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Efficacy of *Ghati Yantra Raktamokshana* (Bloodletting with Modified Cupping) in Pain management of *Ghridhrasi* (Sciatica): A systematic review

Review Article

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Abstract

Background & Objectives: Pain in Sciatica can be incredibly painful and intolerable which seeks immediate medical attention. Various treatment modalities are widely used but have side effects too. One of them is *Ghati Yantra Raktamokshana* (Bloodletting with modified cupping). This systematic review provides an assessment on evidence of pain management of *Gridhrasi* (Sciatica) by *Ghati Yantra Raktamokshana* (Bloodletting with Modified Cupping). Methods: The databases of PubMed, Scopus, Cochrane Library, AYUSH portal, Shodhganga, Clinical trial registry of India, Google scholar were searched systematically (since inception to February 2021) for relevant articles about the effect of *Ghati Yantra Raktamokshana* in pain management of *Gridhrasi*. All randomized controlled trials as well as non-randomized controlled trials, before and after studies and single group clinical studies assessing the efficacy of *Ghati Yantra Raktamokshana* in pain management of *Gridhrasi* was included. Results: The original search yielded 774 articles of which only 6 articles (1-pilot study, 1-case study and 4-single arm studies) met the inclusion criteria and they showed the effectiveness of *Ghati Yantra Raktamokshana* in Pain management of *Gridhrasi*. Interpretation & Conclusions: Though review shows that the *Ghati Yantra Raktamokshana* is effective in Pain management of *Gridhrasi* but due to the methodological and clinical heterogeneity and risk of bias of the included trials requires more strong evidences in terms of RCT's with larger sample size and for longer duration to definitely conclude its effectiveness.

Key Words: *Ghati Yantra Raktamokshana,* Bloodletting, Modified Cupping, Gridhrasi, Sciatica, Pain management.

Introduction

According to Indian glossary, *Ghati Yantra* is a bucket of a well or any machine for raising water. By considering the principle of this work, in *Ayurveda Ghati Yantra* (modified cupping instrument) is used to draw the blood from the affected site. *Ghati Yantra Raktamokshana* (Blood-letting) is one of the type of *Anushastrakruta Raktamokshna.*(1,2) According to the modern science, it can be compared with wet type of cupping therapy in which first superficial skin incision will be taken at the affected site then a bell-shaped instrument is applied to create a vacuum so that blood is withdrawn from the affected site. The World Health Organization (WHO) defined cupping as a therapeutic method involving the application of suction by creating a vacuum.(3) The suction through specific cupped instrument was used since prehistoric time for the treatment of disease. (4–7)

Gridhrasi (Sciatica) is a clinical entity which produces intense pain and hampers day to day activities, affecting valuable hours. The clinical symptomatology of *Gridhrasi* is migrating pain from *Sphika* (hip), *Kati* (waist), *Prushtha* (back), *Uru* (groin), *Janu* (knee) and *Jangha* (thigh) to *Pada* (foot). Classical pain of *Gridhrasi* is accompanied by *Stambha* (rigidity), *Ruk* (pain), *Tod* (pricking pain) and patient feels recurrent throbs along the affected leg.(8–10) On the basis of symptoms *Gridhrasi* can be equated with the disease Sciatica in modern parlance.(11) The prevalence of sciatic symptoms reported in the literature varies considerably ranging from 1.6% in the general population to 43% in a selected working population.(12,13) In modern medicine, the management of sciatica includes analgesics, epidural steroid injections, peri-radicular infiltration and surgical treatment, but all these treatments have adverse effects, complications and also possibility of more reoccurrence rate.(14,15) *Ayurvedic* classics propose the effect of *Raktamokshana* on pain management of various diseases and *Gridhrasi* is disease with pain as pre-dominant symptom. *Ghati Yantra Raktamokshana* is widely used to cure pain ailment of disease. Therefore, a review was planned with the aim of evaluating the clinical efficacy of *Ghati Yantra Raktamokshana* in the pain management of *Gridhrasi*.

