Sustained Acoustic Medicine (SAM)

RAPID REVIEW OF EVIDENCE FOR THE CONCEPT OF FEASIBILITY OF NEW HEALTH TECHNOLOGY

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A rapid and exploratory review of evidence of the Sustained Acoustic Medicine medical device is carried out with the objective of evaluating viability of the concept, with the aim of implementation in Colombia

1. The Food and Drug Administration (FDA) in March 2020 approved Sustained Acoustic Medicine (SAM, ZetrOZ System LLC, FDA 510(k) #K191568, Class II, Medical Device) for prescription home use to treat pain, increase local circulation and improve joint function (1).

2. SAM utilizes high-frequency, low-intensity continuous ultrasound at 3 MHz with 0.132 mW/cm2 intensity delivering 18,720 J over 4 h of the treatment. The SAM device allows for the long duration delivery of ultrasound stimulation to facilitate the healing of injured musculoskeletal tissue in the home of the patient (2). SAM has mechanotransductive and diametric effects at the tissue and molecular level utilizing acoustic forces that have short and long-term effectiveness. The acoustic force increases the permeability of capillary epithelial walls and matrix, allowing the release of nutrients and removing cytokines and damaged tissue (3). Long-term application of SAM augments the healing process by increasing cellular proliferation rate. The ultrasound mechanotransduction process actives the transmembrane ionic channels and regulate the cellular metabolism. The intracellular FAK/NF-κB/P13K/MAPK pathways are also activated with stimulation leading to cellular proliferation, migration (4). Collectively the long-duration ultrasound treatment provided by SAM pass deep into the tissue, increasing vessel diameter and blood flow at the injury site.

3. In a systematic review and meta-analysis published in 2020 (5), sustained acoustic medicine (SAM) was evaluated for the treatment of musculoskeletal injuries. A total of three hundred and seventy-two participants (372) were included in thirteen clinical research studies reviewed. Patients with myofascial pain and injury in the neck and back, moderate to severe knee pain and radiographically confirmed knee osteoarthritis (Kellgren-Lawrence grade II/III), generalized soft tissue injury of the elbow, shoulder, back were included. and ankle with limited function. Primary outcomes included daily changes in pain intensity, changes in Western Ontario McMaster Osteoarthritis Questionnaire, changes in global rate of change, and functional outcome measures including dynamometry, grip strength, range of motion, and diathermic warming (temperature measurement). Sustained Acoustic Medicine treatment provides tissue heating and tissue recovery, improved patient function and reduction of pain. When patients failed to respond to physical therapy, Sustained Acoustic Medicine proved to be a useful adjunct to facilitate healing and return to work. As a non-invasive and non-narcotic treatment option with an excellent safety profile, Sustained Acoustic Medicine may be considered a good therapeutic option for practitioners.

4. A cost-effectiveness analysis of multi-hour SAM treatment versus standard of care (SOC) over a 6-month period for the management of symptoms of knee osteoarthritis. SAM treatment demonstrated improved pain and functional gains compared to SOC. Based on the SAM treatment ICER (incremental cost-effectiveness ratio) score being ≤ $50,000, it appears that SAM is a cost-effective treatment for knee OA (6).

5. To date, clinical practice guidelines have not included formal recommendations for non-pharmacological or complementary therapy based on SAM, which uses continuous high-frequency, low-intensity ultrasound. However, there are few effective therapeutic resources for the treatment of musculoskeletal pain, which makes it a true public health problem due to its repercussions on disability, impact on quality of life and costs. Typical drug regimens include nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, and adjunctive analgesics, all of which have long-term adverse effects, particularly in polypharmacy older adults (7,8).

6. Therefore, it is considered that from the rapid scoping review of evidence, SAM is a promising therapy, but conflicting data remain regarding the parameters used, and further studies are required to fully realize the potential benefits. However, given the limitations in the availability of effective and safe therapies for the management of musciuloskeletal pain, particularly in elderly, high-risk or polymedicated patients, SAM therapy could be a complementary and adjuvant option for the management of people that do not respond to the pharmacological and non-pharmacological measures established in the clinical practice guidelines.

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