A Systematic Review Protocol for Ayurvedic Interventions in Hemiplegia

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Abstract

Background: Hemiplegia is the paralysis/weakness of either side of the body with varying levels of loss of function. Stroke is one among the main causes of hemiplegia. According to Ayurveda, the symptomatic presentation of Pakshaghata resembles hemiplegia. Although different types of time-tested treatment protocols are being followed as per the disease severity or stage, many a time, a common treatment strategy, reliable data regarding a standardized treatment protocol, the cost-effectiveness, or adverse effects of the various treatment protocols are lacking. Hence, a systematic review is planned in this regard. This article comprehensively details the protocol adopted for the planned systematic review.

Objectives: The manuscript reports the study protocol of a proposed systematic review with the prime objective of analyzing the published clinical data in view of safety and effectiveness of Ayurvedic treatment protocols in hemiplegia vis-à-vis Pakshaghata, qualitative review, and meta-analysis of the same.

Materials and methods: The study shall be carried out by screening the published data and the gray literature available from famous search engines, namely, PubMed, Cochrane Library, AYUSH Research Portal, DHARA, Google Scholar, web page—Ancient Science of Life, Online clinical trials registers, Shodhganga@INFLIBNET. Papers on Ayurvedic management of hemiplegia/Pakshaghata will be screened for data analysis. Full articles of potentially eligible trials shall be obtained and independently evaluated for inclusion in the review based on the types of participants (inclusion criteria). Data extraction forms for individual study shall be prepared, which include methods, participant characteristics, interventions, and outcomes. Data extracted shall be systematically analyzed and presented using appropriate software.

Discussion: The study outcome shall be disseminated in public domain. The data will reveal the benefits and adverse effects of Ayurvedic treatment in hemiplegia. This may help the stakeholders for drug/therapy selection, dose fixation, and framing future research.

Keywords: Hemiplegia, Pakshaghata, Protocol, Systematic review.

Introduction

Among the types of disabilities, hemiplegia accounts to the most crippling type of disability. Hemiplegia is defined as paralysis on one side of the body, along with varying levels of motor and sensory deficits. Occurrence of stroke can be at any time and may cause disability for the rest of the life. The estimated adjusted prevalence rate of Stroke ranges, 84–262/100,000 in rural and 334–424/100,000 in urban areas. Large-vessel intracranial atherosclerosis is found to be the commonest cause of ischemic stroke in India. The common risk factors include hypertension, diabetes, smoking, and dyslipidemia. The treatment strategy includes anticoagulants, antiplatelet agents, and physiotherapy. Stroke is such a disease that negatively affects the quality of life of the survivors and hampers the activities of daily living.

Many a time, Ayurvedic treatment is considered as a powerful tool for outpatient recovery and survival especially in chronic phases of hemiplegia/stroke. According to Ayurveda, the symptomatic presentation of hemiplegia matches with the condition Pakshaghata. Though the disease is classified as a Vata Vyadh, the treatment protocol is framed on the basis of its associated Dosha status, that is, in an acute phase it is considered as Vata-Kaphaja or Vata-Pitta; whereas in chronic phase, it appears as a pure Vataja condition. So the treatment protocol is planned according to the stage which patient presents.

Acute or chronic hemiplegia, contributes to a major portion of patients attending Ayurvedic outpatient departments and inpatient departments. Different types of treatment protocols are being followed per the disease severity or stage, which are time-tested strategies. But, unfortunately, many a time, a common treatment strategy, reliable data regarding a standardized treatment protocol, the cost-effectiveness, or adverse effects of the various treatment protocols are lacking from a comprehensive point of view. Hence, it seems an utmost essentiality to conduct a systematic review in this regard.

Objectives

Primary Objectives

• Systematic review of the literature in order to produce a database of outcome measures used in hemiplegia vis-à-vis Pakshaghata.

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• Systematic review of the published clinical data in view of safety and effectiveness of Ayurvedic treatment protocols in hemiplegia vis-à-vis Pakshaghata.

• Meta-analysis of the published clinical data in view of the safety and effectiveness of Ayurvedic treatment protocols in hemiplegia vis-à-vis Pakshaghata.

Secondary Objectives

• Qualitative review of the clinical and methodological characteristics of individual studies and patterns across the study.

• Documentation of strength and limitations of individual studies and patterns across the study.

MATERIALS AND METHODS

Criteria for Selection of Study

Type of Study

Randomized controlled trials, quasi-experimental trials, single-group clinical trials, comparative clinical trials, pragmatic trials, and review papers on Ayurvedic management of hemiplegia will be screened for data analysis.

Population

Cases diagnosed with hemiplegia by imaging or symptom wise, who underwent Ayurvedic treatment protocol (administered for 7–60 days)/cases diagnosed with Pakshaghata (symptom wise), who underwent Ayurvedic treatment protocol (administered for 7–60 days). Exclusion: cases with systemic illnesses other than the nervous system or any major comorbidities who underwent Ayurvedic treatment protocol for hemiplegia/Pakshaghata.

