Evidenced-Based Management of a Chronic Wound in an Elderly Female Patient with Type II Diabetes

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CLINICAL CASE

An 85-year-old woman tripped and fell against a coffee table and sustained a soft-tissue injury to her mid-thigh region. The initial swelling progressively formed into a dense fibrotic mass, and the surface tissue gradually became necrotic. Five weeks after the fall, the patient presents with an open wound measuring 7 cm by 4 cm and 5 mm deep (see Figure 1a). The wound surface is covered in dry, yellow-brown eschar, and the wound edges are vertical, with a rolled-over appearance (see Figure 1b). The patient has a 15-year history of diabetes mellitus type II, which is controlled through diet and oral medications (glyburide and metformin). She has mild distal neuropathy affecting sensory (reduced sharp/dull sensation and protective sensation based on Semmes-Weinstein monofilament testing), motor (clawed toes and prominent metatarsal heads), and autonomic (dry, cracked skin) nervous systems; her pedal pulses are weak. For management of mild peripheral edema, the patient has been prescribed daytime use of full-length elastic support stockings. The patient lives in a retirement residence and ambulates using a low-wheeled walker; however, she is sedentary most of the time.

CLINICAL QUESTION

Physical agents that may have a role in promoting wound repair include ultrasound, electrical stimulation, ultraviolet radiation, low-level laser therapy, and pulsed short-wave therapy. Assuming that ultrasound is the only agent presently available, is there evidence to support its use in the management of chronic wounds?

CURRENT OPINION

Results of *in vitro* and animal studies support the use of ultrasound as a physical agent to improve tissue healing. Beneficial effects include increased tissue perfusion,

chemotactic and stimulatory effects on cells essential for repair (macrophages, lysosomes, fibroblasts, keratinocytes, etc.), release of essential enzymes and growth factors, and increased cell proliferation.¹⁻⁸ However, the literature is inconclusive with respect to ultrasound's efficacy in human wound healing.

RATIONALE FOR TREATING THIS PATIENT'S WOUND

Chronic wounds vary in severity and in their impact on overall health; they are a significant cause of morbidity in persons with diabetes. Wound pain and pain associated with dressing changes can negatively affect quality of life.⁹ There is potential for catastrophic consequences when ulcer infection leads to cellulitis or septicemia.

Wound care also has an impact on the health care system. A 2007 audit of wound-management practices performed by the Niagara Community Care Access Centre, the health care organization responsible for delivery of in-home health care in the Regional Municipality of Niagara in southern Ontario, Canada, covered 915 clients, of whom 470 were receiving wound treatment, 31% of these for leg or foot ulcers. The survey found that the average duration of wound healing was 21 weeks. Based on a random sample of 100 clients treated for wounds in 2006, the average cost per patient amounted to \$2,326 for nursing and \$1,291 for materials.¹⁰

Wound healing consists of three phases that overlap in time.¹¹ The inflammatory phase is marked by early edema and an influx of inflammatory cells (neutrophils followed by macrophages and lymphocytes) that debride the wound of damaged cells and foreign material and, in turn, release growth factors and enzymes that activate tissue regeneration. The proliferative phase is defined by the formation of new blood vessels and the laying down of provisional matrix, involving connective tissue cells and activated fibroblasts. The third phase is a period of

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Figure 1a A stalled chronic wound in an elderly patient with Type II diabetes (full-colour image available at <http://www.utpjournals.com/physio/physio.html>)

Figure 1b Close-up view of the same wound shown in Figure 1a; the ulcer area is approximately 10 cm² (measured via ImageJ software; full-colour image available at <http://www.utpjournals.com/physio/physio.html>)

wound maturation, characterized by the obliteration of new blood vessels and by collagen remodelling.

Many factors inhibit wound healing, including unrelieved pressure, wound infection, inadequate tissue perfusion; presence of necrotic material; a dry wound surface; excess moisture; nutritional deficiencies—calories, protein (serum albumin <3.5 g/dl), vitamins (Vitamin C), and minerals (zinc); metabolic diseases (diabetes); age; and a compromised immune system.¹¹ External inhibitory factors can usually be addressed, for example, by applying dressing materials to keep the wound surface moist. However, there are few strategies to address intrinsic factors that delay healing. Ultrasound is purported to improve tissue perfusion.

