Thermosurgery in dermatology
VA Technology Assessment Program (VATAP)

Record Status
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Citation

Authors’ conclusions
The variability in study protocols make it difficult to draw firm conclusions about the treatment efficacy of radiofrequency heat therapy using ThermoMed™ relative to available therapies for which greater clinical experience exists or for which different dosage schedules than those used in earlier studies are now recommended. In general, ThermoMed™ as a single session local treatment option appears well-tolerated with local anesthesia and without exaggerated scarring or color changes. Evidence suggests that the optimal candidates for ThermoMed™ are patients with less severe forms of infection in areas of the body that are appropriate for heat therapy and without evidence of lymphatic spread. Post treatment wound care is essential, as blistering and secondary infection are the most common adverse effects. There is no consensus regarding the appropriate length of follow up, but evidence of complete or partial healing occurred within two months in the majority of cases. Longer follow up is desirable to detect recurrence or document slower healing lesions.

Anecdotal evidence in Lobo (2006) suggested a systemic cytokinine response effect in both treatment groups, but further study is needed to determine if all lesions of a patient with multiple lesions require local heat therapy. Further study is also needed to determine if degree of healing and duration of infection at clinical presentation and Leishmania species play important roles in treatment effectiveness.

Wortmann (2005) summarized the state of thermotherapy with ThermoMed™ for treatment of CL as follows: “In summary, thermotherapy with a LCF-RF [localized current field-radio frequency] device is an important and useful addition to existing treatment modalities;...The device will be especially useful in situations involving large numbers of patients (in which injections with antimony are impractical); for children (because intralesional injections with antimony are painful); for patients with small, localized lesions; and, potentially, in cases refractory to antimony therapy. There are, however, few data on the efficacy of the device for treatment of large lesions, lesions associated with regional adenopathy, and lesions caused by species (such as L. braziliensis) known to spread outside of the apparent skin lesion and cause late-onset mucosal disease. Significant rates of soft-tissue infection after use have been reported in some studies, and there are scant data on the long-term risk of scarring and keloid formation after treatment.

The LCF-RF device is a technically sophisticated piece of machinery, and its portability and ease of use offer effective therapy to many patients who might otherwise, because of the cost of the unavailability of other therapies, go untreated. Still, the underlying principle (the physical destruction of the parasite, along with some of the host tissue) is not that much different from other direct local therapies, and it is sobering to realize just how far the treatment of cutaneous Leishmaniasis has not advanced over the centuries. Stir the cauldron and sprinkle antimony, or reach for the smoldering brand and cauterize? Between the toxicities of antimony, the medical incongruity of burning a lesion to save the skin, and the modest effectiveness of other, alternative therapies, it is clear that the treatment of cutaneous Leishmaniasis is far from its apogee. We still lack a safe, affordable, and effective treatment, and although LCF-RF device is one more stone laid on the path, we still have a long road to travel.”

Full published results from Aronson and colleagues at Walter Reed Army Medical Center comparing a current therapeutic regimen of SSG versus ThermoMed™ would help inform the knowledge base of available treatment options that are most relevant to US military personnel and veterans exposed to endemic areas in present war zones. Regarding ThermoMed™ for treatment of basal cell carcinoma, Bath-Hextall (2007) lists implications for future research of BCC treatments in general:
• Promising preliminary results from an ongoing long-term study of imiquimod versus surgery should be confirmed before routine use.
• Clinical trials comparing other alternatives to excisional surgery with long-term follow up data (at least three years) should be conducted before recommending for routine use.
• Future trials should make clear which type of BCCs are being studied with respect to size, location and histological types; morpheaform type and recurrent malignancies should be analyzed separately.
• Assessment of adverse effects should include pain, cosmetic appearance and costs.

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