# THE HOMOEOPATHIC HERITAGE

Bringing Classical and Contemporary Homoeopathy Together

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#### **Clinical Trials In Homoeopathy**

- Efficacy of Constitutional Homoeopathic Treatment in A Case of Dysfunctional Uterine Bleeding
- · Vanquish PCOS with Homoeopathy



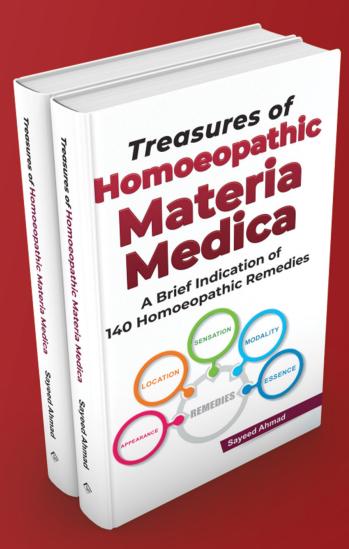




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Word meanings- The author has presented references to the meaning of tricky medical terms at the end of each page as well as at the end of the book. This provides complete insight into the medicine and ensures a comprehensive understanding of the medicines.

# THE HOMOBOPATHIC ERITAGE

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Dear Readers,

Clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human health outcomes. This issue of The Homoeopathic Heritage is themed Clinical Trials in Homeopathy with an intent to bring to light the importance of clinical research in the field of Homeopathy.

This issue introduces a new section-'Readers' Perspective'. The love that our readers hold for us is evident from their responses to our content which shall now be published as open letters to the editor.

As per the World Health Organization, "Clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human health outcomes. People volunteer to take part in clinical trials to test medical interventions including drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments and preventive care.

Clinical trials are carefully designed, reviewed and completed, and need to be approved before they can start. People of all ages can take part in clinical trials, including children".

While this is what holds true for the allopathic system of medicine, in homeopathy too, clinical trials have a significant role to play. Clinical trials validate the existing evidence of efficacy as well as utility and safety of homeopathic drugs, and treatment protocols, thereby providing useful insight into the prevention and treatment of various diseases, as well as decision making for stakeholders in homeopathy. As per a paper published in October 2014, "In evidence-based medicine, a systematic review of randomised and controlled clinical trials, including a meta-analysis of the summarised data, is considered the highest grade of evidence with regard to a given medicinal intervention". In homeopathy, diseases are dealt with, in accordance with the principle of 'Let Likes be Cured by Likes'. The clinical trials in this field though based on modern scientific parameters, adhere strictly to this principle and follow the doctrines of homeopathy. Unlike the conventional pharmacological or biomedical clinical trial, emphasis is laid upon the clinical evaluation of homeopathic medicines in a given disease condition.

The emergence of Randomized controlled studies in homeopathy raised the standards of the field from being an alternative system of medicine to an evidence-based science with established protocols. A research paper published in 2017 stated "In contrast to individualised treatment, placebocontrolled RCTs of non-individualised homeopathic treatment evaluate interventions that have involved the same, standardised, medication allocated to each and every participant randomised to homeopathy in a given trial: single homeopathic medicine, combination or complex homeopathic medicine, or isopathy". (1)

As per the Central Council of Research in HOmeopathy, "Studies in various diseased conditions are taken up from time to time as per the guidance of Scientific Advisory Committee (SAC). Earlier, multi-centric clinical studies were conducted to ascertain therapeutic utility of a smaller group of medicines on the protocols developed in consultation with the experts in respective fields from All India Institute of Medical Sciences (AIIMS), Indian Council of Medical Research (ICMR), National Institute of Communicable Diseases (NICD), National AIDS Control Organization (NACO), eminent homeopathic Educators and Researchers. Presently as per the need of the hour, randomized controlled trials (RCT) are being conducted to es-



tablish the effectiveness of homoeopathic treatment. The results of these studies are published from time to time in the National, International peer reviewed journals of importance".

#### **Quick Word on Issue Content**

This issue of The Homoeopathic Heritage is themed Clinical Trials in Homeopathy with an intent to bring to light the importance of clinical research in the field of Homeopathy. With a topic that reflects continuous growth of the field, this issue introduces a new section that we named 'Readers' Perspective'- another leap forward in the journey of our growth. The love that our readers hold for us is evident from their responses to our content which shall now be published as open letters to the editor. This new section, in this issue brings forth the views of Dr. Anil Singhal (Author, Boger's Legacy) on our editor's desk section of the October 2023 issue (Volume 49, No. 7) penned by Dr. Bipin Jain on 'Role of Homeopathy in Psychosomatic Disorders'.

Besides this new section, and a variety of cases, and subjective write-ups by young and experienced homeopaths, this issue presents the Editor's Desk section written by Dr. Chaturbhuj Nayak (Chairman, Special Committee on Fundamental Research, CCRH, Government of India) et al, the Stalwarts' Expedition featuring the life sketch of Dr. Mahendra Lal Sircar by Dr. Subhas Singh, Director, NIH, Kolkata and review of the book The Essence of Various Groups (The Main Features Of Different Elements Discussed With Practical Case Examples) by Dr. Niharika Jain, Associate Editor, The Homoeopathic Heritage, SRF at CCRH and Founder, Vigyan School of Homoeopathy.

#### REFERENCE:

 Mathie, R.T., Ramparsad, N., Legg, L.A. et al. Randomised, double-blind, placebo-controlled trials of non-individualised homeopathic treatment: systematic review and meta-analysis. Syst Rev 6, 63 (2017). https://doi.org/10.1186/s13643-017-0445-3

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Note: The Homoeopathic Heritage is a peer-reviewed journal since January 2013. All articles are peer-reviewed by the in-house editorial team. Articles selected from each issue are sent for peer-review by an external board of reviewers and marked with a 'peer-reviewed' stamp. For inclusion of articles in the peer-review section, kindly send your articles 3-4 months in advance of the said month at hheditor@bjain.com.

#### Call for papers for the upcoming issues:

Issue	Topic	Date
December 2023	Role Of Homoeopathy In Surgical Cases	October 15, 2023
January 2024	Homoeopathy as Preventive Therapy in Non-Communicable Diseases	November 15, 2023
February 2024	Diabetes Mellitus, Its Complications & Homoeopathy	December 15, 2023



#### **Conflict of Interest: An Overview**

Dr. James Michael, Dr. Eiphrangdaka L. Suchiang, Dr. Chaturbhuja Nayak

#### **ABSTRACT**

This article discusses the concept of conflict of interest, particularly in the context of medical research. It highlights the importance of transparency in disclosing relationships and activities that could potentially bias the planning, implementation, writing, peer-review, editing, and publication of scientific work. The article provides a detailed definition of conflict of interest and discusses its implications in medical research, including examples. It also outlines the responsibilities of authors, reviewers, editors, and editorial board members in disclosing potential conflicts of interest. The article further presents the International Committee of Medical Journal Editors (ICMJE) disclosure form and discusses strategies for managing conflicts of interest in healthcare, emphasizing the need for education, institutional policies, and ethics boards.

Keywords: Conflict of Interest, Disclosure, Bias, ICMJE, Ethics, Institutional Policies, Education.

#### INTRODUCTION

The transparency with which an author's relationships and activities, directly or indirectly related to a work, are dealt with during the planning, implementation, writing, peerreview, editing, and publication of a scientific work determines the credibility of published articles and the public trust in the scientific process to a large extent. There is a potential risk for bias and conflict of interest when a professional judgement about a primary objective (such as the welfare of patients or the validity of research) is affected by a secondary interest (such as financial gain).<sup>1</sup>

Whether an author's relationships or activities represent conflicts or not, can be a highly subjective matter varying from case to case. Although the existence of a connection or activity does not always imply that it has a negative impact on the substance of a work, perceptions of conflict can diminish trust in research just as much as actual conflicts of interest. Ultimately, the readers must be able to determine whether an author's affiliations and activities are relevant to the contents of the work. These decisions necessitate full disclosure of existence of any connection or activity. An attempt at complete disclosure by an author displays a commitment to transparency and contributes to the trustworthiness of the scientific process.1

#### Definition

By definition, 'conflict of interest' is any situation in which there are competing interests or loyalties.<sup>2</sup>

The People's Law Dictionary goes on to define a conflict of interest as "a situation in which a person has a duty to more than one person or organization but cannot do justice to the actual or potentially adverse interests of both parties. This includes when an individual's personal interests or concerns are inconsistent with the best for a customer, or when a public official's personal interests are contrary to his/her loyalty to public business. Often, this means avoiding even the appearance of conflict."

'Conflict of interest' can be defined as any situation in which a decision (or an action) taken by a professional in his/her duty (e.g., medical doctor prescribing a drug to his/her patient, or an investigator recruiting a research participant) is influenced by his/her relationship with a third party, providing personal benefits directly or indirectly to the professional and/or to the third party, whether financial or not.<sup>4</sup>

#### Conflict of Interest in Medical Research

Although conflict of interest is a misconduct identified in various domains (especially law,

politics, business, media, research etc.), let's focus on understanding its role and influence in medical research.

A conflict of interest (COI) can be said to exist when a physician (or his/her company/institution) has an external interest that may appear to alter the way he/she performs research or practices medicine.<sup>5</sup> For example, authors of a research article studying neutralising effect of an indigenously developed vaccine against COVID-196, declared absence of any conflict of interest in the pre-print of the article. As per another article commenting on the above-mentioned research, the obvious conflict of interest that the authors should have declared was that the organizations with which they were affiliated, had together developed the said vaccine, and that eight of the 13 authors were also authors of a paper in a reputed journal that described the phase 2 trial results of the said vaccine.7

In the peer-review and publishing process, not only the authors but also peer reviewers, editors, and editorial board members of journals must consider and disclose their relationships and activities when fulfilling their roles in the process of article review and publication. When authors submit a manuscript of any type, they are responsible for disclosing all relationships and activities that might bias or be seen to bias their work. Reviewers must disclose to editors any relationships or activities that could bias their opinions of the manuscript and should recuse themselves from reviewing specific manuscripts if the potential for bias exists. They must not use knowledge of the work they're reviewing before its publication to further their own interests.<sup>1</sup>

The editors, guest editors and editorial staff, who make the final decisions about manuscripts, should recuse themselves from editorial decisions if they have relationships or activities that pose potential conflicts related to articles under consideration. The journals should take extra precautions and have a stated policy for evaluation of manuscripts submitted by individuals involved in editorial decisions.<sup>1</sup>

The International Committee of Medical Journal Editors (ICMJE) have been encouraging journals and authors to adopt the practice of disclosing all relationships, activities or interests that might be related to the content of their submitted manuscript. The disclosure form suggested by ICMJE to facilitate and standardize author's disclosures, is as given below<sup>8</sup>: -

ICMJE DISCLOSURE FORM					
Date:					
Your Name:					
Manuscript Title:					
Manuscript number (if known):					
In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.					
The following questions apply to the author's relationships/activities/interests as they relate to the <u>current manuscript only</u> .					
The author's relationships/activities/interests should be <u>defined broadly</u> . For example, if a manuscript submitted by an author for publication pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.					
In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.					
1	Name all entities with whom you have this relationship or	Specifications/Comments			
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1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.)	None		
	No time limit for this item.			
2	Grants or contracts from any entity (if not indicated in item #1 above).	None		
3	Royalties or licenses	None		
4	Consulting fees	None		
5 Payment or honoraria for lectures		None		
manuscript writing or educatio	manuscript writing or educational			
	events			
6	Payment for expert testimony	None		
7 Support for attending meetings and or travel		None		
	or traver			
8	Patents planned, issued or pending	None		
9	Participation on a Data	None		
Safety Monitoring Board or Advisory Board				
	Board			
10	Leadership or fiduciary role in other	None		
	board, society, committee or advocacy group, paid or unpaid			
11	Stock or stock options	None		
12	Receipt of equipment, materials,	None		
	drugs, medical writing, gifts or other services			
13	Other financial or non-financial interests	None		
Please place an "X" next to the following statement to indicate your agreement:				
I certify that I have answered every question and have not altered the wording of any of the questions on this form.				

#### **Managing Conflict of Interest**

When it becomes hard to discern whether one has a conflict of interest, *being more transparent is probably the best way* to make the possible conflict of interest visible to the listener or reader.<sup>9</sup> Financial ties (such as employment, consultancies, stock ownership or options, honoraria, pat-

ents, and paid expert testimony) are the easiest to spot, the ones that are most often interpreted as potential conflicts of interest, and thus the ones that are most likely to jeopardise the journal's, authors', and system's credibility. When money is involved, disclosures of exact sums of compensation may enhance transparency. For academic conflicts of interest, unblinding of reviewers and

declaration of publications may help others to judge the possible academic conflict of interest.<sup>9</sup>

Other interests, such as personal connections or rivalries, academic competitiveness, and intellectual convictions, may also represent or be viewed as conflicts. Authors should avoid having agreements with study sponsors, both for-profit and non-profit, that interfere with authors' access to all the data of the study or that interfere with their ability to analyse and interpret the data and to prepare and publish manuscripts independently when and where they choose. Policies that dictate where authors may publish their work violate this principle of academic freedom. Authors may be required to provide the journal with the agreements in confidence.<sup>1</sup> As per the ICMJE, purposeful failure to report those relationships or activities specified on the journal's disclosure form is a form of misconduct.

### How to manage Conflict of Interest in Health-care?<sup>10</sup>

Actions should be taken in three domains to manage conflict of interest in healthcare.

First, *education* programs should be implemented in medical schools. Students should learn about conflict of interests and how to manage them in their future professional life. Physicians should maintain competencies regarding this issue as a mandatory part of their continuing medical education programs.

Second, every institution involved in the health sector, whether public or private, including regulatory agencies, public authorities, hospitals, universities, scientific organisations, scientific journals, should have regularly updated own policies for prevention and early detection of conflict of interests including identification of areas at risk and kit tools. These institutions should implement such regulations in the first place.

Third, institutions should have an ethics board to independently assess every self-declared conflict of interest before they are made transparent through active communication. Ethics board should also propose beforehand, serious sanctions for intentionally undisclosed conflicts of interest, which may help in preventing such misconduct.

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# Dr. Mahendra Lal Sircar Father of Indian Modern Science

Dr Subhas Singh, Dr Vignesh K., Dr Niharika Shaw, Dr Dinesh Sura

#### INTRODUCTION

follower of Ram Mohun Roy ideology, Dr. Mahendra Lal Sircar was a man of next generation science promoter in colonial India. He sowed the seeds of modern science and new research in 19th century India which bore its fruits by producing scientists like Jagdish Chandra Bose, Prafulla Chandra Roy and Sir C. V. Raman in 20th century. All these scientists had their roots somehow connected to Indian Association for the Cultivation of Science which was founded by Dr. Mahendra Lal Sircar in the year 1876. He not only promoted study of science in colonial India but himself took medical degree from Calcutta University and was amongst one of the renowned physicians of Calcutta. His other fields of interests included literature, music, religion, philosophy and history. It is interesting to know how a torch bearer of modern science got interested in Homoeopathy and stood still for it against his own colleagues.

#### Early life and education

Dr. Mahendra Lal Sircar was born on 2<sup>nd</sup> November 1833 in village Paikpara of Howrah, West Bengal. He and his brother were brought up by his maternal uncles as they both had lost their parents very early in their life.

Dr. Sircar's early education started in a Primary School (formerly known as Bangla Pathshala) in his native place Paikpara only. He was introduced to English language by Babu Tarak Kumar Das of Nebutola, Calcutta. Tarak babu, as a teacher greatly influenced Sircar's life. After completing his primary education, he was admitted to David Hare School and he studied here from 1841 to

1849. After receiving a 'junior scholarship' he was promoted for further study to Hindu College. Here he studied natural philosophy, geometry, astronomy, mathematics, and science. With his hard working and appealing personality, Dr. Sircar used to win over his teacher's heart and hence a little extra attention from them. One such teacher he met here was Mr. Sutcliffe. But Hindu College was not sufficing his quest to learn more in the field of modern science. So, despite Professor Sutcliffe's objection Mahendra Lal Sircar left Hindu College in 1854 and took admission in Calcutta Medical College (CMC) and started his journey to become Dr. Mahendra Lal Sircar.

#### Dr. M. L. Sircar and Medical career

Similar to previous institutes, Mahendra Lal Sircar became everyone's favourite and popular amongst faculty and students. Here he came closer to Dr. Archer, professor at Department of Ophthalmology after an incident where Dr. Archer asked a difficult question to fifth year student where nobody answered and Dr. Sircar answered at one go while just passing from nearby place. After this incident Dr. Sircar started attending Dr. Archer clinic regularly. And subsequently grew more closer to other professors like Eatwell, Goodeve, Wilson, Fryer etc. He started taking classes at CMC on 'mechanism of eye as an optical instrument' and even got invitation to give lecture on 'adaptation of the human eye to distance' from Bethune Society.

He appeared for L.M.S. exam in 1860 and passed with flying colours. In 1863, he appeared for M.D. examination and secured top honours and became second Indian to earn his M.D. degree from Calcutta University. Dr. Sircar soon became

### Stalwarts' Expedition

one of the renowned physicians of his time with his practise in Calcutta.

#### Dr. M. L. Sircar and Homoeopathy

Till all this time Dr. Sircar was very reluctant towards the principle of Homoeopathy and he even criticized homoeopaths as 'leeches' who take credit for cures when disease has already run its course. This dispute between allopath and homoeopath was at peak in mid-nineteenth century. It was merely an act of co-incidence when M.L. Sircar was introduced to Homoeopathy. It was when his friend Kissory Chand Mitra, the editor of Indian Field was ill and got cured with Homoeopathic treatment. He handed over Dr. M. L. Sircar, Morgan's *Philosophy of Homoeopathy* and asked him to write a quick review of it. He read it. And to surprise not just once, but twice. And there he was, convinced of Homoeopathic philosophy and ready to give an unbiased chance to Homoeopathy by observing its method of practise.

