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Clinical Research in Ayurveda: A Preliminary Review of 225 Papers Published In Indian Ayurveda Journals

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Abstract: *225 clinical studies reported in three reputed Ayurvedic journals were reviewed for their qualitative outcomes. Conventional medicine diagnoses were used in nearly 90 % of studies and inconclusive outcomes were observed in most of the studies. Failure to validate claims of Ayurvedic treatments, products and or therapies otherwise regularly practiced mostly for chronic disease conditions raise concerns about methodologies followed. Diagnosticspecificities and therapeutic variances are major challenges to design clinical studies to validate Ayurvedic treatments. Inability to adapt to conventional clinical study norms are obvious. There is an urgent need to evolve newer methodologies to evaluate Ayurvedic treatments based on its own paradigm.*
Keywords: *Ayurvedic Clinical Research, CAM Validation.*

I. Introduction

The World Health Organization - WHO has estimated that major percentage of the population in developing countries depends primarily upon herbal medicine for basic health care.[1]The traditional systems of medicine, commonly referred to as 'Complementary and Alternative Medicine' (CAM) are widely used and looked upon for possible and safe solutions to present day health and medical problems. [2] Ayurveda, the Indian system of medicine practiced today has its roots in the Vedic thinking. Ayurveda follows its own unique philosophy and methodologies to address issues of health care. [3,4] It prescribes variety of simple therapies as also certain complex treatments that could comprise of single ingredients, poly-ingredient formulations and combination of drugs, diet, lifestyle changes and therapies like massages, fomentation therapies, enemas and several other cleansing procedures as well.[5] These treatments, oral medications or a combination of both are individualized in nature and ideally meant to be administered only after proper understanding of the ailment as per Ayurvedic diagnostics or *nidaan*.[6]

Since last 4-5 decades major changes have occurred in Ayurvedic education, practice, research and manufacturing of Ayurvedic products. Research in Ayurveda that began with search for new compounds from Ayurvedic plants and formulations based on pharmacological assertions and chemical moeities has come a long way with recent advances in biomedicine and technology. Research as part of learning and essential postgraduate training is expected to contribute towards overall growth of the sector. [7]

It is believed that drifting away from the fundamental principles and concepts had negative impact and therefore integration at the basic level of development of hypothesis of research is felt necessary.[7]

Much research is being carried out on single herbs, poly-herbal formulations or herbo-mineral compounds, pharmaceutical products, combined treatments and disease specific therapies. However, the path remains uncertain in terms of standardization of products along with safety and efficacy for universal acceptance.Though the protocols for clinical studies inAyurvedic treatments by Indian Council of Medical Research – ICMR had been prepared in consultation with Ayurvedists, looking at thoseprotocols however, itis evident that either the consulted Ayurvedistswere not clear about needs of Ayurveda or their opinions were not accepted.[8]

Focus of research that was mainly directed at isolating active ingredients from Ayurvedicmedicinal plants for drug developmentseems now to be shifting towards scientific understanding of basic physiological concepts and disease processes as outlined in Ayurveda.This is an engaging task. It is possible that such a quest for biodynamic mechanisms can generate new disciplines in life sciences. [9]

There is increasing interest and eagerness to look for solutions from CAM to treat difficult and chronic diseases. There definitely exists an anxiety about the quality and reliability about CAM. Evidence based research is being examined for its processes, relevance and implication to CAM. [10] Validation of products or treatments and their safety aspects are crucial for acceptance of specific therapeutic claims. Most of implicit scientific studies with negative results on otherwise beneficial claims warrant a serious reconsideration about the

approach of research and about themethodology applied for research. It is believed that ongoing research is proceeding in such a way that it is of more value to modern medicine than Ayurveda. It does not strengthen Ayurveda and Ayurvedic practice. [11] A question arises whether the understanding of the conventional medicine or developments in biomedical research methodology could be applied for the understanding of Ayurvedic system of medicine?Many serious researchers find current research approaches to be inappropriate and feel need of a major paradigm shift for research oriented and based on principles of Ayurveda. There is an urgent need to understand Ayurvedic principles of treatment and search for inclusive solutions to design clinical studies. [12]

