

Cost and mortality data of a regional limb salvage and hyperbaric medicine program for Wagner Grade 3 or 4 diabetic foot ulcers

J.V. Eggert¹, E.R. Worth^{1,2}, C.C. Van Gils³

¹ Hyperbaric Medicine Department, Dixie Regional Medical Center, St. George, Utah, U.S.

² Department of Anesthesiology, Center for Hyperbaric Medicine and Environmental Physiology, Duke University Medical Center, Durham, North Carolina, U.S.

³ Wound Care Department, Dixie Regional Medical Center, St. George, Utah, U.S.

CORRESPONDING AUTHOR: Joan V. Eggert, M.D. – jveggert@msn.com

ABSTRACT

We obtained costs and mortality data in two retrospective cohorts totaling 159 patients who have diabetes mellitus and onset of a diabetic foot ulcer (DFU). Data were collected from 2005 to 2013, with a follow-up period through September 30, 2014. A total of 106 patients entered an evidence-based limb salvage protocol (LSP) for Wagner Grade 3 or 4 (WG3/4) DFU and intention-to-treat adjunctive hyperbaric oxygen (HBO₂) therapy. A second cohort of 53 patients had a primary lower extremity amputation (LEA), either below the knee (BKA) or above the knee (AKA) and were not part of the LSP.

Ninety-six of 106 patients completed the LSP/HBO₂ with an average cost of USD \$33,100. Eighty-eight of 96 patients (91.7%) who completed the LSP/HBO₂ had intact lower extremities at one year. Thirty-four of the 96 patients (35.4%) died during the follow-up period. Costs for a historical cohort of 53 patients having a primary major LEA range from USD \$66,300 to USD \$73,000. Twenty-five of the 53 patients (47.2%) died. The difference in cost of care and mortality between an LSP with adjunctive HBO₂ therapy vs. primary LEA is staggering. We conclude that an aggressive limb salvage program that includes HBO₂ therapy is cost-effective.

INTRODUCTION

Worldwide in 2014 there were an estimated 382 million people with diabetes mellitus. This includes 24.4 million in the United States, with more than 9 million undiagnosed [1]. In Utah alone, there are 142,000 diagnosed adults with more than 45,000 undiagnosed [2]. The incidence of diabetes mellitus is steadily growing. In addition, costs directly attributable to the disease are also increasing. At least 33% of costs to treat diabetes mellitus can be linked to treating patients with diabetic foot ulcer (DFU) [3].

The yearly incidence of a DFU was 6% of Medicare fee for service (FFS) beneficiaries in 2008 [4]. During their lifetime, 20% to 25% of people with diabetes will have at least one foot ulcer [5]. DFU is the most common cause of non-traumatic lower extremity

amputation (LEA) (>60%) in this patient population. More than 80,000 LEAs per year are attributable to complications of diabetes [6]. Annual reimbursement for all services per Medicare beneficiary with a DFU in 2008 was USD \$38,100, and reimbursement per beneficiary with an LEA was USD \$58,700 [7].

The death rate within one year of DFU hospitalization in Medicare FFS beneficiaries in 2008 was 12.3% [7]. In those with an LEA, mortality within one year was 17% [7]. Other studies report mortality rates in diabetics after amputation were 32.8% at one year, 68.1% at five years and 91.6% after 10 years [8].

In patient populations with Wagner Grade 3 and 4 (WG3/4) DFU, a limb salvage team approach has been reported to reduce LEA. Using a multidisciplinary foot team appears to demonstrate long-term cost savings

KEYWORDS: diabetic foot, episode of care, limb salvage, amputation, hyperbaric oxygenation, critical pathways, cost-benefit analysis

and better access to care that results in lower numbers of foot complications and major amputations [3,9,10].

Intermountain Dixie Regional Medical Center (St. George, Utah) has had an integrated wound care clinic and hyperbaric medicine center since 2005. One author (JVE) has kept extensive records with an Excel® spreadsheet using the electronic medical record (EMR) and electronic data warehouse (EDW) of Intermountain Healthcare. This allows access to individual and pooled cost data between 2005 and 2013.

