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PILOT RANDOMIZED CONTROL TRIAL

Therapeutic effects of connective tissue manipulation on wound healing and bacterial colonization count among patients with diabetic foot ulcer

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Summary This study investigated the therapeutic effects of connective tissue manipulation (CTM) in diabetic foot ulcer (DFU). A total of 20 participants (10 in CTM group and 10 in conventional treatment group (CG)) with DFU underwent the conventional DFU treatment. In addition, the CTM group received CTM twice per week for 6 weeks. The percentage wound area reduction (PWAR) and bacterial colonization count (BCC) in log10 colony-forming units (CFU) per ml wound fluid was evaluated at baseline and six weeks. Results showed a significant change in PWAR in CTM ($p < 0.05$, $t = 3.82$, $Df = 9$, CI L = 0.98 U = 3.81) and CG ($p < 0.05$, $t = 2.97$, $Df = 9$,CI L = 0.26 U = 1.98). Mean reduction of BCC showed a significant reduction ($p < 0.05$), with percentage of BCC reduction higher in CTM group (6.45%) than CG (3.55%). The findings suggest CTM as an effective adjunct therapy for DFU to enhance conventional treatments.

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Introduction

Connective tissue manipulation (CTM) is a specialized manipulative therapy pioneered by Elisabeth Dicke from Germany in the 1930s (Holey, 1995a). This manual therapy technique utilizes a shear force at connective tissue interfaces which creates a stretch in both elastic and viscous components of the tissues (Holey, 1995b). CTM has mechanical and reflex effects in the peripheral vascular system which causes peripheral vasodilatation and increased blood flow to the peripheral areas (Holey, 1995b). The CTM strokes are usually applied by finger tip to the defined zones of the body called connective tissue zones producing therapeutic reflex effects on the tissues that shares the same segmental innervations with the connective tissue zones (Holey, 2000; Holey, 1995a; Reed and Held, 1988). Previous studies suggest that the peripheral vasodilatation achieved is due to the stimulation of autonomic system related cutaneovisceral reflexes and reticular plexus activity (Holey et al., 2011; Reed and Held, 1988) combined with regulation of sympathetic-parasympathetic balance (Castro-Sanchez et al., 2011; Holey, 1995b; Holey et al., 2011).

Diabetes is a serious health concern and around 15% of people develop diabetic foot ulcers (DFU) (Delmas, 2006; Levin, 1997). The ulcerated diabetic foot may result in ischemia, infection (Levin, 1997), and contribute to 85% of lower limb amputations (Delmas, 2006). Therapeutic techniques to prompt revascularization to the ulcerated foot may minimize amputation risk and hospitalization (Levin, 1997). In DFU with an underlying pathology of deprived peripheral circulation to the wound, the therapeutic effects of CTM due to peripheral vasodilatation might be an effective adjunct treatment.

In DFU, local tissue ischemia causes tissue necrosis and the presence of critical bacterial contamination affects the healing status of the wound (Browne et al., 2001; Stojadinovic et al., 2008). This higher bacterial burden hinders the healing mechanism by maintaining the inflammatory state, thereby delaying the formation of collagen tissue which is essential for the healing of the wound (Stojadinovic et al., 2008; Xu et al., 2007). In addition, impaired peripheral blood flow delays the delivery of immune cells and fibroblasts to the ischemic foot, further slowing wound healing (Schramm et al., 2006). If CTM does improve the vascular status of the diabetic ischemic foot, then the increased blood flow may improve oxygenation, the delivery of antibodies and medication in the affected foot subsequently reducing the bacterial count which in turn should enhance wound healing.

Whilst the therapeutic effects of CTM have been reported in several studies (Castro-Sanchez et al., 2011; Ekici et al., 2009; Reed and Held, 1988), there is a paucity of conclusive evidence to support the theoretical basis and the clinical benefits of CTM in diabetic foot ulcer. Therefore the aim of this study was to investigate the therapeutic effects of CTM on wound healing in DFU, measured by the total bacterial colonization count (BCC) and the percentage wound area reduction (PWAR). The hypothesis of this study was that PWAR in DFU would be significantly higher if CTM was applied in addition to usual clinical care.

Materials and methods

This was a pilot randomized control trial conducted in the outpatient physiotherapy department of a university teaching hospital. A total of 26 subjects were recruited for this study. The inclusion criteria includes participants with both fasting blood glucose ($>=110$ mg dl^{-1}) (WHO, 1999) and 2 h post glucose load ($>=180$ mg dl^{-1}) (WHO, 1999), presence of a non-infected DFU on the plantar aspect of the foot with Wagner classification (Wagner Jr., 1981; Wagner, 1987) of grade 1 and 2 (skin ulcer) or Texas grade (Lavery et al., 1996) 1A and below. All the participants included are undergoing conventional treatments such as orthotics, antibiotic therapy, drugs therapy and exercise therapy. The exclusion criteria for this study includes participants with current haemodialysis, past surgical history of lower limb revascularization, participants who are unable to comply a minimum of four treatment sessions continuously, bleeding disorders such as hemophilia, sickle cell disease, thrombocytopenia, leukemia, or blood dyscariasis, glycosylated hemoglobin (HbA1c) level more than 9% and use of immunosuppressive agents. The participants who were accepted for the study were randomized into a CTM (intervention) group or usual (control) treatment group. Pieces of paper were numbered and placed into a closed box. The participants were instructed to draw one each and those who picked odd numbers were allocated to the CTM group and those with even numbers were allocated to the control group. Ethical approval was obtained from the Medical Research Secretariat Ethical Committee from a university teaching hospital with (reference NN-010-2008). Written informed consent was obtained from the participants prior to the participation in the study.

Outcome measures

Demographic data was collected from the participants. Measurement of the PWAR and bacterial colonization count (BCC) were carried out before and after intervention. Acetate surface area tracing for PWAR measurement has been found to be a standard reliable method and hence was used in this study. The baseline PWAR of the wound surface measurement and the corresponding weekly PWAR of the wound surface area of the diabetic foot ulcer was measured using a standardized acetate tracing method (Harding, 1995).

One qualified staff nurse trained in wound surface area measurement with acetate tracing measured the circumference of the wound surface in all participants and was blinded to the applied interventions for the study participants. The margin of the wound was traced on to two layered 0.25 cm2 preprinted sterile acetate tracing, using a black, extra-fine, felt-tipped marking pen. The contact layer was discarded and the area of the wound calculated by counting each square that is more than half within the border of the wound (Harding, 1995). Finally, the total surface area inside each tracing was calculated by multiplying the number of squares with 0.25 cm as each complete square was equivalent to 0.25 cm2. The participant was positioned in the same position (long sitting) at each

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