## Clinical DIGEST 5

## **Lower limb complications**

DIABETES CARE

### DCCT intensivetherapy group reap benefits 8 years on

- The purpose of this study was to evaluate the impact of prior intensive treatment of diabetes on neuropathy in participants from the Diabetes Control and Complications Trial (DCCT).
- Pollowing the conclusion of the DCCT, participants from the intensive group were encouraged to maintain intensive therapy, and those from the conventional therapy group were encouraged to begin intensive therapy.
- The Michigan Neuropathy
  Screening Instrument (MNSI) was
  used to assess neuropathy as part of the
  DCCT follow-up Epidemiology of Diabetes
  Intervention and Complications (EDIC)
  study.
- A total of 1257 people participated in the neuropathy assessment of the first EDIC examination.
- Based on the MNSI questionnaire or foot examination, it was found that the former intensive group of the DCCT showed a lower prevalence of neuropathy than the conventional-therapy group.
- Signs and symptoms of neuropathy remained less prevalent among the former intensive group compared with the conventional group, despite similar levels of glycaemic control.
- Prior intensive therapy at the beginning of the EDIC study reduced the odds of having signs and symptoms of neuropathy by 45% and 64%, respectively, with similar odds reductions observed for both neuropathic signs and symptoms across 8 years of follow-up.
- The benefits of 6.5 years of intensive therapy on neuropathy status lasted for at least 8 years after the conclusion of the DCCT.

Martin CL, Albers J, Herman WH et al (2006) Neuropathy among the Diabetes Control and Complications Trial cohort 8 years after trial completion. *Diabetes Care* **29**(2): 340–4

## Intensive therapy and neuropathy: If I could turn back time...



Matthew Young, Consultant Physician, Edinburgh Royal Infirmary first started working in diabetes in Sheffield in 1990. At that time there was considerable excitement about the use of aldose reductase inhibitors and gamma-linolenic acid to possibly reverse neuropathy. At best they might hold the decline of nerve function that occurs with time. However,

the early promise in animal studies was not sufficiently supported by trials on humans. At least a follow-up to the Diabetes Control and Complications Trial (DCCT; Martin et al, 2006; see left) gives us further hope. Some 8 years after the end of the DCCT, its intensively treated group continued to have a lower prevalence of neuropathy signs and symptoms. This confirms other similar long-term follow-up studies such as EURODIAB (European Community sponsored Concerted Action on the Epidemiology and Prevention of Diabetes) and the effects of intensive control during pregnancy on neuropathy. How long a person needs good control to delay or avoid complications might be an interesting question for the future.

Alternatively we could shine a coloured light on patients in the clinic. I am an advocate of

complementary therapies where conventional therapies fail. However, unless the authors of a study utilising phototherapy (Powell et al, 2006; summarised on page 104) have other data it is hard to see how they can claim to have reversed neuropathy. There are no direct sensory measurements, only falls and symptoms as surrogates. A reduction in falls and painful symptoms over time is hard to evaluate without a control group, and true randomised controlled trials with dummy light treatments need to be performed before this can be accepted without question.

I first read about tarsal tunnel decompression a few years ago. In theory people with diabetes are more prone to entrapment neuropathies due to the so called 'double crush'. Median nerve compression is a standard therapy but the idea of dissecting out the nerves and branches around the ankle seems a little extreme to me. The benefits obtained in this uncontrolled study (Ducic et al, 2006; summarised on page 104), where 11 of 14 patients had diabetes, are statistically significant but are they clinically relevant? It seems hard to perform placebo surgery but a larger series would be needed before this could be accepted as routine too.

THE CLINICAL
JOURNAL OF PAIN

#### Validation of the Neuropathic Pain Scale

- The purpose of this study was to assess the utility of evaluating the multiple components of neuropathic pain in an analgesic clinical trial.
- A total of 159 people with diabetesrelated foot pain were randomly assigned to receive an active opioid analgesic (controlled-release oxycodone) or placebo for 6 weeks; the Neuropathic Pain Scale (NPS) was administered prior

to, during and after treatment.

- The analgesic produced greater decreases in pain unpleasantness, global pain intensity, and sharp, dull and deep pain sensations than the placebo.
- There was a higher rate of response to opioid treatment condition for intense, unpleasant, deep and surface pain, compared with the placebo.
- The analgesic did not significantly reduce hot, cold, sensitive or itchy pain sensations relative to the placebo.
- The use of the NPS as a tool to characterise the multidimensional nature of the experience of neuropathic pain, and for detecting changes in neuropathic pain with treatment, is thus supported, conclude the authors.