A formal limb salvage protocol (LSP) for patients with a Wagner Grade 3 or 4 DFU was implemented when the hyperbaric chamber was installed in 2005 (Figure 1). This protocol involves parallel evaluation of the wound, vascular supply to the extremity, and environment of care. We received Institutional Review Board approval to develop the LSP in order to compare costs, outcomes and mortality of patients with a DFU following the LSP vs. patients undergoing primary LEA. The aim of the current study is to compare the costs and mortality rates of patients in the LSP/hyperbaric oxygen (HBO₂) vs. primary LEA cohorts.

METHODS

Two cohorts of patients totaling 159 were analyzed.

LSP: The first group of 106 patients followed an LSP in the wound care department that included intention to treat with adjunctive HBO₂. All patients in the LSP/HBO₂ cohort had a WG3/4 DFU. These patients had all possible macrovascular disease corrected. Diabetes management was optimized by the primary care provider or diabetes specialist.

All patients without disqualifying conditions for HBO₂ therapy have been included in this review. Each HBO₂ treatment consisted of a 120-minute treatment table with a total of 90 minutes of 100% oxygen breathing time delivered by hood at 222.9 kPa/2.2 atmospheres absolute (45-fsw gauge pressure adjusted for 3,000-foot altitude) in a multiplace hyperbaric chamber.

Patients were assigned and followed in one of four categories: complete, incomplete, failed HBO₂ and delayed failure. We defined a complete series of HBO₂ therapy as more than 20 treatments. In this study any number of treatments fewer than 20 is incomplete. Patients who failed the LSP/HBO₂ protocol were

those who had an LEA within one year of finishing HBO₂ treatments. Delayed failures were those who had an LEA after one year but before the end of September 2014. This cohort of patients was collected from May 2005 until the end of June 2013. Death and LEA data were tracked until September 2014.

LEA: The second group is a historical cohort of 53 patients who underwent primary LEA after admission to the hospital between January 2007 and the end of June 2013. Any patient entering the hospital with an ICD-9-CM code describing diabetes mellitus and having a below-the-knee amputation (BKA) or above-the-knee amputation (AKA) surgical procedure was included. Some patients had multiple LEAs. In these cases, we calculated any time-based variables from the last (or highest) amputation level.

