. The average age of patients (in the period from January 1 to May 31) with a diagnosis of diabetic foot syndrome was 56 years. Five patients due to non-healing wound, were on Sick leaves (more than 2 months), four patients were on invalidity pension due to diabetes complications and two were retired [10].

Below there are presented three clinical cases of patients from the Hyperbaric Oxygen Therapy and Wound Healing Centre in Bydgoszcz, who registered in the Centre with the diagnosis of diabetic foot syndrome.

Clinical case I

A man in the age of 36 with diagnosed ICD 10-E 10.5 – insulin dependent diabetes mellitus with complications within peripheral circulation [11], with unhealed (for 4 months) ulcers of the left foot [12], had amputation of the third finger of the left foot caused by recurrent inflammation. The state after amputation is illustrated in the picture below.



Fig. 1. State after amputation of the third finger of the left foot. Source: own materials.

Diabetic patients with changes within peripheral circulation have got refunded treatments up to 30 compressions of HBOT for 90 minutes 2,5 ATA from the National Fund.

The patient underwent 60 sessions of HBOT for 90 minutes 2,5 ATA due to the fact that there was additionally detected inflammation of the left foot bone during the therapy [13]. In the picture below there has been presented a diabetic foot during the therapy.



Fig. 2. Diabetic foot during the therapy. Source: own materials.

As a result of the applied treatment, the total healing of the wound has been achieved with no signs of inflammation. The state of the foot after the therapy is shown in the picture below.



Fig. 3. Diabetic foot after the therapy. Source: own materials.

The patient, due to the non-healing wound of the left foot, has been on sick leave for 4 months. He had been working before the ulcer's appearance, but later, due to the nature of the work he carried out, was temporary obliged to resign from it. Total time taken for the complete healing of the wound on the left foot was 7 months [14].

Clinical case II

Man of 53 with a diagnosis of ICD 10 E 11.5- insulin dependent diabetes mellitus with complications in terms of peripheral circulation.

From the interview of the patient: non-healing wound after amputation of the right great toe. Amputation was carried out four months before HBOT. The picture below presents the foot with non-healing wound before starting the therapy.



Fig. 4. Foot with non-healing wound before starting the therapy. Source: own materials.

The patient underwent 30 sessions of HBOT for 90 minutes at 2.5 ATA. Besides hyperbaric oxygen therapy, topical dressings were used and they were changed every 2-3 days.

As a result of the applied treatment, an improvement in the healing of the wound was achieved and the final result was complete healing, as it is shown in Fig. 5.



Fig. 5. Diabetic foot after the end of therapy. Source: own materials.

The case presented above concerned a patient who had retired in ill health due to diabetic complications. One of the reasons was that foot ulcers did not heal.

Due to infection and necrosis, the patient has been treated for several months under the guidance of the surgeon. Unfortunately, the toe could not be saved and there was a need for amputation.

In the period after the operation there occurred a complication of infection and therefore it could not be healed. 4 months after amputation the patient was taken to the Hyperbaric Oxygen Therapy and Wound Healing Centre.

The effect of combined treatment was the complete healing of the wound.

Clinical case III

A woman aged 45 with a diagnosis of ICD 10 E 11.5- insulin dependent diabetes mellitus with complications in terms of her peripheral circulation.

From the interview of the patient: a non-healing wound of the right foot was treated for 3 months at the Surgical Clinic with no effect.

The patient was directed for the hyperbaric therapy for 30 sessions of HBOT for 90 minutes at 2.5 ATA. The picture given below (Fig. 6.) shows the foot with non-healing wound before starting the therapy.



Fig. 6. The foot with non-healing wound before starting the therapy. Source: own materials.

The patient underwent 30 sessions of HBOT for 90 minutes at 2.5 ATA after which there was an improvement in the healing of the wound.

At the end of the therapy, due to persistent foot pain, the patient was directed for radiological diagnostic. The diagnosis was osteomyelitis of the right metatarsal. It was decided to continue the therapy (30 sessions of HBOT for 90 minutes at 2.5 ATA).