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Material and Methods

This study was registered on the International Prospective Register of Systematic Reviews (PROSPERO: CRD42021236763).

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) protocols guidelines(16) was used to perform this systematic review. The first phase involved in this systematic review, the development of a specific protocol and a research question based on the Population Intervention Control Outcome (PICO) format.(17)

Review Methods / Search Strategy

Different databases like PubMed, Scopus, Cochrane Library, AYUSH portal, Shodhganga, Clinical trial registry, Google scholar were searched to assess the data. The keywords used for the purpose of search include *Ghati Yantra Raktamokshana*, Modified Cupping, Pain, *Shul, Gridhrasi* and Sciatica with Boolean operators and / or. No limits were adopted such as; journals, years of publication, types of articles, or authors. Articles published in the English language until February 2021 were included for the purpose of review. Titles, abstracts and full texts for compliance with eligibility criteria were reviewed.

Inclusion Criteria

Studies that met the following criteria were included in the review: (a) studies published in English or any other language; (b) Patient with classical features of *Gridhrasi* i.e., pain over the *sphik*, *kati*, *prushta*, *uru*, *janu*, *jangha* extending up to *pada* which is associated with *stambha*, *toda*, tingling & numbness of limbs, difficulty in walking were included in the study. (c) Patients with positive straight leg raise (SLR) test.

Exclusion criteria

Participants with back pain or low back pain but no symptoms of sciatica.

Types of study included

The review considered all quantitative study designs including randomized controlled trials, non-randomized controlled trials, before and after studies and single group clinical studies.

Quality Assessment

The first author reviewed the included papers and the second review was performed by other author who also assessed these selected papers. Because non-randomized studies were included in this study, the methodological index for non-randomized studies (MINORS) scale(18) was used to assess the quality. If two independent evaluations conflicted, all authors participated in a discussion to resolve the controversy.