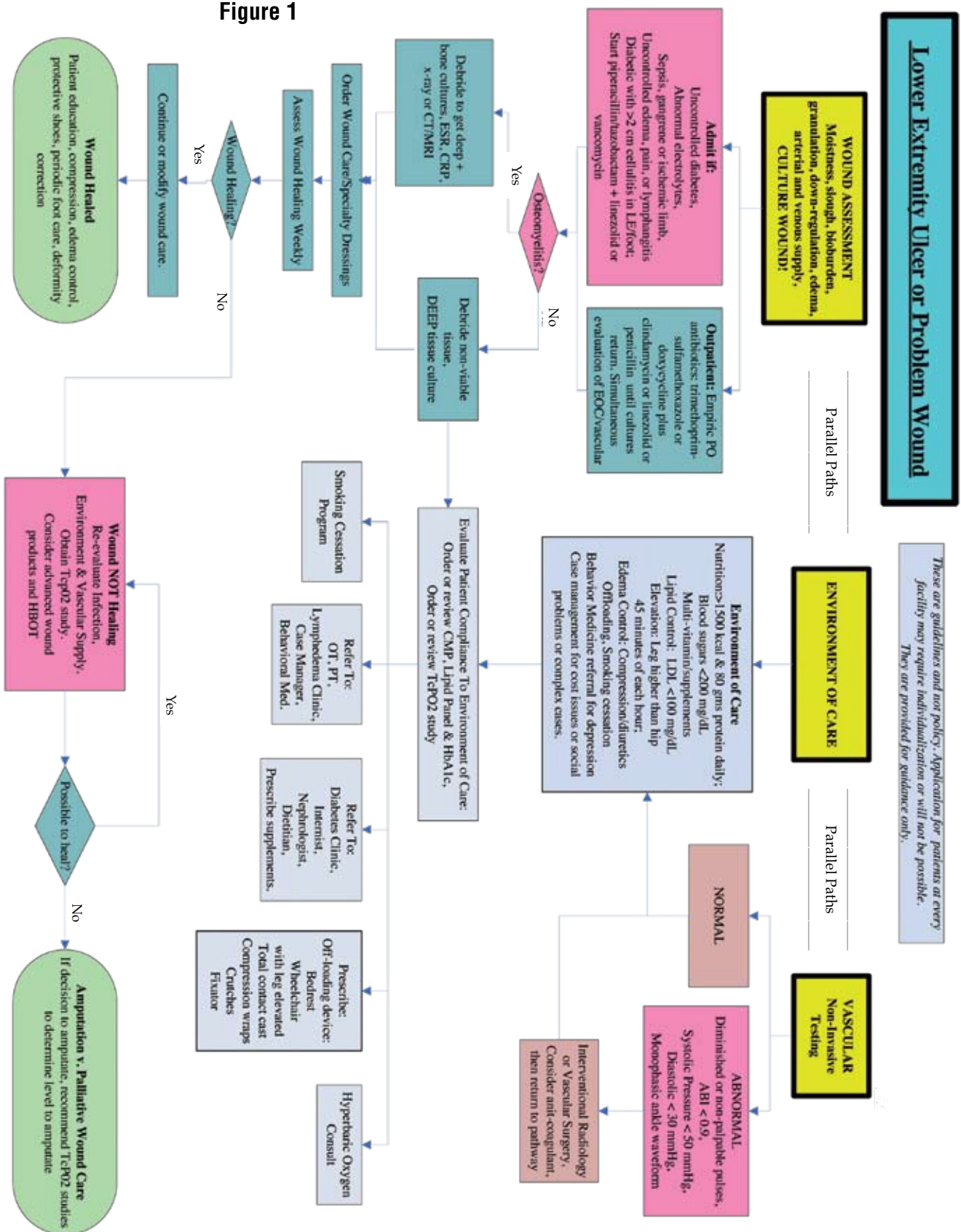
Data-gathering

The Intermountain Healthcare EDW is robust and linked to the Utah Department of Health Vital Statistics database in order to track death dates. Death information for Utah residents was obtained by querying the EMR, the Utah Vital Statistics database, and the EDW. There were a few outliers who lived in Arizona or Nevada. In these exceptions, only the EMR was used to track death dates. The time from the last procedure until death was calculated from the highest level of amputation in those who had a BKA then AKA, or from the last amputation for those who had a BKA on both legs. For the HBO₂ group, time to death was calculated from the start date of HBO₂. Time, in months, was calculated using a Microsoft Excel® user-defined function. All data elements were de-identified and analyzed by the Intermountain Southwest Region statistician using Statit Custom QS™ and Microsoft Excel® software. All currency values have been adjusted to 2014 USD by readily available Internet inflation and currency conversion calculators.

Cost guidelines

Hospital costs for outpatients were calculated from the EDW by tracking administrative costs, staff costs, department overhead, utilities, supplies, maintenance, time-motion studies, building costs, and rent. This was calculated for inpatients in much the same manner, with

Figure 1



the addition of operating room costs for surgical procedures.

LSP: We defined costs for a DFU to include: HBO₂ treatments; any surgical hospitalizations pertinent to the DFU; and wound clinic visits from 30 days prior until six months following the first HBO₂ treatment. Surgical hospitalizations pertinent to the DFU were identified by Current Procedural Terminology® codes that included resection of toes, metatarsal or tarsal bones; debridement; excision of tissue; tendon transfer; arthrodesis; dermal or skin graft; pedicle flap; or insertion or removal of fixation device (internal or external).

LEA: Costs for a primary LEA include the hospitalization encompassing the amputation, a modeled 14-day stay in the inpatient hospital acute rehabilitation unit, and first-year prosthesis costs from a local vendor. Acute rehabilitation minimum costs were calculated using one occupational therapy (OT), physical therapy (PT) and speech evaluation for every admission. In addition, these patients have daily gait, exercise and neuromuscular re-education sessions.

RESULTS

One year following LSP/HBO₂ therapy, 88 of 96 patients (91.7%) had an ambulatory limb. We defined this as any partial foot amputation that is capable of weight-bearing and ambulation. A total of 59 of 96 patients (61.5%) are 57 months since LSP/HBO₂ at the time of this writing.