Dr. Sircar had an incident of being at odds with Dr. Rajendralal Dutta. He wanted to revert back to him after reading the philosophy. Since he got convinced with philosophy, so he decided to observe cases with him only. He started visiting him in his chamber and keenly observed role of diet and management of disease as control in comparison with disease treated with Homoeopathic medicines. In his own words, this is what he noted after his concluded "a great many recovered, and the incurables were benefitted".

#### Dr. M. L. Sircar and his unforeseen path

Soon after realising his mistake of demeaning homoeopathy, he thought it was his duty to aware the physicians of its righteousness. Dr. Sircar delivered a speech at fourth annual Medical Association Meeting on February 1867 in support of Homoeopathy on the topic "On the Supposed Uncertainty in Medical Science and on the Relationship between Diseases and their Remedial Agents". He not only supported homoeopathy with philosophy but he cited his own examples along with that of medical stalwarts who have found the Law of Similia to be efficacious in treating various disease conditions which were quite prevalent at that time.

He thought people who supported him when he criticized homoeopathy will also understand why he was at change of his opinion. He urged the medical profession to give up their dogmatism and conduct experiments to enrich medicine for better serving of humanity. But alas! There was a pin drop silence after his speech. It was the silence before the storm.

The unexpected happened and Dr. Sircar was removed from membership of Association. He was heart-broken but remained strong to his conviction. He soon lost all his practise and fell into powerful lobby against him from famous doctors of Calcutta like Dr. Rathson, Dr. Ewert, Dr. Waller etc. He even faced backlash from different Bengali and English newspapers.

#### Dr. M. L. Sircar and his solace path

There is a song in Bengali which says 'if they pay no heed to your call, then walk alone'. Dr. Sircar held his belief strong and remained faithful to his vision of incorporating homoeopathy into mainstream medicine of that time. He started practising again at his native place. From treating his regular patients to treating some of the celebrities of Bengal. However, Sircar's most famous patient was Thakur Ramakrishna. He even treated reformers like Vidyasagar, Radhakanta Deb, Dwarakanath, Nabinchandra Sen, and Gopalchandra Lahiri. Lord Dufferin, Viceroy of India from 1884 to 1888, and his wife, Lady Dufferin were also regular visitors to Dr. Sircar's clinic.

He started his own journal *The Calcutta Journal of Medicine* to promote the idea of Homoeopathy. He started publishing several case reports he treated successfully with Homoeopathy. Through the articles it can be inferred that he was successful in treating common ailments like cholera, jaundice and neuralgia to diseases like hysteria, pleurisy, hernia and cataract. His detailed case reporting with his keen medical its homoeopathic insights and treatment through journal got widespread acceptance and was greatly appreciated. Subsequently Dr. Sircar also established Indian Association for the Cultivation of Science (IACS) in July 1876 for his larger vision of advancement and development in all the fields of science like physics, chemistry, mathematics and material science etc. He had belief that development of science strengthens the

foundation of any nation. Establishment of IACS is another long story much to be described here.

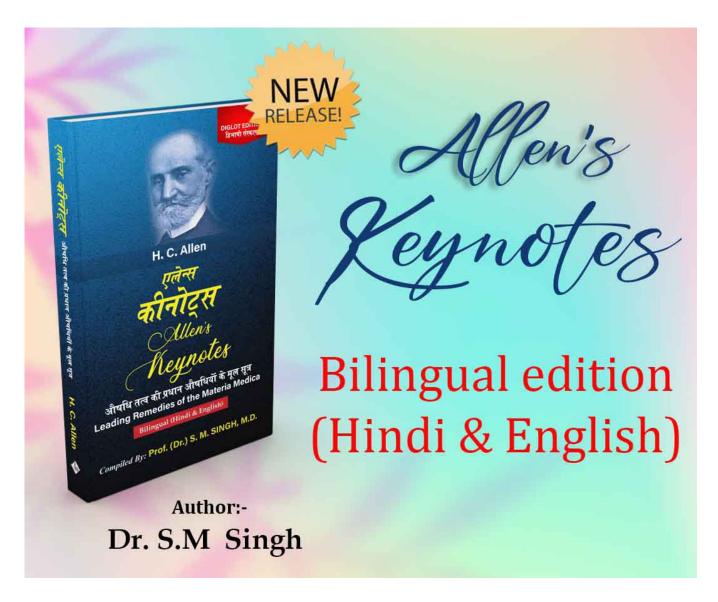
#### CONCLUSION

By the end of 19<sup>th</sup> century Dr. Sircar health was growing weaker. Even the need for better scientific and technical education rose dramatically by the end of century. Dr. Sircar was fortunate enough to have witnessed this emergence for scientific study in India. But he was little disappointed with negligence of government as well as Indian philanthropist for not including IACS in their list of institutes who promoted scientific studies. The same IACS which was once the model of scientific institute for scientists like Jagdish Chandra Bose in India was forgotten without getting its

proper due. Limiting his contribution just to Homoeopathy is a big unfair. Rather it is right to say Homoeopathy was graced and enriched by Dr. Sircar's Homoepathic cure and treatment. He left for his heavenly adobe on 23 February 1904.

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The Homoeopathic Heritage emphatically encourages open exchange of views, opinions and thoughts. Our section 'Readers' Perspective' features insightful and thought-provoking responses by our readers to any of our content. We are delightfully committed to being a genuine space for diverse voices from across the globe.

The following letter by Dr. Anil Singhal expresses his views on the editorial penned by Dr. Bipin Jain published in October 2023, Volume 49, No.7.

Dear Dr. Rashi,

As a fellow practitioner deeply invested in the homeopathic tradition, I found Dr. Jain's insights not only magnificent but also thought-provoking. His editorial succinctly encapsulates the profound impact homeopathy can have on psychosomatic conditions, which is often a complex interplay between the mind and body. Dr. Jain's ability to distill this complexity into a concise narrative is commendable, especially considering the rising prevalence of such disorders in the modern health landscape.

Warmest regards,

Dr. Anil Singhal, MD(Hom.)

# Editorial By Dr. Bipn Jain: Role of Homoeopathy in Psychosomatic Disorders: My Perspective

Dr. Anil Singhal, MD(Hom.)

The intersection of mind and body in medical conditions has long been a subject of intense scrutiny and varying interpretations. The editorial "Role of Homoeopathy in Psychosomatic Disorders" offers a compelling exploration into the holistic application of homeopathic principles to ailments where psychological and physiological factors are intricately linked.

At the core of the editorial lies a detailed explanation of the term "psychosomatic," tracing its etymology and the role attributed by the WHO to environmental factors in influencing neuro-endocrine systems. The historical backdrop serves to not only ground the argument in a broader context but also to position homeopathy within a tradition that has long recognized the psyche-soma connection.

Dr. Bipin Jain pays particular homage to Hahnemann, illustrating how his work in the "Organon of Medicine" presaged the current understanding of psychosomatic medicine. By emphasizing Hahnemann's aphorisms on the interdependence of mental states and physical health, the editorial aligns homeopathy



with the philosophies that underscore contemporary psychosomatic theory.

Two case studies are meticulously chosen to illuminate the practicality of homeopathic interventions in psychosomatic conditions. First case of a married lady with MIL-DIL syndrome relieved with indicated homeopathic remedy. Second case of a school boy where emotional sensitivity increased after being reprimanded and his well-being was restored back to health with homeopathy.

Dr. Jain presents these narratives with a dual aim: to illustrate the understanding of homeopathic practitioners when it comes to individualized treatment and to showcase tangible outcomes following the application of homeopathic remedies. These cases are critical in demonstrating the claimed efficacy of homeopathy beyond the theoretical and into the empirical realm.

The intent of Dr. Bipin Jain appears twofold: to validate the practice of homeopathy as a science well-equipped to handle the complexity of psychosomatic disorders and to reaffirm the founding principles laid down by Hahnemann. The editorial emphasizes the concepts of "disposition" and "diathesis" that underscore the predisposition and vulnerability of individuals to certain stressors leading to disease manifestation.

The language of the editorial is steeped in professional and technical terminology, which lends credibility to the argument. Dr. Jain makes a conscious choice to emphasize historical continuity and innovation within homeopathic practice. The recurring use of terms like "holistic," "predisposition," and "constitution" converge on the principle that homeopathic medicine treats the individual, not merely the disease.

In conclusion, the editorial "Role of Homoeopathy in Psychosomatic Disorders" effectively reiterates the significance of holistic treatment approaches ingrained in homeopathic philosophy. It opens up avenues for further discussion on the integration of homeopathy with other psychosomatic treatment strategies. Most importantly, it reaffirms the need for individualized care, a cornerstone of both homeopathic practice and effective psychosomatic therapy.



### **Clinical Trials in Homoeopathy**

Dr. Apoorva Yadav, Dr. Ghazala Parveen

#### **ABSTRACT**

Clinical Trial is an organized research, conducted on human beings to safety and efficacy of a drug. Even after several years of its discovery, Homoeopathy has not been able to establish itself strongly as an alternative to conventional medicine. The reason has been the lack of research in Homoeopathy. Clinical research in Homoeopathy helps in generating, validating and consolidating scientific evidence (in terms of safety, efficacy and effectiveness) of Homoeopathic medications, procedures and treatment regimens. These researches may be useful in prevention, treatment of various diseases, decision making for stakeholders and thus help in improving clinical care. The aim is to carry out evidence-based trials based on modern scientific parameters (double blinding, objective assessment criteria, statistical analysis, etc.) without conflicting with the doctrines of Homoeopathy. This article provides some hints about the importance of conducting clinical trials in homoeopathy.

**Keywords:** Clinical Trial, Homoeopathy, Randomized Control Trial, Randomization, Evidence-based Trials, Homoeopathic Medicines, Blinding, Placebo.

**Abbreviation:** Central Council for Research in Homoeopathy(CCRH), Indian journal of Research in Homoeopathy(IJRH), Clinical Trials Registry-India(CTRI), Principal Investigator(PI), Good Clinical Practice Guidelines for Clinical Trials in Homoeopathy (GCP-H).

#### INTRODUCTION

Homoeopathy is a medical science which is based on exact empirical facts. All the observations in the system of Homoeopathy are made according to clearly defined criteria. Homoeopathy is a systematic, holistic and quantitative system which is closer to the new bio-psycho-social and systemic therapy<sup>1</sup>.

Homoeopathy is an evidence-based medicine and the treatment decisions are purely individualized. If the principles of Homoeopathy as laid down by Dr Hahnemann are followed, then it is an evidence-based Homoeopathy practice. To make this system achieve today's scientific acceptance, there is a need for research studies and internationally accepted standards. It is essential to "re-search" and "re-validate" the existing works in Homoeopathy with newer outlooks and thoughts<sup>2</sup>.

According to Dr H. A. Robert in his philosophy THE PRINCIPLES AND ART OF CURE BY HO-MOEOPATHY: medicine, while always deal-

ing with the ills of mankind has passed through a continuous barrage of "modern" discoveries. Greater possibilities of investigation of the functions of the body have increased our knowledge of life processes and the circumstances of living; and this increase in knowledge has been of inestimable value in dealing with human suffering<sup>3</sup>.

In aphorism 27 of Organon of medicine, Dr Hahnemann has already mentioned: The curative power of medicines, therefore depends on their symptoms, similar to the disease but superior to in its strength, so that each individual case of disease is most surely, radically, rapidly and permanently annihilated and removed only by a medicine capable of producing (in the human system) in the most similar and the complete manner the totality of its symptoms, which at the same time are stronger than the disease<sup>4</sup>.

#### Definition

"Clinical Trials" are a type of research that stud-

ies new tests and treatments and evaluates their effects on human health outcomes. People volunteer to take part in clinical trials to test medical interventions including drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioral treatments and preventive care<sup>5</sup>.

Clinical trials are carefully designed, reviewed and completed, and need to be approved before they can start. People of all ages can take part in clinical trials, including children.

"Clinical Trial" means any systematic study of existing or new Homoeopathy drug, investigational new drug, in human participants to generate data for discovering or verifying it's clinical, pharmacological, including pharmacodynamics or pharmacokinetics, or adverse effects with the objective of determining safety, efficacy or tolerance of the drug<sup>6</sup>.

Goal of Clinical trials is to determine if these treatment, prevention, and behavior approaches are safe and effective. People take part in Clinical trials for many reasons. People with an illness or disease also take part to help others, but also to possibly receive the newest treatment and to have added (or extra) care and attention from the Clinical trial staff. Clinical trials offer hope for many people and a chance to help researchers find better treatments for others in the future.

#### There are 4 phases of biomedical clinical trials

Phase I (safety and dosage)- The main objective of this phase is to establish initial safety, maximum tolerance and pharmacokinetics of the drug in humans. This phase is usually done on 20-80 Healthy Human Volunteers or certain types of patients<sup>7</sup>.

**Phase II ( efficacy and side effects)-** Phase II trials are increasingly, but not always randomized and are conducted on patients either in an open, non-blind or as placebo controlled, blinded trials. Here 100-200 patients are enrolled to determine the dose and adverse reactions of the drugs.

Phase III (confirm results: effectiveness and long term adverse effects)- This phase involves several hundred to thousand patients and may last for 1-5 years conducted in multicentric manner.Drug safety and effectiveness are studied in different patient subgroups like children, elderly and patients having Hepato-renal impairment.

Phase IV (post marketing studies/trial)- After the prior demonstration of the drugs safety, efficacy and dose definition in the previous trials, this phase is concerned with the application of the drug in the general population.

#### Types of clinical trials<sup>8</sup>

1-Open clinical trial

2-Single-blind clinical trial

3-Double blind clinical trial

4-Triple blind clinical trial

5-Crossover clinical trial

6-N-OF-1 clinical trial

7-Explanatory clinical trial

8-Unicenter clinical trial

9-Multicenter clinical trial

10-Parallel clinical trial

11-Sequential clinical trial

12-Community trial

### HAHNEMANNIAN'S PATHOGENETIC CLINICAL TRIAL

Hahnemann's greatest contribution may be taken as making it possible by his unique method of human "proving" (self–experimentation) to fully apply the similia principle<sup>9</sup>.

In 1796, "ESSAY ON A NEW PRINCIPLE FOR ASCERTAINING THE CURATIVE POWER OF DRUGS" which was followed in 1810 by his famous work "The Organon of the Healing Art".

Hahnemann has also been granted a special place as one of those who carried out "Human Experiment" on himself, his family, friends and students.

In 1790, Hahnemann self experimented with Cinchona bark and that was the starting point of formulating the principle of similia.

#### NEED FOR MORE RESEARCHES AND CLINI-CAL TRIALS IN HOMOEOPATHY

The foundation of Homoeopathy was laid on human experimentation within the confines and process of the late 18<sup>th</sup> and 19<sup>th</sup> centuries. It was no surprise that like any new idea, challenging the existing norms was forced with opposition and criticism<sup>10</sup>.

Hence against these criticism many more researches and clinical trials should be made by improving the research education among homoeopathic fraternity, ensuring precise application of principles of Homoeopathy as well as utilizing correct research methodology as researcher is the person who identifies a problem and seeks way and means at solving them for the benefits of humanity.

The prevalence of Homoeopathy by the general population is increasing consistently worldwide, with results of systematic review showing that a significant percentage of general populations visit homoeopaths and use homoeopathic medicines. Hence, there is a more need for the systematic and standard clinical trials and research to be carried out in homoeopathy<sup>11</sup>.

Till 2/5/2022, CENTRAL COUNCIL FOR RE-SEARCH IN HOMOEOPATHY has conducted 211 studies on various diseases out of which 178 studies are concluded (139 Observational studies and 39 Randomized Control Trial), currently 13 studies are ongoing.

The salient achievements in clinical studies have been in HIV/AIDS, Gastroenteritis, chronic sinusitis, Influenza like illness, Benign prostatic hyperplasia, Acute Haemorrhoids, Cervical spondylosis pain management, Acute encephalitis Syndrome, Covid-19, Hypertension ,Thrombocytopenia due to dengue<sup>12</sup>.

To establish the effectiveness of Homoeopathic treatment, Randomized Controlled Trials(RCT) are being conducted. The outcome of these studies is published periodically in national, international Peer-Reviewed Journals.

#### Clinical trial examples in IJRH:

Homoeopathic therapy for lower urinary tract symptoms in men with Benign Prostatic Hyperplasia: An Open Randomized Multicentric Placebo Controlled Clinical trial<sup>13</sup>.

Clinical trial for evaluation of a Human Immunodeficiency Virus Nosode in the treatment for Human Immunodeficiency Virus –Infected individuals<sup>14</sup>.

#### Criteria for clinical trial:

#### Clinical trials can study<sup>15</sup>

New drugs or new combinations of drugs

New ways to use existing treatment

New ways to change behaviors to improve health

New ways to improve the quality of life for people with acute or chronic illness

#### Clinical trials protocol-

The goal of the study

Who is eligible to take part in study

Protections against risk to participants

How long the trial is expected to last

What information will be gathered

A clinical trial is led by a Principal Investigator(PI). Members of the research team regularly monitor the participants' health to determine the study's safety and effectiveness.

#### Institutional review board-

Central Council for Research in Homoeopathy, an autonomous organization under ministry of AYUSH, Govt. of India which undertakes, coordinates, develops, disseminates and promotes scientific research in Homoeopathy. India has the highest number of practicing homoeopathic physicians compared to other countries and is unique in its institutional mechanism and research frame work. Central Council for Research in Homoeopathy (CCRH), an apex body of the ministry of AYUSH, has developed Good Clinical Practice Guidelines for Clinical Trials in Homoeopathy (GCP-H) for researchers, practitioners, academicians and students interested in conducting ethical and credible homoeopathic research.