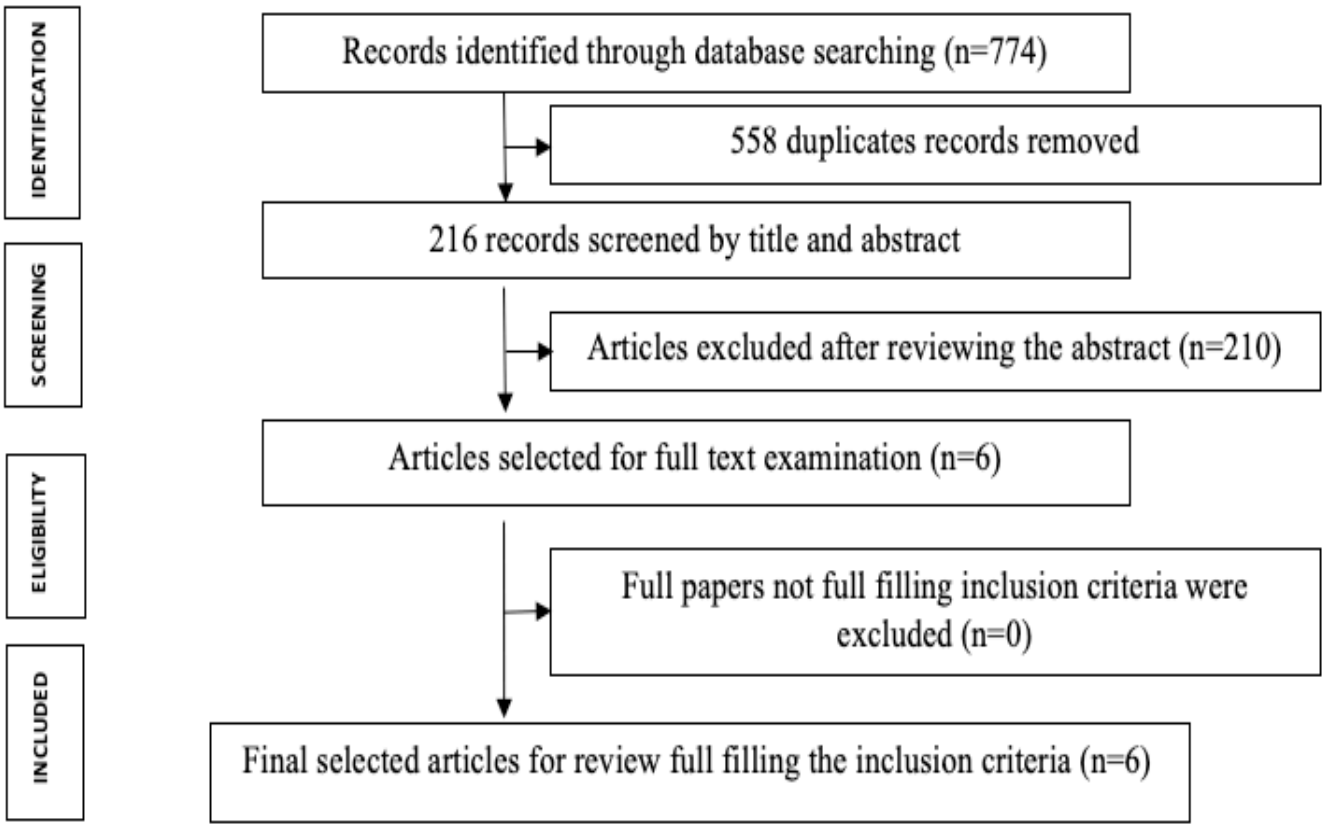
Outcome of assessment

The primary outcome of interest of this systematic review was pain intensity. Any validated measurement scales were included (e.g., Visual Analogue Scale (VAS), Numeric Rating Scale (NRS).

Results of the search

Total 774 articles and clinical trials were identified with the search strategy, out of which 558 duplicates were removed and 216 records were screened by title and abstract. Total 6 articles were selected for full-text examination and after confirmation of full filling the inclusion criteria all articles were selected(7,19–23)(Fig. 1).

Fig. no.1-Flowchart of trial selection process / PRISMA flow diagram



Quality Assessment

Table MINORS Scale for quality assessment of non-RCT and single-arm studies (Table 1).

Table 1- MINORS Scale for quality assessment of non-RCT and single-arm studies

Items	*Minakshi Kumbhare –Patil et al; 2016*	*Durgesh Nandini et al; 2016*	*Muhammad Bilal et al; 2016*	*Jadhav Pradnya et al; 2019*	*Muhammad Amin Baig et al; 2019*	*Nikhat Shaikh et al; 2020*
1.A clearly stated aim	1	1	2	1	2	2
2.Inclusion of consecutive patients	2	2	2	2	2	2
3.Prospective collection of data	2	2	2	2	2	2
4.Endpoints appropriate to the aim of the study	1	1	2	1	2	2
5.Unbiased assessment of the study endpoint	0	0	0	0	0	0
6.Follow-up period appropriate to the aim of the study	2	1	2	2	2	2
7.Loss of follow up less than 5%	2	2	2	2	2	2
8.Prospective calculation of the study size	2	0	2	2	1	2
Total	12	9	14	12	13	14

Risk of bias assessment:

Six studies were included in the final analysis. Methodologic quality was assessed using "Risk Of Bias In Non-randomized Studies of Interventions" (ROBINS-I) scoring system(24), which is a new tool for evaluating risk of bias. ROBINS-I views each study as an attempt to simulate an ideal randomized trial, that is expected to answer a particular clinical problem. Seven domains are investigated for potential risk of introducing bias, that are judged with use of signalling questions. Overall, the risk of bias was moderate in most papers, which is understandable as most studies were single arm studies, and as such are subject to confounding and a range of other biases. At the pre-intervention stage, in most of the studies bias due to confounding variables (age factor, physical exertion, environmental condition) was mainly serious, except in 2 studies in which moderate bias was found because they had selected only middle age group for study which minimizes age and in slight also physical exertion factors. Moderate selection bias found in most of the included studies reflects the lack of randomization and control groups. At the intervention and post-intervention stages, all studies showed low risk of bias (Table 2). The quality assessment was performed by two independent reviewers.