Eight of 96 patients (8.3%) were considered failures of LSP/HBO₂. Seven patients went on to have a subsequent BKA, and one had an AKA within one year after completing HBO₂ treatments. Six of 88 patients (6.82%) had a delayed failure, requiring LEA more than one year after completing LSP/HBO₂.

Costs

LSP: In the LSP/HBO₂ cohort, the average number of HBO₂ treatments was 27. The average cost of care per DFU series was USD \$33,100. This breaks down to costs for HBO₂ at USD \$17,000, wound clinic visits at USD \$6,100, and surgical hospitalizations of USD \$10,000. During the series, 50 of 96 patients (52.1%) had a hospital admission for a surgical procedure on the affected foot.

LEA: Costs for the cohort of 53 patients who had a BKA or AKA were USD \$21,300 and USD \$28,000 respectively for the amputation hospitalization, USD

\$23,000 for acute rehabilitation, and USD \$22,000 in the first year for a prosthesis. Total first-year amputation costs were USD \$66,300 (BKA) and USD \$73,000 (AKA).

Mortality

LSP: Ninety-six patients completed a series of at least 20 HBO₂ treatments with 34 of 96 patients (35.4%) known to be deceased by September 2014. Of the 88 who healed, 30 are deceased (34.1%) as of September 2014. The majority of deaths occurred between one and four years after completing HBO₂, with the highest death rate in the second year.

There were 10 patients who withdrew and did not complete a series of HBO₂ therapy during this period. The average number of HBO₂ treatments was eight sessions. Six patients (60%) of this incomplete group are deceased. One patient, lost to follow-up, has been presumed deceased for this analysis, bringing the deceased total to seven (70.0%) (Figure 2).

LEA: Fifty-three patients had primary LEA. Three of 53 patients (5.66%) had multiple amputations, going from BKA to AKA. This brings a total of 59 amputations in 53 patients. In this cohort, 25 of 53 patients (47.2%) are deceased.

Twenty-eight patients had a BKA as the highest level of amputation, with 14 (50.0%) deceased by September 2014. When AKA was the highest amputation level, 11 of 25 patients (44.0%) are deceased. Average time from amputation to death was 1.7 ($\pm$ 2.0) years (Figure 3).

DISCUSSION

Because of the pathophysiology of diabetes mellitus, multiple comorbid conditions are often present when lower extremity neuropathy progresses to the point of DFU formation. This requires a multidisciplinary limb salvage team following a standardized assessment pathway in order to have positive outcomes in a cost-effective manner [5,12]. Several studies demonstrate that major LEA rates have been reduced by as much as 45% to 48% [11,12]. Multidisciplinary teams, wound care centers of excellence and an aggressive LSP are optimal ways to improve wound healing and ensure better outcomes [13,14].

Equally important to the dedication of clinic staff is proper and streamlined communication between team