All clinical trials relating to Homoeopathy (homoeopathic clinical trials) must be conducted in accordance with Homoeopathy with Good Clinical Practices of Homoeopathy (GCP-H)<sup>16</sup>.

#### Clinical trials sponsors-

Clinical trials sponsors may be people, institutions, companies, government agencies, or other organizations that are responsible for initiating, managing or financing the clinical trial, but do not conduct the research.

**Placebo-** The doctrine of placebo, from the Latin "placere" to "please" or to "satisfy". Both in acute or chronic diseases, when a well selected medicine continues its action, we should not disturb the case. During this period, we have to give placebo to keep the action of the medicine undisturbed. At the same time the patient also knows that he is taking medicine (psychological effect)<sup>17</sup>.

Randomization-Randomization is a statistical procedure by which the participants are allocated into groups usually called "Study" and "control" groups, to receive or not to receive an experimental preventive or therapeutic procedure, maneuver, or intervention. Randomization is an attempt to eliminate "bias" and allow for comparability. RANDOMIZATION IS THE HEART OF CONTROL TRIAL<sup>18</sup>.

#### Blinding-

**Single Blind Trial-** The trial is so planned that the participant is not aware whether he belongs to the study group or control group.

**Double Blind Trial**-The trial is so planned that neither the doctor nor the participant are aware of the group allocation and the treatment received.

**Triple Blind Trial**- This goes one step further. The participant, the investigator and the person analyzing the data are all "blind".

Many different types of people take part in clinical trials. Some research studies seek participants with illnesses or conditions to be studied in the clinical trial, while others need healthy volunteers. Research procedures with healthy volunteers are designed to develop new knowledge, not to pro-

vide direct benefit to those taking part. Healthy volunteers have always played an important role in research.

Researchers follows clinical trial guidelines when deciding who can participate, in a study. These guidelines are called inclusion and exclusion criteria. Factors that allow you to take part in a clinical trial are called INCLUSION CRITERIA. Those that exclude or prevent participation are EXCLUSION CRITERIA. These criteria are based on factors such as age, gender, the type and stage of a disease, treatment history, and other medical conditions.

INFORMED CONSENT is the process of learning the key facts about a clinical trial before deciding whether to participate. The informed consent document also explains risks and potential benefits. Before the enrollment within the trial, the participants will need to sign the informed consent document. The participant is free to withdraw from the study at any time.

All interventional clinical trials-studies shall be registered by the responsible party with Clinical Trial Registry of India (CTRI) before the enrollment of the first participants in the specific clinical trials.

After a clinical trial is completed, the researchers carefully examine information collected during the study before making decisions about the meaning of the findings and about the need for further testing. Results from clinical trials are often published in peer reviewed scientific journals .PEER REVIEW is a process by which experts review the report before it is published to ensure that the analysis and conclusions are sound.

Evidence based trials are the aim of modern scientific parameters (double blinding, objective assessment criteria, statistical analysis, etc.) without opposing the doctrine of Homoeopathy.

#### CONCLUSION

As it has been found many times, the evidence from Homoeopathic trials/studies is considered

### Subjective

and reported of low quality. The reasons could be many including lack of adequate training or exposure to research practices. Thus, it is imperative that adequate training in research methodologies, conducting and reporting is provided along with hands-on training. In homoeopathy there is a need for research. Clinical research requires complex and rigorous testing in collaboration with communities that are affected by the disease. The research conducted in Homoeopathy should be targeted towards enhancing the reliability, validity and credibility quotient of Homoeopathy. There is a need to concentrate on continuing professional development, quality education, validation of Homoeopathic Pathogenetic Trials-drug proving, establishing Peer- Review Homoeopathic Journals, etc. To explore new things and to make Homoeopathy an acceptable scientific science, homoeopaths should use every possible resource. Newer research in homoeopathy is essential to add to its credibility and reliability.

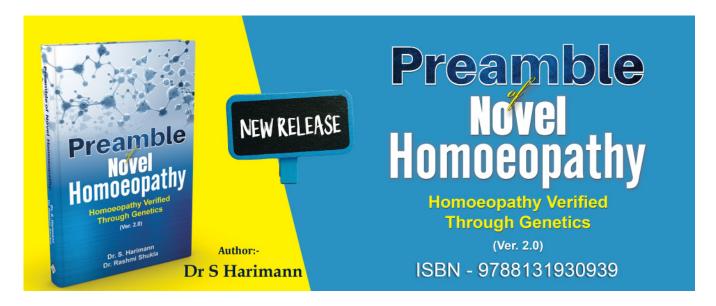
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# Role of Homoeopathic Ogranopathic Drugs in Preventing Cardiovascular Diseases

Dr. Shivakshi Bertwal

#### **ABSTRACT**

Homeopathic organopathic drugs, also known as organ remedies, are used in the treatment of diseases and disorders related to specific organs. The use of organopathic drugs has been gaining popularity in the treatment of cardiovascular diseases. Burnett first combined the views of Paracelsus and Rademacher with the homeopathic teachings and thereby forged this organopathic treatment approach. In this article, we will discuss the role of homoeopathic organopathic drugs in cardiovascular diseases.

**Keywords:** Homoeopathy, Organopathic homeopathic drugs, Burnett, Cardiovascular diseases, Organopathy

#### INTRODUCTION

In the book "Durability of Tumours by Medicines" Dr. JC Burnett says "When drugs affect certain parts of the economy specifically, the general effect is the one elaborated by greatly vilified Paracelsus and it constituted the back bone of its practice."

Remedies owing this quality were his appropriata, i.e.they are appropriated by the organs they respectively and specifically influence, much as we suppose the kidneys seize upon the particles in the blood to form what is then is known a urine. Hahnemannian medicines is based on pure pharmacodynamics; its first and deepest ground work being the principle that given drugs affect given organs (parts) by self-elective preference.

And we thus see that organ-remedies by restoring the disturbed organ to health, cure the organism itself. -James Compton-Burnett

Organopathy is the specific loyal action of drugs on particular parts or organs. It is thus a very convenient term in therapeutics as well as in aetiology and pathology. Burnett first combined the views of Paracelsus and Rademacher with the homeopathic teachings and thereby forged this organopathic treatment approach. Burnett says, Homoeopathy may be said to be based upon organopathy, for a drug to cure the heart of its disease specifically must necessarily affect the heart in some manner. But the homoeopath specializes and says further: The drug that is to cure the heart must affect the heart, certainly — that is one of the foundations of our whole therapeutic edifice, but that is not enough; the nosological organopathy and the therapeutic organopathy must be and are similar.

Cardiovascular diseases are a group of disorders that affect the heart and blood vessels. These diseases include coronary artery disease, hypertension, heart failure, and arrhythmias. They are among the leading causes of morbidity and mortality worldwide. Traditional treatments for cardiovascular diseases include lifestyle changes, medications, and invasive procedures such as angioplasty and bypass surgery. However, there is growing interest in the use of alternative therapies such as homeopathy, including the use of organopathic drugs.

#### Homeopathy: Clinical studies related to CVD

1. In a double-blind randomized clinical study, a group of people suffering from mild-to-moderate hypertension were enrolled. The

study compared individualized homoeopathic therapy with placebo (dummy pill). Successful results were obtained with 82 per cent of those subjects taking homoeopathy compared with 57 per cent of those using placebo [1].

- 2. In another randomized double-blind study, a group of people suffering from essential hypertension (high blood pressure, with no identifiable cause) were treated either with standard conventional pharmaceutical products, or homeopathic remedies. Pharmaceuticals were found to provide superior blood pressure reducing effects, but homeopathic remedies were found to be the better choice for the management of the subjective symptoms of hypertension [2].
- 3. In a controlled study, researchers attempted to determine the effects of potentized aspirin on rats exhibiting reduced platelet aggregation associated with portal hypertension (high blood pressure in the portal vein and its tributaries). Given that material doses of aspirin are known to be associated with a reduction in platelet aggregation, one of the aims of the study was to confirm that the reverse of this would be the case if potentized aspirin were used. The study confirmed that, compared to controls, the potentized homeopathic remedy, aspirin 14C, normalised deficiencies in platelet aggregation in rats that were involved in the study [3].
- A group of people suffering from mild cardiac insufficiency (inadequate blood flow to the heart muscles) were given Cralonin, homoeopathic combination product, homeopathic containing the Crataegus oxycantha, Spigelia anthelmia and Kalium carbonicum or a combination of an ACE inhibitor and a diuretic, the 'standard' conventional medical treatment prescribed for the condition. Both groups showed equally effective results [4].
- 5. The prospective study gathered data of the practical relevance of Cralonin on a total of 665 patients. The study also documented the symptoms for which Cralonin was prescribed as well as dosages and methods of administration. Approximately 50 per cent of the patients in the study took Cralonin as

an adjuvant to standard conventional therapy with antihypertensives, or cardioactive drugs. The participating practitioners assessed patient tolerance of Cralonin as "excellent" or "good" in the great majority of cases. No side-effects were reported. The homeopathic therapeutic efficacy was rated "good" or "very good" in approximately 90 per cent of patients. The treatment was also most effective and fast-acting in cases of functional cardiac symptoms and stabbing pain (cardiodynia). [5]

The study showed that there are advantages with Cralonin as an alternative to ACE inhibitors and diuretics in mild cardiac insufficiency. It may be mentioned that Cralonin is prescribed either alone or as an adjuvant therapy for functional or organic heart disease and post infection cardiac symptoms.

Spigelia anthelmia acts on the heart and the nervous system. It has been homeopathically prescribed to treat pericarditis, anaemia, debility, chilly body parts due to poor circulation, palpitations and weak, irregular pulse, dyspnoea and angina pectoris. The remedy picture, from the homeopathic perspective, relates to excess nervous agitation and frequent palpitations. Evidence-based reports also correspond to the remedy's efficacy in heart murmurs and valve disorders.

Kalium carbonicum is from the homeopathic standpoint, suitable for hypertension in overweight individuals tending to dropsy and paretic conditions. Symptoms often revolve on vertigo, while turning head, occipital headaches, or migraine with nausea, especially while travelling. There may be excess anxiety, besides palpitations with a 'burning feeling' in the heart 'region.'

#### Hypertension: Homoeopathic Research

Clinical research on the effectiveness of homoeopathic treatment, apart from Cranolin, in the management of essential hypertension is relatively small. Most of such published work is not focused or keyed to the homeopathic individualistic approach. Besides, the homeopathic remedies used seem to have a strong evidence-based status, not rigorously documented outcomes.

One would also do well to recall a study conducted by Bignamini et al. [6] which examined the effect

of *Baryta carbonica* 15C in 34 elderly hypertensive subjects <sup>[6]</sup>. Although the results did not show any significant effects of the remedy, when compared with placebo, one interesting outcome was patients, whose symptom patterns 'matched' with the remedy profile of *Baryta carbonica*, showed a substantial reduction in blood pressure. Yet another study conducted by Dr. Farokh J Master <sup>[7]</sup> showed tangible improvement in the hypertensive treatment group <sup>[7]</sup>. The homeopathic remedies used in the study were *Adrenalinum*, *Eel serum* and *Baryta muriatica*, which is regarded by some clinicians as the 'homeopathic amlodipine.'

Arnica montana, commonly known as Arnica, is a homoeopathic organopathic drug derived from the plant Arnica montana. Arnica is used in the management of CVDs, such as hypertension, angina pectoris, and myocardial infarction. Arnica is known to improve blood circulation, reduce inflammation, and relieve pain.

Crataegus oxyacantha, commonly known as Hawthorn, is a homoeopathic organopathic drug derived from the plant Crataegus oxyacantha. Hawthorn is used in the management of CVDs, such as hypertension, angina pectoris, and heart failure. Hawthorn is known to improve blood circulation, reduce inflammation, and strengthen the heart muscle.

Digitalis purpurea, commonly known as Digitalis, is a homoeopathic organopathic drug derived from the plant Digitalis purpurea. Digitalis is used in the management of CVDs, such as heart failure, atrial fibrillation, and tachycardia. Digitalis is known to strengthen the heart muscle, regulate heart rhythm, and improve blood circulation.

Naja tripudians, commonly known as Naja, is a homoeopathic organopathic drug derived from the venom of the Indian Cobra. Naja is used in the management of CVDs, such hypertension, angina pectoris, and myocardial infarction. Naja is known to improve blood circulation, reduce inflammation, and regulate heart rhythm.

#### CONCLUSION

Homeopathy can certainly play a useful role, not only in preventative cardiac care, but also as a sup-

portive (adjuvant) line of treatment, in conjunction with conventional medicine. In most cases of hypertension, where blood pressure control, with conventional medications appears incomplete, the individual may be at risk of possible complications This is an exciting area not only for further research, but also for new, wide-ranging clinical studies. In homoeopathy, the most appropriate treatment protocol is based on the similia principle; however, this may not happen in all the cases. Experienced physicians switch from one method to another based on the case, availability of the symptoms and based on his experience. One must see links between different approaches and how they complement each other without losing their individuality for opening wider scope for the benefit of ailing humanity.

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# Role of Clinical Trials: A Practical Approach in Homoeopathy

Dr. Aradhana Pathak

#### **ABSTRACT**

Clinical trials in homeopathy aim to evaluate the safety and efficacy of specific homeopathic treatments for various medical conditions. While homeopathic research has faced some challenges due to its unique principles and the difficulty of conducting double-blind, placebo-controlled trials, there have been several notable studies in the field. Clinical trials provide a foundation for evidence-based medicine. They help identify potential adverse effects and contraindications of homeopathic treatments, allowing healthcare providers to make informed decisions about their use. Despite many challenges, well-designed and rigorously conducted clinical trials can provide valuable insights into the safety and efficacy of homoeopathic treatments, ultimately benefiting both patients and healthcare providers.

**Keywords:** clinical trials, homoeopathy, healthcare, placebo-controlled trial

**Abbreviation:** Clinical Trial(C.T.), Central Drug Standard Control Organisation (C.D.S.C.O.)

#### INTRODUCTION

Homoeopathic medicine is a system developed by Samuel Hahnemann from the similia concept: "similia similibus curantur." This implies that a diluted, "potentised" agent, which in healthy individuals induces complaints resembling those of the patient, can be used to cure the patient.

Clinical Research in Homoeopathy helps in generating, validating and consolidating scientific evidences (in terms of safety, efficacy and effectiveness) of homoeopathic medications, procedures and treatment regimes. These researches may be useful in in prevention, treatment of various diseases, decision making for stake holders and thus help in improving clinical care. The aim is to carry out evidence-based trials based on modern scientific parameters (double blinding; objective assessment criteria, statistical analysis, etc.) without conflicting with the doctrines of Homoeopathy. More emphasis is laid upon the clinical evaluation of homoeopathic medicines in disease conditions of national health importance, where no curative treatment is available in conventional medicine; endemic diseases in certain parts of the country and the so-called surgical diseases.(1)

Historically, health-related quality of life research has been carried out at a descriptive level, providing rich data regarding the impact of disease and treatment on the physical, functional, psychologic, and social health of varying patient populations. More recently, there has been growing interest in incorporating psychosocial or "quality of life" outcome measures into clinical trials of medical interventions, particularly in the chronic diseases.<sup>(2)</sup>

Clinical trial(C.T.) is an systematic research which is conducted on human being to investigate the safety and efficacy of a drug. C.T. is also applicable with vaccine, medical device, surgical method or test. It is monitored by drug controller general of India under Central Drug Standard Control Organisation (C.D.S.C.O.). It is done in four phases.

#### PHASE I:

Establishment of initial safety, maximum tolerance and pharmacokinetics of the drugs in humans. There are certain types of healthy human volunteers .The drug which has to be investigated has a known potential adverse effect, the study is done on subjects only for whom drug is targeted. The total duration taken by phase I is approximately 3-6 months.

#### PHASE II:

Phase II trial is initiated after completion of phase I to evaluate the safety and efficacy of the drug. Phase II is conducted on individuals either in an open, non-blind or as placebo controlled, blinded trials. About 100-300 patients are enrolled. This phase takes about six months to two years.

#### PHASE III:

This phase confirms effectiveness and long term adverse effects, involving several hundreds to thousands of patients and may last for one to five years conducted in multicentric manner. After completion of phase III trial, the drug companies are in position to apply to the regulatory authorities for marketing approval. Only about 25% of experimental drugs pass through phase III trial.

#### PHASE IV:

After the earlier demonstration of the drug's safety, efficacy and dose definition in the past trials, this phase is concerned with the application of the drug in general population.