The improvement was observed during the treatment until its complete healing. It is illustrated in Fig.7.



Fig. 7. The improvement during the treatment. Source: own materials.

Following 6 months of sick leave, upon completion of the therapy, the patient could return to work. It must be assumed that hyperbaric oxygen therapy previously incorporated into the basic treatment would shorten the total duration of the therapy.

The cases presented above, can be undoubtedly treated as therapeutic successes of the Hyperbaric Oxygen Therapy and Wound Healing Centre. It proves that the combining of hyperbaric oxygen therapy with conventional methods of wounds treatment, including those for treating diabetic foot syndrome, significantly reduce the healing time and often determines the complete healing of ulcers.

Currently, research around the globe is assessing the cost effectiveness of using hyperbaric oxygen in the treatment of chronic wounds, including diabetic ulcers. Previously presented preliminary reports indicate significant efficiencies to be associated with hyperbaric oxygen therapy, reducing the time and costs associated with the treatment of ulcers [15].

The Hyperbaric Oxygen Therapy and Wound Healing Centre in Bydgoszcz does not have a huge amount of experience in this field, but during one year of functioning, the HBOT Centre has admitted 166 patients with different diseases, carrying out about 4,000 personal compressions.

There are now a number of indications as to where hyperbaric oxygen therapy could be utilised and this list is constantly expanding as numerous global studies are being conducted. These studies determine the development of hyperbaric oxygen therapy, increasing the availability of this method and improve the treatment of complicated non-healing wounds including diabetic foot syndrome.

THE EFFECTIVENESS OF HYPERBARIC OXYGEN COSTS

The wounds resulting from diabetes complications are extremely expensive to treat, the reimbursement of the treatment by the payer of benefits is inadequate to the costs of treatment.

According to the standards, currently the problem of diabetic foot involves more days of hospitalization than is actually required for its effective treatment. The average time of required hospitalization for this group of patients is estimated between 22 and 36 days while the system suggests from 10 to 15 days should be achievable.

In Poland, the situation is slightly different, the National Health Fund estimates the procedure of diabetic foot syndrome treatment according to the JGP to be 4000 PLN, in fact, this treatment costs 12000 PLN.

Therefore it is not expedient to treat that syndrome in Polish hospitals. For a purely economic factor, the hospital directs most patients with diagnoses of diabetic foot syndrome for amputation, for which the National Health Fund pays 5000 PLN.

It is a procedure that does not involve additional hospital costs. Statistics, which were created in 2007, are alarming because Mazowsze region alone has this year performed 310 amputations, while across Poland there were several thousand. In Warsaw hospital in Banach Street this phenomenon was studied and in 2007, 103 out of 107 patients who received a recommendation for surgery from their doctor were saved [16].

Amputation turns out to be not a good solution. Patients pay very high personal costs when losing a limb.

The economic costs for one serious amputation in the United States amount to more than \$40,000, while the refunding in this country is only \$12,500. After the amputation, a patient usually remains hospitalized for about 40 days, and to increase the ability to walk, patients may need an additional six-nine months of rehabilitation.

For older patients, that rehabilitation may be ineffective. Many older diabetics after amputation remain in a wheelchair for the rest of their days due to the required energy, difficulty in maintaining balance and lack of strength to walk.

Their sedentary lifestyle leads to other health problems. For example, within two years, most amputees after amputation must undergo another amputation. Although the direct costs of amputation exceed \$1.5 billion per year in the

USA, indirect medical costs make another half a billion dollars each year. It is also worth considering the social costs following each amputation, in addition to the high cost of the operation, the patients cannot remain employed.

As a result, following an amputation, patients do not only stop contributing to GDP growth but they also charge public funds with all kinds of social benefits.

HBOT offers many benefits for patients with diabetic foot ulcers. These include: increased oxygen content on the wound, the development of live tissue, enhancing of phagocytosis and bactericidal activity. Hyperbaric therapy supports the antibiotic therapy, that improves wound healing. HBOT has excellent bacteriostatic effects in the case of anaerobic microbial infections. These observations are confirmed by numerous clinical studies.