Figure 2: Patient procedure and mortality flow sheet

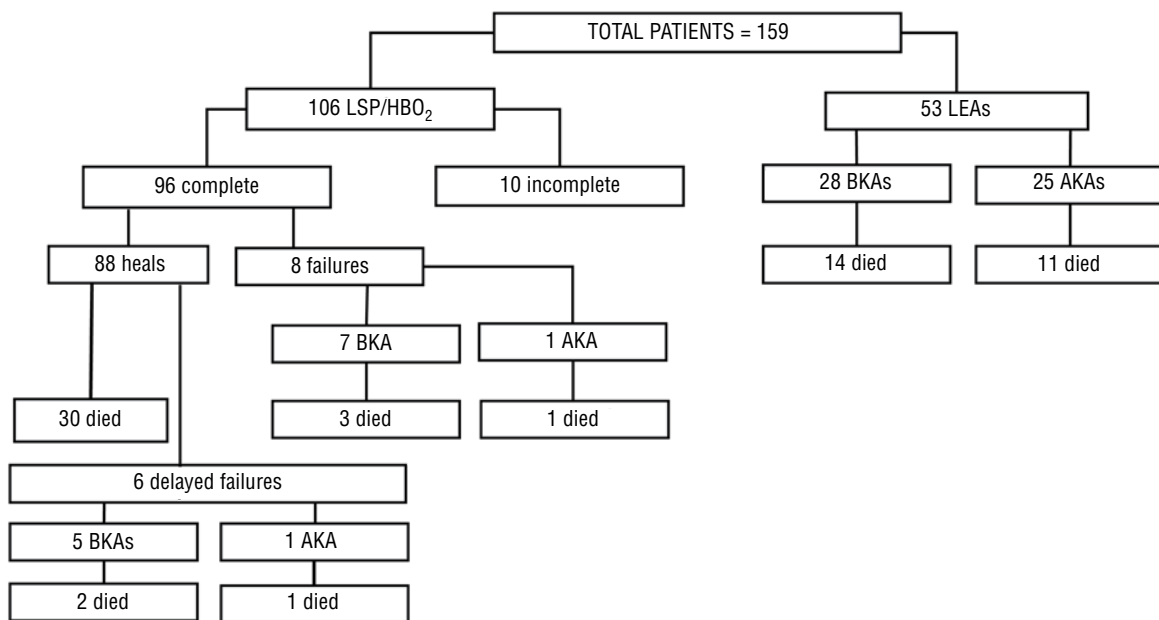
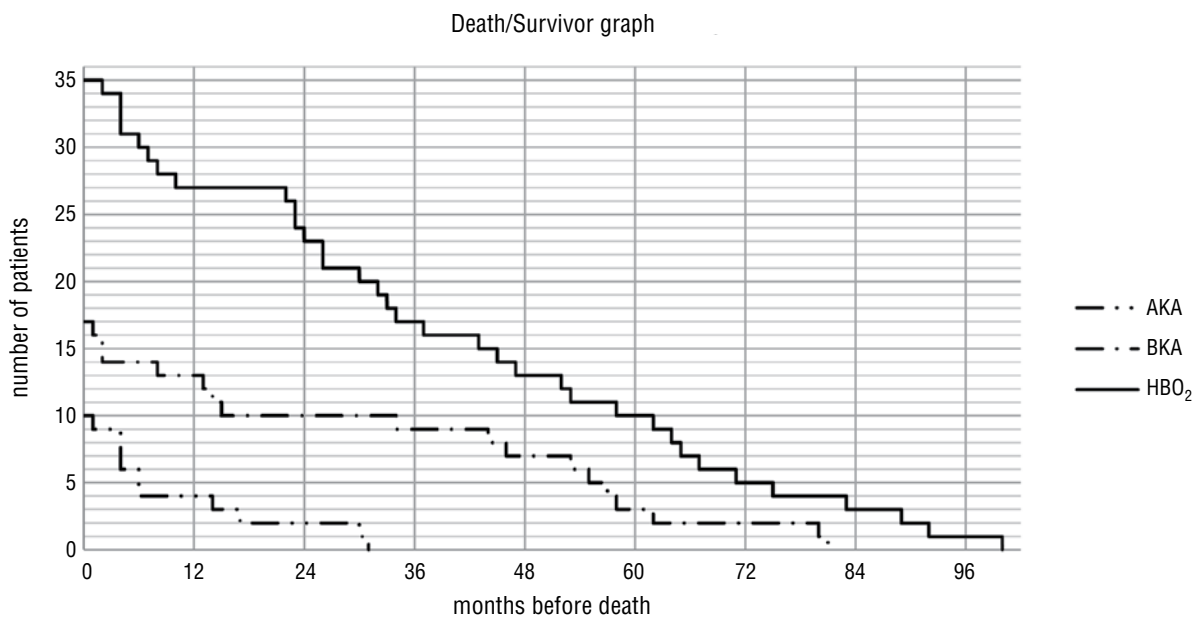


Figure 3: Kaplan-Meier survival plot
Survival times are shorter with higher levels of amputation



members [9,13,15]. Weekly team meetings highlight potential difficulties with patient care, diagnosis, and overall wound progress for each challenging patient. We believe that our strict adherence to LSP explains our successful outcomes, where others not strictly following clinical pathways have not achieved these results.

Cost analysis

Data analysis from the Intermountain EDW provided us with relative costs for LSP/HBO₂, BKA and AKA therapies. Other cost analysis papers have used different markers for cost estimation. These include percentage of billed charges [16,17], Medicare claims data [3,18],

and payments made by third-party payers [19]. We found only one other group that tried to define the actual cost of care using institutional financial data [20]. Gomez-Castillo, et al. determined costs for HBO₂ treatments in Sydney, Australia. At Prince of Wales Hospital, each HBO₂ treatment costs approximately USD \$300. In comparison, each HBO₂ treatment at our hospital costs USD \$630.