#### SOME HOMOEOPATHIC CLINICAL TRAILS:

Clinical trials in homeopathy aim to evaluate the safety and efficacy of specific homeopathic treatments for various medical conditions. While homeopathic research has faced some challenges due to its unique principles and the difficulty of conducting double-blind, placebo-controlled trials, there have been several notable studies in the field. Here are a few examples of clinical trials in homeopathy:

A randomised placebo-controlled clinical trial of homeopathic medicines on osteoarthritis concludes that patients with osteoarthritis reported a significant decrease in WOMAC index score after three months of homoeopathic treatment based on the totality of symptoms. <sup>(3)</sup>

An experimental double-blind clinical trial method in homoeopathy regarding use of a limited range of remedies to treat fibrositis states that homoeopathy produced a statistically significant improvement, but only when the prescribed remedy was well indicated.<sup>(4)</sup>

Another study on homoeopathic remedies in

dermatology negatively reviews on controlled clinical trials. This study concluded that trials of homoeopathic treatments for cutaneous diseases were highly variable in the methods and quality, they did not find sufficient evidence from these studies that homoeopathy is clearly efficacious for any single dermatological condition.<sup>(5)</sup>

#### NEED OF CLINICAL TRIALS IN THE HOMOE-OPATHY:

The prevalence of Homoeopathy by general population is increasing consistently worldwide, with results of systematic review showing that a significant percentage of general populations visit homoeopaths and use homoeopathic medicines. <sup>(6)</sup> In India as well, increasing number of patients visiting homoeopathic wellness centres. <sup>(7)</sup>

Clinical trials help determine whether a homeopathic treatment is safe and effective for a specific condition. This is crucial to ensure that patients are not exposed to unnecessary risks and that they receive treatments that genuinely benefit them. Clinical trials provide a foundation for evidencebased medicine. In modern healthcare, treatments and interventions should be based on scientific evidence to ensure that they are effective and safe. Without clinical trials, it's challenging to establish the efficacy of homeopathic remedies. Clinical trials allow for comparisons between homeopathic treatments and conventional medical treatments or placebos. These comparisons can help determine if homeopathy offers any advantages or disadvantages in treating certain conditions, leading to informed treatment choices. Clinical trials can help identify variations in the quality and potency of homeopathic remedies. This is especially important because homeopathic preparations are highly diluted, and even slight variations in the manufacturing process can impact their efficacy. Clinical trials can help establish the most appropriate dosage and administration protocols for homeopathic remedies. This information is crucial for standardizing treatment approaches and ensuring consistent results.

Ensuring patient safety is a primary concern in healthcare. Clinical trials help identify potential adverse effects and contraindications of homeopathic treatments, allowing healthcare providers to make informed decisions about their use.

### Subjective

In many countries, regulatory authorities require evidence of safety and efficacy through clinical trials before allowing the marketing and sale of homeopathic remedies. Conducting clinical trials can facilitate regulatory approval and increase the acceptance of homeopathy within the mainstream healthcare system. Clinical trials can enhance public confidence in homeopathy by providing scientific evidence of its effectiveness. This can encourage more people to consider homeopathy as a complementary or alternative treatment option.

Clinical trials can be valuable for training healthcare professionals in the proper use of homeopathic treatments. They can also help practitioners gain a better understanding of which conditions are most likely to respond to homeopathy. Clinical trials can contribute to the ongoing research and development of homeopathic treatments. As new evidence emerges, it can lead to the refinement and improvement of homeopathic remedies and treatment protocols.

#### CONCLUSIONS

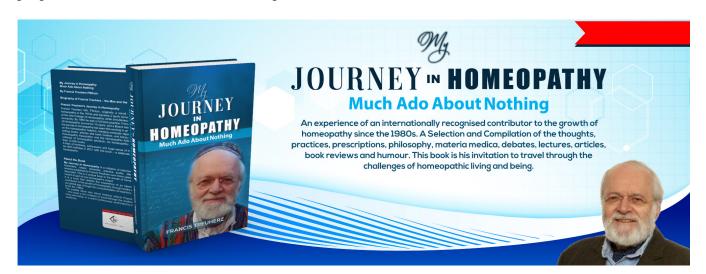
There is a high rising number of treatment innovations which require proper investigation to look into if they are of genuine benefit to patients. The clinical trials has become widely regarded as the principal method for obtaining a reliable evaluation of treatment effect on the patient. The homoeopathic profession at large and others concerned with the treatment and management of patients may benefit from an increased understanding of how clinical trials are conducted. The proper use of statistical methods is important at the planning stage of a clinical trial as well as in the analysis and interpretation of results. Despite many challenges, well-designed and rigorously conducted clinical trials can provide valuable insights into the safety and efficacy of homoeopathic treatments, ultimately benefiting both patients and healthcare providers.

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# **Evolution of Holistic Concept of Health, Disease, and Cure: A Homoeopathic Perspective**

Dr. Sumanta Kamila, Dr. Rayba Khatoon, Dr. Sanjay Sarkar, Dr. Aloke Kumar Ghosh

#### **ABSTRACT**

Medical Scientists of the modern era are now trying to include the holistic approach in modern medicine, this is evident from the emerging concepts of personalised medicine or precision medicine, but this holistic concepts of health and healing is already an indispensable part of our traditional systems of medicines like Ayurveda, Unani, and Homoeopathy. In this article we have presented how this holistic concept has emerged through the ages.

Keywords: holism, homoeopathy, santiago theory, ayurveda

Abbreviation: Deoxyribonucleic acid (DNA), World Health Organization (WHO),

#### INTRODUCTION

The term holistic health is used many times in literature with a variety of different meanings. The word Holism also has its origin in the Greek word holos, which means "whole". Holism is not about any cult or religion, rather, it is an approach that looks at things in a total perspective. As far as we know, it was first used in 1926 by Jan Smuts, in his book Holism and Evolution. Holistic health typically considers the whole person—body, mind, and spirit. A holistic approach to healing goes beyond just eliminating symptoms.

#### **Definition of Holistic:**

As per Cambridge dictionary:

Dealing with or treating the whole of something and not just a part.

As per Oxford dictionary:

- 1. Considering a whole thing or being to be more than a collection of parts.
- 2. Treating the whole person rather than just the symptoms.

#### **Definition of Health:**

The widely accepted definition of health is that given by the WHO which is as follows: "Health is a state of complete physical, mental and social well being and not merely an absence of disease or infirmity" In recent years, this statement has been amplified to include the ability to lead a "socially and economically productive life".

Concept of Disease: There have been many attempts to define disease. The Oxford English Dictionary defines disease as "a condition of the body or some part or organ of the body in which its functions are disrupted or deranged".

Concept of Cure: according to Taber's cyclopaedic medical dictionary 'Cure' is defined as:

1.course of treatment to restore health 2.restoration to health

According to Master Hahnemann in Materia Medica Pura [1] under the drug *China*, cure has been defined as "recovery undisturbed by after sufferings".

# Evolution of understanding of the concept of health through the ages:

There has been many attempts to conceptualise the health, according to the traditional systems of therapeutics like: Ayurveda, Greek medicine, Unani medicine; cure has been conceptualised as a balanced condition of certain humours and according to eighteenth and nineteenth century old school physicians healthy condition means devoid of any kind of obnoxious/harmful matter in human body. Now it's widely defined as per the WHO as mentioned before, Health is multidimensional <sup>[2]</sup>. The WHO definition talks about mainly five specific dimensions: the physical, the mental and the social, emotional, spiritual and many others like: philosophical dimension socio-economic dimension - environmental dimension etc. Master Samuel Hahnemann had mentioned similar words (with regard to the spiritual dimension) in the definition of vital force in his organon of medicine.

Now let me mention about Rene Descartes (1596-1650A.D) who stated that mind and body are two distinctly separable entity in health. He also stated that mind is non-physical therefore distinct from material body and formulated the concept of the mind-body dualism also known as cartesian dualism. This dualism theory gained popularity in 17<sup>th</sup> century and influenced many scientist and philosophers [3] but in nineteenth century—the pendulum swung to particularism at opposite pole to holistic vision at earlier times.

The Santiago theory of cognition is the first scientific theory <sup>[5]</sup> that overcomes the Cartesian division of mind and matter, and will thus have the most far-reaching implications. Mind and matter no longer appear to belong to two separate categories, but can be seen as representing two complementary aspects of the phenomenon of life – process and structure. At all levels of life, beginning with the simplest cell, mind and matter, process and structure, are inseparably connected. For the first time, we have a scientific theory that unifies mind, matter, and life.

#### **Evolution of Concept of Disease** [2]:

There were many theories like supernatural theory, theory of contagion. In the year 1873, Louis Pasteur <sup>(8)</sup>\_advanced the new theory the "germ theory of disease" but the doctrine of one-to-one relationship between cause and disease has been shown to be untenable, even for microbial diseases, e.g., tuberculosis, leprosy.

Modern concept of disease occurrence: According to the theory of this model disease occurs due to complex interaction between agent host and environment.

The germ theory of disease gave place to a newer

concept of disease - "multifactorial causation" that is not a single or some factors but the whole of the offending agents. In fact, it was Pettenkofer of Munich who first advocated the concept of multifactorial causation of disease.

Web of Causation: This model of disease causation was suggested by MacMahon and Pugh. This model is ideally suited in the study of chronic disease, where the outcome of interaction of multiple factors.

Modern physics can show the other sciences that scientific thinking does not necessarily have to be reductionist or mechanistic that holistic and ecological view are also scientifically sound. There is already a considerable pressure on the physicians to go beyond the narrow mechanistic view of contemporary medicine and develop, a broader holistic approach to health. [6]

Homeostasis, as currently defined, is a self-regulating process by which biological systems maintain stability while adjusting to changing external conditions.

Claude Bernard was the first to develop the concept of "a fixité du milieu intérieur," that is, organisms maintain a stable internal environment despite changing external conditions. Bodily mechanisms that work in a co-ordinate fashion to make body's internal environment constant and unchangeable despite changing external environment. It's nothing but a holistic idea.

# Application of holistic approach in different medical fields to establish a cure:

- Ayurvedic system of medicine: According
  to this system of medicine a person is said
  to be healthy when there is perfect balance
  and harmony between those three humours
  namely vata, pitta, kapha and disease occurs
  when there is imbalance between these
  humors and when this balance is restored
  cure takes place.
- Yogic science: As per B.K.S IYENGAR<sup>[7]</sup> Yogic science does not demarcate where the body ends and the mind begins, but approaches both as a single, integrated entity".
- Chinese medicine: it is considered to be world's first organized body of medical science

which dates back to 2700 BC. According to this system human body is composed of yang and yin and in health there is a dynamic equilibrium in between the two when this dynamic equilibrium is lost disease occurs and cure takes place upon restoration of this equilibrium.

- Greek medicine: The Greeks used to believe that matter made up of four elements: earth, air, fire, water and were represented in the body by four humours namely phlegm, yellow bile, blood and black bile and when this balance is disturbed disease is the result.
- Medicine in middle ages [2]: According to this theory human body is composed of four humours namely sanguine (damawl), phlegmatic (balgami), choleric (safrawl), melancholic (sawdawl). As per theory of Hippocrates, any disturbances in their equilibrium can cause disease, so restoration of health only occurs upon restoration of their normal equilibrium.

#### **Holistic Homoeopathy**

We know that Master Hahnemann was a contemporary of Robert Koch, French bacteriologist Louis Pasteur etc. when revolutionary discoveries were being made in the field of medicine.

Soul of medicine was again revived in an explosive manner.

Germ theory, theory of contagion, doctrine of signature advocated by Paracelsus was adopted mainly by different system of therapeutics for example: allopathy, antipathy, isopathy.

According to these theories any disease is caused by ingestion or inoculation of germs or presence of any offending agent in body such as excess of blood, pus etc which they imagined as the cause of disease but in reality they are the end product the product of the disease and nothing else.

Master Hahnemann has criticised this concept again and again. In Introduction *para 17* regarding old school's futile attempts to find out the cause of the disease as the morbid products of the disease process— he says that the cause of our diseases cannot be material because the least foreign medical substance, however small it appear to us,

if introduced into our blood vessels, is promptly ejected by the vital force. Dr Kent has said "well then who is this sick man"? [9] The tissues could not become sick unless something prior to them had been deranged and so make them sick. The real sick man is prior to the sick body. That which is carried away is primary and that which is left behind is ultimate.

Here are few examples of the holistic involvement of the bodily organs in the pathology of a disease:

- As per a recent review article it is has been shown that there is a connection between brain and skin<sup>[10]</sup>, This review paper focuses on the skin as a neuroendocrine organ and summarizes what is known about the skin immune system, the brain–skin connection and the role played by the serotonergic system in skin.
- Chronic stress also has a relationship to cancer development [11] chronic stress on account of reasons like adversity, depression, anxiety, or loneliness/social isolation can endanger human health. Recent studies have shown that chronic stress can induce tumorigenesis and promote cancer development.
- Personalized medicine, also referred to as Individualized Medicine, is a new concept, simply means the prescription of specific treatments and therapeutics best suited for an individual taking into consideration both genetic and environmental factors that influence response to therapy.
- Different genetic mutations may play a role in determining how a patient will respond to the commonly used TB medication isoniazid [12]. The standard drug dose currently administered to patients, regardless of their genetic, bio-physical, environmental status, may not be appropriate for certain people. Individualization of isoniazid therapy may help to prevent the adverse drug reactions.
- According to a French surgeon and biologist also noble laureate 'Alexis' carrel': there are diseases of the heart, stomach, and nervous system; but in illness the body preserves the same unity as in health, it is sick as a whole [13].
- Somatoform disorders is said to be a originated



or aggravated by some psychological[14] All such risk Factors[15] like divorce of parents, death of parents, experience of violence and sexual abuse represent psychological factors, which make the patient susceptible to developing a somatoform disorder.

# Epigenetics in context of holistic aspect of a disease process: [16]

Epigenetics is the study of heritable phenotypic changes that do not involve DNA sequences, unlike genetic changes, epigenetic changes are reversible and do not change our DNA sequence, but they can change how our body reads a DNA sequence. Modern science has recognized the relation between lifestyle factors, food habits, and environmental factors in making a person either prone or directly causing the disease, which our master Samuel Hahnemann realised and instructed us to enquire about the same to obtain the holistic view of the case brought before us.

#### CONCLUSION

From the above discussion it is evident that modern medicine is also exploring the necessity of looking at the health or disease of any individual from a holistic perspective, moreover they are also trying to tailor the medications to be administered for them to be modified according to their genetic, bio-physical, environmental, characteristics. So homoeopathy with its holistic approach is equally relevant as it were 200 years ago.

#### **ACKNOWLEDGEMENTS**

We as a homoeopath must feel proud because what our mentor master Hahnemann had said is being revived by the researchers of the present era, we express our cordial gratitude to our master Hahnemann for blessing us with this magnificent system of therapeutics.

Conflicts of interest: None

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# Homoeopathic Organopathic Drugs: An Asset for the Prevention of Cardiovascular Diseases

Dr. Ashok Yadav, Dr. Virendra Chauhan, Dr. Bhavneet Kaur

#### **ABSTRACT**

The burden of cardiovascular diseases are increasing at great pace. There are several risk factors which are responsible for the rise and progress of these diseases such as obesity, tobacco consumption and sedentary lifestyle. Prevention is the only key to combat this situation. This article highlights the role of homoeopathic organopathic drugs in prevention of cardiovascular diseases with special emphasis to their physiological action and clinical findings.

**Keywords**: cardiovascular diseases, homoeopathy, homoeopathic medicines, organopathic drugs, prevention

**Abbreviation:** cardiovascular diseases, homoeopathy, homoeopathic medicines, organopathic drugs, prevention

#### INTRODUCTION

Cardiovascular diseases are the major cause of death in the adults in the western world and with the rise in the incidence of such cases, it will soon become the leading cause of death in all the continents.[1] In India, CVD is the ,most common non communicable disease and in 2017, it was responsible for 26.6% of total deaths and 13.6% of total DALYs [2] There are several risk factors for the development of CVD such as smoking, obesity, alcohol, hypercholesterolaemia, diabetes mellitus, physical inactivity and diets deficient in fresh fruits, vegetables and polyunsaturated fatty acids. Thus prevention, early detection and proper management is the need of the hour. [1]

#### What can Homoeopathy offer?

Homoeopathic materia medica contains numerous drugs which act on the cardiovascular system but there are certain drugs which have special affinity for the heart. These organopathic drugs are well proven and clinically verified in cardiovascular disorders. Some of the most commonly indicated organopathic drugs are *Adonis vernalis*, *Crategus*, *Cactus grandiflorus*, *Convallaria majalis*, *Digitalis*, *Kalmia latifolia*, *Latrodectus mactans*, *Ly*-

copus virginicus, Spartium scoparium, Strophanthus hispidus, Terminalia arjuna and Rauwolfia With the help of Homoeopathy, we can prevent the progress of disease and improve the prognosis by managing hypertension, atherosclerosis, angina pectoris, cardiac insufficiency etc. As Homoeopathy is based on the law of 'Similia Similibus Curentur' and there are no specific medicines for a disease, Individualization is a must. In cases of CVD, medicine should be prescribed after thorough study of symptomatology, investigation and physical examination of the patient and similar medicines should be differentiated on the basis of their physiological action and characteristic symptoms.

Some organopathic drugs are described and differentiated below on the basis of different criteria [3.4.5.6.7.8]

# I. On The Basis Of Physiological Action And Clinical Conditions:

 Crategus is said to have a solvent action upon the calcareous and crustaceous deposits in the arteries and thus can be efficiently used in cases of arteriosclerosis. It is also known as heart tonic. It acts on the musculature of the heart where the muscles are flabby and in worn out condition and thus is useful in myocarditis where the compensatory mechanism of the heart fails and the action is irregular. It helps in sustaining the heart in infectious diseases. It aids in insomnia of irritable aortic sufferers by acting as a sedative.

- Adonis vernalis is suited in conditions such as fatty degeneration of heart, rheumatic endocarditis, myocarditis and cardiac dropsy with low vitality and weak, rapid and irregular pulse. It acts by regulating the pulse and increasing the contractile power of the heart and urinary secretions.
- Cactus acts best in the cases of incompetence of heart due to arteriosclerosis. There is inflammation of the endocardium with mitral insufficiency and left ventricular hypertrophy.
- Convallaria majalis should be prescribed when the ventricles are overdistended and there is absence of compensatory hypertrophy with extremely rapid and irregular pulse. It is also of use in cases of tobacco heart disease, especially because of cigarettes. It increases the energy action of the heart and makes it more regular.
- *Digitalis:* It is of great use in clinical conditions such as heart failure with auricular flutter and fibrillation subsequent to rheumatic disease, pericarditis with copious serous exudation, cardiac dropsy, mitral diseases and heart block. In the condition where there is weakness and dilatation of myocardium and asystole is present, *digitalis* stimulates the musculature of heart and increases the length and force of systole.
- Kalmia latifolia is a remedy for rheumatic and gouty metastasis of heart and tobacco heart.
- Latrodectus mactans is of great use in cases of angina pectoris.
- *Lycopus virginicus* increases the length of systole to a greater extent and lowers the rate of heart and blood pressure.
- Spartium scoparium: It is indicated in cases when primarily the musculature of heart, especially the nervous apparatus is affected producing myocardial degeneration. It is used homoeopathically in cases of hypotension and

its action of lowering systolic and diastolic blood pressure was well proven in provers as in physiological doses, it depresses the heart by acting on myocardium and stimulates the vagus and thus produces lowered blood pressure and bradycardia. It helps in eliminating action of kidneys and reduces the distress on the heart and thus can be of great use in cardiac dropsy.

