



Original article

Can Leech Therapy Be Used as an Alternative Treatment for Controlling Migraine Headache? A Pilot Study

Mahmoud Bakhshi¹, Babak Jalalian², Maryam Valian¹,
Saeide Shariati¹, Tahere Saeidi¹, Hossein Ranjbar³

¹Department of Nursing, Shahrood Branch, Islamic Azad University, Shahrood, Iran

²Neurologist, Imam Hossein Hospital of Shahrood, Shahrood, Iran

³Community Health Nursing, School of Nursing and Midwifery, Torbat Heydariyeh University of Medical Sciences, Torbat Heydariyeh, Iran

SUMMARY

Leech therapy is likely to cause symptomatic relief in migraine headache sufferers, but there is little clinical data in this field. This study aimed to investigate the effectiveness of leech therapy in the management of migraine headaches.

This is a quasi-experimental pilot study with a three-month post-treatment follow-up. Twenty-six patients with migraine headaches were allocated into two groups to receive either routine drug therapy (Propranolol 80 mg/day and Amytriptyline 50 mg/day) as preventive therapy or leech therapy (1-3 leeches in a single session). The severity and duration of headache were measured before intervention, as well as at week 1, and at months 1, 2, and 3 after intervention. The visual analog scale (VAS) was used to assess the severity of headache.

The mean severity and duration of headaches were significantly decreased within both groups during the study period, whereas there was no significant difference between the groups after three months. The declining trend of severity and duration of headaches was seen to be highly significant in the first week of the treatment in both groups.

The results of this study showed that a single session of leech therapy offers benefits equal to drug therapy in reducing pain in women with migraine headache, and can provide great symptomatic relief, lasting for at least three months.

Key words: leech therapy, drug therapy, migraine headache, clinical trial

Corresponding author:

Hossein Ranjbar

e-mail: ranjbarh881@yahoo.com

INTRODUCTION

Primary headaches are amongst the most common disorders of the nervous system (1). Migraine is a primary headache characterized by recurrent attacks of moderate to severe unilateral throbbing pain (2). The World Health Organization has described migraine as one of the most disabling chronic diseases (3). In the general population, the prevalence of migraines is 18% for women and 6% for men (4). This disorder has a powerful effect on the quality of life and a high economic cost for the patients and their families (5).

A variety of pharmacological treatments has been suggested to prevent or decrease migraine headache attacks, but medication alone does not control migraines (6). For this reason, headache sufferers may try complementary and alternative medicine (CAM) therapies (7). Leech therapy (LT) has become increasingly popular amongst CAM specialists and more patients have shown tendencies towards using leeches as a complementary treatment to deal with pain (8, 9). Although a specific analgesic substance has not been found in the leech saliva, clinical experience strongly supports its existence (10). The anti-inflammatory and analgesic substances in the leech saliva may reduce the release of vasoactive neuropeptides from neurovascular terminals which result in inhibition of trigeminal nerve activation and thus trigger the analgesic action. Also, physical effects of leech therapy in reducing pain might be due to the excretion or dilution of various inflammatory mediators such as cytokines (11).

Many clinical studies and case reports have examined the usage of LT against pain, but these were mainly focused on symptomatic treatment of knee osteoarthritis (11-16). A single course of LT has been shown to provide symptomatic relief and improvement in functional ability and quality of life in women with symptomatic arthritis in their carpometacarpal joint for at least two months (17). LT was also successfully used for symptomatic relief of severe cancer pain in the lumbar region (9). Effectiveness of leech therapy in other chronic pain syndromes has been also empirically proven (18).

The high prevalence of migraine headaches (19), no efficient drug therapy, high costs and side effects of drugs would necessitate the use of complementary therapies in Iran. Taking into account the anti-inflammatory and analgesic effects of leech saliva (20), leech therapy is likely to cause symptomatic relief in

migraine headache sufferers, but no studies have yet dealt with this likelihood. Therefore, this research was undertaken at a bloodletting clinic of Iran with the aim of investigating the effectiveness of leech therapy in the management of migraine headaches.

