



Effective Health Care

MIST Therapy System

Nomination Summary Document

Results of Topic Selection Process & Next Steps

- MIST therapy system is not feasible for a full systematic review due to the limited data available for a review at this time. No further activity will be undertaken on this topic.

Topic Description

Nominator: Public payer

Nomination Summary: The nominator is interested in the comparative effectiveness of the MIST therapy system versus negative pressure wound therapy with vacuum assisted closure (VAC).

Staff-Generated PICOS:

Population(s): Patients with open wounds including subgroups based on co-morbidities (e.g., diabetes, stroke, disabled, elderly with mobility issues), wound size, treatment setting, and caregiver training

Intervention(s): MIST therapy

Comparator(s): VAC, negative pressure wound therapy

Outcome(s): Cost, morbidity, mortality, healing times, progression to stage IV wounds, amputation, sepsis, nursing care burden

Setting(s): Outpatient, long-term, community, and home health care settings

- Key Questions from Nominator:**
1. What is the comparative effectiveness of the MIST low-frequency ultrasound therapy with or without debridement and cleaning versus negative pressure wound therapy (wound VAC)?
 2. If one modality is more effective than the other, what are the conditions and parameters associated with the better outcomes including co-morbidities, wound size, treatment setting, caregiver training, etc.?
 3. Are there significant cost differences associated with one therapy versus another based on healing times, adverse events, nursing care burden, etc.?
 4. What are the common and serious risks and harms associated with MIST versus negative pressure wound therapy (wound VAC)?

Considerations

- The topic meets EHC Program appropriateness and importance criteria. (For more information, see <http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/>.)

- Chronic wounds represent a significant disease burden in the United States. Treatment approaches for chronic wounds vary widely, and new methods have proliferated in recent years. The MIST therapy system is an FDA-approved wound cleaner system that delivers low-frequency ultrasound through a saline mist to the wound bed.

- Ramundo and Gray evaluated the evidence for the MIST therapy system through February 2008 to determine whether ultrasonic MIST therapy effectively removes necrotic debris from the bed of chronic wounds and promotes wound healing. The authors reported that no studies meeting inclusion criteria were identified that evaluated the efficacy of direct contact ultrasonic MIST therapy for the debridement of chronic wounds. The authors found only 2 RCTs that evaluated the effectiveness of MIST therapy for wound healing. One trial compared standard wound care alone to standard wound care plus MIST therapy for the treatment of ischemic lower-extremity wounds, and the second trial compared MIST therapy to a sham device. Overall, the review found insufficient evidence to determine whether ultrasonic MIST therapy effectively debrides necrotic tissue in chronic wound beds and limited evidence to suggest that noncontact, low-hertz frequency ultrasonic MIST therapy promotes wound healing when used in conjunction with standard wound therapy.
 - Ramundo J, Gray M. Is ultrasonic mist therapy effective for debriding chronic wounds? *Wound Ostomy Continence Nurs.* 2008 Nov-Dec;35(6):579-83.

- A literature scan since the last search date of the Ramundo and Gray review was conducted. Although studies evaluating general ultrasound therapy were identified, no studies evaluating the MIST therapy system were found. Therefore, the research on this topic is too limited for a full systematic review on the MIST therapy.

- Two in-process reviews by the EHC Program will evaluate treatments for pressure ulcers and other chronic wounds. This nomination will be forwarded to the reviewers to be considered for inclusion in the scope of these reviews.
 - To sign up for notification when these in-process reviews and other EHC Program topics are posted, please go to <http://effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/>.