- Strophanthus hispidus: It is useful in cases of arteriosclerosis, mitral regurgitation, cardiac dropsy etc. as this medicine has great anti diuretic properties and it restores the tonicity of heart muscles and valves.
- Rauwolfia serpentina is used in cases of hypertension without marked atheromatous changes in vessels.
- Terminalia arjuna is used in organic and functional diseases of heart, hypertension and angina pectoris.

# II. Characteristic findings during general and systemic examination:

- Cactus: pulse is weak, feeble, quick and irregular and blood pressure is low. Endocardial murmurs are heard and precordial dullness is increased. Hands and feet are icy cold and oedematous.
- Crategus: pulse is irregular, intermittent and accelerated. Valvular murmurs are heard and first heart sound is weak. There is marked chilliness and blueness of fingers and toes which is aggravated by exertion or excitement.
- *Digitalis:* pulse is slow, thready in recumbent position and irregular and dicrotic on sitting up and intermits on every 3<sup>rd</sup>, 5<sup>th</sup> and 7<sup>th</sup> beat, cardiac impulse is undulating, irregular and intermittent. A murmur is heard indicating involvement of aortic or mitral valve. Central cyanosis is present, jugular veins are distended and the face is dusky and livid.
- Kalmia latifolia: Pulse weak and slow and tough to perceive and is about 35 to 45 beats per minute. Face is pale and extremities are cold
- *Lycopus:* cyanosis and precordial tenderness is present, pulse is weak, rapid, irregular and intermittent

# III. Prescription on the basis of keynote subjective symptoms:

- Cactus: feeling of constrictions as if the whole body is caged and each wire is being twisted tighter. Aggravation lying on the left side, walking and the approach of menses, 11a.m., 11p.m..
- *Convallaria majalis*: There is sensation as if heart stopped beating and then starting suddenly
- Crategus: The patient experiences extreme dyspnea on least exertion and pain in the region of heart and under the left clavicle. Patient feels better in fresh air , being quiet and rest and the complaints are aggravated in warm room
- *Digitalis:* The patient experiences frequent stitching pain in chest and violent palpitation on least movement with sensation as if heart would cease beating if he moves. The patient is unable to lie down in bed and is obliged to sit in chair or head drawn backwards or leaning forward on some support.
- *Kalmia latifolia*: Tachycardia with visible rapid heart action and pain which takes away the breath.
- Latrodectus mactans: constriction of chest muscles causing violent precordial pain extending to axilla, arm and forearm to fingers along with numbness.
- *Lycopus virginicus:* The patient experiences precordial pain with sensation of constriction. Haemoptysis is seen due to valvular heart disease.

#### Past researches in homoeopathy:

• A prospective, double-blind, randomized, placebo-controlled, parallel-arm clinical trial was conducted at the Outpatient Clinic of the Mahesh Bhattacharyya Homoeopathy Medical College and Hospital, West Bengal to evaluate whether individualized homoeopathy can produce any significant effect different from placebo in essential hypertension by comparing the lowering of blood pressure between groups. Out of 150 enrolled patients, 132 patients were followed regularly and outcome was assessment after three months

- and six months. After six months, mean Systolic Blood Pressure (SBP) reduction was 26.6 mm Hg in the homoeopathy group and Systolic Blood Pressure increased by 3.6 mm Hg in the placebo group. Mean Diastolic Blood Pressure in the homoeopathy group reduced by 11.8 mm Hg and increased by 1.6 mm Hg in the placebo group. Most frequently prescribed medicines were Natrum muriaticum, Calcarea carbonica, Sulphur, Thuja occidentalis, Nitric acid and Medorrhinum [9]
- A study was conducted for exploring the role of homoeopathy in managing the cases of dyslipidemia. Search of the Four preclinical studies, three observational studies and two case records were included in the study.

Results of preclinical studies are as follows:

- 1. In a study conducted on fifteen monkeys, it was found that Cholesterinum 3x-trituration lowered the increased VLDL-cholesterol levels to an extent of 32% within 48 hrs.
- 2. Another study conducted on rats showed that mother tincture of Syzygium jambolanum has a protective effect on diabetic induced carbohydrate and lipid metabolic disorders in STZ-induced diabetic animal.
- 3. Study conducted on 48 rats showed that Fucus vesiculosus prevented the rats from becoming obese and the biochemical and physical parameters were maintained to normal levels.
- 4. In another study conducted on 54 chickens, concentration of various serum lipids was experimentally increased. Baryta carbonicum and Baryta muriaticum resulted in reduction of serum Total cholesterol , phospholipid, Triglycerides , total lipids, and total Cholesterol/phospholipid ratio.

#### Results of clinical studies:

1. A study was conducted to evaluate efficacy of homoeopathic medicines in lipoproteinemia. Out of 293 cases, 77 cases (26%) have shown marked improvement, 113 cases (39%) moderate improvement, 100 cases (34%) mild improvement, and 3 cases (01%) were having no improvement. It was observed that the medicines were effective in relieving their clinicopathological findings and their associated complaints and for restoring the

- general health of patients
- 2. Another study was conducted to evaluate the Role of Homoeopathy in hypercholesterolemia. Sample size was 57. Values of serum cholesterol were reduced below 250 mg% in all patients. Follow ups were maintained for 2 years with investigations at 6 months interval and normal levels were maintained throughout the study period.
- 3. A study was conducted on Treatment of arteriosclerosis cases with sample size of twelve patients. Twice-daily doses of *Baryta carbonica* 6X or 30C for 6 months were found to be effective.

Results of case reports are as follows:

- 1. A case paper included three cases of atherosclerosis and has recommended remedies such as Lolium temulentum, Plumbum iodatum, Allium sativum, Antimonium arsenicum, Aurum iodatum, Baryta carbonica, and Capsella bursapastoris
- 2. Another record of two cases published in which *Cholesterinum* 3X and 6C was prescribed for hyperlipidemia and positive results were found. [10]

#### **DISCUSSION & CONCLUSION**

Cardiovascular diseases can be efficiently managed and prevented by managing hypertension, dyslipidaemia, atherosclerosis and cardiac myopathy and on the basis of past researches, homoeopathic medicines are proven to effective in these cases.<sup>[9,10]</sup> In this article, few organopathic drugs are discussed but there are many other homoeopathic medicines such as spigelia, aconitum napellus, viscus album, tabaccum, naja tripudians, veratrum viride, iberis etc. which has special affinity for heart. It is mentioned in aphorism 4 of organon of medicine, physician is known as preserver of health if he knows the things that derange health and how to remove them from persons in health.[11] We should focus on the aetiology of the cardiovascular disease and the lifestyle of the patient and select appropriate similimum and advice the needed lifestyle modification and thus contribute towards preventing the major cause of deaths in our country.

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### Making Homoeopathy an Evidence Based System of Medicine: Importance of Clinical Trials

Dr. Tasneem Hashmi, Dr. Sankha Subhra Sengupta

#### **ABSTRACT**

Homoeopathy has been a centre of controversy for many years. There are many countries like Australia, France, Belgium, Israel etc. who have raised questions on the credibility of homoeopathic practice and dismiss its efficacy on the grounds of lack of scientific evidence. It has been stamped as a pseudoscience and the effects are generally considered to be "placebo effect". Since the advent of the practice of Evidence-based medicine (EBM), the homoeopathic fraternity has been trying to establish homoeopathy as a scientific and effective system of medicine. Consequently, there is an increasing pool of evidence for the scientific and plausible understanding of the mechanisms of homoeopathic medicines. Several clinical trials have been published in indexed journals showing the effectiveness of Homoeopathy, along with systematic reviews and meta-analysis.

**Keywords:** Case reports, clinical trials, effectiveness, efficacy, evidence-based medicine, homoeopathy, individualisation, meta-analysis, observational studies, open-label placebo treatments, pragmatic trials, randomized-controlled trials, systematic reviews.

#### INTRODUCTION

vidence-Based Medicine is an approach of  $oldsymbol{\Gamma}$  practicing medicine with the goal to improve and evaluate patient care. It requires the judicious integration of best research evidence with the patient's values to make decisions about medical care. This approach allows the practitioner to critically assess research data, clinical guidelines, and other information resources in order to correctly identify the clinical problem, apply the most high-quality intervention, and re-evaluate the outcome for future improvement. Thus, the best available science is combined with the healthcare professional's clinical experience and the patient's values to arrive at the best medical decision for the patient<sup>[1]</sup>. Thus, the key to evidence-based medicine are well-designed clinical trials, systematic reviews, and metaanalyses.

Clinical trials, in their purest form, are designed to observe outcomes of human subjects under "experimental" conditions controlled by the scientist. A clinical trial design is often favoured because it permits randomization of the intervention, thereby effectively removing the selection bias that results from the imbalance of unknown/immeasurable confounders. The impact of clinical trials not only extends to the individual patient by establishing a broader selection of effective therapies, but also to society as a whole by enhancing the value of health care provided[2].

Globalization, internet and technological advancements has empowered the public to access a wide range of knowledge and diverse perspectives, contributing to a more informed and critical mindset. There is a growing recognition of the importance of healthier lifestyles especially after the COVID-19 pandemic. At such times, people anticipate receiving high quality medical care and effective treatments backed up by scientific research. Hence, it becomes necessary to establish homoeopathy as an evidence-based medicine.

#### NEED FOR EVIDENCE IN HOMOEOPATHY

It is a common pattern in the history of science that disciplines dealing with new kinds of phenomena have their scientific status questioned in the initial phase of their development. Not only their theoretical concepts, principles and methods are regarded with suspicion by the scientific establishment, but also the very reality of the phenomenon is sometimes not acknowledged. Disputes can last for years or decades until the proponents of the emerging discipline manage to develop the theory and its experimental basis beyond the threshold of what, at the time, is considered to be scientific. If they fail, the discipline is labelled non-scientific and ceases to be of any concern to the scientific community. Homoeopathy constitutes a particularly interesting example of this sort of dispute. Critics of homeopathy often claim that it is non-scientific.

Two much disputed meta-analyses on homoeopathy have been published in The Lancet one of Linde et. al. [3] and others of Shang et. al. [4]. Shang's meta-analysis concluded that clinical effects of homoeopathy are merely placebo effects. It found that homoeopathic medicines were no better than dummy pills. The one by Linde painted homoeopathy slightly more positively for homoeopathy than recent published evidence implies. This started a worldwide debate and raised serious questions on the authenticity of the meta-analyses done in favour of homoeopathy. Another systematic review was published in the British journal of clinical pharmacology in which sixteen systematic reviews were analysed which collectively failed to provide strong evidence in favour of homoeopathy. It concluded that the best clinical evidence for homoeopathy available to date does not warrant positive recommendations for its use in clinical practice<sup>[5]</sup>.

Inspite of such findings Homoeopathy remains a popular choice of treatment worldwide, with more and more people choosing it for holistic and individualised treatment. The recent surveys suggest many people integrate, use and value Homoeopathy as a complementary treatment option. It is estimated that there are more than 200 million users of Homoeopathy worldwide<sup>[6]</sup>. With growing popularity of Homoeopathy comes the necessity to build upon the scientific evidence. By offering adequate tools for the analysis of the foundations, structure and implications of scientific theories, philosophy of science can help to clarify the medi-

cal controversy surrounding homoeopathy.

#### CLINICAL TRIALS, RCTs, SYSTEMATIC RE-VIEWS AND META ANALYSIS

Although numerous study designs can address these goals, clinical trials (and specifically randomized controlled trials [RCTs] remain the benchmark for comparing disease interventions. At present there are more than 200 RCTs in homoeopathy<sup>[7]</sup>.

A recent review article published in Wiley Health and Social Care in which PubMed/Medline, Embase, Google Scholar, and Cochrane Library were systematically searched for systematic reviews and meta-analyses on homoeopathy efficacy, and 61 studies were included. Same databases plus Journal of Interdisciplinary Placebo Studies (JIPS) were also systematically searched for randomised controlled trials (RCTs) on Open Label Placebo (OLP) treatments, and 10 studies were included. The review was checked for bias using various tools. The study concluded that the efficacy of homoeopathy as a whole can be considered at least comparable to placebo. Sixteen reviews concluded that homoeopathy is more effective than placebo. Nine of them were rated as high quality while five appeared to be of fair quality. However, the authors encountered heterogeneity in terms of search strategy, inclusion criteria, and methods of data synthesis which hampered the result presented. In three out of six studies including only trials about individualised homoeopathy, it was suggested that this approach has a significant effect over placebo. The authors suggested that the rituality of individualisation (history taking, active listening, observation, physical examination) adopted by the practitioner to choose the appropriate individualised homoeopathic remedy depending on the disease and the specific characteristics of the patient produce effects that go beyond the traditional placebo effect as studied in blinded RCTs, namely the sole administration of an inert drug with little or no interaction with physicians and limited exposure to contextual factors [8].

Another systematic review was conducted which included 32 eligible RCTs and studied 24 different medical conditions in total but this also turned out to be inconclusive. There was a small, statistically

significant, treatment effect of individualised homeopathic treatment that was robust to sensitivity analysis based on 'reliable evidence'. The overall quality of the evidence was low or unclear, preventing decisive conclusions.

There are many more systematic reviews and meta-analyses in homoeopathy all of which could not establish any significant or clear evidence in support of the effectiveness of the same. One of the reasons being that RCTs in homoeopathy have their limitations, including inadequate sample sizes and poor recording/reporting. Another significant reason is that homoeopathy is essentially an individualised therapy, where treatment is based primarily on the individual's characteristics of the disease, the physician is, therefore, a strong confounding element that is virtually impossible to eliminate. Hence, it takes considerable effort to ensure a minimal level of standardisation in the training of the clinician-researcher<sup>[10]</sup>.

#### ROAD AHEAD IN HOMOEOPATHY

Dr. Hahnemann in his Organon of Medicine (aphorism 28), says that "...it matters little what may be the scientific explanation of how it takes place; and I do not attach much importance to the attempts made to explain it...". He was of the opinion that scientific explanations of the material phenomenon can be given effect; but, it is difficult to give explanations to dynamic phenomenon like nature's law. Still (in aphorism 29), he tried to give a satisfactory explanation to the modus operandi of homoeopathic cure<sup>[11]</sup>. But the lack of scientific evidence became one of the reasons why people found it difficult to accept it. However, in recent times, initiatives have been taken by imminent homoeopaths to back up the modus operandi of homoeopathic medicines with science. Studies have revealed that homoeopathic remedies contain nanoparticles of source materials; [12] they act by modulating biological function of the allostatic stress response network<sup>[13]</sup> and by stimulating hormetic adaptive systems rather than by linear pharmacological effects[14-16]. Several research organisations worldwide are also focusing on building the evidence base for Homoeopathy citing studies which state that electromagnetic signals can be transduced in highly diluted aqueous solutions originally containing some bacterial or viral DNA<sup>[17]</sup>.

The WHO Traditional Medicine Strategy 2014– 2023 document endorses the clinical education and research in complementary and alternative medicine (CAM) including Homoeopathy to ensure safety, efficacy and quality of traditional medicines. Further, keeping in view the resolution on traditional medicine adopted by the World Health Assembly in 2003, and the outcomes of the WHO Global Survey of Traditional Medicine (2005), the WHO aims to provide technical support to the Member States in the development of an appropriate framework for research, with guidelines and methodologies for research and evaluation, to ensure the quality, safety and efficacy of traditional medicine in order to facilitate the integration of traditional medicine into the broad health sectors[18].

#### CONCLUSION

Despite the growing popularity and evidence, Homoeopathy continues to face criticism for its plausibility, safety, efficacy, etc. The reasons for this could be many; the current research evidence may not be sufficient with reluctance of many practitioners to engage in evidence-based practices, lack of appropriate training to conduct highquality research, inadequate or poor funding for researches, etc. Multiple barriers exist for the conduct and application of research in CAM. Further, 'bias' is found to be an important barrier, as innate negative perceptions about CAM, specifically Homoeopathy, are there. Another significant barrier was found to be complexities of CAM including Homoeopathy. The individualistic nature, homoeopathic principles and philosophy, nature of treatment, etc., are not completely reflected in the conventional research framework, thus it is difficult to capture the true effect of Homoeopathy<sup>[19]</sup>.

To offer patients the most effective and safest therapies possible, it is important to understand the key concepts involved in performing clinical trials. Well-designed and executed clinical trials can contribute significantly to the national effort to improve the effectiveness and efficiency of homoeopathic interventions in the world.

Sound observational studies and pragmatic trials need to be encouraged. The data generated from these studies must be showcased as they bring out

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the benefits accruing to the patients after homoeopathic treatment. All homoeopathic educational institutions must encourage their faculty and students to publish observational studies. This will ensure a good amount of evidence-based data. Case reports need to be presented as per the HOM CASE (Homoeopathic Clinical Case Reports) guidelines and with appropriate scales of assessment along with homoeopathic remedy response evaluation of the follow-ups<sup>[10]</sup>. A set of guidelines specific to reporting of Homoeopathy trials (Reporting data on homoeopathic treatments: a supplement to Consolidated Standards of Reporting Trials) must be unvaryingly followed to address the issue of disparities in reporting<sup>[19]</sup>.