Batoni, et al., and Hart, Strauss, Perrins, and Barr. Baroni, et al., conducted studies using a random double-blind trial for hospitalized patients with diabetic foot infections and partial gangrene of the foot.

The results of these studies showed that the wounds of 16 out of 18 patients treated with HBOT in contrast to the control group, in which 1 out of 10 patients had improvement, were healed in 89% of cases, while in the control group, only 10% [17].

The study also confirms that hyperbaric oxygen therapy reduces the number of major amputations and improves the quality and length of life by successfully facilitating the therapeutic process.

However, it should be stressed that the cost effectiveness of hyperbaric oxygen therapy is dependent on the classification of patients corresponding to treatment; patients who are not predisposed for hyperbaric therapy should be excluded according to the result of a transdermal oxygen tension.

The inclusion of hyperbaric therapy for the primary treatment of diabetic foot syndrome is more efficient. The proportion of major amputations decreased from 32% among patients receiving standard therapy to 11% among hyperbaric patients.

The cost of a straight forward diabetic foot standard treatment is higher than in the case of a standard treatment combination with HBOT. Besides cost reduction, there appears to be an improvement in the quality of the patient's life as well as their longevity of their lifetime [18].

CONCLUSIONS

Hyperbaric medicine is a relatively young field of medicine, although its dynamic development can be observed. This results in a small number of studies, not only in terms of treatment and search for new indications, but also in costs.

Specialists in that field of medicine often emphasize the large lack of scientific reports in terms of cost-effectiveness of this treatment method considered in the context of social benefits. Hyperbaric oxygen therapy is poorly co-financed branch of medicine. Good and insightful study of the cost effectiveness of this treatment will help to put pressure on the authorities deciding on the placement of public funds in the medical sector.

Taking into account the fact that the number of diabetics is growing, more attention should be paid to preventive measures in this area. It is also necessary to educate all specialists, not just diabetologists, in the area of the appropriate model of treatment for patients with diabetes, as only the multidisciplinary team approach makes it possible to carry out the treatment with minimum costs.

The number of amputations performed is alarmingly high, certainly it might have been limited, if we could realistically coordinate diabetic foot treatment procedure in combination with hyperbaric treatment, which is much more cost effective. It will take lots of efforts to change the observed trends for carrying out amputations, which is treated as savings in treatment. Without taking into account indirect, direct, social and personal costs, associated with limbs loss, it is impossible to do this.

Therefore, it is necessary to change the approach of decision-making institutions and to possess a strong will to look at the bigger picture when dealing with this problem.

The above cases are undoubtedly therapeutic successes of the Hyperbaric Oxygen and Wound Healing Centre. They are proof that the inclusion of hyperbaric oxygen therapy to the conventional methods of treating wounds, including diabetic foot syndrome, significantly reduces the healing time and often determines the complete healing of ulcers.

Currently, world research is assessing the costs associated with the treatment of chronic wounds including diabetic ulcers and the cost effectiveness of using hyperbaric oxygen therapy. The preliminary reports presented in this text, demonstrate a significant efficiency arising from the use of hyperbaric oxygen therapy in the treatment of such ailments as a means to reduce the time and cost associated with it [19].

The Hyperbaric Oxygen Therapy and Wound Healing Centre in Bydgoszcz does not have a huge amount of experience in this field, but during one year of functioning, the HBOT Centre has admitted 166 patients with different diseases, carrying out about 4,000 personal compressions.

There are now a number of indications as to where hyperbaric oxygen therapy could be utilised and this list is constantly expanding as numerous global studies are being conducted. These studies determine the development of hyperbaric oxygen therapy, increasing the availability of this method and improve the treatment of complicated non-healing wounds including diabetic foot syndrome.

It is also worth considering the social costs which follow each amputation. In addition to the high cost of the operation, the patients cannot remain employed. As a result, following an amputation, patients do not only stop contributing to GDP growth but also charge public funds with all kinds of social benefits.

The study also confirms that hyperbaric oxygen therapy reduces the number of major amputations and improves the quality and length of life by successfully facilitating the therapeutic process.

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