Interventions

Ayurvedic treatment protocol (Shamana or/and Shodhana) with different dosage forms, type, schedule, drug, treatment procedures, with or without Pathyapathya (lifestyle modifications and or specific diet charts) as the intervention group in hemiplegia shall be screened for data analysis.

Comparators/Control Group

(1) Ayurvedic treatment protocol (Shamana or/and Shodhana) with different dosage forms, type, schedule, drug, treatment procedures, with or without Pathyapathya (lifestyle modifications and or specific diet charts) as the comparative group to intervention(s)/exposure(s) in hemiplegia shall be screened. (2) Placebo and/or sham therapy and/or Shamana therapy and/or non-Ayurveda interventions in hemiplegia too shall be screened.

Types of Outcome Measures

• Effectiveness/efficacy parameters
  • Response to treatment (improvement in subjective and/or objective criteria of assessments)
  • Improvement in quality of life: Timing and effect measures of effectiveness parameters: Administration timings vary from 7 to 60 days as different categories of medications are included for review. During the study period or up to 1 month after completion of the study

• Safety/morbidity parameters
  • Serious adverse events (resulting in death, disability, or incapacity) or complications that were life-threatening and led to hospitalization or prolongation of hospitalization

• Withdrawals due to adverse events or lack of efficacy or inconvenience of therapy/treatment.

• Number of patients with specific adverse event.

Search Methods for Identification of Studies

The following electronic databases—PubMed, Cochrane Library (Cochrane Central Register of Controlled Trials: Issue 6 of 12, June 2018), Google Scholar, AYUSH Research Portal (Govt. of India), DHARA, Ancient Science of Life, Shodhgang@INFLIBNET, online clinical trial registers. Manual search in Central and departmental libraries of Government Ayurveda College, Trivandrum (Manual Search) IPGT and RA, GAU, Jammagar, with due permissions and Ayurveda Research Database from authorities. There will be no language restrictions. Studies published till date (until March 2019) will be sought. The searches will be conducted again immediately before the final analyzes for including available remaining papers.

Search Strategy (Keywords)

Ayurveda OR Ayurvedic OR Ayurvedic treatment OR Ayurvedic treatment protocol OR hemiplegia OR Pakshaghata AND stroke OR hemorrhagic stroke OR ischemic stroke OR as title, abstract, or keyword.

Data Collection/Synthesis

Three investigators shall independently screen all citations and abstracts identified by a primary comprehensive search to sort out potentially eligible trials. Full articles of potentially eligible trials shall be obtained and independently evaluated for inclusion in the review based on the types of participants (inclusion criteria). Data extraction forms for individual study shall be prepared. This shall include (1) methods used in the study (randomization/ allocation/concealment/blinding/sampling and sample size calculation/length of follow-up); (2) participant characteristics of individual studies (along with disease characteristics/number of participants randomized/number of participants completing follow-up/reasons for withdrawal from the study); (3) interventions (treatment protocol administered/formulations used/standard operating procedures (SOPs) administered/adverse events during the treatment protocol); and (4) outcomes (in terms of safety/effectiveness/efficacy/ improvement in quality of life). For each outcome measured from individual studies, efforts shall be taken to discuss the risk of bias, consistency, precision, and reporting bias. When disagreement persists or in case of ambiguity at the time of data extraction, efforts shall be initiated to obtain clarifications directly from authors/coauthors as much as possible.

Data Analysis

The analysis of the systematically collected data shall be conducted by appropriate software. Dichotomous data will be presented and merged using relative risks, continuous data will be summarized by arithmetic means and standard deviations and will be combined by using weighted mean differences; both will be accompanied by 95% confidence intervals. Medians and ranges will be reported in tabular forms. When the data are assumed to be normally distributed, arithmetic means and standard deviations will be used to summarize the continuous data. Separate summary effect estimates will also be generated for studies that meet and do not meet the individual quality criterion. Heterogeneity among trials will be assessed by inspecting forest plots, to look for overlapping confidence intervals, applying the chi-square test, with a p value of 0.05, indicating statistical significance and using the I² test with
A value of 50% used to denote moderate levels of heterogeneity. If heterogeneity is observed and still considered clinically meaningful to combine studies, then a random-effects model will be used. A sensitivity analysis to investigate the robustness of the results to the quality components will be done, provided there are sufficient trials. A funnel plot will be incorporated to indicate publication bias, heterogeneity of results, or differences in the methodological quality. Certain relevant articles were referred for framing the methodology part of the present protocol. The time duration and methodology of the planned protocol is presented in Flowchart 1.

