

The "Cost" Of Amputation In Diabetics

Guest Editorial

A Role For HBO In Diabetic Foot Infections: Compelling Evidence At Last?

Diabetic foot infections exact a terrible cost on the U.S. health care system. It is estimated that 5-6% of the U.S. population is diabetic and the annual cost of their health care exceeds \$20 billion, of which more than \$1.5 billion is due to lower extremity amputations caused by diabetic foot infections! Diabetic patients account for approximately fifty percent of all the lower extremity amputations performed for non-traumatic indications.

These actual health care dollars spent may be insignificant compared to the lost productivity of these patients and the emotional impact on them. Couch, et al., found that only 77% of patients undergoing major lower extremity amputations were candidates to be fitted with a prosthesis and only 90% of below knee amputees with prostheses could be successfully rehabilitated. The rehabilitation rates dropped to 76% and 45% for above-knee and bilateral amputees, respectively. Finally, the surgical mortality of major leg amputation is 11-13%.

The etiology of diabetic foot ulcerations and infections is complex and multifactorial. Peripheral vascular disease, diabetic neuropathy, and increased susceptibility to infection due to immunologic compromise, are all known to be contributing factors. Delayed wound healing, quite possibly due to hypoxia at all cellular levels, may also have significant impact on the morbidity observed in these patients.

As noted in the accompanying article, Baroni et al. (1987) demonstrated the efficacy of hyperbaric oxygen and reducing the incidence of major amputation in patients with diabetic gangrene (11% in the HBO group vs. 40% in controls). In 1990 Oriani reported a major amputation rate of 5% in patients who received HBO, compared to 33% in similar patients who either refused or had contraindications to HBO therapy. However, although prospective, neither of these studies had randomized control groups and thus did not pass "academic muster", at least for those who questioned the role of HBO in diabetic foot infections.

Faglia and colleagues have now reported the results of a prospective and randomized trial of HBO in diabetic foot ulcers which is reviewed in this edition of HMU. The results were impressive - 8.6% major amputation (below knee or higher) rate in the HBO patients compared to 33.3% for the controls. This was a well-designed and carefully-controlled clinical trial and several points deserve emphasis.

Of particular note is the use of the word "adjunctive" to describe HBO therapy. All of these patients were entered into a protocol to provide good metabolic control of their diabetes, antibiotic therapy directed at the causative organism, and meticulous wound debridement and management. In addition, every patient underwent appropriately aggressive peripheral vascular diagnostic evaluation and, when indicated, therapeutic intervention. The authors in no way suggest that HBO can replace any of the above elements so vital to the care of diabetic foot infections.

Faglia does not provide any long term follow-up data about these patients (at least at this time). It would be reassuring to know that the healing which occurs is durable, although our personal experience suggests that it is if the patients participate in an appropriate foot care regimen.

A final question which will be raised by the doubters in 1997 is the cost effectiveness of HBO. While Faglia does not attempt to address this issue, Apelquist (1995) analyzed the three-year

follow-up costs for patients with diabetic foot ulcer from the time of healing (with or without amputation). Total costs for patients who achieved primary healing and did not have critical ischemia were \$16,000 compared to \$63,000 for patients who had required major amputation. It would certainly seem that a course of HBO in appropriately selected patients is cost-effective therapy. Just ask those patients who avoided major amputation.

Certainly there is a need for additional similar studies to confirm (or refute) Faglia's findings. However, based on the data which is currently available and the high financial and psychological impact of major amputations, I would suggest that future trials be designed to include a cross-over provision so that all randomized patients might have the opportunity to receive HBO therapy prior to amputation.

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