MATERIALS AND METHODS

This study is a quasi-experimental pilot study with prospective individual matching that was performed in a bloodletting clinic in Shahrood, situated in East of Iran from 2009 to 2011. The study protocol was approved by the Research Council and Ethics Committee of the Islamic Azad University of Shahrood (number: 88/088, April 14, 2009) and was registered in Iranian registry of clinical trials (number: IRCT2014032717090N1). Each participant was informed about anticipated risks and discomforts. Then, an informed written consent was obtained from each participant prior to performance of the study. Inclusion criteria were: women with the diagnosis of migraine headache for at least two years according to the International Headache Society (HIS) criteria, patients who had headache severity ≥ 5 based on a Visual Analogue Scale (VAS), and age between 25-55 years.

Exclusion criteria were pregnant or breastfeeding women or while menstrual periods, and those that had diagnosed brain tumors and other structural disorders of the brain, sinusitis, anemia ($Hb < 10$ g/dl), and patients with a history of stroke, bleeding or clotting disorders and patients who were on anti-coagulants and those that had acute medical condition e.g. heart, renal or liver failure were excluded from the study.

In this study, randomization was not feasible due to the specific nature of intervention. Leech therapy as intervention is not desirable for all patients, so we could not prevent patients' access to routine treatment. The total of 31 patients fulfilled all the study criteria, from whom 15 patients were enrolled for intervention which received leech therapy. The control group, 16 patients were selected for conventional drug therapy and matched to the intervention subjects with respect to age, marital status, duration of disease and baseline severity headache. Two patients from the treatment group and three from the control group withdrew from the study for different reasons. Leech therapy was an invasive intervention and there was no placebo treatment possible. Therefore, patients

could not be blinded to the therapy. At first visit, patients were assessed through history, physical examination and diagnostic studies by neurologist.

To perform leech therapy, the patient was placed in either the position or prone sitting. One to three leeches were placed behind each ear after washing the application sites with warm water. No special technique was used to fix leeches onto the skin. Leeches remained attached for 30 to 50 minutes until the time they spontaneously detached from the sites of the bites. Further bleeding was allowed to happen for a few minutes, and then the application sites were dressed using a compressed bandage. Patients were instructed about how to remove the bandage the next day and were discharged. Each leech was applied just once and then was disposed of under hygienic conditions. Patients in the control group were discharged after the first visit to the neurologist and were prescribed to continue usual routine drug therapy (Propranolol 80 mg/day and Amytriptyline 50 mg/day) as preventive therapies at home. In case of headache after discharge, patients in both groups were allowed to take acetaminophen/codeine (A+C) or non-steroidal anti-inflammatory drugs (NSAIDs) and had to keep a daily record. Conditions of the patients in both groups were followed up in the 1st week as well as in at months 1, 2 and 3 after intervention. The severity and duration of headache, the amount of drugs taken and complications of the intervention were recorded by one of the researchers who was unaware about the group status of the sample under study, for preventing any potential reporting bias.

The data gathering tools consisted of: a demographic information form, Visual Analogue Scale (VAS) for evaluating the intensity of headache, and checklists designed for recording intensity and

duration of daily headache as well as for recording the drugs used. VAS is scored as an integer number between 0 and 10 that is determined by the patient to best reflect the intensity of their pain. (Zero represents no pain whereas 10 represents intolerable pain). The reliability and validity of VAS as a standard tool has been approved through different studies (21, 22).

Data were analyzed using the SPSS software, version 11.5. Descriptive statistics were used to describe the characteristics of the samples in both groups. Then, inferential statistics were used to investigate the mean difference of pain severity and duration, and dosage of drugs between the two groups after the 1st week, and at 1st months 1, 2, and 3 after treatment. The independent t-test was used to compare the mean dose of (A+C) and NSAIDs in the two groups. Between-group comparison of mean scores of pain severity and duration for sequential time intervals was performed using repeated-measures analysis of variance (RANOVA), and the paired t-test was used to compare the mean scores within each group.

RESULTS

A total of 26 female patients with primary headache (mean age 35 ± 11) participated in the study of whom 13 received leech therapy (intervention group) and 13 received drug therapy (control group). The main reason mentioned by all patients for undertaking leech therapy was a lack of efficacy in past drug treatments. Table 1 indicates characteristics of the research samples in both groups. As per the table, no significant difference was observed between the two groups for any of the demographic and disease-related variables.

