Clinical DIGEST 5

Lower limb complications

Life is what you make it: Quality of life in people with diabetic foot ulcers



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he longer I work with patients with diabetes and foot ulceration the more I learn about the major impact that ulceration and painful neuropathy have on their lives. Isolation, loss of income, restriction of activities, pain and infection often lead to depression and despair. Trying to maintain

the hope that the ulcer will heal, minimising the fears of amputation where healing is unrealistic and supporting patients through amputation when it is required, is a critical skill in managing foot ulceration. Valensi et al's paper on quality of life in patients with diabetic foot ulcers (see right) brings this into focus.

In the Valensi study, 59% of 239 patients with at least one current ulcer had also had a previous ulcer, in keeping with previous reports of re-ulceration rates. Almost one-third of this group had experienced two or more ulcers. Patients with ulcers were more likely to be male, to have

had diabetes for a longer time, to have more other diabetes complications and to be on insulin. These findings make this population typical of most series. The study found that the higher the Wagner grade the worse the perceived quality of life. Importantly, quality of life was also worsened by the extent to which the patient was irritated with the appearance of his/her ulcer or the duration of the healthcare process. Raising the awareness of these issues among health professionals can only aid care.

One of the more difficult aspects of foot care is the management of painful neuropathy. We have recently seen the release of pregabalin, and, in America, duloxetine is now available for use. Sadly, trials of new agents continue to be compared against placebo, rather than against each other. A study on the effects of duloxetine by Goldstein et al (see below) showed that, while there appears to be a dose-dependent relationship, 20 % of patients had to stop the trial due to adverse events. Hopefully there will be more, and better, evidence when the drug is launched in the UK.

PAIN

Duloxetine safe and efficacious in treating painful diabetic neuropathy

Readability	11
Applicability to practice	1111
WOW! factor	111

- Studies in animals have suggested that duloxetine could be effective in treating persistent pain in humans.
- This 12-week, multi-centre, double-blind study was designed to assess the safety and efficacy of duloxetine compared with placebo. Four-hundred-and-fifty-seven people experiencing neuropathic pain as a result of type 1 or type 2 diabetes

were randomly assigned to receive duloxetine 20 mg/day (once-daily), 60 mg/day (once-daily), 120 mg/day (60 mg twice-daily) or placebo.

The primary efficacy measure was mean 24-h Average Pain Score calculated weekly.

Treatment with duloxetine 60 mg/day and 120 mg/day resulted in statistically significant improvement in mean 24-h Average Pain Score compared with placebo. The improvements began 1 week after randomisation and were sustained until the end of the trial. Benefits were also observed in secondary measures.

The investigators concluded that duloxetine 60 mg/day and 120 mg/day is safe and efficacious in the relief of painful peripheral diabetic neuropathy.

Goldstein DJ, Lu Y, Detke MJ et al (2005) Duloxetine vs. placebo in patients with painful diabetic neuropathy. *Pain* **116**: 109–18

DIABETES METABOLISM



Correlation between quality of life and foot ulcer properties

Readability	1111
Applicability to practice	1111
WOW! factor	1111

This study aimed to compare healthrelated quality of life (HRQL) in people with diabetes with and without foot ulcers.

In addition, the study aimed to investigate the relationships between diabetes, HRQL and clinical characteristics of diabetic foot ulcers.

This cross-sectional, observational study was carried out in France and involved 355 people with diabetes (239 with diabetic foot ulcers [Group 1] and 116 without [Group 2]).

A generic HRQL questionnaire was used to assess HRQL in all participants, and socio-demographic and clinical variables were also measured. For people in Group 1, foot ulcer severity was assessed using Wagner's classification and the Diabetic Foot Ulcer Scale (DFS) was used to determine disease-specific HRQL.

For all 36 domains of the HRQL questionnaire, HRQL was significantly lower in Group 1 than in Group 2 (*P*=0.0001).

In Group 1, poorer HRQL was found in people with more severe ulcers in the DFS domains of Leisure, Side Effect, Daily Activities, Emotions and Treatment. HRQL was also found to be inversely associated with the number of foot ulcers.

The authors concluded that low HRQL is associated with both the number of foot ulcers and their severity.