Table 2 - Risk of bias assessment

Study		**Pre-intervention**		**At intervention**	**Post intervention**				**Overall risk of bias**
First Author	Year	Bias due to confounding	Bias in selection of participants into the study	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	Low / moderate / serious / critical
Minakshi Kumbhare–Patil	2016	Serious	Moderate	Low	Low	Low	Low	Low	Serious
Durgesh Nandini	2016	Serious	Moderate	?	Low	Low	Low	Low	Serious
Muhammad Bilal	2016	Moderate	Moderate	Low	Low	Low	Low	Low	Moderate
Jadhav Pradnya	2019	Serious	Moderate	Low	Low	Low	Low	Low	Serious
Muhammad Amin Baig	2019	Serious	Moderate	Low	Low	Low	Low	Low	Serious
Nikhat Shaikh	2020	Moderate	Moderate	Low	Low	Low	Low	Low	Moderate

Data Analysis

Since, very few numbers of studies fulfill the inclusion criteria, the methods were kept simple and no statistical techniques were applied to the selected papers. Articles were then analyzed for the outcome measures and results of the study. All the details regarding the included studies are explained (table 3 & 4).

Table 3-Characteristics of included studies

Sr. no.	Study	Place	Type of study	Sample Size	Age Group	Site of Ghati Yantra Application	Intervention details
1	Minakshi Kumbhare–Patil *et al; 2016*	-	Pilot Study	20	30-60yrs	Single cup at highly affected area on *Sphika* or *Kati-Prishta* (lower back region)	4times at interval of 5days

2	Durgesh Nandini *et al; 2016*	I.P.G.T. & R.A., Gujarat Ayurved University, Jamnagar, Gujarat	Case Study	1	44yr	4 cups on lower back region & 2 at four *angula* (fingers) above *Janu Sandhi* (knee joint)	2 setting at 15day interval
3	Muhammad Bilal *et al; 2016*	Pharmacy and Pharmaceutical Sciences, University of Karachi, Karachi, Pakistan	Single arm study	92	18 - 75 years	1 Cup applied at C7, T2 & L5/ S1 vertebrae, 2 cups bilaterally on L4/L5 vertebrae, 4 cups on hip joint, back of thigh, knee & calf muscle	thrice at an interval of 15 days
4	Jadhav Pradnya *et al; 2019*	APM`S Ayurved Mahavidyalaya Sion, Mumbai	Single arm study	20	30-70 yrs	Single cup at highly affected area on *Sphika* or *Kati-Prishta* (lower back region)	4 settings at 5 days interval
5	Muhammad Amin Baig *et al; 2019*	Ajmal Unani Medical College, Pakistan	Single arm study	250	18-80years	1 cup applied between shoulders at T1 & C7 vertebrae, 2 cups applied on L3-L4 or L4-L5 & L4-S1 vertebrae.	3 settings on alternate day
6	Nikhat Shaikh *et al; 2020*	PRIUM, OPD, JJ Hospital Campus, Byculla, Mumbai	Single arm study	20	40-60years	5 disposable cups of large site (2 at lower back region, 2 at the thigh region % 1 at calf region)	every fortnight for four visits