Table 1: Demographic and disease-related characteristics of patients in the two groups of the study

Variables	Drug therapy (n=13)	Leech therapy (n=13)	p-value
Age (years)	36 ± 11.76	35 ± 10.45	0.147
Level of education			0.353
	Under diploma	9	
	Diploma or higher	2	
Nausea	11	12	0.402
Vomiting	3	2	0.265
Blurred vision	7	5	0.242
Tinnitus	6	8	0.382
Photophobia	12	12	0.894
Phonophobia	10	11	0.435
Mean duration of symptoms \pm SD (months)	52 ± 26.52	54 ± 24.23	0.818

Figure 1 shows changes in pain severity and duration in both groups during the study period. The mean of pain severity and duration had no significant difference before treatment between the groups. Two-way repeated measures ANOVA showed that there was no significant difference in the mean of pain

severity and duration between drug therapy and leech therapy in the 1st week, and at months 1, 2, and 3 after treatment. However, in each group, there was statistically significant reduction in the mean of pain severity and duration at months 1, 2 and 3 after treatment compared to the baseline (Table 2).

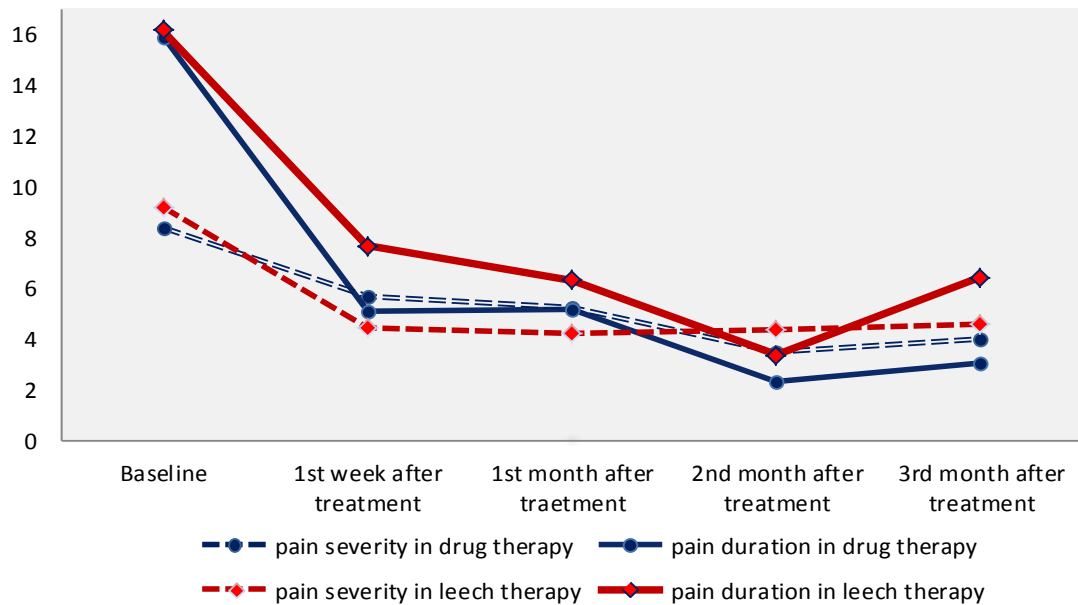


Figure 1: The effect of treatment on pain severity and duration in both groups

Table 2: The mean (SD) of variables under study before and after each treatment session in both groups

	Baseline	1 st week after treatment	1 st month after treatment	2 nd month after treatment	3 rd month after treatment	F; df; p-value
Pain severity						
Drug therapy	8.4 ± 1.65	5.67 ± 2.92	5.23 ± 2.50	3.50 ± 2.48	4.01 ± 1.98	F=19.40, df=2.70, P=0.000
Leech therapy	9.15 ± 1.06	4.46 ± 2.29	4.19 ± 2.28	4.34 ± 2.91	4.57 ± 3.23	F=12.12, df=2.57, P=0.000
Pain duration						
Drug therapy	15.87 ± 9.86	5.05 ± 6.97	5.16 ± 5.94	2.28 ± 1.80	3.06 ± 2.82	F=19.36, df=2.22, P=0.000
Leech therapy	16.15 ± 9.02	7.65 ± 8.27	6.29 ± 5.40	3.35 ± 2.18	6.41 ± 7.72	F=8.64, df=2.57, P=0.000

In the leech therapy group, maximum improvement in lowering pain severity was 55% in the first month, whereas the maximum reduction in pain duration was 80% recorded at month 2 after leech therapy. Also, the increase in pain severity in the first month, and pain duration in the second month were not statistically significant. Within the drug therapy group, the maximum reduction in pain severity and duration were 59% and 86%, respectively

in the second month after drug therapy. Although the data showed a slight increase in pain severity and duration in the second month within drug therapy group, the increase was not significant.

