

Balneotherapy in knee osteoarthritis: a cost/effectiveness analysis alongside an Italian randomized controlled clinical trial

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Objective

To perform a cost-effectiveness analysis of mud-bath therapy (MBT) in addition to usual treatment compared to usual treatment alone in patients with bilateral knee osteoarthritis (OA).

Design and Method

This is a prospective randomized, controlled single-blind (assessor) trial. The study protocol was approved by the Ethics Committee of Siena University Hospital and registered on <http://www.clinicaltrials.gov> (NCT01538043).

Patients aged between 40 and 80 years of both sexes with primary symptomatic bilateral knee OA (ACR criteria) and with a Kellgren - Lawrence radiological score between I–III were recruited in the area near the Health Resort of Chianciano Terme (Siena, Italy), allowing them to continue to live at home and carry out their daily routines during the study period.

Patients were randomly assigned to receive either a 2 weeks cycle of MBT in addition to their usual treatment or to continue routine care alone. The European Quality-of-Life Questionnaire-5 Dimensions (EQ-5D) was administered at baseline, 2 weeks, 3, 6, 9, and 12 months. Direct healthcare resource consumption (drug's consumption, laboratory and imaging tests, general practitioners and specialists visits, physical therapies and devices) for the treatment of knee OA up until 12 months were derived from a daily diary given to patients and returned at prescheduled follow-up visits.

Results

A total of 103 patients were included (MBT = 53, control = 50). Overall, patients in the MBT group accrued on average 0.703 (\pm 0.23 standard deviation, SD)

quality adjusted life years (QALYs) compared to 0.523 (\pm 0.25 SD) in the control group ($p < 0.001$). Patient average direct costs (€302.8 vs 975€, $p < 0.001$) were higher in the control group, primarily because of hospitalization and use of intra-articular hyaluronic acid.

Bootstrapping replications of costs and QALYs sample distributions indicated that the MBT therapy combined with standard therapy represents a dominant strategy vis-a-vis standard therapy alone, with a consistently negative incremental cost-effectiveness ratio (ICER, mean: -3,752€/QALY, 95%CI: -8,134€/QALY to -2,139€/QALY).

Conclusions

The results of this cost-effectiveness analysis support a positive recommendation to the use of the mud bath therapy as complementary therapy in the management of knee OA.