Leech therapy for symptomatic treatment of knee osteoarthritis: Results and implications of a pilot study

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Leech Therapy for Knee Osteoarthritis

OBJECTIVES

The objectives of this observational, controlled, nonrandomized pilot study with self-selected participants were (1) to determine the effect of leech therapy as an adjunctive treatment in painful knee osteoarthritis, (2) to investigate the onset of action, (3) to evaluate patients’ acceptance of this method, and (4) to investigate the side effects of the procedure.

METHODS

Subjects

Subjects were recruited over a period of 3 months from patients admitted to the academic teaching hospital at the University of Essen, Germany. These patients had a primary diagnosis of severe, chronic back pain with concomitant primary knee osteoarthritis resulting in persistent knee pain for more than 6 months. All patients received prestationary, conventional orthopedic treatment for knee pain with exercise, physiotherapy, and use of nonsteroidal anti-inflammatory drugs (NSAIDs) and analgesics as needed.

Further inclusion criteria were (1) radiographic evidence of knee osteoarthritis without previous injury, (2) no current indication for surgical therapy, (3) knee pain evaluated as clinically relevant by the subjects.

Major exclusion criteria were (1) treatment with anticoagulants or a history of hemophilia, (2) history or active presence of other rheumatic diseases that could be responsible for secondary osteoarthritis, (3) severe obesity with a body mass index (BMI) greater than 35 kg/m², (4) substantial abnormalities in hematological, hepatic, renal, or immune function, (5) insulin-dependent diabetes mellitus, (6) intra-articular injections or systemic corticosteroids in the 3 preceding months, and (7) history of joint replacement.

Within the concept of our integrative treatment program all subjects were inpatients for 14 to 16 days and received a health education program focusing on exercise, physiotherapy, behavioral and relaxation techniques, and, for those whose BMI exceeded 30 kg/m², a low-calorie diet.

Patients received information regarding the leech therapy, the procedure they would undergo, and possible side effects. Those who agreed to participate signed informed consent forms, which were examined by the Kliniken Essen-Mitte Institutional Review Board.

All patients were offered treatment with medicinal leeches (Hirudo medicinalis). Patients were asked to stop NSAID and analgesic intake during the 4-week study period. Patients (n=10) who agreed to leech treatment received 1 application of 4 leeches supplied by Zaug GmbH (Biebertal, Germany). Patients who did not wish to be treated with leeches (n=6) were treated only with the health eduation program and physiotherapy. Physiotherapy consisted of a graded exercise program with isometric and isotonic exercises to strengthen the quadriceps, walking, and local thermal applications. No patient refused to participate in the study.

Method of Leeching

Before the leeches were applied, patients were informed in detail about the procedure and reassured about the method to reduce anxiety. A quiet environment was maintained throughout the procedure.

Investigators followed published recommendations for preparation and monitoring of leech therapy as used in reconstructive surgery with the exception of concomitant antibiotic therapy. Patients were advised not to use any antiseptics, cremes, lotions, or perfumes as these can deter leeches from attaching. Disposable gloves and gentle handling with forceps were used to reduce the possibility of the leeches being injured or attaching themselves to the physician’s hand. The treatment site was prepared with water and 4 leeches were applied topically at the most painful periarticular sites of the subject’s painful knee joint. Exact placement was ensured by a small cup.

Leeching finished spontaneously in all patients within 40 to 90 minutes of application, and leeches were not reused. Premature removal was discouraged because the teeth of the leech could detach with a subsequent higher risk of infection. Nurses monitored leech activity during the first 10 minutes, then assisted subjects when their leeches finished and fell off.

A single leech can remove approximately 20-60 mL of blood. Figures 1 and 2 show one of the attached leeches at
different stages of the procedure. The trifoil-shaped puncture sites continued to ooze for approximately 1 to 4 hours after application. Blood counts with hemoglobin were measured the day after leeching.

Statistical Analysis

The primary outcome measure was change in total knee pain score, assessed by visual analog scale (VAS) daily at 8 PM. Subjects were asked to rate their average joint pain over the last 24 hours (0=no pain, 10=extremely painful) for 10 days daily, starting 3 days before treatment and continuing for 7 days following treatment. Subjects completed an additional VAS 28 days after treatment.

Mean scores of the VAS were calculated to a 95% CI using the following formula: mean ± 1.96 • (SD ÷ √N). Differences between baseline and Day 10 pain scores were rated using the Student t-test at a significance level of .05.

RESULTS

Ten subjects (mean age 69±9 years, mean BMI, 28.0±4.6 kg/m², 8 women) agreed to leech therapy, 6 subjects (mean age 68±8 years, mean BMI, 27.3±3.0 kg/m², 5 women) received conventional treatment only and served as controls. Subjects who did not wish to be treated with leeches explained their subjective aversion to this form of therapy or fear of the leech bite. No subject received analgesics or NSAIDs during the 4-week study.

