



Effectiveness of Leech Therapy in *Gambhira Vata-Rakta* (Acute Gout): A Pilot Study

Ashok Kumar Panda* and Saroj Kumar Debnath

Department of Ayurveda Research, Ayurveda Regional Research Institute - A unit of CCRAS, Department of AYUSH, Government of India, Gangtok, Sikkim, India

Abstract

Bloodletting is a mainstay of *Panchakarma* therapy as per Susruta. Leech therapy has been indicated as means of bloodletting for both types of *Vata-rakta* where pain, burning and redness found as per *Charaka chikitsa*. Medical science has enormous leaps in terms of diagnosis and treatment yet there is renewed interest in leech therapy among modern as well as traditional medicine practitioners. Most of studies of leech therapy are found for plastic surgery and pain reduction in osteo- arthritis. US, FDA also approves leech therapy as tool of skin graft. Therefore, we conducted a non randomized controlled pilot study in between June 2011 to Sep 2011 to assess the efficacy of leech therapy in *Gambhira Vatarakta* as diagnosed as acute Gout. Twelve patients (eight male and four female) with a mean age of 47 (9) years were treated with two - four leeches for seven days with a follow up to four weeks. Another 10 patients those were not willing for leech therapy was treated with tropical Diclofenac sodium gel for 7 days as control. The mean length of blood sucking is 32 (5) minute. The mean quantity of blood sucked by Individual leech per suck is 6 (2) ml. In comparison with control, leech application led to rapid relief of pain and swelling immediate after the detachment of leech. Most significant clinical improvement was noted after 14 days and slightly reduction of serum uric acid were also noted after three weeks of treatment. 90% Patient described the initial leech therapy as a painless and two patients had mild to moderate itching but no local infection was noted in treated group. Our study was limited to small sample size but it had remarkable treatment effect. Larger randomized control trial should be undertaken to study the safety and efficacy of leech therapy in acute gout.

Keywords: Leech; Bloodletting; Ayurveda; Acute; Gout; Patients

Introduction

Rakamokshyana (Bloodletting) is an ancient procedure that was utilized in Ayurveda in the setting of a humoral and pathological concept as a general treatment for all ailments, as well as during the middle ages primarily as a remedy for the treatment of inflammatory and infectious diseases by other traditional medicines of world. The general population was convinced of the efficacy of this treatment for centuries, even requesting it on occasion on a prophylactic basis. Leech has been used from ancient days in Greece, Rome and Arabian countries. Susruta (1000 BC) and Charak (600-200 BC) are two sages from India to describe about leech therapy whereas western literature mentioned about Themison (80-40 BC) – a pupil of Asclepiads is the first person to describe about leech therapy [1].

Leech is an Anglo-Saxon word derived from “Loece” meaning “to heal” and the oldest therapeutic book about leech is leechdom [2]. Leech is an: “aquatic worm with a flattened body, tapering toward each end, and terminating in circular flattened discs, the hinder one being the larger of the two. It swims with a vertical undulating motion, and moves when out of water by means of these discs or suckers, fastening itself first by one and then by the other, and alternately stretching out and contracting its body. The mouth is placed in the center of the anterior disc, and furnished with three cartilaginous lens-shaped jaws at the entrance of the alimentary canal. These jaws are lined at their edges with fine, sharp teeth, and meet so as to make a triangular incision in the flesh. The head is furnished with small, raised points, supposed by some to be eyes. Leech belongs to the Phylum Annelida family of fresh-water parasitic invertebrates [3]. It was noticed that leech bites continued to bleed after the leech was withdrawn. This phenomenon was finally explained in 1884 when John Berry Haycroft, a Birmingham chemist, discovered an anticoagulant, called “hirudin”, that the leech injected into the blood, which kept the capillaries flowing [4].

The resurgence of Leech therapy in treatment of hypertension,

migraines, phlebitis, varicose veins, arthritis, hemorrhoids, and ovarian cysts were introduced in Russia after 1990's [5,6]. In the United States, plastic surgeons use them to drain blood from wounds after limb or tissue reattachment [7,8]. Some Indian clinical trials of leech therapy in Osteoarthritis, Frostbite, Hypertension, Migraine are in Progress from Unani Research Council [9]. Recent research also supports leech use in relieving pain in patients with osteoarthritis of the knee, as well as in treating purpura fulminans, periorbital hematoma, sublingual hematoma, systemic lupus erythematosus, and ear infection [10].