One of the first studies to show the cost benefit of HBO₂ as part of an integrated team approach in patients with limb-threatening DFU was Cianci, et al. [16]. They reported an 89% success rate in limb salvage similar to our rate of 91.7%. They demonstrated that hospital charges for wound care and HBO₂ treatments were considerably lower than those for major LEA.

Cianci and Hunt then followed a total of 42 patients with DFU who had at least seven HBO₂ treatments between 1983 and 1990. Follow-up data were collected in 1991 and 1993. In 1993, six patients were deceased (27%), but 15 of the 16 living (94%) had an intact limb for a durable repair lasting 55 months [17]. These rates are consistent with the results of the High Risk Foot Clinic at the Phoenix Veterans Administration Hospital, with an 85% limb salvage rate over an average follow-up of 55 months [14]. In our study, 59 of 96 patients (61.5%) now have been followed for 57 months, with a comparable durable repair of 93%.

Two studies have used a hypothetical patient model to show that adjunctive HBO₂ was cost-effective for DFU patients. Chuck, et al. used clinical outcomes from seven studies between 1987 and 2003 to predict amputation percentage in a model patient 65 years old with a life expectancy of 12 years. Cost data was extracted from Canadian Ministry of Health data. Standard care cost was CAD \$49,786 vs. standard care plus HBO₂ cost of CAD \$40,695 [21]. Guo, et al. used data from four prospective controlled clinical studies between 1987 and 1997 and developed a decision tree that predicted 205 major LEAs in the standard care group vs. 50 LEAs in the group with HBO₂. The estimated cost for 29 HBO₂ treatments in 2013 was USD \$17,114 vs. major LEA costs of USD \$57,135. They also estimated that incremental costs per additional quality-adjusted life-years gained for one, five and 12 years were USD \$35,117; USD \$6,643; and USD \$2,900, respectively

[22]. Both of these studies show limb salvage to be cost-effective and positively influences overall quality of life.

Current study

The patients in our study who followed the LSP and completed HBO₂ therapy had an overall 35.4% (34 of 96) mortality rate, while there was a 50% and 44% mortality rate for the BKA and AKA groups respectively. Our reported LSP/HBO₂ mortality rate is higher, but it is consistent with the 27% mortality rate reported by Cianci and Hunt [16,17]. In a study of midfoot amputations for DFU, Stone, et al. report one- and three-year mortality rates of 33% for trans-metatarsal amputation [23]. They also noted that functional ambulation occurred in 92% of patients.

Our data of avoiding a delayed amputation in 93 of 96 patients (93%) is similar to the 94% reported by Cianci and Hunt [17]. We have a reamputation rate of four of 28 patients (14.3%) converting a BKA to an AKA. This rate is identical to Ploeg, et al. [24].

LEA comparisons

In our LEA cohort, there was an overall mortality rate of 25 of 53 patients (47.2%). Ploeg, et al. reported on a series of LEA with a five-year mortality of 71% [24]. Using Medicare claims data from 1996, Dillingham, et al. documented a 33% mortality within one year of the index LEA [18]. Johannesson, et al. reported a 45% mortality among Swedish diabetes patients within one year of the index LEA [25].

While much of the DFU literature focuses on amputation and mortality rates as outcome indicators, there are those who recognize that these endpoints are primarily treatments for end-stage complications [26]. The disease process leading to this final outcome was cast many years previously for most patients. Changes in diabetes management earlier in the disease state may impact end-stage changes ultimately requiring LEA. The high rate of amputation-related complications and mortality suggests the palliative nature of LEA.

Strengths and weaknesses of this study

Strengths of this study are that two of the authors (JVE, CCVG) have provided care to all the individuals in the LSP/HBO₂ cohort and are able to abstract data

in detail from the EMR. This is a retrospective case series, but this database includes every WG3/4 DFU patient treated in our hyperbaric chamber. The other strengths are the extensive EDW and the detailed cost accounting techniques developed by the Intermountain Healthcare finance department.

