

Extracorporeal Shock Wave Treatment in Chronic Diabetic Ulcers

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ABSTRACT

This prospective study compared the ESWT (Extracorporeal shock wave therapy) with the standard cleaning and dressing of chronic diabetic ulcers.

INTRODUCTION

Diabetes is one of the most common medical problems in the world affecting millions. The majority is treated but the main problem with diabetes is not the high sugar but its serious complications over the years and one of the worst complications is the leg ulcer which can easily turn to gangrene and amputation if not treated properly. The pathological problem in the ulcer is the lack of microcirculation. A bypass operation to blocked main arteries would not always improve the healing but improving the local microcirculation would and this is the key to treatment. The patient must have a positive psychological attitude as in our developing country there is no optimal management of the foot ulcer that includes the proper control of diabetes, the general health of the patient and the local management of the ulcer.

We work in the Specialized Diabetic Centre in the south of Iraq. Our Centre has been modernized with the latest technology such as an insulin pump and we were the first to introduce this to Iraq. We also searched for a shock wave machine and were convinced that the CellSonic shock wave machine is perfect and much cheaper than other brands. All these machines simply generate shock waves which in physics are a simple procedure and the fact is that the CellSonic machine is electro-hydraulic and better than the electromagnetic machine in performance because the CellSonic has a faster shock; it is more sudden. There are various other non-invasive ways to treat diabetic ulcers but none proved as good to us. We believe in technology and this century there are a lot of

changes in the method of treatment of the patients. Unless we try we cannot proceed forward in applying the advances in treatment of our patients.

PATIENTS AND METHODS

All our patients agreed to the procedure and a full explanation was given that the treatment is non-invasive and even if it did not help it will not harm the patient, adding to which it is painless. All of the patients went through a complete recording of their history, a clinical examination and full investigations including Doppler, Ankle/brachial pressure, neurological assessments and other checkups. The patient's ulcer is classed as chronic meaning they have had it for more than three months.

We followed the rules and regulations of our health board protocols and guide lines to set our research project which is the standard procedure in our country. It was agreed that we can present our results to the world and the procedure is harmless.

Debridement of the local ulcer and exclusion of osteomyelitis by doing an X ray to the foot prior to ESWT.

Also the general health of the patient should be looked at and any serious cardiovascular problem should be stabilized before the patient is included in the study. We had slight problems with some patients' attendance and follow up and all these were considered in this study. In our study we were managing the patient's lifestyle; their general management of diabetes including HbA1C and looking at cardiovascular risk factors like stop smoking, controlling the

blood pressure, weight reduction and all diabetic patients should take cholesterol lowering drugs.

We started collecting the patients in March 2010 and we followed up our patients until November 2011. To start with we got 76 patients. Some were excluded as 3 ended in surgical procedures of skin grafting, 2 developed major cardiac ischemia. The other 3 did not finish the full follow up.

68 (sixty eight) diabetic patients were randomly divided in to two groups on bases of attendance: 34 patients were treated with ESWT and 34 were treated with the standard classical method of cleaning and dressing.

SHOCK WAVE APPLICATION

We start with a full explanation of the procedure to the patient and showing them the CellSonic machine. The patient was shown a video of the treatment. The average time for each session is 30 minutes. The patient can go home immediately afterwards.

We have a special room for the machine and all the procedure is done in a sterile environment.

Apart from cleaning the ulcer with salt and water, we do not use any antiseptic or antibiotic locally. A dry dressing is put on the ulcer.

The treatment was according to the CellSonic protocol of 100 shocks for each square centimeter of wound plus 350 shocks. We applied shocks to the wound and the surrounding area because infection is under the wound and in surrounding tissues. Most patients had 3 to 6 treatments that were given on a week by week basis. We believe that one week is enough to show the effect of ESWT and reflect the time required for injury/healing, pathologically speaking.

We set the number of the shocks on the counter of the machine's control panel. Ultrasonic gel was used to conduct the shocks into the body as it is important to have direct contact with the head to let the wave be effective.

The standard treatment – cleaning and dressing daily for 30 – 60 days.

The evaluation was by clinical procedure: photo documentation, blood flow check and bacteriology examination. We lack the other more specific ways of measuring the local biochemical changes and most of the patients did not like to take a biopsy to look at the histopathological improvement; still the clinical

improvement is the best parameter proving the outcome.

We found there is significant reduction in the number of bacterial growth for patients treated with ESWT and we believe the bacteria was disabled and could not multiply; their cell walls were destroyed by the direct effect of the shock wave

Regular weekly culture and sensitivity show more reduction with ESWT- we do not use antibiotics, local or systemic and the way we do the cleaning is to soak the foot ulcer in hypertonic salty water for 20-30 minutes. Then we dry it and we advise to expose the foot to the sun to get natural ultraviolet and infrared lights which kill the bacteria. We did this for both study groups. Photos were taken of all the patient ulcers on their follow up.

The best evaluation is the clinical outcome. For every patient's ulcer we recorded the site, size, depth, floor, base, local sepsis, surrounding area of neurovascular assessment and that was done and saved in the computer system on every patient visit.

RESULT

The overall result for the ESWT showed completely healed 39%, improved 52% and unchanged for 9%.

The other group with only standard treatment showed 21% completely healed, 48 % partially healed and 31 % unchanged.

It is obvious that there is a better result with adding the shockwave to the standard treatment. We believe it does two jobs: it kills the bacteria which is the worst enemy delaying healing and enhances micro vascularity and healing. By shocking the affected area it induces mini-injury, similar to massaging the ulcerated area and mini-injury enhances the healing process. We also believe there is an increase of the local chemical and hormones such as nitric oxide synthase, endothelial growth factors and others.

DISCUSSION

There are no twin identical ulcers to compare. Diabetic ulcers vary and are multi factorial: the local neuro-vascularity, the circulation to the limbs, the cardio vascular system if affected and the other organs like the liver, the kidney and the immune system. The lung as an originator of tissue is of prime importance for survival adding to which on any open ulcer the invasion of

various micro-organisms will complicate the picture and delay the healing.

We got to say still the basic standard care for the diabetic ulcer is required plus the adding of the new technology of ESWT to speed up the healing and reduce the recurrence.

After-care to prevent recurrence is important by local cleaning, reducing pressure on the affected area with special shoe appliances and following the foot care nursing advice and seeing the specialist immediately if any skin changes occur.

It is multidisciplinary team work involving local foot management, control of the diabetes and good general care of the patient by minimizing cardio vascular risk factors.

CONCLUSION

ESWT appears to be more effective than standard treatment in the management of the chronic diabetic ulcer.

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