The prevalence of Gout is now as high as 12.6% may due to increased frequency of obesity and hypertension. Monosodium urate crystal is the active constituent for acute inflammatory reaction in Gout [11]. Colchine, corticosteroid and NSAID are the choices of drugs in acute gout with their proven adverse effect [12]. Leech therapy has been indicated as means of bloodletting for both types of *Vata-rakta* where pain, burning and redness found as per *Charaka chikitsa* [13,14]. Some Chinese evidences of Bloodletting in Gout with Cupping and herbal medicinal are there with significant result [15]. Some traditional healers of Sikkim have been practicing leech therapy in acute gout also [16]. But no clinical studies available on leech therapy in acute gout except some review. Therefore, we conducted a non randomized Controlled pilot study in between June 2011 to Sep 2011 to assess the efficacy of leech therapy in *Gambhira Vatarakta* as diagnosed as acute Gout.

***Corresponding author:** Ashok Kumar panda, Department of Ayurveda Research, Ayurveda Regional Research Institute - A unit of CCRAS, Department of AYUSH, Government of India, Gangtok, Sikkim, India, Tel: 03592-231494; E-mail: akpanda_06@yahoo.co.in

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Patients and Methods

We recruited 22 patients of acute gout from the OPD of our Institute by preset exclusion and inclusion criteria. An informed consent was obtained from all participants in the study and all patients were informed about 2-4 leech application. The patients were male and nonpregnant women in between the age of 18-60 years were included in the study based on the American College of Rheumatology 1980 classification criteria [17]. The major exclusion criteria were treatment with anticoagulants, haemorrhagic disorders, treated with western medication and preexisting arterial insufficiency. The patients were treated with two - four leeches in the affected area for seven days with a follow up to four weeks. Leech (*Hirudo medicinalis*) was used for the treatment after identified by local zoologist and conformed from literature [18]. The leech were attached, monitored and detach as per the published recommendations [19]. Eligible patients also had at least 1 CBC, blood chemistry, and urinalysis performed within 1 year prior to trial, the results of which revealed no abnormalities that would contraindicate treatment with either study medication.

Efficacy & Safety Evaluation

The primary outcome (0-7 days) was measured by pain intensity in the index joint by Visual analogous scale (VAS) i.e. 0= no pain & 10= extremely painful on D0, immediately after therapy for 7 days daily with a fellow up for 28 days.

The secondary outcome i.e. tenderness (0-3-point scale), and swelling (0-3-point scale) are also assessed. The patient's and investigator's global assessments of response to therapy (0 = excellent; 4 = poor) and the investigator's assessments of study joint tenderness (0 = no pain; 3 = patient states there is pain, winces, and then withdraws), swelling (0 = none; 3 = bulging beyond the joint margins), and erythema (present, absent, or not assessable) were conducted on day0, immediately after therapy for 7 days daily with a fellow up for 28 days. The patients were advised for visit if problem arise in between. The serum uric acid was measured on D0, D1, D4, D8, D14, D21 and D28. The outcome of safety measured by patient's and investigator's global response to treatment with any adverse effect was observed during the therapy and observed period.

Observations and Results

Total 22 patients were recruited in the study and man patient 14 (64%) are dominant in the study with more educated people 16 (73%) are attracted to this Ayurveda therapy (Table 1). All the patients have the classical symptoms of acute gout but elevated uric acid observed in only 10 (83.33%) in leech therapy group and 7 (70%) in control group. Presence of trophy is very less in both the groups. Polyarticular joint pain was found in maximum patients. The most affected joint was great toes in both the groups (Table 2).

We attached the leech by gripping in dry gauze to the site or by placing a drop of glucose on desired site. We noticed that some time leech migrate from one site to another. 90% Patient described the initial leech therapy as a painless. The mean feeding time was 32(5) minute. The mean quantity of blood sucked by Individual leech per suck is 6(2) ml. Three patients had mild to moderate itching and Bleeding from the site of application was seen in 2 patients and was easily managed with compressive dressings. No other complications or infections were noted.

The mean changes in primary outcome i.e. Pain (VAS) was significantly reduced immediate after the leech therapy and completely

disappear in 28 days, whereas pain in control group was poorly reduced and reappeared after the cessation of application of Diclofenac gel in the affected area (Table 3). The secondary outcomes were also assessed by the patient's and investigators global assessment to response to the therapy, tenderness, swelling and noting erythema in leech and control groups. Leech group was responded well even after the cessation of treatment but control group had reappeared the symptoms after the cessation of treatment (Table 4,5). The primary and secondary endpoints were also compared in trial and control group and significant response was observed in trial group compared to control group (Table 6).