The need of the hour is to sensitise homoeopathic students and practitioners who are doing good clinical work toward publishing their cases in sufficient numbers to create an impact. These are vital links in creating an evidence base that will foster research values in our profession.

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## Vanquish PCOS with Homoeopathy

Dr. Prastuti Jaiswal, Dr. Sristi Chakraborty, Dr. Shayantan Kumar Das

#### **ABSTRACT**

Polycystic ovarian syndrome (Stein-Leventhal Syndrome), is a widespread disorder that encompasses many associated health conditions and has an impact on various metabolic processes. PCOS is depicted by hyperandrogenism, polycystic ovary and anovulation. This article brings forth rare drugs, biochemic, nosodes, bowel nosodes and sarcodes. Considering the adverse effects of conventional medication and the substantial percentage of patients who do not react to such measures, there exists a need for alternative treatment that alleviates PCOS symptoms without causing side effects.

#### INTRODUCTION

In Polycystic Ovarian Syndrome (PCOS), the ovaries release excessive levels of androgens, the male sex hormones that are typically present in women in trace amounts. Numerous tiny fluid-filled cysts that develop in the ovaries during reproductive age are known as polycystic ovarian syndrome. The prevalence rate ranges from 6% (National Institute of Health Consensus 1990) to 20% (Rotterdam 2003).

Aetiology<sup>2</sup>

- 1. Unknown
- 2. It is believed that hyper-thecosis is androgen producing.
- 3. It is suggested that there is enzyme defect perhaps of autosomal dominant perhaps of genetic origin in the thecal cells as a result there is block in the biosynthesis of the androgen to oestrogen. Malfunction of hypothalamic and pituitary axis and adrenal cortex is also suspected.
- 4. Insulin resistance beta cell dysfunction.
- 5. Life style disorder, body mass index, obesity, lack of exercise, poor diet/ high calorie diet, smoking -active and passive and stress increased levels of cortisol and prolactin.
- 6. Hereditary
- 7. Antiepileptic drug such as Valproate drug
- 8. Bisphenol A (BPA) is a commonly used industrial compound in plastic products, used for packaging can be a probable cause of PCOS

Pathophysiology<sup>2,3</sup>:

The pathogenesis of PCOS has been linked to altered Luteinizing hormone(LH) action, Insulin resistance(IR) and predisposition to hyperandrogenism. One theory maintains that underlying IR exacerbates hyperandrogenism by suppressing synthesis of Sex Hormone Binding Globulin (SHBG) and increasing adrenal and ovarian synthesis of androgens, thereby increasing androgen levels.

IR with hyperinsulinaemia to overcome IR the body secretes more insulin thus causing hyperinsulinemic state, leading to Type-2 Diabetes Mellitus (T2DM). Increase circulating level of testosterone are noted with PCOS in women because high level of insulin decreases circulating SHBG this leads to free testosterone and these are worsening signs of hyperandrogenism.

There is anovulation. Ovarian morphology shows thickened cortex forming thick ovarian capsule, multiple follicular cysts lined with hyperplastic theca interna cells but without corpus luteum.

Clinical features<sup>2</sup>:

Oligomenorrhoea/amenorrhoea, obesity, acne,

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hirsutism, acanthosis nigricans, male pattern alopecia – frontal and temporal balding, deeping of voice, decreased breast size, increased muscle mass, infertility / 1<sup>st</sup> trimester abortion, libido, virilization leading to clitomegally.

#### Investigations2:

- 1. Ultrasound:
  - Presence of 12 or more cyst of 2-9 mm in subscapular region
  - Ovarian volume equal to or more than 12cm
  - Bright echogenic stroma
- 2. Bio chemical test
  - Fasting insulin level normal <30 mU/I
  - Fasting blood sugar normal 90mg/dl
  - Dehydroepiandosterone sulphate(DHEAS) normal <350mg/dl</li>
  - LH raised
  - Follicle stimulating hormone(FSH) normal 2-8IU/L
  - Decreased SHBG normal 16-119nmol/L
  - Serum prolactin increased
  - Thyroid stimulating hormone(TSH)
  - Lipid profile

#### Management<sup>2</sup>:

- To manage troubling signs and symptoms e.g.: hirsutism, acne, menstrual irregularity, obesity.
- Prevent long term health problem
- Managing weight
- Diet low glycaemic index, limiting simple carbohydrates, complex carbohydrates and foods high in Polyunsaturated fatty acid(PUFA), higher intake of protein and fibre.
- Exercise- moderate physical exercise 30 60 minutes daily like walking, jogging, etc.
- Reducing hyper insulinemia.
- Treating anovulation and regulating cycle.
- Prevention of endometrial hyperplasia.
- Antonizing androgens to treat hirsutism and acne.
- Offering psychosocial support.

**Homoeopathic approach**<sup>4,5,6,7,8,9,10,11,12,13</sup> – According to Homoeopathic principles there is no specific medicine for any disease or symptoms. It is solely based on individuality of the patient and symptoms similarity.

According to their predominant action, following medicines are classified as:

- Obesity-Calcarea carbonica, Thyroidinum,
- Acne Kali bromatum, Pulsatilla, ovininum, Calcarea silicata
- Irregular menses- Thyroidinum, Pinus lambartina, Senecio aureus, Gossypium, Oleum jecoris aselli, Aurum muriaticum natonatrum, Sycotic compound, Ferrum iodatum, Sabina officinalis, Apis mellifica, Aristolochia clemastis, Pulsatilla.
- Dysmenorrhoea Magnesia Phosphorica, Colocynthis, Pallid
- ium metallicum, Senecio aureus, Sabal serrulata, Sabina officinalis, Apis mellifica, Colocynthis
- Leucorrhoea Pallidium metallicum, Senecio aureus, Ferrum iodatum
- 1. Apis mellifica Amenorrhoea of puberty, ovaries numb, congested with suppressed menses, ovarian cyst. Burning, stinging, sharp, cutting pain in right ovary, swollen <during menstruation. Dysmenorrhoea with scanty discharge of slimy blood or with ovarian pain mainly from suppressed menses with congestion of head <coition. Right ovary enlarged the ovaries >lying on right side.
- 2. Aristolochia clemastis Menses lighter, shorter, darker and no pain. Profuse vaginal discharge before menses. Leucorrhoea transparent and slippery. Shooting pain in the vagina going upward short and sharp.
- 3. Aurum muriaticum natronatum Profuse, premature menses atonic amenorrhoea, scanty delaying menses, palpitation of young girls. Ovaries indurated, enlarged and dropsical. Leucorrhoea with spasmodic contraction of vagina.
- Calcarea carbonica Menses too early, too profuse, too long in young girls with vertigo, toothache and cold damp feet. Mental excitement brings on dysmenorrhoea or

- causes return of menses. Menses late in fat flabby girls with palpitation, dyspnoea and headache. Suppressed menses after working in water. Thick, milky, gushing, yellow leucorrhoea <during urination with itching and burning. Leucorrhoea before the catamenia <after exercise. Breast tender and swollen.
- 5. Calcarea silicata Acne rosacea, comedones, pimples; scurfy eruptions on face pain <cold >warmth. Eruption of the face, cheeks, chin, forehead, lips, on nose and around the mouth. Leucorrhoea excoriating, bloody, copious before and after menses, milky, white or purulent and yellow or yellowish-green. Menstrual flow acrid, bright red, copious, too soon, protracted or scanty, painful and irregular. Flow of blood between the menstrual period with backache.
- 6. Colocynthis Clutching pain as if squeezed in left ovarian region better by doubling with restlessness. Dysmenorrhoea <eating and drinking. Ovarian cyst with pain >flexing thigh on pelvis. Suppression of menses from indigestion or chagrin, menses copious in women with sedentary habits.
- 7. Ferrum iodatum Menses absent with exophthalmic goitre. Amenorrhoea, menses scanty preceded by pain in right breast followed by profuse leucorrhoea like boiled starch, stringy <during bowel before, during and after menses. During menses pain in sacrum as if broken lumbar region with stiffness <rising from bed, at night dull pain in dorsal region each side of spine extending through chest.
- 8. Gossypium Stinging intermittent pain in both ovaries, at the same time drawing towards uterus. Powerful emmenagogue. Tardy menses, sensation that the flow is about to start and yet does not do so. Amenorrhoea; menses late scanty, watery and painful or painless lasts 24hours and then become very sparse and painful too watery 19days late.
- 9. *Kali bromatum* Cystic tumours of ovaries, menorrhagia with sexual desire. Acne simplex indurated, rosacea bluish red on face, chest, shoulders leave slightly scars in young fleshy people of gross habit.

- 10. Magnesia phosphorica Menstrual colic >by flow, warmth, doubling up <right side, membranous dysmenorrhoea. Menses too early, dark stringy, tardy flowing at night leaving a fast stain. Great weakness during menses along with intensely sore bruised feeling all through abdomen could hardly be up at all time but <lying down.
- 11. *Ovininum/oophorinum* Ovarian cyst; menses frequent, too early, too late. Prurigo >after menses. Acne rosacea.
- 12. Oleum jecoris aselli Establish menstrual flow and restoring it when in ambience, amenorrhoea, acts as emmenagogue. Soreness of both ovary, dysmenorrhoea, leucorrhoea yellow with weak back, anaemia, abnormal growth of hair.
- 13. Palladium metallicum Right sided ovarian cyst and backpain <jar, after menses from excitement; >rubbing, pressure, bending leg, lying on left. Apprehension that something horrible will happen. Menses appeared later, at full moon instead of new moon, and accompanied by headache. Leucorrhoea transparent like jelly worse before and after menses, yellow leucorrhoea turned white and thicker and then disappear. Menorrhagia. Bearing down sensation in pelvis.
- 14. *Pinus lambartina* Amenorrhoea, suppressed menses restores the flow and removes painful sensation resulting from suppression
- 15. Pulsatilla nigricans Amenorrhoea from wet feet nervous debility or anaemia feels like menstruating. Menses dark, thick, too late, scanty after bathing, clotted changeable intermittent, irregular, vicarious, delayed at puberty. Dysmenorrhoea- more the pain more the chill. Pain in uterus with amenorrhoea first menses delayed, flows more during day while walking. Painful menses with great restlessness tossing in every possible direction. Leucorrhoea milky thick like cream with pain in the back and exhaustion acrid. Acne during menses. Headache before during after menses > when flow gets normal. Prior to menstruation in young girls especially things get black before eyes like a gauge or a veil. Diarrhoea before and after menses.
- 16. Sabal serrulata Ovaries tender enlarged, pain

- down the right thigh. Dysmenorrhoea <after going to bed. Sharp pain in right ovary, coming and going between 2 to 7PM. Awakened by stinging pain running up from left ovary into abdomen. Obesity. Menses delay 4–9days.
- 17. Sabina officinalis Menses too profuse, too early, gushing of hot bright watery blood mixed with dark clots <least motion often >by walking with pain in joints. Bleeding between periods with sexual excitement. Leucorrhoea foul acrid, thick, yellow from suppressed menses with itching of pudenda. Dysmenorrhoea pain from sacrum to pubes >lying flat on back, with limbs extended, labour like pain. Metrorrhagia <at night.
- 18. Senecio aureus Functional amenorrhoea in young girls with backache. Anaemic dysmenorrhoea with urinary disturbance. Aching in both ovarian regions. Menses two days early, very scanty, less pain than usual, followed by excessive thirst. Menstrual flow suppressed sometimes many months, begins to look pale has a dry hacking cough with bleeding from the lungs instead of menstrual flow, a vicarious spitting of blood. Menses every 3<sup>rd</sup> week, very profuse, lasting 8/9 days, accompanied by severe cutting pains in region of sacrum, hypogastrium, and groins. Chlorosis in scrofulous girls, with dropsy. Thin leucorrhoea streaked with blood, and dull pelvic pains. Leucorrhoea instead of menses, suppressed menses from cold.
- 19. Sycotic compound Pain in the left ovary at menstrual period, dysmenorrhoea. Ovarian cyst. Menorrhagia, metrorrhagia, amenorrhoea upto 6months, leucorrhoea yellowish white, dark brown, offensive and corrosive, profuse and bland pruritis vulvae.
- 20. Thyroidinum Excessive tendency to obesity. Menses profuse, prolonged, more frequent, early; amenorrhoea, menorrhagia, metrorrhagia. Constant left ovarian pain. Insanity with menstrual disorder in young girls. Deficiency of milk is associated with return of menses.

#### DISCUSSION AND CONCLUSION

This work is enriched with therapeutics of PCOS where medicines are described according to their

predominant action. In addition to a recent paper on PCOS mentioning on constitutional medicines for menstrual irregularity, this study focuses on rare medicines that practitioners and academicians overlook in everyday practice.<sup>14</sup>

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# Homoeopathic Drug Proving on Sick: First Step Towards a Model

Dr Manpreet Kaur, Dr S M Singh, Dr Pankaj Aggarwal, Dr Vandana Gambhir, Dr Chaturbhuja Nayak

Then, these symptoms were re-arranged as per the schema of the *Boger Boenninghausen's Characteristics and Repertory* <sup>18</sup> in the 'Proforma for clinical verification of the symptoms'. This arrangement of symptoms was followed since it is similar to the arrangement of symptoms in *Chronic Diseases* of Hahnemann. Thereafter, the presence or absence of each symptom obtained in the study was compared and verified in either one or more of the source books (as mentioned above) containing proving symptoms of *Pulsatilla nigricans* on healthy provers. The presence of each symptom was indicated by denoting against it the symptom

number given in the source book with which it was verified. The absence of any symptom was denoted by mentioning 'Not found' against it. For indicating the presence of any symptom in *Materia Medica Pura* and *Allen's Encyclopedia*, the standard numbering as given in these source books was mentioned. But, for indicating the presence of any symptom given in *Hering's Guiding Symptoms*, symptom codes were manually given (by the author) to all the symptoms of *Pulsatilla nigricans* in *Hering's Guiding Symptoms*; and for representing the presence of any symptom in this source, these symptom codes were used. This data is elaborated in TABLE 5.

Table 5: Proforma for Clinical Verification of The Symptoms

Chapter Number	Chapter name	Symptoms	Verification from sources with Number of symptom			
			Materia Medica Pura	Hering's Guiding symptoms	Allen's Encyclopaedia	
		1. Irritable (1)	1128	30	35	
		0. Anger (1)	1130	32	37, 38	
		O. Attacks of suffocative feeling at night accompanied with great anxiety, restlessness and palpitation (1)	Not found	Not found	Not found	
1.	MIND (8)	0. Weepiness of mood (4)	1129, 1135	22	28	
		0. Depression of mood (1)	1137	15	30	
		0. Anxiety that someone may demand something from her; wants to help others but too much helping others brings her a fear of ruining herself (1)	1113	Not found	Not found	
		0. Concentration difficult (1)	Not found	Not found	Not found	
		0. Anxiety with palpitation in afternoon (1)	1108	Not found	21	

Chapter Chapter Number name		umber name Symptoms		Verification from sources with Number of symptom			
2.	SENSORIUM (0)		No symptoms found				
2	` '	0.	Vertigo (1)	1	58	61	
3.	VERTIGO (2)	0.	Vertigo, <standing (1)<="" td=""><td>16</td><td>Not found</td><td>Not found</td></standing>	16	Not found	Not found	
	HEAD (5)	0.	Headache, <morning (1)<="" td=""><td>59</td><td>Not found</td><td>153</td></morning>	59	Not found	153	
	TIEAD (3)	0.	Itching over scalp (1)	142	131	165	
4.	INTERNAL	0.	Headache (4) (2,2)	47	65	120	
		0.	Heaviness in head (1)	29	63	86	
	EXTERNAL	0.	Boils over the back of head (1)	911	Not found	1132	
	EYES (3)	0.	Eye: haziness, unclear vision;	95			
			watery; black spot before eyes;		145, 196	209	
	Eyebrows		stitching in eyes (1)				
	Ouleito	0.	Darkness before eyes (1)	98	150	221	
5.	Orbits						
3.	Eyelids						
	Lychas		7. 7	100	100	100	
	Canthi	0.	Itching in eyes (1)	130	198	180	
	Vision						
6.	EARS (0)		No symptoms found				
0.	Hearing		No symptoms round				
	Ticaring	0.	Obstruction of nose (2)	585, 590	276	270, 271	
		0		Not	272 272	Not found	
		0.	Sneezing, coryza with cough (1)	found Not	272, 273	Not found	
	NOSE (7)	0.	Running nose, watery eyes,		273	Not found	
		0.	<pre><morning (1)="" nose,="" pre="" running="" sneezing="" with<=""></morning></pre>	found			
7.	Smell		watering of eyes at change of	Not	273, 274	Not found	
			weather (1)	found			
	Coryza	0.	Cold, coryza with sneezing,	593, 597	273, 274	264, 265	
		0.	running nose (1) Sneezing (1)	593	272	256	
	_					-	
		0.	Running nose (1) Small, papular, pimple-like red	596	273	263	
		0.	eruptions on face/Red coloured,	Not		1122	
			pimple-like eruptions on the	found	Not found		
			face (2)				
	FACE (7)	0.	Sudden clenching of jaws (1)	Not	Not found	Not found	
	FACE (7)	0.	Brown discoloration over the	found Not			
	Lips	0.	cheeks (2)		Not found	Not found	
		0.	Burning sensation in blackish	found Not	Not found	Not found	
8.	Lower jaw _		spots on the cheeks (1)	found	1101104114	1131134114	
	and Maxillary	0.	Eruptions over the cheeks with	Not	NIat Car 1	Nat C- 1	
	joints		pus; painful on touch; leaving reddish scars (1)	found	Not found	Not found	
	Chin	Ω					
	Cimi	0.	Acne bilaterally symmetrical, blood and pus, mixed leaving	Not	Not found	Not found	
			marks behind- bluish (1)	found	INOLIGITIA	Notiouna	
		0.	Blackish discoloration over the	Not			
		0.	face (1)	found	Not found	Not found	
	TEETH (0)		1400 (1)	Tourid			
9.			No symptoms found				
	Gums						

