

Family Physician Corner

Diabetic Foot-Evidence that counts

Abeer Al-Saweer, MD*

Evidence-based medicine has systemized the medical thinking in each and every branch of the health profession. Chronic diseases like diabetes have enjoyed a major share in evidence-based medicine. It is the intention of this paper to highlight the evidence in the care of diabetic foot both in prevention and management.

Why evidence?

Grunfeld (1991), in a review of diabetic foot management, noted that “Much of what is written in textbooks about diabetic foot ulcers is the result of personal clinical experience of talented clinicians and teachers who feel strongly about their views. Yet, one group may state dogmatically that a procedure is contraindicated and dangerous, while another views it as the treatment of choice¹”.

The previous quotation denotes the controversy over the management of diabetic foot. It shows the diversity in the practice and the need to establish a standardized approach. Diabetic foot disease affects nearly two million patients with diabetes in the United States annually. It is estimated that almost \$200 million is spent annually strictly for the care of the diabetic foot².

Amputation rate is more in people with diabetes than the general population, with a rate of major amputations per year of 3.83 per 1000 in people with diabetes and 0.38 per 1000 in the general population (Wrobel et al, 2001)².

All the above facts oblige a standardized methodology in dealing with diabetic foot to reduce the cost and the morbid consequences. This will be ascertained through randomized clinical trials (RCTs) in both prevention and management.

* Consultant Family Physician-Diabetologist
Directorate of Health Centres
Ministry of Health
Kingdom of Bahrain

Evidence is also needed to answer troublesome clinical questions that have vague answers like:

- In people with diabetes, who should be screened for diabetic foot disease, when after diagnosis of diabetes should screening start, and how often should foot screening is done?
- Which test(s) or method(s) should be used to screen for diabetic foot disease?
- Does foot care education improve patient knowledge and foot care skills or prevent foot problems developing?
- Which interventions have been shown to be effective in preventing and treating ulceration, and in preventing amputation?³

All the above questions and others should be answered in a scientific systemized manner. It is not until evidence is well-established that we can answer these questions.

Is there enough evidence?

Online literature search and journals search specialized in the care of diabetic foot have produced corroboration that there is lack of evidence in the practice of diabetic foot³. This paucity in knowledge is due to the lack of adequately sized high quality clinical studies⁴. This may be attributable to several factors. These factors may include the need for great number of patients over long period of time to measure the effect of one parameter. Also, the variability of the origin and effect of diabetic foot like the wound depth and patient factors makes it difficult to standardize the trials. The funding of such huge trials is costly and unjustifiable to drug and dressing companies⁵.

The lack of evidence in the management of diabetic foot has led to decision on appropriate clinical management made with uncertain evidence. Even when randomized controlled trials (RCT) have been performed, the quality of a specific study cannot be ascertained, since there is no agreement about certain parameters that may affect the end result and interpretation of the study.

How to develop evidence in the practice of diabetic foot?

Lots of collaboration, funding and consultation are needed to establish a base of recent evidence in diabetic foot prevention and management. To create recent evidence base would require hundreds and possibly thousands of participants. How do we decide which trials to prioritize and how to standardize protocols to conduct the trials?⁶

Tables 1 and 2 depict the levels of recommendations adopted from reference 7 and the following is summary of recommendations in prevention and management of diabetic foot disease⁸.

Table 1: Types of Evidence

Level	Type of Evidence
Ia	evidence from meta-analysis of randomised controlled trial
Ib	evidence from at least one randomised controlled trial
IIa	evidence from at least one controlled study without randomisation
IIb	evidence from at least one other type of quasi-experimental study
III	evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies
IV	evidence from expert committee reports or opinions and/or clinical experience of respected authorities

Table 2: Grading of recommendations

Grade	Evidence
A	directly based on category I evidence
B	directly based on category II evidence, or extrapolated recommendation from category I evidence
C	directly based on category III evidence, or extrapolated recommendation from category I or II evidence
D	directly based on category IV evidence, or extrapolated recommendation from category I, II or III evidence

- **PATIENT EDUCATION**

Foot care education is recommended as part of a multidisciplinary approach in all patients with diabetes. **B**

- **STRUCTURED FOOT REVIEW**

All patients with diabetes should be screened for foot disease.

There is no evidence to support how frequent the screening is; however the guideline group considers that at least annual screening from the diagnosis of diabetes is appropriate. **D**

Clinical neuropathy disability scores, 10 g monofilaments, or vibration perception thresholds are all appropriate methods for neuropathy screening. **C** The mentioned tests are used to ascertain the presence of neuropathy in diabetics.

- **STRUCTURED FOOT CARE**

All patients with diabetes should have access to structured diabetic foot care.

- **FOOTWEAR, ORTHOSES AND TOTAL CONTACT CASTING**

Patients with diabetic foot disease should be advised to wear high-quality, cushioned-soled trainers rather than ordinary shoes. **B**

- Custom-built footwear or orthotic insoles should be used to reduce callus severity and ulcer recurrence. **B**
- Patients who have unilateral plantar ulcers should be considered for treatment using total contact casting to optimize the healing rate of ulcers. **B**

- **ARTERIAL RECONSTRUCTION**

All patients with tissue loss (various degrees of necrosis) and arterial disease should be considered for arterial reconstruction. **B**

- **PHARMACOLOGICAL THERAPY**

In non-healing chronic neuropathic ulcers after optimal pressure relief, use of topical RGD peptide, CT-102 or becaplermin should be considered to speed up healing rates. **A**

The above quoted topical agents are used to promote wound healing through various growth stimulating techniques.

Subcutaneous granulocyte-colony stimulating factor (g-csf) should be considered in the treatment of diabetic foot infections. **B**

- **PAINFUL DIABETIC NEUROPATHY**

Tricyclic antidepressants (TCAs) should be used as first line therapy in painful diabetic neuropathy. **A**

TCAs exert analgesic effect independent of its antidepressant activity.

Gabapentin is also recommended in painful diabetic neuropathy and is associated with fewer side effects than TCAs and older anticonvulsants. **B**

Topical capsaicin should be considered for the relief of localized neuropathic pain. **A**

- **CHARCOT'S FOOT**

Diagnosis of Charcot's foot (joint softening caused by neuroarthropathy) should be made by clinical examination supported, where available, by the use of thermography. 

Total contact casting and non-weight bearing are effective treatments for acute Charcot's foot. 

From the above recommendations we can observe that the evidence is obviously scarce and insufficient when it comes to the implication of education in the prevention and treatment of diabetic foot and the diagnosis and treatment of Charcot's foot. On the other hand, when it comes to the use of new treatments like subcutaneous g-csf the evidence becomes abundant and strong. The reason may be that not many institutes are ready to sponsor studies that cost a lot with insufficient financial rewards like studies on education.

CONCLUSION

The Evidence in diabetic foot prevention, management and treatment needs to be revisited and enhanced by further studies to unify the guidelines in order to optimize the diabetes foot care. This means collaborative effort to develop worldwide accepted standards and guidelines to sustain ideal foot care for diabetics.

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