Discussion

A seven days course of leech therapy was effective in relieving pain, tender, swelling, erythema in acute gout and the effect was intact up to 28 days of observed period. These types of pain relieving effect was also observed in other randomized control studies in the treatment of Osteoarthritis and epicondylitis [20,21].

The saliva of leeches contains a variety of substances such as hirudin, hyaluronidase, histamine-like vasodilators, collagenase, inhibitors of kallikrein and superoxide production, and poorly characterised anaesthetic and analgesic compounds [22,23]. Therefore, a regional analgesic and antiphlogistic effect by these substances enforced by hyaluronidase as well as counter-irritation might be possible. Leeches might be considered as an additional option in the therapeutic approach to acute Gout. Our study was limited to small sample size but it has remarkable treatment effect. Larger randomized control trial should be undertaken to study the safety and efficacy of leech therapy in acute gout.

Variables	Test group	Control Group	Total
No of patients	12	10	22
Percentage of Male	8(66.66%)	6(60%)	14(64%)
Mean age in Years	47(9)	50(10)	
Percentage of Educated person (above matric)	9(75%)	7(70%)	16(73%)
Duration of diseases	8.1(6.2)	7.3(4.5)	7.9(4.9)
Monoarticular joint pain	5	4	09
Polyarticular	7	6	13
Metatarsophalangeal (foot)	3	3	6
Ankle	2	2	4
Knee	1	1	2
Great toe proximal interphalangeal joint	6	4	10
Others	0	0	0

Table 1: Patient's demographic variables of studied 22 patients.

Clinical variables	Test group	Control group
Pain in Joint	12	10
Swelling of the joints	12	10
Joints of limited mobility	12	12
Redness of Joint	11	10
Elevated uric acid	10	07
Presence of Trophy	03	02

Table 2: Clinical variables of studied 22 patients.

Group	Baseline	Day1	Day4	Day8	Day14	Day21	Day28
Leech (n=12)	7.6	3.4	2.3	1.4	1.0	1.0	1.0
Diclofenac gel (n=10)	6.4	5.8	4.8	4.0	6.0	6.0	6.0

Table 3: Mean changes in the primary outcome (Pain Score-VAS) in different duration of treatment in Studied & Control group.

Assessment Scale	Day0	Day1	Day4	Day8	Day14	Day21	Day28
Patient global assessment to response to therapy (0-4)	NA	2.26	1.06	0.86	0.86	0.56	0.56
Investigator's global assessment of response to therapy (0-4 scale)	NA	2.16	1.02	0.72	0.72	0.34	0.34
Study joint tenderness (0-3 scale)	2.56	2.24	1.16	0.84	0.84	0.20	0.20
Study joint swelling (0-3 scale)	2.58	2.26	1.16	0.34	0.34	0.20	0.20
Study of Erythema	p	p	p	A	A	A	A

Table 4: Mean changes in secondary outcome in leech therapy group (n=12).

Assessment Scale	Day0	Day1	Day4	Day8	Day14	Day21	Day28
Patient global assessment to response to therapy (0-4)	NA	1.06	1.16	1.26	0.96	0.96	0.96
Investigator's global assessment of response to therapy (0-4 scale)	NA	0.98	0.62	0.48	0.72	0.72	0.92
Study joint tenderness (0-3 scale)	2.46	2.46	2.36	1.88	2.64	2.64	2.64
Study joint swelling (0-3 scale)	2.34	2.16	2.16	1.84	2.34	2.34	2.34
Study of Erythema	p	p	p	A	p	p	p

Table 5: Mean changes in secondary outcome in control group (n=10).

Assessment Scale	Baseline mean	Treatment Mean	P value	REMARK
Pain Scale				
Leech Group	7.6	1.0		
Control group	6.4	6.0		
Patient global assessment to response to therapy (0-4)				
Leech Group	NA	0.56		
Control group	NA	0.96		
Investigator's global assessment of response to therapy (0-4 scale)				
Leech Group	NA	0.34		
Control group	NA	0.92		
Study joint tenderness (0-3 scale)				
Leech Group	2.56	0.20		
Control group	2.46	2.64		
Study joint swelling (0-3 scale)				
Leech Group	2.58	0.20		
Control group	2.34	2.34		
Study of Erythema				
Leech Group	P	A		
Control group	P	P		

Table 6: Mean change in the primary and secondary end points from baseline in both studied and Control Groups.

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