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**| RESEARCH ARTICLE**

## **Hyperbaric Chamber Access, Difficulties and Major Diabetic Foot Amputation: Hyperbaric Chamber and Diabetic**

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**| ABSTRACT**

Diabetes mellitus (DM) is a chronic systemic disease that affects around 15.8 million people in Brazil. Diabetic-related vascular complications, such as major and minor amputations, constitute a significant challenge in medicine. The aim of the present study was to evaluate the incidence of lower limb amputations in patients with diabetic foot undergoing treatment with a hyperbaric chamber. The medical records of all diabetic patients with foot lesions who were indicated for hyperbaric oxygen therapy at a teaching hospital were evaluated in a cross-sectional study. Sex, age, number of hyperbaric chamber sessions and major amputations were recorded. One of the basic aims of treatment was to achieve full granulation without leaving the tendons exposed. Participants underwent local hyperbaric oxygen therapy at a pressure of 2.5 atmospheres (exposures of 30 minutes each) once a day for five days per week. The data were entered into an Excel spreadsheet and statistical analysis was performed using the Stats Direct program. The study was approved by the Research Ethics Committee of the institution. Eighty women and 203 men receiving hyperbaric oxygen therapy were evaluated (chi-square test: p-value <0.001). The mean ages of the male and female patients were 58.38 and 57.01 years, respectively (unpaired t-test; p-value = 0.4). The men received 10,014 sessions (mean: 50.07/man) and the women had 3082 sessions (mean: 41.64/woman). Thirty (10.63%) major amputations were performed in three months of follow-up; 26 (12.8%) in men and 14 (17.5%) in women. The diabetic foot is a challenge in daily medical practice. Strategies using techniques that accelerate healing, such as hyperbaric oxygen therapy, have not reduced the mortality rate of these patients, nor eliminated the possibility of amputation, but can reduce the number of major amputations.

**| KEYWORDS**

Hyperbaric chamber, amputation, diabetes.

**| ARTICLE INFORMATION**

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### **1. Introduction**

Diabetes mellitus (DM) is a chronic systemic disease that affects approximately 15.8 million people in Brazil <sup>1</sup>. Involvement of the kidneys, eyes, coronary arteries and other blood vessels, and peripheral nerves a common complication of this disease. The diabetic foot is a clinical entity that directly causes morbidity and mortality and results in increased treatment costs <sup>1,2</sup>. Approximately 5% of patients with diabetes have foot lesions for less than ten years however, 5.8% of diabetics have lesions for more than ten years <sup>2</sup>.

Current evidence shows that hyperbaric oxygen therapy (HBOT) can reduce the risk of major amputation <sup>3</sup>. A study reports that HBOT reduced oxidative and pro-inflammatory mediators, and may participate in the activation of healing, angiogenesis and regulation of vascular tone, increasing the release of growth factors <sup>4</sup>. Research has demonstrated that HBOT has a beneficial effect on perfusion in chronic wounds by improving angiogenesis and reducing hypoxia. Additionally, there is potentially a role for indocyanine green angiography in the early identification of patients who would benefit most from HBOT <sup>5</sup>.

Retrospective cohort and case-control studies suggest that the use of HBOT in the treatment of necrotizing soft tissue infections can significantly reduce mortality rates and complication incidence rates. However, due to the retrospective nature of studies, the evidence is weak, and more research is needed to establish its effectiveness <sup>6</sup>. A meta-analysis showed that HBOT increased the healing rate of diabetic foot ulcers, shortened the healing time and reduced the necessity of major amputations <sup>7</sup>. Another meta-analysis showed a lower risk of amputation, but no differences were found in respect to minor amputations and healing rates <sup>8</sup>.

Measures such as adequate glycemic control, smoking cessation, good nutritional and improved circulation to the extremities are important for treatment. Currently, there are other therapeutic methods used to treat difficult-to-heal ulcers, such as HBOT and negative pressure therapy. Thus, the objective of the present study was to evaluate the incidence of lower limb amputations in patients with diabetic foot undergoing treatment with a hyperbaric chamber.

## **2. Method**

The medical records of diabetic patients with foot ulcers who were indicated to use the hyperbaric chamber at Hospital de Base of the Medical School in São José do Rio Preto (FAMERP) were evaluated. The hyperbaric chamber was recommended for the most severe lesions. However, one of the requirements for the indication of HBOT was the presence of viable arterial circulation for wound healing. Use of the hyperbaric chamber depended on its availability on the day of indication.

All diabetic patients who underwent a surgical procedure and who received HBOT to treat foot lesions were included in this study. One of the minimum objectives was to achieve complete granulation without leaving the tendons exposed. Hence, these patients received treatment until the full granulation of the lesion was attained. The treatment time for each patient varied according to the wound, the availability of the chamber, and the patient's readiness to attend the service. Patients who could not tolerate being in the hyperbaric chamber were excluded from the study.