II. Objective Of The Study

Methods for validation of natural products or CAM are areas of increasing academic interest.[13]In India majority of the clinical studies on Ayurvedic treatments, products or therapies, form part of institutionalized research. These studies are published mainly in Ayurvedic journals. A detailed analysis of clinical research activities carried over a period of time would provide an insight into the research methodology followed therein and the applicability of this research for the progress of Ayurveda or health sciences in general. This is a primary review of papers that were published in three well established Ayurvedic journals with more than 15 years of regular publication that were available with private clinic library of authors. The purpose of this exercise was to examine different approaches taken for clinical studies and methods applied therein. Initially a quantitative assessment with an established method of scoring was considered but the idea was dropped in view of its non-applicability due to multiple poorly defined variables observed in most of studies.

III. Method

Three journals namely **'Journal of Research in Ayurveda and Siddha'** [JRAS] published by the Central Council of Research in Ayurveda and Siddha under Department of AYUSH, Ministry of Health, Government of India; **'Aryavaidyan'**, a journal published by Arya Vaidya Sala, Kottakal, a highly reputed organization of Ayurveda and **'Ancient Science of Life'**, another pioneer journal in the field of Ayurveda from Arya Vaidya Pharmacy, Coimbatore; were searched for papers on clinical studies published between the years 1967 to 2007. The papers published only in these journals werereviewed as available in the private library of one of the authors. Though all the three journals did have clinical studies on Siddha, Unani and Yoga, the papers only on Ayurvedic treatments were considered in view of non-availability of expertise to examine these systems. Papers dealing with individual case reports and conceptual interpretations having non-specific clinical reports were not considered. The review covered two hundred twenty five [225] papers covering wide range of clinical studies.

IV. Compilation Of Data

After preliminary observations a format – data sheet - was evolved to compileinformation under several categories and to examine different criteria in terms of design of study, diagnostics, treatments and outcome.Several variables that contribute to design of a clinical study were considered during compilation of the data. The data was classified as per thetreatment or drug tested againsta disease condition and diagnostic criteria used in the study as of conventional (modern) medicine or Ayurvedicdiagnostics –*nidaan*.

The compiled data included Ayurvedictreatments used along with specifics of name and type, name of single ingredient or plant or compound, compound formulations, coded drugs if any, nature of indoor or ambulatory treatment, details on measure of dose and administration (route), study design, sample size, treatment period, clinical, diagnostic and or laboratory investigations carried out, inclusion and exclusion criteria,report of adverse events or side effects, effectiveness of treatments offeredand observations or recommendations on outcome including need for further evaluation.

The objective was to compile data that will give a broad idea about each of the clinical study conducted and the approach taken by investigator/s and to examineits relevance for therapeutic outcome.

V. Limitations Of The Study

The study was limited to articles published in only three but highly used journalsas available in the private clinic library. Currently applied standard scales[14]were considered for objectivity but could not be applied due to lack of availability of relevant data. Similarly a critical quality analyses could not be undertaken for reasons of insufficient details. This review therefore is restricted to subjective parameters only. These journals are popular within Ayurvedic discipline in India. This review covers earlier period and does not reflect changes that might have occurred in recent times. The authors opted to capture and analyze basic and preliminary data as available for the benefit of faculty, students and researchers ofAyurvedic fraternity.

VI. Observations

Thedetails of 225 published papers under different components of clinical studies are presented in the Tables 1.1 to 1.9.

Table –1Review: 225 Clinical Studies (3 Ayurvedic Journals; 1967-2005)

Table - 1.1 Design Of Study

Open Label	Single Blind	Placebo Controlled	Double Blind	Randomized trials	Total
180	4	18	12	11	**225**

Table - 1.2 Sample Size

5<50	51<100	101<200	201<	Total
161	43	17	4	**225**

Table - 1.3 Diagnostic Specificity

Ayurvedic	Ayurvedic-General	Conventional	Conventional-Nonspecific	Mixed	Total
13	11	121	37	43	**225**

Table - 1.4 Investigations

Clinical	Haemato	Biochem	Haemato + Biochem	Serological	Radiological	ECG	Organ Specific Function
225	103	118	90	13	34	13	1

Table 1.5 Therapeutic Intervention

Oral	External	Oral + External	Therapies	*(Dietetics)	Total
161 + 15*=176	12	21 + 6*=27	10	*(15+6)	**225**