**Current Status (As on January 28, 2020)**

- PROSPERO Registration obtained on July 27, 2019 (Reg. No. CRD42019131887)
- Institutional Ethical Committee approval obtained on November 07, 2019
- Number of articles screened: 37
- Number of articles that had undergone tabular data extraction (PICOT format): 23

**Discussion**

The protocol has been registered in PROSPERO. A primary search in web yielded the information that multiple clinical trials and narrative reviews are available on Ayurvedic treatments adopted in hemiplegia and their efficacies. But this has not been collectively assessed and evaluated. The purpose of the prescribed systematic review is to generate the empirical evidences on Ayurvedic treatment strategies adopted in hemiplegia. Hence, all the literatures (narrative and experimental) are taken up for the study. Searches via databases will help to collect published works and manual searches through gray literatures will cover unpublished works. Accordingly, all the articles/theses shall be imported to the library and after proper scrutiny based on the eligibility criteria, these will be exported to data analysis sheets. The narrative review will be prepared for individual work followed by a collective review. If data are found to be eligible for quantitative pooling, meta-analysis will follow. The consequent findings will be disseminated through publication of the review in a peer-reviewed journal. The study will also disseminate through electronic and print media. The review may guide in efficacy assessment, drug/therapy selection, dose fixation, framing of research questions, outcome assessment, and safety measure for Ayurveda treatment in hemiplegia.

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**References**


हिंदी सारांश

हेमिल्लोजिया में आयुर्विदिक उपचार - एक सिस्टेमेटिक रिव्यू प्रोटोकॉल

आकाशलाल मनीरिय, प्रतिभा पी. नायर, देवी आर. नायर

पृष्ठभूमि: भारत में विकलांगता का एक मुख्य कारण स्ट्रेक है। आयुर्वेद के अनुसार, पक्षाधात की रोगमूलिक प्रसूति हेमिल्लोजिया से मिलती जुलती है। यदयदि विशिष्ट प्रकार के समय-समय पर परीक्षित उपचार प्रोटोकॉल का पालन न हो तो गंभीरता / अभाव में अनुसार होता है, अधिकांश एक समान्य उपचार पद्धति अथवा मानसिक उपचार प्रोटोकॉल के बारे में एक विश्वसनीय डेटा, विशिष्ट उपचार प्रोटोकॉल की लागत प्रभावशीलता या प्रतिकूल प्रभाव व्यापक इंटरकैंपोजेंशन से अभाव है।

इसलिए इस संबंध में एक व्यवस्थित समीक्षा का आयोजन किया गया है। प्रस्तुत अध्ययन में योजनाबद्ध व्यवस्थित समीक्षा के लिए अपनाए गए प्रोटोकॉल का विस्तार से वर्णन हैं।

उद्देश्य: प्रस्तुत लेख इस प्रस्तावित व्यवस्थित समीक्षा के अध्ययन प्रोटोकॉल की रिपोर्ट करता है जिसका प्राथमिक उद्देश्य हेमिल्लोजिया / पक्षाधात में आयुर्विदिक उपचार प्रबंधन की सुरक्षा और प्रभावशीलता को देखते हुए प्रकाशित नैदानिक आंकड़ों का विश्लेषण, गुणात्मक समीक्षा और मेटा एनालिटिक्स करना है।

कार्यविधि: यह अध्ययन प्रकाशित आंकड़ों की जांच के साथ तथा प्रतिदिन सयन इजन जैसे पब्लिक, कोक्रेन लाइब्रेरी, आयुर्विदिक रिसर्च पोर्टल (भारत सरकार), डीपआरआरएस, ग्लूंस्ट्रायर्स, वेबपेज- ऐल्फिशीएंड साइड ऑफ लाइफ, ऑनलाइन विलियम्स त्रामल रेसिक्स, शैक्षणिक @ इंफोलैबनेट में उपलब्ध गर्व साहित्यों से किया जाएगा। डेटा विश्लेषण के लिए हेमिल्लोजिया / पक्षाधात के आयुर्विदिक प्रबंधन पर दस्तावेजों की जांच की जाएगी। संभावित पात्र परिक्षणों के पूर्ण लेख प्राप्त किए जाएंगे और स्वतंत्र रूप से प्रतिकूलितियों के प्रकार के आधार पर (समावेश मानदण्ड) समीक्षा में शामिल करने के लिए मूल्यांकन किया जाएगा।

प्रत्येक अध्ययन के लिए निष्कर्षण प्रचार तथा विविध विधियों, सहभागी संशोधन, लिए गए उपचार और परिणाम शामिल होंगे। निष्कर्षित आंकड़ों का व्यवस्थित रूप से विश्लेषण किया जाएगा और उपयुक्त सोफ्टवेयर का उपयोग करते हुए प्रस्तुत किया जाएगा।

चर्चा: परिस्थिति दोमेन में अध्ययन के परिणामों को प्रसारित किया जाएगा। इस डेटा से हेमिल्लोजिया में आयुर्विदिक उपचार के लाभों और प्रतिकूल प्रभावों का पात्र चलेगा। यह अध्ययन द्वारा / चिकित्सा, युक्ति निर्धारण और लक्ष्य के अनुसंधान के लिए हितदायक की मदद कर सकता है।

मुख्य शब्द: अर्थागात्त, पक्षाधात, प्रोटोकॉल, व्यवस्थित समीक्षा।