Figure 3 shows the baseline level and duration of knee pain in both groups. Subjects in the leech group showed slightly higher baseline pain scores (VAS=7.4; 95% CI, 6.3-8.5) compared to the baseline score of the control group (VAS=6.3; CI, 4.8-7.8). Application of leeches led to rapid relief of knee pain in all treated patients, being most effective within 24 hours of treatment. At the end of the in-hospital observation period (Day 10), subjects treated with leeches showed clear improvement by a highly significant, lowered pain score on the VAS of 1.3 (CI, .5-2.1; P<.001). This improvement seemed to be sustainable because the VAS scores remained stable at the 4-week follow-up (mean 1.0; CI, .5-1.5). In contrast the pain score of the control group did not change significantly (Day 10 VAS=5.2; CI, 3.8-6.5, P>.1; follow-up VAS=4.8; CI, 3.8-5.9).

Leech therapy was well accepted by all treated patients. There were no serious adverse effects and no secondary local infections. Two patients reported moderate itching at the application site during the first 4-5 days after treatment. Complete wound healing was observed in all patients after 4 weeks. In most patients a small, trifoil-shaped scar was still visible at 4 weeks but subjects rated these as cosmetically irrelevant. All patients described the initial leech bite as only slightly or moderately painful. We found no noticeable decrease in hemoglobin values the day after leeching.

COMMENT

This nonrandomized pilot study examined the use of leech therapy outside its accepted application in reconstructive surgery and microsurgery. In view of its widespread ethnomedical and traditional use in regional pain syndromes2,3,8 and the increasing numbers of treatments in the CAM field (M. Roth, telephone conversation, April 12, 2001), a clinical evaluation of this treatment modality seemed necessary. We conducted this pilot study to assess the possible effect and onset of action of leech therapy for pain reduction in knee osteoarthritis. All treated patients rated their initial pain as clinically relevant. We found a clear and rapid pain-relieving effect from the leeches with no complications. Our results confirmed preliminary data from another trial that tested the pain-relieving effect of leech therapy in knee osteoarthritis.11 However, we must emphasize the preliminary nature of the present investigation. Limitations in the present study include the lack of randomization, the small sample size, and the self-selection of study participants.
Moreover, given the unusual treatment modality, there is a large potential for a placebo effect, but blinding for leech therapy is not feasible. Future studies in this field should assess subjects’ outcome expectations to further evaluate potential bias. These study limitations notwithstanding, there are several explanations for the observed treatment effect. The saliva of leeches contains several substances that have not been completely characterized. Most prominent among these are hirudine and other antihemostatic factors, hyaluronidase, histamine-like vasodilators, collagenase, inhibitors of kallikrein and superoxide production, and poorly characterized analgesic compounds. In addition, leech-derived tryptase inhibitor (LDTI) and inhibitors of leucocyte elastase were found in leeches’ saliva. Therefore, regional analgesic and anti-inflammatory effects by these substances enforced by hyaluronidase as a spreading factor might be possible. Hirudin could possibly contribute to an improvement of regional tissue perfusion and tissue decongestion, which seems not to be relevant for pain in the majority of knee osteoarthritis cases. Besides, counter-irritation may have contributed to the pain relief. Further, we do not know the placebo effects in the present study. An apparent mood-enhancement during leeching could be observed and the subjects themselves chose leech therapy. This points to a possible bias, but hardly explains the lasting pain relief observed in the 4-week follow-up.

No serious treatment complications were observed in this small study. Yet subjects must be informed about the slight initial pain and the possibility of lasting but small and barely visible scars. Clinically relevant blood loss was not observed in our subjects and is not expected by 1 application of 4 to 5 leeches, provided hemophiliacs and patients on anticoagulant medication are excluded. Moreover, according to the general empirical experience in the estimated 70,000 cases treated yearly in Germany (M. Roth, telephone conversation, April 21, 2001), leech therapy seems to be a safe approach in a patient population without severe comorbidity. Principally, there is a potential for infection and septicemia due to Armstrong's hydrophila infection, a bacterium commonly found in the intestinal flora of leeches and therefore physiologically present in their saliva. In a recent review of the use of Hirudo medicinalis for salvage of compromised pedicled flaps and microvascular free-tissue transfers, successful salvage of tissue occurred in 80% of cases and the infection rate was between 7-20%. Cases of septicemia due to Aeromonas hydrophila have been reported only in the context of reconstructive surgery. Mostly these infections followed leech application to tissue with questionable arterial perfusion.
Hence, in the field of microsurgery, leech application should be restricted to tissue with adequate arterial perfusion and supplemented by concomitant prophylactic short-term use of broad-spectrum antibiotics. This approach seems unnecessary in patients with knee osteoarthritis who are not immunocompromised. Clearly, data from larger controlled trials and systematic documenting of side effects are necessary to further assess the safety of leech therapy for symptomatic treatment in osteoarthritis.

In summary, leech therapy led to rapid and relevant symptomatic relief for at least 4 weeks and was well accepted by the patients in this pilot study. Yet the conclusions that can be drawn from this study are limited by the preliminary nature of the investigation and its design. Considering the increasing healthcare burden of knee osteoarthritis, the limited therapeutic options of conventional approaches, and the side effects of long-term NSAID and analgesic intake, this traditional alternative treatment should be tested in larger randomized controlled trials with longer observation periods.

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References