Table - 1.6 Type Of Therapeutics Used

Single Ingredients	Compound Formulations	Combined	Total
85	122	18	**225**

Table - 1.7 Study Duration

Weeks(1wk to 12 weeks)	Months (6 to 9 months)	years	Total
210	12	3	**225**

One study duration is 60 min (ref 220)-preanesthetic drug

Table - 1.8 Outcome

Effective	Effective - Need Further Studies	Not Effective	Unclear	Total
173	34	8	10	**225**

Table - 1.9 Adverse Effects

Not Reported	Not Observed	Reported	Total
134	67	24	**225**

6.1 Design of Study

180 studies were open label, 4 single blind, 18 placebo controlled, 12 double blind and 11 randomized trials. (Table 1.1)

6.2 Sample Size

161 studies were found to have sample size between 5>50 participants, 43 studies observed to have 51<100 participants, 17 studies had 101<200 patients and 4 trials had more than 201 sample size. The study on contraceptive with 281 sample size reported high dropout rate at 90%. (Table 1.2)

6.3 Diagnostic Specificity

13 studies followed Ayurveda*nidaan*, diagnostics based on Ayurveda. 11 studies used general diagnostics along with primary Ayurvedic criteria. Interestingly 121 studies followed diagnostic approach as per conventional medicine. However, 37 studies applied conventional but non-specific diagnostics. (Table 1.3)
A list of diseases on which the clinical studies were undertaken is provided. (Appendix - A)

6.4 Investigations

Of 225 studies reviewed almost all mention the use of hematological, biochemical, serological, radiological investigation parameters.
The data was collected on gross level for diagnosis and investigations. Detailed clinical and investigational parameters were not analyzed due to poor relevance to outcomes. (Table 1.4)

6.5 Therapeutic Interventions

Majority clinical studies were on outdoor (ambulatory) and few were on hospitalized cases.
Variable methods of treatment administration were followed. Majorityof studies numbering 176 were on oral administration of medications. Only twelve studies were on external or topical application. Oral dosage along with external application were reported in 27 studies. Ten studies were done on Ayurvedic therapies like one or more of *panchakarma* or similar. Specific *pathaya-apathya*, dietary regimen were advised in 21 studies. (Table 1.5)

6.6 Types of Therapeutics used

85 studies were carried on single herb ingredients, 122 studies used compound formulations and 18 studies used combination of formulations for external and internal treatment. (Table 1.6)

The range of therapeutics used included Ayurvedic herbs, combinations, preparations, tablets, coded drugs, extracts, ras*a aushadhis*and *bhasma*, herbo-mineral compounds and plant extracts or fractions were also used. One study was on the use of pigeon's fecesburnt to ashes used as medicament.

It was noted that *anupana* was prescribed in 44 studies.*Anupana*is the accompaniment offered along with the medications like honey, ghee (clarified butter), warm water and such others. Accompaniments have multiple applications wherein they may be used as a vehicle, adjuvant or carrier for the medicine for specific absorption or to target a functional system orpart of body. It may also be useful for enhancing the beneficial attributes of the medication, decreasing the harmful effect of the medication or improving the palatability of the drug by enhancing the taste, consistency, masking the odor.

6.7 Study Duration

The treatment period for these studies varied from a maximum of 1year to a minimum period of 4 days. 210 studies had duration of 1 week to 12 weeks, 12 studies had duration of 6 months to 9 months and 3 studies had duration of 1 year. Only one each study was for the duration of 1 year, 6 months and 9 months.One treatment period involving anesthetic evaluation was for 60minutes only. (Table 1.7).