The inclusion criteria were diabetic patients with ulcerated foot lesions who underwent surgical treatment and were indicated for HBOT. Patients with other diseases associated with foot ulcers, non-diabetic patients and those who could not tolerate being in the hyperbaric chamber were excluded. Patients underwent local HBOT at a pressure of 2.5 atmospheres (exposures of 30 minutes each) once a day for five days per week.

The study was approved by the research ethics committee of the Medical School in São José do Rio Preto (FAMERP)# 7.531.147. Characteristics of the patients and treatment were extracted from medical records including the sex and age of patients and the number of sessions of HBOT they received. The data were entered into an Excel table and statistical analysis was performed using the Stats Direct program.

## **3. Results**

Eighty female and 203 male patients undergoing diabetic foot treatment with a hyperbaric chamber were evaluated (chi-square test: p-value <0.001). There was no significant difference between the ages of the male (mean = 58.38; standard deviation [SD]: 11.62 years old) and female patients (mean = 57.01; SD: 12.8 years old - unpaired t-test: p-value = 0.4). The men received 10,014 sessions with a mean of 50.07 sessions each and the women had 3082 with a mean of 41.64. Thirty (10.63%) major amputations were performed in three months of follow-up, 26 (12.8%) in males and 14 in females (17.5%).

## **4. Discussion**

The present study is retrospective and provides information on the sex and age of patients undergoing HBOT, with an evaluation of the mean number of sessions required to achieve full granulation and wound healing. This data is important because Hospital de Base is a public service where demand for the device is very high. Travel costs and lost working days of these patients limit access to this type of treatment. However, the benefits, with the acceleration of wound granulation, are substantial. As a clinical observation, patients who had access to this therapy had better wound granulation.

The literature demonstrates that this approach accelerates healing and reduces the number of amputations, however, it does not reduce mortality <sup>7-9</sup>. A meta-analysis reported that the amputation rate decreased from 26.03% to 45.00%, but the incidence of adverse events was significantly higher in patients who used the hyperbaric chamber (17.37% vs. 8.27%), while there was no significant difference in mortality (6.96% vs. 12.71%).<sup>8</sup> In the present study, major amputation were necessary in 10.6% of the cases, thereby confirming published data.

Diabetes is associated in around 87.5% of patients with minor amputations and in 52.5% of those with major amputations,<sup>10</sup>. Diabetic microangiopathy, which affects these patients, further aggravates the microcirculation. A study by this research group reported an improvement, albeit not statistically significant, of the one-year mortality rate which used to be 9.25% but in the most recent evaluation, it had dropped to 8.4% (study in press).

Reducing death rates continues to be a significant challenge; this involves identifying the factors associated with mortality. In one Study evaluating mortality, 95% of patients, who were hospitalized with critical ischemia and treated clinically, were re-admitted to four hospital wards. Most (52.84%) were readmitted by the vascular surgery service (mortality rate: 3.5%), followed by cardiology (29.79% - mortality: 21.42%), neurology (10.9% - mortality: 9.6%) and nephrology (6.47% - mortality: 6.38% in the first hospitalization and 11.1% in the last)<sup>11</sup>. Therefore, arteriosclerosis is the main link between these specialties.

The present study shows that the use of the hyperbaric chamber did not eliminate the possibility of a major amputation. However, these patients were the most severely ill and underwent toe and transtarsal amputations. One study (in press) identified that the mortality rate of amputee patients in one month was 14% and in three months, it was 18% with infections being identified in all cases. Therefore, controlling infection is the most important strategy necessary to reduce mortality rates. The routine for amputations in the vascular surgery service is the mechanical resection of the necrotic material during surgery, followed by cultures and antibiogram of the bone, tendon and soft tissues to guide antibiotic therapy. In summary, mortality is the biggest challenge when managing these patients and so mortality is directly linked to the clinical condition.

Accelerating healing is fundamental: several therapeutic options such as hyperbaric chamber, negative pressure, ozone, photobiomodulation and several types of dressings may be useful. However further studies are required to better define the different methods of application of these techniques and the outcomes<sup>12-15</sup>.

The limits of this study are that it is retrospective, and some assessments were not made such as the rate of wound healing, the mortality of these patients over time, and the pairing of patients with others with similar lesions, comparing new surgical techniques, and investigating different types of infection. However, this study opens up the research field for prospective assessments.

## 5. Conclusions

The diabetic foot is a challenge in the daily medical approach, where strategies using different techniques, such as the hyperbaric chamber, can accelerate healing. However, HBOT does not reduce the mortality of these patients, nor eliminates the possibility of an amputation, but it can reduce the number of major amputations.

## Author's contribution

Conception and development of the study: Bellomo ALM, Estacio FK, Rossini GJ, Moura RP, Godoy HJP, Godoy JMP

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## Conflict Interest

The authors declared no have conflict interest.

The study was development in Hospital de Base-Sao Jose do Rio Preto-Brazil

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