Mean (SD) of total analgesics dosage (NSAIDs and A+C) during the three-month follow-up is shown in Table 3. No significant difference was found in the total dose of analgesics in the two groups by using the independent t- test.

Table 3: Mean (SD) of total analgesics dosage (NSAIDs and acetaminophen/codeine) in the intervention and control group

Drug /group	Intervention group	Control group	Statistical test
NSAIDs (mg)	1891 ± 1403	3514 ± 1846	t=-1.86, df=24, p=0.08
A+C (mg)	5370 ± 5488	3128 ± 3341	t=0.95, df=24, p=0.36

DISCUSSION

This clinical trial provided evidence that a single treatment with leeches can cause a significant reduction in the severity and duration of headache for a relatively long period, of at least three months. LT was seen to be nearly as effective as drug therapy as the mean pain severity at the end of the three-month follow up was seen to be improved by 51% in both groups compared to the pre-intervention. Although the reduction in pain severity was not statistically significant in the patients receiving LT compared with patients in the drug therapy group in the same time period, it appeared to be 18% and 16% higher within the first week and first month post-treatment, respectively.

Though mostly focused on treatment of osteoarthritis of the knee, previous studies lend support to the hypothesis that LT causes pain relief (11, 12, 16, 17, 23). Michalsen et al. conducted a clinical trial investigating the impact of LT versus topical diclofenac in patients with osteoarthritis of the knee; the outcome of the research showed that there was no significant difference in VAS pain score between the two groups at the end of the three-month treatment, but VAS pain scores were 12 points better in patients who received LT compared to the patients in the control group (12). In another randomized clinical trial, patients in the intervention group received LT as a supplementary treatment to the conventional Ayurvedic herbal formulation, whereas the patients in the control group only received the conventional treatment. During the second month of the treatment, both groups experienced remarkable pain relief (measured by VAS) at month 1 and 2 post-intervention, but compared to Ayurvedic treatment alone, LT showed superior improvement that persisted for at least two months (11).

Our study also showed a decreasing trend in

severity of pain during the first month and in pain duration over the two months after LT, so much so that this decrease was notable from the first week after treatment. Pain severity reduction within the first week after LT was about 52%, whereas this reduction was 7% in the first month compared to the first week. These results suggest that the benefits of LT manifest themselves shortly after treatment. This finding is consistent with the results of other studies on the efficacy of LT in management of pain (18, 24). Lauche et al. in their systematic review and meta-analysis found strong evidence that LT can help relieve pain and improve physical function with a rapid-onset/short-term action (24).

Another noticeable fact in this study is the data found on the dosage of analgesic drugs. Though no significant difference was found between the two groups in the total amount of analgesics used, prescribing a lower dose of NSAIDs in the intervention group could reduce the risk of more serious events, such as gastric irritation and peptic ulcer (25).

Medicinal leech therapy is a simple and effective method and the cost efficiency of the treatment is high (26). When comparing the cost of conventional modern therapy with LT in the treatment of migraine headaches, LT is much less expensive than visiting a neurologist and following a daily drug regimen. Moreover, the main reason expressed by patients for the use of LT was a lack of satisfaction from drug therapy. Thus LT, as a secondary treatment, is likely to help treat patients who have received an unsuccessful drug treatment.

The only side effects of LT were transient local skin reactions with itching. No side effect was observed in the control group. All patients were informed that itching is a common side effect requiring no special treatment (8). On the whole, LT is a safe and simple approach with a low risk of serious

adverse effects (11, 27).