Our wound care and hyperbaric medicine clinic serves a suburban and rural area where all of the hospitals in the north or east part of our catchment area belong to the same healthcare system. With our geographic isolation and the fact that the same EMR is used by all Intermountain hospitals, it is unlikely that we would have missed a hospital admission or death relevant to DFU.

LIMITATIONS

Limitations of the study are that it is a retrospective chart review on a sample of convenience that reflects standard medical practice in a regional referral center. Our DFU patients who received HBO₂ treatments had failed at least 30 days of advanced wound care. They are not comparable to DFU patients who are progressing toward healing by 30 days or those who present with obviously unsalvageable limbs. This adds an element of selection bias. However, these patients were motivated to show up for daily treatments and were closely case-managed according to the LSP.

Given the nature of this disease process and the outcomes of LSP with possible partial foot amputation vs. major LEA, it would be nearly impossible to design a blinded, randomized controlled study in order to obtain and analyze cost data. Our study design using intention-to-treat and a rich clinical database mitigates criticisms commonly leveled at retrospective cohort studies.

The amputee group is diverse. All were diabetics, and the majority of the amputees showed up in the emergency room with a non-salvageable limb. Some amputees chose amputation not knowing that an LSP/HBO₂ program was available.

Another limitation of the study is that some of the patients in the study have not yet passed the five-year mark since either LEA or HBO₂. Consequently our mortality statistics may underestimate five-year mortality. We have therefore chosen to present the overall mortality rate rather than stratifying by years from an arbitrary starting point.

Finally, cost estimates in our study do not include professional fees or skilled nursing facilities (SNF). Trying to normalize professional fees in cost accounting is fraught with difficulty and is not equitable to the physicians, since some are private practice FFS and others are part of large, multispecialty medical groups. In addition, costs for a stay in a skilled nursing facility are equally elusive.

CONCLUSION

Wagner Grades 3 and 4 diabetic foot ulcers, as well as below-the-knee and above-the-knee amputation, are associated with high five-year costs and mortality. Our limb salvage protocol, which includes HBO₂ therapy as part of the series of care, resulted in 88 of 96 patients (91.7%) healing at approximately half of the first-year costs of a lower extremity amputation. In addition, 82 of 88 of those patients (93.2%) initially healed and did not require a delayed amputation.

We conclude that a key impact on DFU healing is a collaborative, multidisciplinary team where all members of the team function with the highest level of expertise. Following an evidence-based protocol is cost-effective vs. having a primary LEA.

Conflict of interest

The authors have declared that no conflict of interest exists with this submission. All authors have participated in writing, editing, and reviewing the final paper.

