Köybaşi M, Borman P, Kocaoğlu S, and et al. The effect of additional therapeutic ultrasound in patients with primary hip osteoarthritis: a randomized placebo-controlled study. Clin Rheumatol 2010; 29:1387–1394.

Critique author: Linda Metzger 6-1-15

Design: Randomized clinical trial

Objective: To evaluate the short and long-term efficacy of ultrasound (US) treatment in combination with conventional physical therapy in patients with primary hip OA with regard to pain, functional status, and quality of life (QoL).

Population /sample size/setting:

- A total of 45 participants (33 females, 12 males, mean age 65 years) with primary hip OA who self-referred to the Physical Medicine and Rehabilitation outpatient clinic were enrolled in the study and randomized to one of 3 groups, each containing 15 participants; 1) group I (standard physical therapy), group II (sham ultrasound in addition to standard physical therapy), or group III (ultrasound and standard physical therapy).
- Study design was a prospective, 3 parallel group, randomized, assessor blinded, placebo-controlled clinical trial.
- Inclusion criteria included the presence of hip pain for more than 3 months (not due to secondary causes including trauma, congenital hip dislocation, malalignments, metabolic bone diseases, or endocrine dysfunction) and having Kellgren–Lawrence scores of II–III on radiologic evaluation.
- Exclusion criteria included low back pain, dysfunction of the knee or ankle/foot, local or generalized polyarthritis, neurologic abnormality, any contraindication for physical therapy, lower limb arthroplasty, or any previous physiotherapy program or received intra-articular hip injections in the preceding year.

Interventions/Methods/Outcomes:

- Allocation was concealed after baseline assessment using sealed envelopes from a box. Envelopes were identical in size and color.
- The Kellgren–Lawrence radiographic grade was determined for each patient.
- Standard physical therapy included hot packs and an exercise program that was administered to patients in all 3 groups for 2 weeks directed by a physiotherapist who was blinded to the group allocations. Hot packs were applied on the hip joint for 20 minutes before the US therapies. The patients performed strengthening exercises for the hip muscles and lengthening exercises for the ligaments around the hip joint for a duration of 20 minutes.
- The US parameters used were 1 MHz frequency, continuous mode, intensity 1 W/cm^2, and head size 5 cm^2. The hip joint was treated from the anterior, posterior, and lateral fields, 5 minutes for each field by a physiotherapist that did not administer the standard physical therapy. The US treatment area was applied about 70–80 cm^2 around the

affected hip joint with slow gliding, rotating movements over the multiple fields on the affected hip.

- In the sham ultrasound group, the applicator was disconnected from the rear of the working US machine and was applied to the target hip in the same manner as true US. Patients were unable to see whether or not the cable was connected.
- Sham and true US patients were treated for 10–15 minutes in each session, five times weekly, and given ten treatments in total over 2 weeks.
- After the 10 physiotherapy sessions, all patients were instructed by the blinded physiotherapist on the home exercises including the strengthening exercises for the muscles around the affected hip. Patients were instructed to perform the exercises 3 times a week with 10 repetitions for each exercise.
- The primary outcome measurements were:
    - Hip pain at rest measured by the VAS, 0-100 scale
    - Hip pain during activity by the VAS, 0-100 scale
- Secondary outcomes were:
    - Function using the 15 minute timed walking test
    - Function measured by the Western Ontario McMaster Osteoarthritis Questionnaire (WOMAC)
    - Quality of life (QoL) measured by the Short Form-36 survey (SF-36)
- Assessments of the outcome measures were conducted by a blinded examiner at the clinic at baseline before the interventions, after treatment completion (2 weeks), and at one and 3 months after therapy.
- A total sample size estimation of 42 patients (14 per group) was required to detect at least a 20-point difference on activity and 10-point difference at rest between any two groups with a power of 90% at the 5% significance level. All the statistical analyses were performed by a blinded statistician.

Results:

- The pretreatment demographics and clinical characteristics of the groups displayed no differences between the groups.
- At baseline, outcome measurements did not differ between the groups. The baseline values of pain, functional status assessed by WOMAC and the 15 minute timed walking test, and SF-36 physical and mental scores were similar between the groups ($p>0.01$).
- The mean disease duration for all patients was 2.5 ± 1.7 years.
- All 45 patients completed the study and no patient was lost during the follow-up.
- At the end of the physical therapy sessions, each group showed significant improvement in the main outcome variables of pain intensity, WOMAC scores, and the 15-minute walking test, but these statistically significant improvements continued at the end of the first and third months follow-ups only for patients in group III that received the additional US therapy ($p<0.001$).
- The reduction in pain levels during activity and at rest as assessed at all follow-ups was significantly higher in group III than in the other 2 groups. In group III, pain during activity (VAS) decreased 42 points after therapy, 35 points one month post therapy, and 25 points 3 months post therapy from baseline. In group III, at rest (VAS) decreased 29 points after therapy, 24 points one month post therapy, and 15 points 3 months post

therapy from baseline. All of these reductions in VAS pain levels at all time points were clinically relevant as well.

