MULTI-CENTER RCT ON WOUND CLEANSING AND HEALING EFFICACY OF A BIO-CELLULOSE DRESSING COMPARED TO BIO-CELLULOSE + PHMB IN DIABETIC FOOT ULCER PATIENTS

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Introduction :

Diabetic foot ulcer (DFU) is one of the major complications of Diabetes Mellitus (DM). It occurs in 15% of all patients with diabetes and precedes 84% of all lower leg amputations[1].
A major increase in mortality among diabetic patients, observed over the past 20 years is considered to be due to the development of macro and micro vascular complications, including failure of the wound healing process. Fibroblasts from DFU exhibit proliferative impairment that probably contributes to a decreased production of extracellular matrix proteins and delayed wound contraction and impaired wound healing[1]. Diabetic foot conditions develop from a combination of causes including poor circulation and neuropathy. Diabetic neuropathy can cause insensitivity or a loss of ability to feel pain, heat, and cold. Diabetics suffering from neuropathy can develop minor cuts, scrapes, blisters, or pressure sores that they may not be aware of due to the insensitivity. If these minor injuries are left untreated, complications may result and lead to ulceration and possibly even amputation[1,3].

Definitions :

According to the [2]WHO definition a diabetic foot ulcer can be defined as follows:

- Infection, ulceration and/or destruction of deep tissues associated with neurological abnormalities and various degrees of peripheral vascular disease in the lower limb.
- Diabetic neuropathy is described as the presence of symptoms and/or signs of peripheral nerve dysfunction in people with diabetes, after exclusion of other causes.
- In case of a neuro-ischaemic ulcer there is a combination of diabetic neuropathy and ischemia.
- Ulcers my be combined with peripheral vascular disease, when there is presence of clinical signs such as the absence of the pedal pulses, a history of intermittent claudication, rest pain and/or abnormalities on non-invasive vascular assessment, indicating disturbed or impaired circulation.
- Patients may have ischaemia in which case there are signs of impaired circulation verified by clinical examination and/or vascular testing[2] .
- Critical limb ischaemia is present when there is persistent ischemic rest pain requiring regular analgesia for more than two weeks and/or ulceration or gangrene of the foot or toes, both associated with an ankle systolic pressure of <50 mmHg or a toe systolic pressure of <30 mmHg[2.]

Fig 1:
A typical diabetic foot ulcer on the plantar.

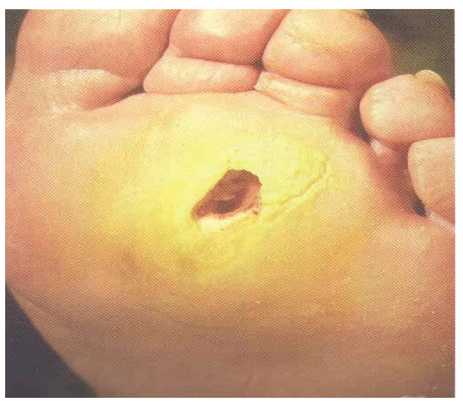

Fig 2:
A thick callus layer is present around the wound edges. Callus removal is one of the treatment measures.

Aim :

The multi-center prospective randomized controlled study evaluated a bio-cellulose dressing and the same dressing combined with PHMB in the treatment of patients with diabetic foot ulcers. Alvarez et al (2004) looked at the efficacy of debridement and reduction of fibrin layers in the wound bed, when applying the bio-cellulose dressing compared to a Moist Wound Healing (MWH) dressing[3]. Various studies have reported the effectiveness of polihexanide (PHMB) when applied in different wound types[4,5]. Especially when combined with the bio-cellulose dressing it allows for continuous wound cleansing.

Patients included in the RCT had ulcers according to Wagners' classification of grade 1, 2 and 3, with local signs of inflammation. Table 1. Ulcers that showed invasive clinical manifest infections were not included as were those that had severe ischemia or an infection combined with ischemia (class D).

Method :

RCT N=30 (n=15/n=15) Group 1: Bio-cellulose* dressing (BWD), Group 2: Bio-cellulose dressing + polihexanide** (BWD + PHMB). The choice of secondary dressing was at the discretion of the clinicians and depended on wound bed condition and level of exudate which was either a foam*** or a super absorbent**** dressing. Wound bed condition, wound cleansing and healing was assessed at visits: 0 7, 14, 28, 56 days using clinical observation and digital photographs. The results were analysed per patient, per group and by comparing groups. The assumption was that a better and faster cleansing effect and reduction of inflammation was obtained in group 2 compared to group 1, with similar healing rates and equal comfort in both groups.

Results :

The interim results demonstrate a faster cleansing and reduction of inflammation in group 2 versus group 1. The bio-cellulose dressing was shown to be comfortable in both groups.

Conclusion :

The interim results indicate the use of the dressings is safe in both groups, with a faster reduction of inflammation and a faster onset of healing in the BWD+PHMB group.

Class	0	1	2	3	4	5
A	Pre or post ulcerating foot	Superficial ulcer	Ulcer till the level of tendons or capsules	Ulcer till the level of bones or joints	Necrosis of foot parts	Necrosis of the entire foot
B	With infection	With infection	With infection	With infection	With infection	With infection
C	With ischemia	With ischemia	With ischemia	With ischemia	With ischemia	With ischemia
D	With infection and ischemia	With infection and ischemia	With infection and ischemia	With infection and ischemia	With infection and ischemia	With infection and ischemia

Table 1: Diabetic foot syndrome - classification according to Wagner and Armstrong

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