6.8 Outcome

173 studies report results to be effective, 34 studies mentions effective outcomes with a need for further evaluation, unclear or ambiguous outcome was mentioned for 10 studies and 8 studies mention about treatment failure. (Table1.8)

6.9 Adverse Effects

24 studies mention of some side effects like constipation, nausea, vomiting, loose motions, and pain and such others. 67 studies reported that no side effects were observed. However, most of the studies failed to explain the actual method for record of adverse effect or evaluation used. Remaining 134 studiesout of 225 total studies did not have any reference to any adverse effects; therefore it remains unclear whether any adverse effects occurred or not. (Table 1.9)

VII. Discussion

Validation of effectiveness of Ayurvedic treatments is necessary in view of changing environment of institutionalized practice and industrial production. Confirmed clinical outcomes are necessary to establish reliability of Ayurvedic interventions. This review was aimed at examining newer methods adapted by the Ayurvedic academics and institutions to undertake clinical studies to establish effectiveness of products or treatments. It has proved useful for understanding different aspects of clinical studies in the fieldof Ayurvedic research. It provides an interesting overview of the methods in which the clinical studies are to validate efficacy of Ayurvedic treatments, therapeutics and therapies.
In view lack of quantifiable parameters selective observations with examples on important constituents of a clinical study are discussed.

7.1 Study Design

The good trial design gives reliable results. Over all the methodological quality and study design was found to be poor in almost all the papers. This may be due to small sample size, lack of standardization of products, high dose and high number of loss of cases on follow-up. However, the lack of diagnostic specificity in the context of expected outcome contributed most to poor designs of studies. An urgent need is felt to evolve novel design of studies to evaluate Ayurvedic treatments.

7.2 Sample Size

Most of the studies had low sample size. Most of the studies did not explain the sample size calculation or the methods applied.The efficacy of the formulations can be effectively determined only with appropriate sample size. Poor sample size lead to poor outcome. In some studies with large sample size the lack of specificity of diagnostic and outcome parameters were obvious. Efforts to evolve specificity with multiple variables in small but critically evaluated studies are desirable particularly in studies that involve more than one intervention either in the form of a drug or a therapy.

7.3 Diagnostic Specificity and Investigations

Diagnostic approach for clinical studies predominantly was of conventional medicine. Almost all the studies reported used modern diagnostic criteria for understanding the anomaly and administered Ayurvedic treatments, drugs and therapies for management of the same. It is obvious that an investigator faces the dilemma about diagnostic specificity with Ayurvedic diagnosis for clinical studies. Ayurvedic description of an illness and its functional subtypes are quite different from that of conventional medicine. Ayurvedic criteria are complex and clinically oriented that require close and frequent critical and analytical observations and functional changes on follow-up. Influence of therapeutic variance add to the complexity ofthe process. Ayurvedic diagnosis rests primarily on the '*hetu*' (~ causative factors) and the '*lakshana*'(~ clinical signs and symptoms) of the disease as mentioned in the texts. It should also be understood that any anomaly as per the Ayurvedic principles primarily results from an imbalance between the three *dosh*a(functional systems) and that the Ayurvedic*chikitsaa*,the treatment centers on restoration of the balance of the*dosha*.[15] The diagnosis and treatment thereby tends to be highly individualistic and comprehensive in nature which concerns itself with elimination of the disease as well as restoration of health.

Diagnosis in conventional medicine on the other hand is clinically taxonomical in nature, identified with causative agent and mostly dependent on investigational support to narrow down the therapeutic target. Interestingly the investigators in several studies even failed to bring in attainable objectivity with conventional diagnosis. This clearlyshows either ignorance about methodology or commitment to objectivity.

One study was on healthy volunteers to examine hypolipidemic effect of Isabgol (Psyllium husk). [16] The contradiction about the very aim of this study shall be evident to most Ayurvedic physicians. Isabgol is an Ayurvedic medication which helps facilitate bowel movements by providing ample fiber. The use of isabgol fiber for lowering cholesterol levels amounts to the use of this herb for treatment of anomaly observed as per conventional medicinal diagnostics. To use the psyllium husk for lowering of cholesterol is an extrapolation of the medicinal properties. A question could be raised about this study Ayurveda does not consider it necessary to supplement the diet of a healthy individual (as per in healthy volunteers and its relevance to laboratory investigations aimed to prove its hypolipidemic efficacy.

Surprisingly only 13 studies out of 225 used exclusive Ayurvediccriteria for diagnostic and evaluation purpose. The rest of the studies either applied conventional medical diagnostic investigative tests or used both. The correlation and the treatment outcomes when applied jointly were not well justified in either or integrated manner.Use of nonspecific terms like arthropathies or *vaatavyadhi* or uropathies in general indicate lack of effort on the part of investigator to search for conclusive outcomes.

