

Lower limb complications



Picking up the pieces

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Amputation is typically viewed as the final event in the management of diabetic foot ulceration. Over the years, the reduction of amputations has been regarded as the primary aim of multidisciplinary foot care teams and, despite a realisation that amputation can be a positive outcome for a patient racked by sepsis and debilitated by chronic ulceration, amputation is often seen as a failure.

Among the four articles summarised in this quarter's digest are three related to amputation. The first, by Fedorko et al, is another nail in the coffin of hyperbaric oxygen therapy (HBOT) for managing foot ulceration. In a well-conducted randomised trial, the authors concluded that HBOT does not offer any additional advantage to comprehensive wound care in reducing the indication for amputation or facilitating wound healing in people with chronic diabetic foot ulceration.

The next two articles deal with the aftermath of amputation. Davie-Smith and colleagues used an amputation rehabilitation database to look at outcomes following major amputation in people with and without diabetes in Scotland. They confirmed that people with diabetes account for nearly half of all the

major amputations performed, despite comprising only 4% of the Scottish population. In addition, people with diabetes were younger at amputation and were more likely to have a below-knee amputation. Despite this, prosthesis fitting rates were low in both groups, with under 40% of people receiving a prosthesis. We can expect 60% of our patients with a major amputation to be wheelchair-reliant for the rest of their lives.

As Wanivenhaus and colleagues report, even if initially amputated at the transtibial (below-knee) level, up to 25% of people with diabetes may require revision to more proximal levels within the year. Indeed, the authors suggest that primary selection of a more proximal level of amputation might actually be better in the long run, despite the negative impact on limb fitting as a result.

Sadly, as Walsh et al report, the increased mortality rate after foot ulceration – in this case, 42.2% at 5 years – persists. We are still no closer to preventing this toll in the wider diabetes foot community than we were 8 years ago (Young et al, 2008).

Young MJ, McCordle JE, Randall LE, Barclay JI (2008) Improved survival of diabetic foot ulcer patients 1995–2008: possible impact of aggressive cardiovascular risk management. *Diabetes Care* 31: 2143–7

Diabetes Care

Hyperbaric oxygen therapy does not reduce amputation risk for DFUs

Readability ✓✓✓

Applicability to practice ✓✓✓

WOW! Factor ✓✓✓

1 In this double-blind, randomised controlled trial, people with non-healing diabetic foot ulcers were randomised to receive hyperbaric oxygen therapy (HBOT; breathing oxygen at 244 kPa) or sham treatment (breathing air at 125 kPa), both in combination with comprehensive wound care.

2 A total of 107 people with diabetes and foot lesions of ≥ 4 weeks' duration were enrolled, of whom 103 were available for final analysis. All received the active treatment or sham for 90 minutes every day for 1 month.

3 At 12 weeks after randomisation, 11 of 49 people in the HBOT group and 13 of 54 in the sham group met the criteria for amputation, as assessed by an independent vascular surgeon (22% vs 24%; $P=0.846$).

4 Conversely, 10 HBOT recipients and 12 sham recipients were healed (20% vs 22%; $P=0.823$).

5 Other assessments of healing (wound size, wound scores and wound classification) were all similar between the two arms.

6 The authors note that their findings may be limited by the fact that actual amputation rates were not used as an endpoint; however, this has the benefit of eliminating the confounding influence of other factors that affect the final decision to amputate.

7 The authors conclude that HBOT confers no additional benefit over comprehensive wound care in reducing amputation risk.

Fedorko L, Bowen JM, Jones W et al (2016) Hyperbaric oxygen therapy does not reduce indications for amputation in patients with diabetes with nonhealing ulcers of the lower limb: a prospective, double-blind, randomized controlled clinical trial. *Diabetes Care* 39: 392–9

ADA 2016

An automated home monitor to detect foot ulceration



1 These authors have developed an automated, telemedicine foot mat for home use that can predict development of ulceration by measuring temperature disparities

between the left and right feet at six plantar locations.

2 In this prospective study, the foot mat was evaluated in 129 high-risk people with diabetes over 34 weeks.

3 The system predicted as many as 90% of the 53 non-acute plantar ulcers that occurred, at an average of 5 weeks prior to clinical presentation.

4 Different temperature asymmetry cut-offs led to sensitivities ranging from 50% to 97% and specificities ranging from 43% to 81%.