Chapter Number	Chapter name	Symptoms		Verification	Verification from sources with Number of symptom		
		0.	Recurrent blisters in mouth with intense pain, sensitiveness; <warmth,>cold with sour taste in mouth (1)</warmth,>	Not found	Not found	Not found	
	MOUTH (8) Palate	0.	Frequent blisters in mouth with increased salivation (1)	Not found	Not found	Not found	
		0.	Tongue: white coated (2)	223	331	349	
10.	Throat (and	0.	Blister over the tongue (1)	225	325	318	
	gullet)	0.	Burning in throat (1)	Not found	350	Not found	
	Saliva	0.	Dryness in throat (2)	246	Not found	393	
	Tongue	0.	Finds mucus accumulated in the throat in the morning on waking up (2)	252	Not found	392	
		0.	Rawness in throat (1)	242	345	411	
		0.	Decreased appetite with no desire to eat (1)	Not found	Not found	Not found	
11.	APPETITE (5)	0.	Changeability in eating desires: sometimes feels like eating salty things, and sometimes sweet things (1)	Not found	Not found	Not found	
		0.	Decreased appetite (5) (1,4)	311	362	434	
		0.	Increased appetite (1)	318	361	432	
		0.	No desire to eat though hun-	319, 310	361	428, 431	
	THIRST (3)	0.	gry, likes cold food (1)  Decreased thirst (5)	312	364	452	
12.		0.	Increased thirst (3)	Not	363	446	
12.		0.	Dryness of throat, has to get up at night to have water (1)	found 244	Not found	394	
13.	TASTE (0)		No symptoms found				
14.	ERUCTA- TION (1)	0.	Eructations of gas (1)	Not found	372	462	
15.	WATER- 0. BRASH AND HEART- BURN (1)		Acidity and gas formation in abdomen; burning sensation felt in chest due to acid reflux from the stomach (1)	Not found	375	Not found	
16.	HICCOUGH (0)		No symptoms found				
17.	(0) NAUSEA AND VOM- ITING (1) STOMACH	0.	Feeling of nausea after eating food (1)	Not found	377	484	
18.	STOMÁCH (0)		No symptoms found				
19.	EPIGASTRI- UM (0)		No symptoms found				
20.	HYPO- CHONDRIA (0)		No symptoms found				

## Special Section -

Chapter Chapter Number name		Symptoms		Verification from sources with Number of symptom		
		0.	Pain in lower abdomen due to exercise (1)	Not found	Not found	Not found
		0.	Acidity after eating oily or spicy food (1)	Not found	391	Not found
		0.	Pain in abdomen on lying down (1)	Not found	Not found	563
21.	ABDOMEN (7)	0.	Gas formation with bloating of abdomen, <eating (1)<="" td=""><td>418</td><td>424</td><td>543</td></eating>	418	424	543
		0.	Pain and heaviness in abdomen after eating meal (1)	413	430	561
		0.	Gas formation because of fried food leading to headache and vomiting (1)	81	98	Not found
		0.	Pain and heaviness in abdomen and chest after eating food (1)	Not found	Not found	588
22.	EXTERNAL ABDOMEN (1)	0.	Boil over lower abdomen (1)	911	Not found	1132
23.	INGUINAL AND PUBIC REGION (0)		No symptoms found			
	Mons pubis					
24.	FLATU- LENCE (0)	No exemptome tour				
		0.	Obstinate constipation (2)	442	471	650
25.	STOOL (3)	0.	Pain in abdomen during and after stool (1)	433	459, 460	554
		0.	Constipation: difficulty in passing the stool, has to stain a lot (1)	444	469	651
26.	ANUS AND RECTUM (0)		No symptoms found			
27.	PERINEUM (0)		No symptoms found			
28.	PROSTATE GLAND (0)		No symptoms found			
29.	URINE (0)		No symptoms found			
	URINARY ORGANS (3)	0.	Pain due to ureteric stone (1)	Not found	Not found	Not found
	Kidneys	0.	Frequent desire to urinate (1)	489	486	671
30.	Ureters					
50.	Bladder	0.	Burning during urination (1)	520	514	678
	Urethra					
	Meatus					

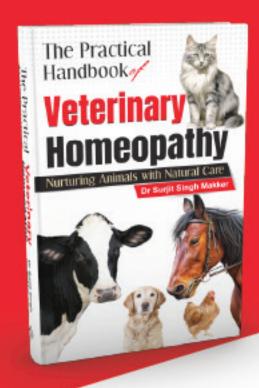
Chapter Number	Chapter name	Symptoms	Verification from sources with Number of symptom			
31.	GENITALIA (0)  MALE OR- GANS  Penis  Glans  Prepuce  Spermatic cord  Testes  Scrotum	No symptoms found		of symptom		
32.	FEMALE ORGANS SEXUAL IM- PULSE (0)	No symptoms found				
	CLOL (V)	0. Profuse menstrual flow (1)	583	552	730	
		0. Menses occurring at shorter duration- every 20 days (1)	581	568	731	
	MENSTRUA-	0. Menses: offensive, black (1)	570	552, 562, 568	725	
		0. Pain in lower abdomen during menses (3)	568	571	583	
		<ol> <li>Pain in lower abdomen during menses; agg. standing, after flow begins; amel. rest (1)</li> </ol>	Not found	Not found	Not found	
		0. Irregular menses (1)	Not found	Not found	Not found	
33.	TION (14)	0. Backache during menses, >dur- ing flow (1)	Not found	571	Not found	
	Leucorrhoea	0. Paĭn in lumbar region of back	Not	571	Not found	
		during menses (1)  0. Absence of menses (3)	found 574, 582	544	732, 734	
		0. Menstrual flow increased, pain-	583	562	730	
	-	less heavy bleeding (1) 0. Craving for fresh air before	Not	Not found	Not found	
	-	menses (1) 0. Pain and heaviness of breasts	found Not	Not found	Not found	
		during menses (1) 0. Profuse leucorrhoea with	found Not	11001001101		
		pain in lumbar region of back; <stooping (1)<="" td=""><td>found</td><td>576</td><td>Not found</td></stooping>	found	576	Not found	
		0. White discharge per vagina (1)	565	576	720	
		Difficulty in breathing with suffocative feeling in throat and	Not found	645	Not found	
34.	RESPIRA- TION (3)	restlessness (1)  0. Difficulty in breathing (1)	Not	645	776	
		Difficulty in breathing (with bronchitis) (1)	found 648	647	773	



## The Practical Handbook



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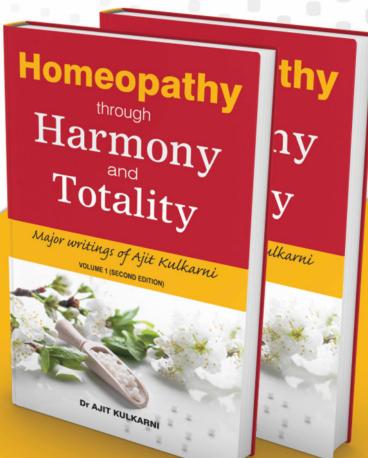
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Chapter Chapter name			Symptoms	Verification	Verification from sources with Number of symptom			
35.	COUGH (1) Expectoration	0.	Cough (1)	602	657	741		
36.	LARYNX AND TRA- CHEA (0)		No symptoms found					
37.	VOICE AND SPEECH (0)		No symptoms found					
	NECK AND	0.	Cervical pain and stiffness, < after waking up in morning, >afternoon (1)	688	717	837		
38.	EXTERNAL THROAT (4)	0.	Pain in neck with vertigo (1)	Not found	Not found	Not found		
	Nape	0.	Pain in neck (1)	688	717	837		
	-	0.	Pain in the left side of neck (1)	Not found	716	835		
	CHEST (3)  INNER  EXTERNAL		Swelling around the nipple over the left side of chest, with tenderness in lateral lower part on the left side, pricking pain, <touch (1)<="" td=""><td>Not found</td><td>Not found</td><td>Not found</td></touch>	Not found	Not found	Not found		
39.	Axillae	0.	Palpitation felt in the chest (1)	1103	705	825		
	Mammae Nipples Heart and region of	0.	Pain in ribs (1)	666	Not found	788		
	BACK (7)	0.	Severe backache (whole back); feels as if the back would break down; > lying down (1)	704	Not found	847, 848		
	Scapular region	0.	Small, papular, pimple-like red eruptions on back (1)	686	1214	1122		
	Back proper- Dorsal region	0.	Sudden stiffness in lumbosacral joint, as of a cramp; >rubbing (1)	Not found	Not found	Not found		
40.	region- Small of back in general Sacrum and	0.	Pain in waist: shifts places in the waist; stretching and pricking; <walking, bending<br="">forward, lifting heavy weight, &gt;lying down (1)</walking,>	717	726	865		
	Coccyx	0.	Backache (1)	702	721	842		
	Spinal column and	0.	Pain in left flank (1)	724	728	872		
	vertebrae	0.	White spot on the skin of back (1)	Not found	Not found	Not found		

Chapter Chapter Number name			ymptoms	Verification from sources with Number of symptom		
			d stiffness in joints of	Not	750	Not found
		0. Pain in i	of hands (2) (1, 1) right shoulder joint (1)	found 733	Not found	Not found
		0. Tingling	g in hands (1)	779	Not found	Not found
			iates from shoulders to	Not	Not found	Not found
		hands (1		found Not		
	UPPER EX-	0. Pain in s	shoulders (1)	found Not	736	909
41.	TREMITIES (8)	0. Pain in l	nands (1)	Not found	Not found	Not found
	(0)	0. Small er	uptions in palm, in	Tourid		
			ı fingers and back of			
			nds, reddish in colour,	777	Not found	1129
			letergent, >scratching,			
		daytime		011	NI-1 C I	1122
			er the shoulders (1)	911 820	Not found Not found	1132 1040
		0. Cramps	eet (3) in calves of legs (more	845	Not found	1040
		in left le	g) (1)			
		0. Pain in l		814	Not found	998
			egs, right leg more	Not found	Not found	Not found
			than the left leg (1) eling in legs (1)	828	779	996
		0. Pain and	d stiffness in joints of	Not		
	LOWER EXTREMITIES (21)	knees (1	)	found	Not found	Not found
			knee joints; pricking	Not	Not found	Not found
		pam, <b water (1</b 	ending the joint, >hot	found	Not found	Not found
		0. Tingling	g in feet (1)	831	793	1045
			knees with knocking	801, 809	764, 768	979, 987
		sound (2 0. Pain in	l) left leg, especially in	001,005	701,700	373,307
		calf mi	iscles; unable to walk			
			nd; desire to lie down;			
			mes suddenly and goes	845	1022, 782	1008, 1009
			ly; <walking, summer;<="" td=""><td></td><td>,</td><td>,</td></walking,>		,	,
42.			ss and swelling of calf			
		muscles	(1)	N		
			eft leg; <climbing,< td=""><td>Not</td><td>Not found</td><td>Not found</td></climbing,<>	Not	Not found	Not found
			, summers (1) eft lower limb; diffi-	found Not	Not found	Not found
		•	standing up (1)	found Not		
		0. Itching	over thighs (1)	found Not	Not found	Not found
		0. Numbn	ess of left thigh (1)		Not found	Not found
			tion in left thigh,	found Not	Not found	Not found
		<u><walkin< u=""> 0. Itching a</walkin<></u>	g, standing (1) and eruptions over the	found Not	Not found	Not found
		soles of		found	Not found	Not found
			pain in both the legs (1)	814	Not found	998
		0. Pain rad	liates from hip to ankles	Not	Not found	Not found
		(1)	oft lenga is in t (1)	found Not		
			eft knee joint (1)	found Not	Not found	Not found
			neels, right heel more than the left (1)	Not found	Not found	Not found

Chapter Number	Chapter name	- 5vmbioms		Verification from sources with Number of symptom		
		0.	General weakness (6) (2, 3, 1)	942	883	1084
		0.	Bodyache (3)	Not found	Not found	Not found
		0.	Pain with swelling in joints: elbow, knee, hip bones and on sides of both eyes (1)	Not found	Not found	Not found
43.	SENSATIONS AND COM- PLAINTS IN GENERAL (7)	0.	Pain felt in bones, <motion, cold="" rainy="" weather,="" weather;="" winters,="">pressure of tight bandaging with cloth, &gt;lying down, massaging and wrapping with cloth (1)</motion,>	Not found	Not found	Not found
		0.	Pain in one joint increase while pain in another joint decreases (1)	Not found	817	Not found
		0.	Pain in multiple joints, wandering pains, >lying down (1)	Not found	Not found	Not found
		0.	Sensation as if body weight lost (1)	Not found	Not found	Not found
44.	GLANDS (0)		No symptoms found	Tourid		
45.	BONES (0)		No symptoms found			
		0.	Eruptions over the body (lipoma) (1) Itching over whole body, <rainy< td=""><td>Not found</td><td>Not found</td><td>Not found</td></rainy<>	Not found	Not found	Not found
	SKIN AND EXTERIOR BODY (4)	0.	season (1)	910	1209	1145
46.		0.	Itching over whole body, <change (1)<="" of="" sleep="" td="" warm,="" weather,=""><td>910</td><td>1209</td><td>1145</td></change>	910	1209	1145
		0.	Urticaria with excessive itching over whole body; burning after scratching; cannot cover it, must be in open (1)	912	1212	1116
47.	SLEEP (2)	0.	Sleep decreased (2)	981, 960	909	1201, 1205
<b>T7</b> .	SELET (2)	0.	Unrefreshing sleep (1)	981	913	1200, 1201
48.	DREAMS (0)		No symptoms found			
	FEVER (0)					
	CHILL					
49.	HEAT AND FEVER IN GENERAL		No symptoms found			
	SWEAT					
50.	CONDI- TIONS IN GENERAL (0)		No symptoms found			
	Time					

Chapter Number	Chapter name	Symptoms	Verification from sources with Number of symptom
51.	CONDI- TIONS OF AGGRAVA- TION AND AMELIORA- TION IN GENERAL (0)	No symptoms found	

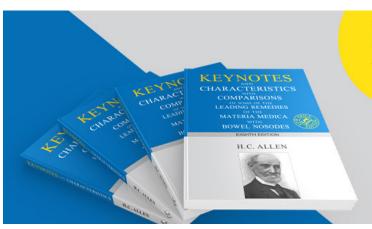
Note: The symptoms written in red are Symptoms observed as appeared/aggravated. The symptoms written in green are Symptoms observed as disappeared/ameliorated. The symptoms written in blue are Symptoms observed as re-appeared (old symptoms). The number within the brackets alongside each symptom indicates the number of patients in whom that symptom was elicited. For the symptoms appearing in more than one category, the number of patients in whom the symptom was elicited is also written in the colour corresponding to each category. The number of symptoms observed under each chapter is written within brackets alongside the chapter name.

Ethical Issues: The cases under study were informed about the treatment plan in detail. Both, 'Informed Consent Form' and 'Patient Information Sheet' were given to the patients. The patients were assured that no harm (physical/mental) would be done to them during the study. Right to withdrawal was included in the 'Patient Information Sheet'. Debriefing was done during every follow-up visit of each patient. Ethical clearance was obtained from the Ethical Committee of

University, before initiation of the study.

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## **Readers' View**

"Homeopathy is a subject that requires many years of learning. This book is by no means is A-Z as far as what one can learn in homeopathy.

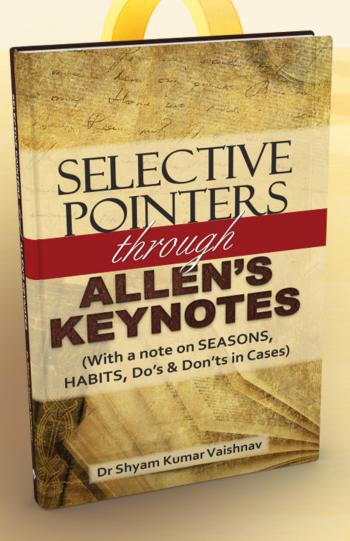


# SELECTIVE POINTERS

# through

# **ALLEN'S KEYNOTES**

with a note on SEASONS, HABITS, Do's & Dont's in Cases



Be to the point by learning " THUMB RULE" of each remedy

Differentiate medicine as per age and gender Sharpen your knowledge of Materia Medica

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## Methodology for Validity and Reliability Testing of a New Questionnaire Used in Medical Research: Course Content for Research Methodology Subject

Dr. Seema Gupta Sahu

#### **ABSTRACT**

It is important for researchers to choose a correct and relevant research tool, to obtain a result that has internal as well as external validity. Validity and reliability, which measure how accurate and consistent is the research tool (primarily questionnaires), have been shown in different studies; but researchers normally overlook them before using a particular primary questionnaire. This has been connected to the lack of understanding of these tests. In medical science, the impact of a chronic disease on health and/or the effects of medical intervention is measured through Health-related quality of life (HRQoL). Here, an attempt is made so that researchers try to choose the right research instrument by reading review articles that look into and discuss the reliability and validity of a research instrument (questionnaires in particular). This article delineates the various types of tests regarding reliability and validity. In a new data tool, a pilot test can be used to assess reliability by gathering data with a sample size ranging from twenty to thirty, excluded from the main study sample. The dataset for the pilot study can be analysed using IBM's Statistical Package for the Social Sciences (SPSS) or any comparable tool.