How to evolve specific diagnostic, evaluation and outcome parameters to evaluate functional changes as observed clinically is a challenge that is required to be taken up.

7.4 Therapeutic Interventions

18 clinical studies were on combined, oral and external treatment or therapies. 122 studies were conducted with compound formulations meaning the poly-ingredient and may be more than one products were used in the studies. However, with 85 studies on either single plant or a single formulation the trend seems to be towards evaluation of these classical or industrial products.

Unlike conventional synthetic or molecule based therapeutic agents the difficulties in standardization of compound formulations contribute to questions with respect to efficacy of the products. Similarly use of combined treatment contribute to multiple variables leading to difficulties of attributing efficacy.

An important observation of concern was administration of the conventional medicaments along with Ayurvedic interventions. The frequent use of conventional analgesics or such biomedicine without any specific criteria for its permissible use and nonspecific mention raise doubts about the effectiveness of the treatments in some if not all such situation. It is observed that Ayurvedic treatments are offered for several chronic and debilitating diseases. Use of pain relievers, continuation of anti-diabetic or anti-hypertensive agents or such essential use biomedicine could be ethically justified. However, clearly laid down parameters for such use and how to evaluate its impact on therapeutic outcomes are necessary to establish actual effectiveness of treatment under study. Most of the reported studies were non-specific about such parameters. Another relevant issue is potential adverse effects of combination of such treatments or therapies.

A study for treatment of duodenal ulcer with Shatavaripermitted use of baralgan, an analgesic combination, and gelusil, an antacid to treat severe pain. A question does arise about effective outcome reported of the treatment with poorly specified parameters for use of rescue medicine.(17)

A clinical study to treat different arthropathies with Semecarpus marsupium – Bhallatak, a plant advised to be used with clinical discretionshowed positive effects though with several adverse effects where toxicity studies were recommended by authors. [18]. In an another studyto treat amoebiasisand giardiasis adverse effects like constipation and burning sensation were ascribed totoxicity of higher dose of themedicament under investigation. [19]Selection of certain therapeutics, known to have some potential adverse effects, without diagnostic discretion to exclude such patients in the study is an area of concern. Failure to recognize such diagnostic and therapeutic discretion will not give conclusive results.

This shows poor knowledge amongst investigators to address such situations.

7.5 Therapies used

Studies on therapies as in case of *panchakarma* or such other combined treatment are a challenge to the investigator. It needs comprehensive approach with detailed preparations for administration.

A simple study on treatment of *Gridhrasi* – sciatica, with an incremental administration of 50 ml of medicinal oil, internal and external, faced problems with individual variability to responses and its continuance?[20]Possible issues about patient compliance and acceptance of therapy require beforehand considerations, particularly with large sample size. It is not difficult bring in objective parameters based on Ayurvedic principles of treatment.

Though totalistic individual variation of manifestation of an illness and response variation to a treatment as in Ayurveda are difficult to quantify it is possible to apply objective criteria to clinical parameters. Investigator has to innovate methods to objectivize simple clinical manifestations. These need to be addressed while designing of the study.

Patient compliance was an area of concern in many cases with higher rate of drop outs. This could be one of the reasons of poor standards. A well thought and properly designed study explained to the subjects ensures better compliance.

Frequency of dose, type of administration and combined therapies require careful considerations for better patient compliance.

7.6 Study duration

Duration of the treatment is an important factor to compliance. It was observed that there were very few studies in acute conditions. Most of the studies were on chronic disorders. Treatments offered in several conditions required comparatively longer periods with treatment aimed at functional normalcy.

In diseases like*Aamavaata*– rheumatoid arthritis the treatment period is quite prolonged even with conventional medicine. Such disease condition require meticulous documentation and follow up. Preparation of right format – case record form is important. Recurrences of symptoms or changes in severity is another issue faced in long duration studies. Several papers failed to justify outcome variances. This could be due to poor formats. Evolving right outcome criteria conducive to treatment approaches have higher significance in clinical studies with Ayurvedic treatments.

Study duration is an important factor contributing to good clinical design for understanding the efficacy of a drug. In this review a lot of variation was observed in the same type of chronic conditions like *Aamavaata*, diabetes, and heart related disorder.