Table 4: Characteristics of included studies

Sr. No.	Study	Assessment criteria	Statistics & Result
1	Minakshi Kumbhare−Patil *et al; 2016*	Subjective: symptoms given score and were assessed before and after Objective: SLR test & angle with the help of protractor was noted for comparison.	1. *Ruja*: The mean score for *Ruja* before treatment was 2.55, while after treatment, the mean score was 0.75 which was statistically significant with $p < 0.001$. Eight patients out of 20 (40%) got 100% relief with reduction of intensity and in remaining patients, 50–90% reduction in pain was seen. 2.*Toda*: The mean score for *Toda* before and after treatment was found to be 2.35 and 0.35 respectively which was statistically significant. In 14 patients out of 20 patients *Toda* reduced to 100% and in remaining patients,70–90% reduction was seen. 3.*Stambha*: The mean score of *Stambha* was 2.35 before treatment and 0.75 after treatment which was statistically significant. 6 patients out of 20 have got reduction in *Stambha* 100%, and in remaining patients, 60–80% improvement was seen. 4.*Spandana*: The mean score before treatment was 1.55 which was observed to decline to 0.30 with $p < 0.001$ which was statistically highly significant. 14 patients out of 20 got 100% relief in *Spandana* and in remaining patients, 60–90% relief was seen. 5.SLR: The mean value for SLR test was found to be 36.25° before treatment which has increased to 80° with statistically high significance. The SLR test shows improvement up to 25% in first 5 days, 40% in 10 days, and 80–90% at the end of 15 days.
2	Durgesh Nandini *et al; 2016*	Subjective: symptoms Objective: (S.L.R.) test /Lasegue sign	After 1st sitting, patient got 50 % relief in *Ruka*, *Toda*, *Stambha*, *Sakthanakshepananigrahaniyat* (inability to move limbs). S.L.R was increased up to 50°. After 2nd sitting, she got 90% relief in above symptoms. S.L.R. raised to 70°. She has no pain during walking, less burning sensation in foot.
3	Muhammad Bilal *et al; 2016*	Pain was assessed on numeric pain rating scale (NPRS).	The results show that 85% relief in pain was observed in 9.8 percent of patient's, 15.21 percent patient's experienced 70% relief, 5.43 percent patient's experienced 60% relief in pain, 9.78 percent patients experienced 50% relief in pain, 9.78 percent patients experienced 40% relief in pain, however 32.60 percent patients did not show any relief in pain after 3 sessions of *Hijama*

4	Jadhav Pradnya *et al; 2019*	Subjective: symptoms given score and were assessed before and after Objective: SLR test & angle with the help of protractor was noted for comparison.	1.Pain: The mean score for pain before treatment was 3.4, while after treatment, the mean score was 1.55 which was statistically significant with $p < 0.001$. 2.*Toda*: The mean score for *Toda* before and after treatment was found to be 2.95 and 0.9 respectively which was statistically significant with $p < 0.001$. 3.*Stambha*: The mean score of *Stambha* was 2.9 before treatment and 1 after treatment which was statistically significant with $p < 0.001$. 4.SLRT: The mean value for SLR test was found to be 40.25° before treatment which has increased to 71.75° with statistically high significance with $p < 0.001$.
5	Muhammad Amin Baig *et al; 2019*	The decrease in Sciatic Pain and improvement in Quality of life of patient was assessed by Visual analogue Score, Numeric Pain rating scale, and WHOQOL scale at before treatment, After Treatment, 1year after treatment, 2 years after Treatment, and 5 years after treatment.	Out of 250 patients about 225 (90%) of patients have shown marked decrease in sciatic nerve pain. After 1year of treatment 175 (70%) of patients were satisfied and doesn't need any further treatment of sciatic pain, after 2 year of treatment more than 125 (50%) patients showed marked decrease in pain as compared to before treatment. 5 years after treatment 92(37%) of patients were enjoying good quality of life as shown by their WHOQOL scale.
6	Nikhat Shaikh *et al; 2020*	Parameters of the Study 1. Straight leg raising test 2. Radiating pain in affected limb 3. Numbness in the affected limb 4. Pain in lower back 5. Tenderness in lower back	1.Straight leg raising test- shows efficacy of 41.86% after 1st follow up, 74.42% after 2nd follow up and 93.02% efficacy after 3rd follow up. 2.Radiating pain in affected limb- shows 6.98% improvement after 1st follow up, 48.84% after 2nd follow up & 90.70% improvement after 3rd follow up. 3.Numbness in the affected limb- shows 2.50% improvement after 1st follow up, 65% after 2nd follow up & 100% improvement after 3rd follow up. 4.Pain in lower back- shows 34.09% improvement after 1st follow up, 68.18% after 2nd follow up & 100% improvement after 3rd follow up. 5.Tenderness in lower back- shows 36.36% improvement after 1st follow up, 72.73% after 2nd follow up & 100% improvement after 3rd follow up.