Frykberg RG, Rothenberg GM, Fitzgerald RH et al (2016) An automated home monitor for the early detection of diabetic foot ulcers. *American Diabetes Association 76th Scientific Sessions*: abstract 141-OR

Prosthet Orthot Int

Prosthesis fitting rates after major amputation in Scotland

Readability ////
 Applicability to practice ////
 WOW! Factor ////

- In this retrospective cohort study, the authors looked at prosthesis fitting rates in 1735 people who underwent major lower limb amputation owing to peripheral artery disease with or without diabetes.
- Of the overall cohort, 834 (48%) had diabetes. Compared to people without diabetes, those with the condition were significantly younger (mean age, 67.5 vs 71.1 years) and were more likely to be male (70%).
- People with diabetes were more likely to undergo amputation below the knee than above it compared with people without the condition (transtibial:transfemoral amputation ratio, 2.33 vs 0.93). This is probably due to diabetes-related distal arterial disease below the knee, with relative sparing of the proximal vessels.
- Only 38% of the overall cohort were fitted with a prosthetic limb (72% of those with a below-knee amputation and 16% of those with an above-knee amputation). Prosthesis rates were similar between people with and without diabetes.
- In a binary logistic regression model, men were more likely than women to receive a prosthesis (odds ratio [OR], 1.71), as were those with a below-knee rather than an above-knee amputation (OR, 2.17). Age was negatively correlated with prosthesis fitting (OR, 0.97 per year increase).
- The mortality rate during the rehabilitation period was 17% overall and 22% for above-knee amputation.

Davie-Smith F, Paul L, Nicholls N et al (2016) The impact of gender, level of amputation and diabetes on prosthetic fit rates following major lower extremity amputation. *Prosthet Orthot Int* 5 Feb [Epub ahead of print]

Orthopedics

Revision rates and risk factors after lower extremity amputation

Readability ////
 Applicability to practice ////
 WOW! Factor ////

- In this retrospective review from the University of Zurich, the authors sought to determine the risk factors for revision amputation in people with T2D and/or peripheral artery disease who underwent amputation of the lower limb.
- A total of 421 consecutive patients who underwent primary amputation between 2002 and 2012 were evaluated, of whom 69.4% were men and the mean age was 68.8 years.
- Following primary amputation, the overall revision rate was 25.2% ($n=106$), half of which ($n=53$) were at the same level and half ($n=53$) were at a more proximal level. More than one revision was required in 26 participants (24.5% of revisions).
- Both T1D (odds ratio [OR], 3.73) and T2D (OR, 2.30) were independent predictors of a more proximal revision. Use of insulin was also a risk factor (OR, 1.77).
- Polyneuropathy (OR, 1.68) and diabetic nephropathy (OR, 2.26) were associated with revision. Revision rates also increased in line with preoperative Fontaine stage.
- People who underwent revision amputation were significantly younger (mean age, 65.2 years vs 68.5 years). This may be because younger people are more likely to refuse a more proximal operation at first.
- Need for revision surgery was independent of smoking, alcohol consumption, BMI, gender, duration of diabetes and preoperative HbA_{1c}.

Wanivenhaus F, Mauler F, Stelzer T et al (2016) Revision rate and risk factors after lower extremity amputation in diabetic or dysvascular patients. *Orthopedics* 39: e149–54

Diabet Med

Independent link between DFUs and mortality risk

Readability ////
 Applicability to practice ////
 WOW! Factor ////

- These authors used data from THIN (The Health Improvement Network), a UK-based registry of anonymous general practice data, to determine whether the known association between diabetic foot ulcers (DFUs) and death could be attributed to comorbidity with other risk factors.
- Data on 414 523 people with diabetes (mainly T2D) from 2003 to 2012 were evaluated. Of these, 20 737 (5.0%) developed a DFU and 77 520 (18.7%) died.
- Of those with a DFU, 8.1% died within 12 months of diagnosis, and the 5-year death rate was 42.2%.
- People with a DFU were more than three times as likely to die during the study period (unadjusted hazard ratio [HR], 3.43).
- As expected, adjustment for other risk factors, including age, gender, HbA_{1c}, chronic kidney disease, Charlson Comorbidity Index score, myocardial infarction, stroke, peripheral vascular disease, congestive heart failure, malignancy and smoking, reduced the HR, but only by around 28% (adjusted HR, 2.48).
- The authors point out that a DFU is unlikely to be the direct cause of death; therefore, it is likely that other unknown factors are involved in the increased mortality risk. It is also possible that a DFU is a marker of increased medical frailty necessitating increased healthcare provider vigilance in the care of the patient.
- Whatever the explanation, DFUs should be viewed as a major warning sign of increased mortality risk.

Walsh JW, Hoffstad OJ, Sullivan MO, Margolis DJ (2015) Association of diabetic foot ulcer and death in a population-based cohort from the United Kingdom. *Diabet Med* 15 Dec [Epub ahead of print]

“The authors conclude that hyperbaric oxygen therapy confers no additional benefit over comprehensive wound care in reducing amputation risk.”