- Although the improvement in functional status according to WOMAC scores was similar in all groups after the therapy (12 pts in groups I and II and 14 pts in group III), the changes in WOMAC scores at the first and third month follow-ups were significantly more improved and clinically relevant in patients in group III compared to the other 2 groups. In group III, function improved 14 pts after therapy, 11 pts one month post therapy, and 7 pts 3 months post therapy from baseline. In comparison, groups I and II, improved in function 12 pts after therapy, 4 and 3 pts one month post therapy, and 3 and 1 pts 3 months post therapy, respectively, from baseline.
- The changes and improvement in the scores of the 15-minute walking test were significantly better in group III at the third month of follow-up than in groups I and II.
- The SF-36 physical subscores were improved only in group III at the end of the first month of follow-up, and this statistically significant difference was maintained at the end of the third month. The mental subscores of SF-36 remained relatively unchanged in all groups after the therapies and during the follow-ups.
- All patients reported during their follow-up visits that they had performed the home exercise program routinely.
- No side effects were reported during or after the treatment periods.

Authors' conclusions:

- The results of this study indicated a significant long-term improvement in pain and function, in favor of the additional US therapy.
- The addition of therapeutic ultrasound to the traditional physical therapy showed a longitudinal positive effect on pain, functional status, and physical QoL in patients with hip osteoarthritis.
- In this study, all groups showed improvement in pain and functional outcome measures at the end of the therapy sessions, which may reflect the spontaneous recovery arising from placebo effects and/or conventional methods. This improvement was maintained only in group III after one and 3 months, which received US therapy in addition to standard physical therapy.
- Patients with OA of the hip who were treated with standard physical therapy and US experienced clinically and statistically significant improvements in pain, functional disability, and quality of life. The beneficial effects of the US treatment protocol persisted at the first and third months after the conclusion of therapy sessions. Given that the study was well designed and given the lack of improvements in the placebo and control groups after one and 3 months, it is unlikely that the desirable outcomes were caused by factors other than the US therapy.
- This study is the first randomized placebo-controlled study assessing the long-term additive effect of US to a standard heat and exercise therapy in patients with primary hip OA.
- In this study, both the subjective WOMAC and the objective 15-minute timed walking test were used to determine functional status. The continuing positive additional effects of US on functional improvement at the end of the third month are significant. In

addition, the objective gains in functional performance did not persist in the absence of US therapy, which can only be explained by the therapeutic effects of US over placebo.
- The use of therapeutic US in the treatment of hip OA should be encouraged, and it seems worthy to continue with large clinical trials on US in the treatment of degenerative hip disease in order to standardize the treatment modality in this patient group.

Comments:

- The study was well designed in that it included random assignment to study groups, inclusion of a placebo group, relatively homogeneous groups at baseline, and assessors who were blinded to group assignments.
- In the literature, there is no clear agreement on dose, intensity, frequency, or the number of US treatments that patients should receive for pain relief. This study used an output intensity of 1 W/cm^2, applied on three areas around the hip for 5 minutes each. This may be a relatively high dose when compared with previous trials, and may account for the positive outcomes found.
- The addition of US to traditional physical therapy methods was superior to not adding it when pain, functional status, and physical domains of QoL were considered in the long term.
- It was not clear which long-term time point, one or 3 months post-therapy, was the primary follow-up time point.
- Even though all patients reported during their follow-up visits that they had performed the home exercise program routinely, a more quantitative tracking method of collecting this data, such as daily exercise logs, should have been used. Then comparisons between groups in regards to home exercise adherence could be made.
- One limitation of this study is its very small sample size.
- The addition of the sham US group (group II) helped to eliminate the possible risk of attention bias. However, it is possible that the potential risk of attention bias was still present in group I, since this group was not given any additional therapy over the standard physical therapy.
- The study did not measure the success of assessor blinding, but this may not be important, since primary and secondary outcomes were mostly self-reported and thus not subjected to possible assessor bias.
- The study was adequately powered to detect significant differences.

Assessment*:*

- This adequate study provides some evidence that the addition of ultrasound (US) treatment with conventional physical therapy is more effective in reducing pain and improving function one and 3 months after treatment compared with conventional physical therapy alone in patients with primary hip osteoarthritis.