

Sam[®] Sport Chronic Low Back Pain Health Economics

Background:

Recently a portable home-therapy continuous ultrasound device, the sam[®] Sport (Sustained Acoustic Medicine (SAM)) device was introduced into the US market in 2013. Prior to its introduction, the use of ultrasound therapy for pain relief of various maladies including non-specific chronic lower back pain (CLBP) was performed in the physician office setting using ultrasound therapy over very short periods of time (e.g. 30 days) and over short durations during each session (e.g. 15-20 minutes). However, with the introduction of SAM, ultrasound can now be delivered over longer durations per session (e.g. up to 4 hours) and over longer periods of time (e.g. >60 days). The treatment of non-specific CLBP includes several therapies and commonly begins with non-invasive (e.g. physical therapy) to more invasive (e.g. surgery) based on the response of the patient to the therapy (defined as standard of care [SOC]).

Objective:

To determine over a one year's timeframe if the use of SAM±exercise as an initial therapy is cost savings compared to the SOC for patients with CLBP.

Methods:

A decision tree analysis (TreeAge Pro 2015) was undertaken examining 2 potential initial clinical pathways for treatment over one year's time: SAM±exercise vs. SOC. Associated probabilities for success and failure as well as costs for care were derived from the peer reviewed literature. Corresponding assumptions were also made on therapies used in failure situations (e.g. patients being refractory to one therapy and reflexing to the next best alternative) and based on the literature. Success of treatment was defined as a clinically meaningful and statistically significant reduction in pain with any one therapy. One way sensitivity analyses were performed on those variables included in the model which had the most meaningful effect on costs. Threshold values were identified for each variable pertaining to when SAM became more costly than SOC in treating patients. Lastly, indirect costs (lost productivity time, costs for going to and from a clinician) were calculated in comparing SAM to other therapies.

Results: Savings of over \$200-360/patient/year were achieved in using SAM±exercise as first line therapy vs. SOC in patients with CLBP (overall costs per year of \$4,443 with SAM±exercise vs \$4,805 with SOC). Cost of SAM device rental is equivalent to standard of care therapies at \$75.50/day (and used mainly for one month's duration) (Figure 1). Indirect costs included travel time of \$9.50/session and lost productive time of \$17.80/session. In total, the overall direct and indirect costs were \$102.80/session.

Conclusions/Discussion: Since SAM's success at relieving pain (with durable one-year relief of pain) over a one month treatment duration approaching 95% ($\$75.50 \times 0.95 = \71.70) and indirect costs totaled $\$27.30 \times 0.95$ success = $\$25.95$; a daily rental of $\$95-\100 to a patient is reasonable. If the cost of coupling patches which are $\$6/\text{day}$ are included in this analysis, then the rental cost/patient per day would be in the $\$100 - \105 range.

Other "indirect" costs which were not included in the above analysis but likely should be:

- Cost of travel for a patient – assume 15-20 mile round trip per day @ $\$0.54/\text{mile} = \285 (for one month of therapy) or $\$9.50/\text{session}$
- Ability for the patient to get back to work faster and/or not miss work due to more invasive interventions such as surgery. In the US, the average hourly wage is $\$25.80^1$. Additionally, patients with lower back pain have an average of lost productive time of 5.2 hours per week². Assume that over a month, this lost productive time = $\$537$. On a per session basis (assuming 30 sessions) this translates into = $\$17.80$.
- Total of indirect costs = $\$27.30$

The use of sam® Sport for the treatment of chronic low back pain provides significant advantage to reducing healthcare costs, improving patient outcomes and reducing the use of prescription drugs and addictive narcotics.

Analysis Completed by:

Jeff Voigt
 Medical Device Consultants of Ridgewood, LLC. 99 Glenwood Rd.
 Ridgewood, NJ, 07450
 Phone : 201-251-8204
 Cell: 201-790-1521
 Email: MedDevConsultant@aol.com

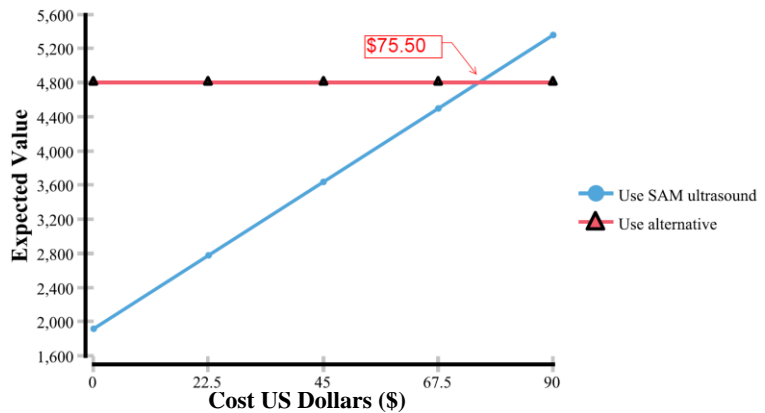


Figure 1. sam@Sport for the daily treatment of chronic low back pain provides significant cost savings when used for 60-days. Total cost $\$75.5 \times 60$ days = $\$4,530.00$

¹ Accessed on 10/24/16 at: <http://www.bls.gov/news.release/empsit.t19.htm>

² Accessed on 10/24/16 at: masspaininitiative.org/files/Cost_of_Pain_Fact_Sheet.pdf