7.7 Adverse effects

Ayurvedic medicines in general are of natural origin and therefore believed to be safe. Ayurvedic therapies when administered as per prescribed norms under qualified supervision are also considered safe. Use of reliable drugs under specific guidance for its administration and dietary advises are strength of Ayurvedic practice, particularly its safety aspects. Any compromise on administrative form of Ayurvedic treatment compromises not only its effectiveness but safety as well. If so, to design clinical studies inclusive of several variables as per Ayurveda in itself is challenging.

Present day practice of Ayurveda has undergone major changes. Non-availability of fresh raw material, newer dosage forms, use of new technologies to extract and manufacture Ayurvedic products and new and new formulations developed to treat certain disorders as in case of pharmaceutical proprietary products have developed newer challenges. Similarly the ease of practice and institutionalized administration of therapies have added to needs of standardization of administration of Ayurvedic treatments.

This has given rise to issues of adverse effects due to several reasons. In conventional methodology of research and regulations a drug or a therapy has to undergo safety evaluation during early stages of its development. Critical considerations with respect modifications and or administration of products and therapies

undertaken for clinical studies are necessary. Any diversion from the original must be carefully evaluated before assuming it to be safe.Even the external applications must be advised only after considerations of safety factor.

In one of the studies the external use of 90ml oil twice in a day for treatment of vitiligo, though beneficial, showed allergic reaction in presence of sunlight. [22]

7.8 Other observations

The age criteria mentioned in the 23 studies ranges form 7-70 years, 2 studies did not mention about the dosage form (administration) and one study did not specified dose quantity. One study to examine effect of 100 ml of Kutaja to be given twice daily had large age group without any dose variance for children. [21] Inclusion of much variable age groups has influence on therapeutic outcome and may contribute to undesirable effects. While undertaking studies with Ayurvedic treatments the restriction of the use of other primary or supplementary medication to the patient is difficult. There is need to evolve a methodological approach this contemporary issue when patients already on conventional medicament are looking for Ayurvedic treatment solutions.

Maximum trials were open label and the inability of adherence to norms and lack of stringent follow up, poor monitoring and contamination of data affect the outcome of a study.

Though quantitative standardization of Ayurvedic treatment, product and or therapies, is very difficult efforts for qualitative objectivity in terms of constituents and standard operating procedures for specific therapeutic activity might be of help.

Efforts to integrate the principles of Ayurveda and conventional medicine are welcome. Clinical studies based on conventional diagnosis without following comparable rigor of scientific inquiry neither help evaluate Ayurvedic treatments nor does it contribute to enrichment of experience. A combined approach rather than restricted to diagnostic level is needed to be applied for integrated approach in terms of understanding disease processes and expected outcomes of therapeutic interventions.

Defining the purpose of a clinical research endeavor requires true sense of inquiry, comprehensive overview and an unbiased approach. Though seemingly easy, the task of defining clinical research objectivity in Ayurveda is daunting, due to multitude of intrinsic and extrinsic factors.

VIII. Conclusion

This review of 225 papers publishedin three Ayurvedic journals published between1967-2007 exposes a broad gap between the research methodologies and studies carried out to validate effectiveness of Ayurvedic treatments.Most of the clinical studies on Ayurveda products and or therapies remain inconclusive due to poorly defined correlation with disease process and lack of specific parameters for clinical evaluation and outcomes. It is difficult to include comprehensive Ayurvedic individualized diagnostic and prognostic approach, mainly clinical in nature, to design a clinical study.

Clinical trials based on conventional medicine to establish safety and efficacy mostly required narrowing down of Ayurvedicdiagnostic approaches and therapeutic interventions. This disconnect between the Ayurvedic treatment and its expected outcome leads to confusion about its effectiveness and safety.These limitations have led to blind following of conventional diagnosis with poor recognition of Ayurvedic principles in the study that further complicates the outcome evaluation. Poor design of clinical studies on Ayurvedic products or therapies leads to poor adherence to various constituents of clinical studies like sample size, inclusion or exclusion criteria and such others.

There is an urgent need for newer investigational approaches for studies with Ayurvedic treatments to justify its own paradigm.

Conflict of Interests: None

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