Discussion

Discussion on Assessment of complication

As the study selected for the systematic review includes invasive therapy i.e., application of *Ghati Yantra* for *Raktamokshana* (Cupping instrument for bloodletting), there can be chances of complications like burn, infection after treatment. But no protocol for management of any complications that can be occurred during the treatment was described in all included studies. Also, none of the studies included in the systematic review has stated the occurrence of any complications during the treatment except Muhammad Bilal et. al study(20) stated no any side effects found.

Discussion on Mode of action of *Ghati Yantra Raktamokshana* on Pain management of *Gridhrasi*

Cupping targets soft tissue by applying local pressure to pain points and areas of swelling. It helps to extract blood from the body which may be harmful and in turn, overcome the potential adverse effects, leading to physiological well-being. Vitiated *Doshas* (Humours) responsible for the Sciatica along with *Rakta Dhatu* (Blood) was let out by pricking with needle on affected area and the vacuum created by *Ghatiyantra* helps the vitiated blood to ooze out which gives spontaneous relief from symptoms of *Gridhrasi* due to release of *Doshas* (Humour) with the blood from the body.(19,21) It is thought to act mainly by increasing local blood circulation and relieving the painful muscle tension. It mainly involves improving microcirculation, promoting capillary endothelial cell repair, accelerating granulation and angiogenesis in the regional tissues. This helps in normalizing the patients functional state and progressive muscle relaxation.(7) Thus, it can be stated that most of the studies accept principle of vacuum extraction or principle of evacuation and diversion of morbid humours. But this hypothesis was not confirmed because post cupping MRI scans were not obtained in all the studies.

Ghati Yantra Raktamokshana has shown positive results in pain management of *Gridhrasi*. The systematized analysis showed that there is a need of standardization in the intervention treatment i.e., method of *Ghati Yantra* application for *Raktamokshana*. Regarding the evaluated outcomes, one of the study used a numeric pain rating scale (NPRS)(20), another one used a Visual analogue Score, Numeric Pain rating scale, and WHOQOL scale for assessment of pain.(22) But in other four studies, no scale is used instead they use only a subjective criterion i.e., symptoms and objective criteria i.e., SLR test for the assessment of pain.(7,19,21,23) So, there is a clinical heterogeneity in terms of assessment of outcome.

The limitation of this systematic review is unavailability of RCT and non-RCT. Thus, we include 1 pilot study(19), 1 case study(7) and 4 single-arm studies(20–23) for this systematic review, which might reduce the degree of reliability. Also, there is a heterogeneity in the included trials regarding methodology as there is a difference in the duration of conducted intervention i.e., *Ghati Yantra Raktamokshana*.

Conclusion

The result of this systematic review suggests that the *Ghati Yantra Raktamokshana* is a valuable treatment option for patients suffering from pain of the *Gridhrasi*. However, due to the methodological and clinical heterogeneity and risk of bias of the included trials, it is impossible to conduct meta-analysis of the review studies. So, it's needed to conduct more high quality randomized controlled clinical trials in which the *Ghati Yantra Raktamokshana* can be compared to other effective treatments. Also, it is required to compare these treatments with an appropriate design and methodology along with safety protocol in a future to strongly clarify the role of *Ghati Yantra Raktamokshana* in pain management of *Gridhrasi*.

Authorship Confirmation Statement

All authors certify that they have participated sufficiently in the work to take public responsibility for the content, including participation in the concept, design, analysis, writing, or revision of the manuscript. Furthermore, each author certifies that this material or similar material has not been and will not be submitted to or published in any other publication before its appearance in *The Journal of Alternative and Complementary Medicine*.

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