

Background, Diabetes Care

Early diagnosis of Diabetic Neuropathy & other Peripheral Neuropathies

The global prevalence of diabetes mellitus (Diabetes) is constantly increasing and the illness is estimated to affect 350 million people of the global population by 2030, that is 4.4%. Diabetic Foot Ulceration (DFU) is complex and costly and the health care cost for diabetes mellitus can be above 2.5 % of the gross domestic product (GDP) mostly linked to treat complications of DFU.

Already in 1991, the high morbidity following major amputations in diabetic patients was recognized. Moreover, it was noticed that a program for preventive foot care and a multidisciplinary treatment could decrease the incidence of major amputations with more than 50%. Therefore, WHO (Europe) and the international Diabetes Federation (IDF, European Region) accepted a program for improved diabetes care (the Saint Vincent Declaration).

DFU is certainly a serious complication for diabetic patients and the prevalence in patients is 4-10% with a lifetime incidence of 25%. DFU decreases quality of life because of mobility limitation, pain and discomfort feelings. Moreover, DFU decreases the life length of the patient. A serious problem is recurrence of DFU after healing of the first DFU and a global mean value is 22.1 % per PY, however the variation is large and range from 0.0% to 83.8% with a large regional variation. (3)

Cost: Average cost for each ulceration was nearly USD 13 000 in the USA. Expenses for treating patients with ulcers is 1.5 up to 4 times higher than treating patients without ulcers. (3)

Diabetic foot ulcer (DFU) prevalence is as high as 25% and 40–80% of DFUs become infected (DFI). About 20% of infected ulcers will spread to bone causing diabetic foot osteomyelitis (DFO). DFU costs Medicare \$9–13 billion/year. The most expensive costs associated with DFU are in-patient costs and hospital admissions. DFO costs are driven mostly by surgical procedures. DFU patients have a 3-year cumulative mortality rate of 28% and rates approaching 50% in amputated patients. (4) A recent systematic review has shown that the incidence of lower extremity amputation is 78 to 704 per 100 000-person year and the relative risks between diabetic and nondiabetic patients varied between 7.4 and 41.3. (5)

Conclusion: The increasing global prevalence of diabetes mellitus and the serious secondary effect such as DFU that not only diminish the life quality of the patient but also limits the lifetime itself, calls for new methods for early detection of DFU and also methods for following up treatments in preventive health care. This is the main objective of our project.

Method for diagnostics and decision-making

More than half of all amputations in the lower leg were performed in diabetic patients in 1995 (1) and because of the overall increase of diabetes incidence this number is continuously increasing as discussed above. It is now worldwide accepted that preventive health care is essential to lower the number of these amputations.

Current situation: Diagnostic methods are several types of Quantitative Sensory Tests, QST, in combination with clinical investigations. Some examples are determination of perception thresholds for pain, vibrations, heat and cold. However, QST are time consuming and requires especially trained nurses.

DermaProbe: Since the development of diabetic neuropathy is length-dependent, measurements and diagnosis have to be performed on a regular basis to follow changes in the extremities, not only primarily on the foot. The DermaProbe system is built for very fast diagnosis and has a very short introduction-period for the health care staff. Some of the features of DermaProbe are:

- Suitable for preventive Health Care
- Sensitive and reproducible
- Easy-to-interpret the clinical test reports
- Easy data export to excel and other datasheets