Jensen MP, Friedman M, Bonzo D, Richards P (2002) The validity of the neuropathic pain scale for assessing diabetic neuropathic pain in a clinical trial. *The Clinical Journal of Pain* **22**(1): 97–103

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## Lower limb complications Clinical DIGEST

<sup>C</sup> Although there is widespread use of topical agents and dressings that contain silver for the treatment of diabetic foot ulcers. the authors conclude that no **randomised** clinical trials or controlled clinical trials exist that evaluate their clinical effectiveness. <sup>5</sup>

COCHRANE DATABASE OF SYSTEMATIC REVIEWS

### Lack of trials that examine silverbased dressings

Readability	1	1	1	/
Applicability to practice	1	1	✓	
WOW! factor	1	1	1	

- This article reviewed the effects of silver-containing topical agents and dressings on infection rates and healing of foot ulcers in people with diabetes.
- The Cochrane Wounds Group
  Specialised Register, the Cochrane
  Central Register of Controlled Trials,
  MEDLINE, EMBASE and CINAHL were
  searched.
- The Journal of Wound Care was hand-searched, researchers, manufacturers and international wound groups were contacted to find unpublished trials, and websites for wound groups and www.worldwide

wounds.com were searched.

- Randomised controlled trials and non-randomised controlled clinical trials were eligible if they involved people with type 1 or type 2 diabetes and foot ulcers; met requirements for allocation, randomisation and concealment; compared the intervention with a placebo or sham dressing, an alternative non-silver-based dressing or no dressing; and reported outcomes representing healing rate or infection.
- No trials were identified as being eligible for inclusion in the review; in the absence of data it was not possible to perform planned analyses.
- Although there is widespread use of topical agents and dressings that contain silver for the treatment of diabetic foot ulcers, the authors conclude that no randomised clinical trials or controlled clinical trials exist that evaluate their clinical effectiveness.

Bergin SM, Wraight P (2006) Silver based wound dressings and topical agents for treating diabetic foot ulcers. *Cochrane Database of Systematic Reviews* **Issue 1**: CD005082

oppose their shilling to stand still

**ANNALS OF PLASTIC SURGERY** 

### Peripheral nerve decompression offers new hope

This exploratory study aimed to determine whether decompression of the four medial ankle tunnels could improve foot sensibility, increase balance and proprioception and decrease falls in people with impaired lower extremity sensation. Fourteen people with peripheral neuropathy participated in the study. Ten were females. The average age was 67 years.

- Neuropathy was the consequence of diabetes in 72% of people, a combination of diabetes and hypothyroidism in 7%, and chemotherapy in 7%. In 14% of cases neuropathy was idiopathic.
- Participants were evaluated preoperatively and postoperatively to

assess their ability to stand still maintaining their balance with their eyes open and closed (sway), as well as their lower extremity sensibility.

Six participants had bilateral lower extremity peripheral nerve decompression; eight participants had unilateral peripheral nerve decompression.

- Mean heel and toe sensibilities improved by 7% and 9% in the unilateral group, respectively, and by 32% and 42% in the bilateral group, respectively.
- In the unilateral group, preoperative and postoperative sway comparison showed a reduction with eyes open and closed by 5% and 31%, respectively, and by 23% and 145% in the bilateral group, respectively.
- The authors conclude that bilateral lower extremity peripheral nerve decompression may help improve pedal sensibility and balance in people with peripheral neuropathy.

Ducic I, Taylor NS, Dellon AL (2006) Relationship between peripheral nerve decompression and gain of pedal sensibility and balance in patients with peripheral neuropathy. *Annals of Plastic Surgery* **56**(2): 145–50

# AGE AND AGEING

# Rise in quality of life with reversal of diabetic neuropathy

- This study aimed to determine if restoration of sensation that was impaired due to diabetic peripheral neuropathy (DPN) would reduce the fear of falling and the number of falls and improve activities of daily living (ADLs) in a Medicare-aged population in the US.
- Participants comprised 252 people (with a mean age of 76 years) who had documented monochromatic near-infrared phototherapy-mediated symptomatic reversal of DPN (of a mean duration of 8.6 months).
- Participants responded to a health status questionnaire, after the symptomatic reversal of DPN.
- The fear of falling and the incidence of falls decreased within 1 month after reversal of peripheral neuropathy, and stayed low after 1 year.
- Improved ADLs were evident soon after reversal of peripheral neuropathy, and improved further after 1 year.
- Reversal of peripheral neuropathy in a clinician's office and subsequent use of monochromatic near-infrared phototherapy at home was associated with a 79% decrease in balance-related fear of falling, 78% reduction in falls and a 72% increase in ADLs.
- The authors conclude that their results suggest that reversal of DPN has a substantial, favourable, long-term socioeconomic impact on people with DPN and the Medicare system in the US, and improves the quality of life for older people with diabetes and peripheral neuropathy.

Powell MW, Carnegie DH, Burke TJ (2006) Reversal of diabetic peripheral neuropathy with phototherapy (MIRE<sup>Th</sup>) decreases falls and the fear of falling and improves activities of daily living in seniors. *Age and Ageing* **35**(1): 11–6

'Bilateral lower extremity peripheral nerve decompression may help improve pedal sensibility and balance in people with peripheral neuropathy.'