Valensi P, Gilrod I, Baron F et al (2005) Quality of life and clinical correlates in patients with diabetic foot ulcers. *Diabetes Metabolism* **31**: 263–71

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Peripheral angioplasty as an alternative to primary amputation

- Lower extremity bypass surgery as a treatment for critical limb-threatening ischaemia (CLI) is supported by robust evidence. Recently, however, there has been interest in catheter-based treatments.
- In this study, the investigators aimed to assess outcomes following the use of limb-salvage peripheral angioplasty in poor surgical candidates who would otherwise be considered for primary amputation.
- This retrospective clinical study examined 67 people (76 limbs) with CLI over a 33-month period. The limbs were treated for rest pain, non-healing ulcers or gangrene.
- Limb salvage (defined as the preservation of a foot, functional without the aid of a prosthesis) was achieved in 64 (83.5%) limbs.
- Clinical failure (defined as major amputation; n=12) correlated with the combined presence of diabetes, gangrene and arterial occlusion (P=0.018), and with gangrene (P=0.032).
- Outcomes were not adversely affected by the following single variables: age, sex, diabetes, renal failure.
- The investigators concluded that peripheral arterial angioplasty should be considered in people with CLI who are not suitable for bypass surgery.

Terefa G, Hoch J, Turnipseed WD (2005) Limbsalvage angioplasty in vascular surgery practice. *Journal of Vascular Surgery* **41**(6): 988–93

ARCHIVES OF INTERNAL MEDICINE

Low ankle-brachial index predicts rise in creatinine level

Readability / / / /
Applicability to practice / / / /
WOW! factor / / / /

- 1 It has been shown that a low ankle-brachial index (ABI) is associated with increased risk of cardiovascular mortality, myocardial infarction, stroke and peripheral vascular disease events.
- The investigators hypothesised that low ABI would also be associated with a decline in renal function over time.
- The investigators examined the relationship between ABI at baseline and the change in serum creatinine level occurring over 3 years in 13 655 participants in the Atherosclerosis Risk In Communities (ARIC) study. The ARIC trial was a prospective cohort study on cardiovascular disease in men and women from several USA communities aged 45–64 years.
- An increase in serum creatinine of 50% or more was observed in 2.16% of participants with ABI <0.9 at baseline; in 0.9% of those with ABI 0.9–0.99; and 0.48% of those with ABI >1.
- In multivariate analysis, those participants with ABI <0.9 were more than twice as likely to experience an increased serum creatinine level than those with ABI ≥1 (odds ratio 2.5; 95% confidence interval 1.1-5.7; P=0.04).
- The authors concluded that a low ABI predicts an increase in serum creatinine over time.

O'Hare AM, Rodriguez RA, Bacchetti P (2005) Low ankle-brachial index associated with rise in creatinine level over time. *Archives of Internal Medicine* **165**: 1481–5



Post-amputation outcomes predicted by preoperative clinical factors

Ambulation following limb amputation has not been well studied despite being an important factor in determining functional independence. Indeed, limb salvage and arterial reconstruction patency have typically been used as measures of treatment success rather than independent living status or ambulation.

- The investigators of this study sought, therefore, to investigate the relationship between a number of preoperative clinical factors and postoperative functional outcomes following a major limb amputation.
- A retrospective review of 627 major amputations (553 people) was carried out to correlate preoperative factors (such as age, comorbidities, ambulatory and independent living status) with postoperative factors (such as prosthetic useage, survival, maintenance of ambulation and independent living status).
- Among other correlates, it was found that statistically significant preoperative factors associated with a failure to maintain ambulation included age ≥70 years, bilateral amputation and the presence of end-stage renal disease.
- The authors concluded that, in younger, healthy people who undergo below-knee amputations, amputation should not necessarily be perceived as treatment failure, since these patients achieved functional outcomes comparable to those associated with revascularisation therapy.

Taylor SM, Kalbaugh CA, Blackhurst DW et al (2005) Preoperative clinical factors predispose postoperative functional outcomes after major lower limb amputation: An analysis of 553 consecutive patients. Journal of Vascular Surgery 42: 227–35 In younger, healthy people, amputation should not necessarily be perceived as treatment failure.

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