EVIDENCE FROM THE LITERATURE

The effects of ultrasound on wound healing were evaluated by meta-analysis in 1998¹²; several Cochrane

Group reviews followed.^{13–15} The reviews consistently stated that the methodological limitations of the small number of trials, the small number of participants in most trials, and the heterogeneity of methods limited pooling of results and, therefore, the analyses that could be performed and the conclusions that could be drawn.

The 1998 review included six randomized controlled trials involving leg ulcers: five trials treated venous ulcers exclusively, and the sixth treated mostly venous ulcers.¹² Each of the six trials showed a statistical trend toward benefit from ultrasound. Meta-analysis showed a significant effect for ultrasound on reduction in ulcer area. One of the included studies used low-frequency (30 kHz) ultrasound delivered via a water footbath, and it is not clear to what extent the findings of this particular study influenced the results.¹⁶ Low-frequency ultrasound is not widely available, and because of unavailability it was not an option in the present case; furthermore, an underwater treatment would be cumbersome, given the mid-thigh location of the patient's ulcer.

A 2002 Cochrane review of ultrasound on venous leg ulcers included seven RCTs, six of which had been included in the 1998 review.¹⁴ The additional trial used 30 kHz ultrasound applied under water.¹⁷ The 2002 Cochrane authors concluded that there was a possible but not certain benefit of using ultrasound.

A 2008 Cochrane update¹⁵ included the seven prior RCTs plus one new study that used traditional ultrasound applied in contact via gel coupling.¹⁸ Pooling trials for the outcome of relative risk of healing showed that more ulcers were healed using ultrasound (risk ratio = 1.49, 95% CI: 1.07–2.09). For trials reporting the percentage of ulcer area remaining, pooled results showed that ultrasound was beneficial (weighted mean difference = –5.34%, 95% CI: –8.38––2.30).

The literature lacks RCTs using ultrasound on ulcers of non-venous origin. A Cochrane review of ultrasound effects on pressure ulcers was published in 2000, and the original version of the review is the one currently available in the Cochrane Library. Three RCTs were included in the review.^{19–21} The authors concluded that there was no evidence of benefit; however, “the possibility of benefit or harmful effect could not be ruled out due to the small numbers of trials, some with methodological limitations, and small numbers of participants.”^{13(p.1)}

LIMITATIONS OF THE EVIDENCE

The evidence is inconclusive regarding the effects of ultrasound on chronic wounds of non-venous origin. Although arterial and venous ulcers differ in aetiology, there are underlying tissue problems that are common to both, in particular diminished skin blood flow, and therefore it is reasonable to look to the literature on venous ulcers for guidance in deciding whether to use ultrasound in the present case. Although the most recent meta-analysis supports using ultrasound for venous

ulcers, this support is somewhat undermined by the methodological limitations of the individual studies and by the fact that the results pooled to reach the positive conclusion included two studies that used substantially different ultrasound approaches. It is debatable whether long-wave 0.03 MHz and traditional 1 or 3 MHz ultrasound studies should have been considered in the same pool for purposes of meta-analysis. On the other hand, since the 2008 review a further study has been published that found a significant benefit from using ultrasound on venous ulcers.²² While the positive results of this new study might strengthen the case for using ultrasound on wounds, the findings, like those of previous studies, are compromised by methodological limitations.

A further limitation of existing reviews is the fact that they have failed to reveal the optimal ultrasound dosing characteristics for wound management. In the 2008 Cochrane review, trials were pooled if they used common outcomes at certain time points; however, heterogeneity precluded pooling for sub-group analysis of dosing effects.¹⁵ Johannsen et al. (1998), based on six studies, concluded that ultrasound was more effective when applied to the wound periphery of venous ulcers than when applied directly into the wound.¹² Interestingly, in only one of the three studies of ultrasound on pressure ulcers was ultrasound applied directly into the wound (plus 0.75 cm of wound margin), and in that study the ultrasound was found to be ineffective.²⁰ Thinking about a direct approach prompts a very basic question: Can adequate coupling be achieved when a transducer is applied directly to the wound surface, given that most wounds have uneven and slightly concave surfaces? Transmission losses might explain the lack of efficacy reported by authors who treated using this direct approach.^{20,23,24}

SELECTING ULTRASOUND TREATMENT CHARACTERISTICS

Because of limitations in review findings, it was necessary to revert to individual studies to select treatment parameters for the present patient.