■

REFERENCES

1. International Diabetes Federation. IDF diabetes atlas, 6th ed. Brussels, Belgium: International Diabetes Federation, 2014 Update.
2. Utah Department of Health, Fact Sheet. Diabetes in Utah. http://www.choosehealth.utah.gov/documents/pdfs/factsheets/factSheet_diabetes.pdf. Last accessed 06/01/2015.
3. Driver VR, Fabbi M, Lavery LA, Gibbons G. The costs of diabetic foot: the economic case for the limb salvage team. *J Vasc Surg* 2010; 52(3 Suppl):17S-22S.
4. Margolis DJ, Malay DS, Hofstede OJ et al. Economic burden of diabetic foot ulcers and amputations. *Diabetic Foot Ulcers. Data Points #3* (prepared by the University of Pennsylvania DEcIDE Center, under Contract No. HHSA290200500411). Rockville, MD: Agency for Healthcare Research and Quality. January 2011. AHRQ Publication No. 10(11)-EHC009-2-EF.
5. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. *JAMA* 2005; 293(2):217-228.
6. Centers for Disease Control and Prevention: Number of hospital discharges for nontraumatic lower extremity amputation with diabetes as a listed diagnosis, United States, 1988-2009 <http://www.cdc.gov/diabetes/statistics/lea/fig1.htm>. Last accessed 06/01/2015.
7. Margolis DJ, Malay DS, Hoffstad OJ, et al. Incidence of diabetic foot ulcer and lower extremity amputation among Medicare beneficiaries, 2006 to 2008. *Data Points #2*. (Prepared by the University of Pennsylvania DEcIDE Center, under Contract No. HHSA290200500411). Rockville, MD Agency for Healthcare Research and Quality. January 2011. AHRQ Publication No. 10(11)-EHC009-1-EF.
8. Schofield CJ, Libby G, Brennan GM et al. Mortality and hospitalization in patients after amputation: a comparison between patients with and without diabetes. *Diabetes Care*. 2006; 29(10):2252-6.
9. Brem H, Sheehan P, Rosenberg HJ, Schneider JS, Boulton AJM. Evidence-based protocol for diabetic foot ulcers. *Plast Reconstr Surg* 2006; 117(7 Suppl):193S-209S.
10. Brem H, Sheehan P, Boulton AJM. Protocol for treatment of diabetic foot ulcers. *Am J Surg* 2004; 187(5A): 1S-10S.
11. Centers for Disease Control and Prevention. National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States, 2011. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011.
12. Frykberg RG, Zgonis T, Armstrong DG et al. Diabetic foot disorders. A clinical practice guideline (2006 revision). *J Foot Ankle Surg* 2006; 45(5 Suppl):S1-S66.
13. Gottrup F. Optimizing wound treatment through health care structuring and professional education. *Wound Repair Regen* 2004; 12(2):129-133.
14. Van Gils CC, Wheeler LA, Mellstrom M, et al. Amputation prevention by vascular surgery and podiatry collaboration in high-risk diabetic and non-diabetic patients. *Diabetes Care* 1999; 22:678-683.
15. Gottrup F. A specialized wound-healing center concept: importance of a multidisciplinary department structure and surgical treatment facilities in the treatment of chronic wounds. *Am J Surg* 2004; 187(5A):38S-43S.
16. Cianci P, Petrone G, Drager H, et al. Salvage of the problem wound and potential amputation with wound care and adjunctive hyperbaric oxygen therapy: an economic analysis. *J Hyperbaric Medicine* 1988; 3:127-141.
17. Cianci P, Hunt T. Long-term results of aggressive management of diabetic foot ulcers suggest significant cost effectiveness. *Wound Repair Regen* 1997; 5(2):141-146.
18. Dillingham TR, Pezzin LE, Shore AD. Reamputation, mortality, and health care costs among persons with dysvascular lower-limb amputations. *Arch Phys Med Rehabil* 2005; 86(3):480-486.
19. Rice JB, Desai U, Cummings AKG, Birnbaum HG, Skornicki M, Parsons NB. Burden of diabetic foot ulcers for medicare and private insurers. *Diabetes Care* 2014; 37(3):651-658.
20. Gomez-Castillo JD, Bennett MK. The cost of hyperbaric therapy at the Prince of Wales Hospital, Sydney. *SPUMS J* 2005; 35:194-198.
21. Chuck AW, Hailey D, Jacobs P, Perry DC. Cost-effectiveness and budget impact of adjunctive hyperbaric oxygen therapy for diabetic foot ulcers. *Intl J Technol Assess Health Care* 2008; 24(2): 178-183.
22. Guo S, Counte MA, Gillespie KN, Schmitz H. Cost-effectiveness of adjunctive hyperbaric oxygen in the treatment of diabetic ulcers. *Intl J Technol Assess Health Care* 2003; 19(4): 731-737.
23. Stone PA, Back MR, Armstrong PA, et al. Midfoot amputations expand limb salvage rates for diabetic foot infections. *Ann Vasc Surg* 2005; 19(6):805-811.
24. Ploeg AJ, Lardenoye JW, Vrancken Peeters MP, Breslau PJ. Contemporary series of morbidity and mortality after lower limb amputation. *Eur J Vasc Endovasc Surg* 2005; 29(6):633-637.
25. Johannesson A, Larsson GU, Ramstrand N, Turkiewicz A, Wiréhn AB, Atroshi I. Incidence of lower-limb amputation in the diabetic and nondiabetic general population: a 10-year population-based cohort study of initial unilateral and contralateral amputations and reamputations. *Diabetes Care* 2009; 32(2):275-280.
26. Jeffcoate WJ. The incidence of amputation in diabetes. *Acta Chir Belg* 2005; 105(2):140-144.