The main limitation of this study was the non-random allocation of patients to the two groups due to a phobia of leech in most people. In order to increase the study's validity, patients in control group were selected using a prospective individual matching strategy in which equalization is accomplished by selecting appropriate control patients to make the distributions of individual risk factors as similar as possible between the intervention and control groups. The second limitation of the study is due to the nature of LT (the leech bite, the sucking time and the voluntary referral of patient) which does not allow the use of credible 'blinding' techniques. Therefore, the placebo effects of LT cannot be precisely assessed. To enhance the credibility of results, a placebo effect must therefore be taken into account when interpreting any LT study result.

A single leech therapy application often suffices to cause long lasting symptom relief in patients. Although in this study pain severity and duration showed an increasing trend after the first and second month, respectively, pain severity and duration were lower than baseline values at the end of the third month of the study period. While in the trial on LT for knee osteoarthritis, the beneficial effect of a single LT application decreased after three months (17). Thus, a longer follow-up period seems to be necessary to fully assess the long-term efficacy of the treatment.

The difference in VAS pain scores between the groups remained in favor of LT until the end of the study, but it was statistically not significant. One possible explanation for this result may be a small sample size. Despite sufficient length of the study (37 months), very few patients preferred LT. Therefore, it is recommended that future research addressing the efficacy of LT in the management of headache must be done with a larger sample size, a longer follow-up

period and possibly covering a larger geographical area. There is also no substantive evidence that proves that the results of this study are not gender-biased. Consequently, both genders must be included in future research performed in this field.

CONCLUSION

This study indicates that a single course of LT offers benefits equal to drug therapy in reducing pain in women with migraine headaches and its benefits persists at least for three months. This approach can be used as a second-line treatment in patients previously unsuccessfully treated with drugs. LT is a safe and lasting alternative treatment. The result of this research can only be considered preliminary as the sample size was small and intervention was not blind.

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Da li lečenje pijavicama može da se primenjuje kao alternativni način lečenja u kontroli migrenoznih glavobolja? Pilot studija

Mahmoud Bakhshi¹, Babak Jalalian², Maryam Valian¹, Saeide Shariati¹, Tahere Saeidi¹, Hossein Ranjbar³

¹Departman za sestrinstvo, Islamski univerzitet Azad, Shahrood, Iran

²Neurolog, Šahrudska bolnica Imam Hossein, Shahrood, Iran

³Sestrinstvo u primarnoj zdravstvenoj, Fakultet za sestrinstvo i akušerstvo, Univerzitet medicinskih nauka Torbat Heydariyeh, Torbat Heydariyeh, Iran

SAŽETAK

Moguće je da lečenje pijavicama dovodi do simptomatskog smanjenja tegoba izazvanih glavoboljom. Međutim, postoji malo kliničkih podataka iz ove oblasti. Cilj ove studije bio je da ispita efikasnost terapije pijavicama u lečenju migrenoznih glavobolja.

Ovo je kvazi-eksperimentalna pilot studija sa tromesečnim periodom praćenja nakon sprovedene terapije. Dvadeset šest pacijenata sa migrenoznim glavoboljama bilo je podeljeno u dve grupe, pri čemu je prva grupa primala terapiju lekovima (Propranolol 80 mg/dnevno and Amytriptyline 50 mg/dnevno), dok je druga grupa lečena pijavicama (1-3 pijavice po sesiji). Ozbiljnost i trajanje glavobolja su mereni pre, kao i nakon prve nedelje intervencije i prvog, drugog i trećeg meseca nakon terapije. Za procenu ozbiljnosti glavobolje korišćena je vizuelno analogna skala (VAS).

Srednja vrednost težine i trajanja glavobolja značajno je smanjeno kod obe grupe u toku ispitivanja, dok značajnije razlike između grupa nakon tri meseca nisu utvrđene. Opadajući trend težine i trajanja glavobolje zabeležen je u obe grupe kao visoko značajan u prvoj nedelji terapije.

Rezultati ove studije su pokazali da pojedinačni tretman pijavicama pruža benefite jednake rezultatima terapije lekovima u cilju smanjenja bola kod žena koje pate od migrenoznih glavobolja, kao i da dovodi do simptomatskog olakšanja tegoba koje traje najmanje tri meseca.

Ključne reči: lečenje pijavicama, terapija lekovima, migrenozne glavobolje, kliničko ispitivanje