Comparing the size of ultrasound effects on wound closure for treatment applied directly to the wound surface as opposed to the wound periphery led to the conclusion that ultrasound should be administered to the wound periphery in the present case.¹⁵

Support was found for an ultrasound frequency of 1 or 3 MHz.^{18,22,25–27} In the present case, the superficial location of the ulcer supported a decision to use 3 MHz ultrasound (based on a half-depth penetration of 3 MHz ultrasound in soft tissue of approximately 1.6 cm).

Ultrasound intensity at 0.5 W/cm² or 1.0 W/cm², spatial average–temporal peak (SATP), delivered in pulsed mode using a 1:4 ratio, consistently produced favourable results in the individual trials.^{18,22,25–27} Treatment of 1.0 W/cm², SATP, 1:4 ratio, was favoured in this case, based on personal experience treating similar wounds,

with a plan to re-evaluate intensity if there was no evidence of improvement after three treatments.

Treatment duration of 15 minutes was selected based on the original work of Dyson,²⁶ later replicated by others,^{18,27} using 5 minutes of ultrasound for ulcers less than 2.5 cm² (the size of a dime) with an increase of 1 minute for each extra 0.5 cm² of ulcer area. Callam,²⁵ and more recently Taradaj,²² used similar protocols.

Two studies supported treatment three times per week.^{26–27} However, once a week²⁵ and daily^{18,22} ultrasound were also beneficial. Three-times-weekly treatment was decided on for the present case because of possible patient discomfort and the nursing resources and costs associated with more frequent dressing changes: occlusive-type dressings need only be changed when there is fluid leakage.

A hospital-standard antibacterial solution would be used to clean the ultrasound head before and after each treatment, as it has been shown that ultrasound transducers are a potential source of bacterial transmission.²⁸

THE ROLE OF DRESSINGS IN PROMOTING WOUND REPAIR

Dressings themselves will not heal a chronic wound; on the other hand, wounds will not heal in a hostile environment.²⁹ The characteristics of an ideal dressing include moisture balance, conformity, absorbency, thermal insulation, provision of a barrier to bacteria, cost effectiveness, and pain reduction. Wound assessment should be the driving element in treatment decisions. Research has shown that the old practice of using the same dressing material for the entire healing time is no longer valid.²⁹ Removal of non-viable tissue is a key component of wound management; therefore, to assist with wound rehydration and autolytic debridement, a hydrogel dressing was selected for the initial phase of managing this patient's wound.³⁰

OUTCOME MEASURES

Wound measurement using a valid and reliable measure is essential for monitoring the efficacy of wound treatments. The patient's ulcer was traced using an acetate sheet, because this seemed a practical approach in a residential setting. To overcome possible inaccuracy from manually counting square centimetres of wound area, the tracing was photographed and the area of the wound was calculated digitally using free ImageJ software (Research Services Branch, National Institute of Mental Health, Bethesda, MD). The reduction in ulcer area (cm²) would be used to evaluate healing.³¹ Maximum wound depth and any undermining would be measured using a cotton-tipped probe and measured against a ruler.

The Bates-Jensen Wound Assessment Tool, which has demonstrated validity and reliability, would also be used to assess healing.³² The tool yields a score that characterizes the appearance of the surrounding intact skin, ulcer edge, depth, wound bed, and wound exudate.

Biweekly photographic documentation was considered a useful tool for keeping the patient, the physician, and other professional staff informed about progress.

CLINICALLY MEANINGFUL IMPROVEMENT

Ultrasound treatment would be considered effective if the wound area were reduced by at least 30% over a 4-week period, based on guidelines from the Registered Nursing Association of Ontario.^{33(p.43)}

FUTURE DIRECTIONS

Certainty regarding the efficacy of ultrasound for chronic wounds has yet to be established. The next step is a large multi-centre clinical trial. However, the investigators would need to reach consensus on the treatment protocol to implement, including the treatment area; ultrasound frequency, intensity, and duration; and frequency of treatments. Critical analysis of the findings of systematic reviews and careful study of the treatment characteristics of individual trials is indicated to determine best practices in this area.

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