Keywords: Validity, Reliability, QuestionnaireDesign, Research Methodology

#### INTRODUCTION

survey instrument consists of a series of standard questions meant to collect information.<sup>[1]</sup>There are a variety of questionnaire formats, including social status, clinical information, and activity fields.[2] HRQoL is a multidimensional construct that consists of least three broad domains - physical, psychological, and social functioning - that are affected by one's disease and/or treatment.[3] Questionnaires are a tool for collecting evidence on a particular research topic.<sup>[1,4]</sup> Still, those pieces of evidence are based on the reason for the study, which can be found in the study's problem statement.[1,4] Since quantitative results are numbers that are easy to understand (how satisfied? How often? how many?), a structured questionnaire is often used to do a quantitative study. In health-related social science research, qualitative data collection

approaches are frequently employed.<sup>[5]</sup> When it comes to health-related social science research, questionnaires can be done by mail, post, in person, or over the phone.<sup>[5]</sup>

It could be based on a data tool that has already been tried and tested, or it could be made from scratch to quantify or measure a certain trait. These circumstances necessitate evaluating the validity and reliability of questionnaires.<sup>[1,4,5]</sup>

#### Discussion:

Validity and reliability are terms that are used to talk about how accurate and consistent research tools are. [6] Researchers are constantly worried about whether or not the tool they are using to measure the topic or construct they want to study is valid or whether or not the measurements are accurate. Whether the instruments used to measure the variables produce stable or consistent re-



sults. (are they reliable? do they repeat?)[1]

#### Validity:

Validity refers to the extent to which a measurement measures what it purports to measure. The internal and external validities comprise the two main categories of the validity test.<sup>[2,4,7]</sup> External validity is how well the results of the study sample describe the whole population from which the study sample was taken. In contrast, internal validity is the degree to which a study's results are reliable with the hypothesised characteristics of the target population.<sup>[4]</sup>

The level of systematic or inherent error in a questionnaire is its validity.<sup>[4,5]</sup> The validity of a questionnaire can be determined by an expert panel through an investigation of theoretical components. This type of validity considers how accurately an operational measure conveys the idea underlying a theoretical construct (questionnaire). Translational or representational validity is the term used to describe this. validity mainly are of two forms: face validity and content validity.<sup>[8]</sup>

Face validity entails the expert examining the questionnaire items and agreeing that the test is a valid measure of the subject being measured, based solely on its presentation. [9] This means they are figuring out if each thing they are measuring fits into a specific idea about the term. [10]

Content validity is how well an instrument measures or evaluates the target construct. [9,11,12,13] A content-valid instrument is typically built after a rational examination of the instrument by experts familiar with the construct of interest or professionals on the study issue. [9,12,13] In particular, experts will evaluate the readability, coherence, and thoroughness of each survey questionnaire and form a consensus on which items should be included in the questionnaire survey.[9] The rating could be either "positive" (given a score of "1") or "negative" (given a score of "0"), depending on what the rater thought.[9] However, several ratings have been produced and presented over time. These may be absolute numbers or Likert scale scores.[14,15,16,17] Item rating and scale level rating have been proposed for content validity. [9]

Criterion-related validity is examined while determining the relationship between test scores of a specific criterion. [18,19] It evaluates the comparability of questionnaire results to other questions or predictors. [4,19]

Construct validity is how well an instrument measures the intended attribute or theoretical construct it was made to measure. [4,12,20,21,22,23,24] The comparison is based on a theoretical concept rather than a criterion. [4,10,20,21,22,23,24] It is the most valuable and difficult metric of validity. Essentially, it measures the scale or instrument's practical importance. [4,18] Four types of evidence can be used to illustrate construct validity, relying on the nature of the research problem: convergent validity, discriminant validity, know-group validity, and factorial validity. [6]

#### Reliability:

Reliability is how well the same measurements and procedures can be used to get the same results multiple times.<sup>[2,4,7]</sup> The validity of a questionnaire will always be affected by differences between observers or measurement tools, like a questionnaire, or by the instability of the thing being measured.<sup>[2,7]</sup> Equivalence, stability, and internal consistency (homogeneity) are the three pillars of reliability.<sup>[4]</sup>

The questionnaire's reliability is typically tested with a pilot test. Three main ways could be used to evaluate reliability.

**Test-retest reliability -** is measured by having the same people fill out a survey twice at different times. This shows how consistent the answers are. Generally, it is considered good if the correlation coefficient (r) is more than 0.70.<sup>[25,26]</sup>

Alternate form reliability is the degree of concordance between two or more research instruments, including two different questionnaires based on the same study construct, administered at approximately the same time.<sup>[11]</sup> Equivalency is even more important when multiple people give their subjective ratings or evaluations as part of measures.<sup>[4,11]</sup> In such cases, equivalency may be established by examining inter-observer reliability, i.e., the consistency with which observers or raters form opinions.<sup>[11]</sup>



The method for calculating inter-observer reliability is:

No. of agreements / no. of opportunities for agreement × 100.

Thus, in a state when raters concur 75 times overall out of 90 opportunities (i.e., distinct observations or ratings) results in an 83% agreement, or 75/90 = 0.83 or 83%.

Internal consistency reliability - refers to the degree to which the items on a survey measure the same thing. [4] The split-half reliability index[6] and coefficient alpha index[19,27,28,29,30,31,32,33,34] are used to evaluate internal consistency. On occasion, the Kuder-Richardson formula 20 (KR-20) index was implemented. [11,35] Both alpha and KR-20 indicate the mean of all potential split-half estimations. [11]

**The split-half assessment -** splits the test into two segments (e.g., even or Odd items; initial half or latter half of the items), presenting both forms to the same sample and correlating the results.<sup>[8,11]</sup>

The coefficient alpha-When making scales for questions with different possible answers, like "5" for "strongly agree" and "1" for "strongly disagree,".

**The Kuder-Richardson** formula 20 (KR-20) is a predictor of the reliability of dichotomous variables (i.e., yes/no; true/false) in data scales.<sup>[11]</sup>

The formula for computing KR-20:

$$KR - 20 = n / (n - 1) [1 - Sum (piqi) / Var (X)].$$

Where;

n= Total no. of items

Sum(piqi)= Sum of the product of the probability of alternative responses

Var(X)= Composite variance.

Calculation of coefficient alpha ( a ) by Allen and Yen,  $1979^{[36]}$ 

a=n/(n-1)[1-Sum Var(Yi)/Var(X)]

Where n = No. of items

Sum Var(Yi)= Sum of item variances

Var(X) = Composite variance.

As a general rule, the greater the reliability value, the more reliable the measurement. Nunnally and Bernstein have outlined the standard procedure for doing research which specifies that reliability values of 0.70 or above should be pursued.

#### CONCLUSION

This paper highlighted the significance of questionnaire validity and reliability as crucial research tools in medical science and health research. This article considered both the literary and technical relevance of these measures. To enhance researchers' skills and knowledge of these tests, several forms and techniques of analysing questionnaire reliability and validity were examined.

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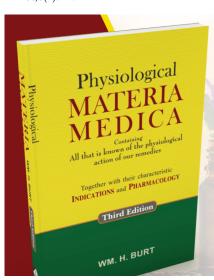


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## PHYSIOLOGICAL MATERIA MEDICA

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  action on various tissues and organs of human body.
- A brief description about the pharmacology and highlights its importance is also given.



## Unveiling the Current Landscape of Clinical Research in Homoeopathy-Where Do We Stand

Dr. Nitin Kumar Saklani, Dr. Bhavya verma

#### **ABSTRACT**

Background: Homoeopathy, an alternative medicine system, has been a subject of debate and controversy in the medical community regarding its efficacy and scientific basis. In recent years, an increasing number of clinical studies have been conducted to evaluate the effectiveness of homeopathic treatments. This article aims to provide a comprehensive overview of the current landscape of clinical research in homeopathy, highlighting the advancements made and the challenges faced. Methods: A scoping literature review was conducted using electronic databases and relevant sources, focusing on clinical trials and systematic reviews published in the concern field. The identified studies were analyzed for their design, methodology, outcomes, and overall quality. Results: The analysis revealed a significant increase in the number of clinical trials conducted on homeopathy during the study period. A wide range of medical conditions were investigated, including but not limited to respiratory disorders, musculoskeletal conditions, mental health disorders, and gastrointestinal disorders. Various study designs were employed, such as randomized controlled trials (RCTs), observational studies, and comparative effectiveness trials. RCTs remained the gold standard for evaluating treatment efficacy, with a growing emphasis on high-quality studies with rigorous methodology. Discussion: Despite the increased volume of research, the quality and methodological rigor of some studies were found to be suboptimal, which limits the overall strength of evidence. Several challenges, such as the use of individualized treatment protocols, placebo effect, blinding, and standardization of homeopathic remedies, were identified and discussed. The lack of consensus regarding appropriate outcome measures and the heterogeneity of homeopathic interventions further complicate the interpretation and generalizability of study findings. Conclusion: The landscape of clinical research in homeopathy has shown promising growth in recent years, with an expanding body of evidence examining its efficacy and safety. However, challenges in study design, methodology, and standardization persist, hindering the establishment of conclusive evidence. Continued efforts to improve the quality of research through welldesigned studies, adherence to rigorous methodologies, and collaboration between researchers, clinicians, and regulatory authorities are essential to enhance our understanding of homeopathy's role in healthcare and enable evidence-based decision-making.

**Keywords:** Clinical Research, Homoeopathy, Systematic review, randomized control trial, efficacy, challenges.

#### INTRODUCTION

#### Background

Homeopathy has long been a subject of controversy, with conflicting viewpoints on its effectiveness. Critics argue that homeopathy is a pseudoscience and that there is no scientific evidence to support its efficacy, citing large-scale studies that found it to be no more effective than a placebo.

The National Health & Medical Research Council (NHMRC) <sup>(1)</sup> of Australia, in a 2015 administrative report, concluded that there was no reliable evidence from research in humans supporting the effectiveness of homeopathy. Consequently, government funding for homeopathy was stopped in Australia, and other developed countries like Germany, the US, UK, Israel, and Russia have also ceased funding it. However, the World Health Organization recognizes homeopathy as the sec-



ond largest medicine stream, with over 600 million people worldwide using it. This conflicting landscape has created confusion and a dilemma regarding the efficacy of homeopathy compared to a placebo.

The statistical evidence was classified into two main schools, the frequentist school and the prognostic school, reflecting the diverse approaches to evidence generation and application in the field of healthcare and research. The frequentist school relies on a well-established hierarchy of evidence, ranging from systematic reviews and randomized controlled trials to case reports, encompassing various research methods and documentation approaches.

On the other hand, the prognostic school highlights recent advancements, particularly in the application of likelihood ratios (LR), to enhance and restructure homeopathy repertories and materia medica. This innovative use of statistical concepts demonstrates the adaptability of statistical methods in various medical domains, even in alternative therapies like homeopathy.

Ultimately, both schools contribute to the broader landscape of evidence-based practice and research, highlighting the importance of flexibility and innovation in the pursuit of meaningful and effective healthcare solutions.

#### Few landmark systematic reviews and metaanalyses:

- Mathie RT, 2014 [3]: This latest meta-analysis concluded that medicines prescribed in individualised homeopathy may have small, specific treatment effects [OR = 1.53; 95% CI 1.22, 1.91]; however, the low or unclear overall quality of the evidence prompts caution in interpreting the findings.
- Shang A, 2005 [4]: This earlier meta-analysis concluded that there was weak evidence for a specific effect of homoeopathic remedies, but strong evidence for specific effects of conventional medicine. Overall, the clinical effects of homoeopathy are placebo effect.
- Cucherat M, 2000 <sup>[5]</sup>: This earlier meta-analysis concluded that there was some evidence that homeopathic treatments are more effective

- than placebo; however, strength of evidence is low because of low methodological quality of trials. Also, studies of high methodological quality were more likely to be negative.
- Linde K, 1997 <sup>[6]</sup>: This earlier meta-analysis concluded that the combined OR for the 89 studies was 2.45 (95% CI 2.05, 2.93) in favour of homoeopathy. The OR for the 26 good-quality studies was 1.66 (1.33, 2.08). The results were not compatible with the hypothesis that the clinical effects of homoeopathy were completely due to placebo.

#### Few landmark RCTs:

- HIV trial by Rastogi DP, 1997 [7]: A randomized double blind placebo controlled clinical trial of individualized homeopathic treatment in HIV infection was conducted by CCRH at RRI(H), Mumbai during 1995-97 on 100 patients with 6-months follow-up. In symptomatic stage III infection (Persistent Generalized Lymphadenopathy; PGL), a statistically significant difference was observed in CD4+T counts between pre and post trial levels in the verum group (P<0.01). In the placebo group, results were non-significant (P=0.91). Change in the pre and post-trial counts of CD4+T cells between groups was also statistically significant (P=0.04). However, results were non-significant in asymptomatic stage II HIV infection. So a possible role of homeopathic treatment in HIV infection in the symptomatic phase was suggested.
- Fibromyalgia trial by Bell IR, 2004 [8]: A double-blind, randomized, parallel-group, placebo-controlled trial of individualized homeopathy was performed with 6 months follow-up on 62 patients suffering from fibromyalgia at a private clinic in Arizona, USA. Individualized homeopathy was significantly better than placebo in lessening tender point count and pain, improving quality of life and global health (all P<0.05), and a trend toward less depression.
- Cerebral palsy trial by Sajedi F, 2008 [9]:
   A double-blind, randomized, parallel-group, placebo-controlled trial of add-on individualized homeopathy to routine

- rehabilitation technique was performed with 4 months follow-up on 24 subjects suffering from spastic cerebral palsy with mild to moderate spasm at Saba clinic in Tehran, Iran in 2004. The modified Ashworth scale showed no statistically significant difference in tonicity of upper and lower limbs, trunk and neck (all P>0.05).
- Migraine trial by Strausheim P, 2000 [10]: A double-blind, randomized, parallel-group, placebo-controlled trial of individualized homeopathy was carried out on 73 patients suffering from migraine with 4 months followup at Arena Medisinske Senter, Norway in 1996-97. Both the homeopathy and placebo groups had reduction in attack frequency, pain intensity and drug consumption, with statistically non-significant difference favouring homeopathy. Migraine diaries showed no difference between groups. The neurologists' trial evaluation showed a statistically significant reduction in attack frequency in the homeopathy group (P=0.04) and non-statistically significant trends in favour of homeopathy for pain intensity and overall evaluation.
- Post-mastectomy trial of Arnica 1000K by Sorrentino L, 2017 [11]: A randomized, doubleblind, placebo-controlled study was carried out using homeopathic Arnica monatana 1000 Korsakovian dilution during 2012-14 on 53 women who underwent unilateral total mastectomy in the "Luigi Sacco" University Hospital, Milan, Italy. Analysis revealed a lower mean volume of blood and serum drainages with A. montana (P = 0.11). Volume collected on the day of surgery showed a statistically significant difference in favor of A. montana (P = 0.03). Volumes collected on the following days were also significantly lower with A. montana at days 2 (P = 0.033) and 3 (P = 0.022).
- Depression non-inferiority trial by Adler UC, 2011 [12]: A prospective, randomized, doubleblind double-dummy, 8-week, single-center trial was conducted on 91 patients with moderate to severe depression comparing individualized homeopathic medicine and Fluoxetine 20 mg/day (up to 40mg/day) using the Montgomery & Åsberg Depression

- Rating Scale (MADRS) depression scores at the outpatient clinic of Homeopathy and Depression of Jundiaí Medical School, São Paulo, Brazil during 2006-08. Mean MADRS scores differences were not significant at the 4th (P = .654) and 8th weeks (P=0.965). There were no significant differences between the percentages of response or remission rates in both groups. A higher percentage of patients treated with Fluoxetine reported troublesome side effects and greater treatment interruption. Thus the study indicates the non-inferiority of individualized homeopathic Q-potencies as compared to Fluoxetine in treatment of moderate to severe depression.
- Cancer trial by Frass M, 2015 [13]: A pragmatic randomized controlled trial was conducted on 410 patients using classical homeopathic adjunctive therapy in addition to standard anti-neoplastic therapy. The study took place at the Medical University Vienna, Department of Medicine I, Clinical Division of Oncology, Austria. The improvement of global health status between visits 1 and 3 was significantly stronger in the homeopathy group (P=0.005) when compared with the control group. A significant group difference was also observed with respect to subjective wellbeing (P<0.001) in favor of the homeopathic as compared with the control group. Control patients showed a significant improvement only in subjective wellbeing between their first and third visits. Results suggest that the global health status and subjective wellbeing of cancer patients improve significantly when adjunct classical homeopathic treatment is administered in addition to conventional therapy.
- MDR-TB trial by Chand KS, 2014 [14]: A randomized, double blind, placebo controlled study was conducted from 2003 to 2008 on 120 patients diagnosed with MDR-TB comparing standard regimen + individualized homeopathic medicine (SR + H) or standard regimen + identical placebo (SR + P) at the Gulabi Bagh Chest Clinic, New Delhi. Statistically significant improvement was noted in the additive homeopathy group in comparison with placebo in CXR findings (P=0.002), weight gain (P=0.071), and ESR reduction (P=0.068). The cure rate was 11.4%



more in SR + H group as compared to placebo group. Change in sputum culture conversion, was not statistically significant. Overall, add-on homeopathy in addition to standard therapy appeared to improve outcome in MDR-TB.

• Capsicum HPT by Shah R, 2014 [15]: In a double blind, randomized placebo-controlled homeopathic pathogenetic trial with 22 volunteers, 15 received a combination of capsaicin and dihydrocapsaicin as a single remedy in 30c potency, while 7 received placebo. The volunteers' symptoms during 5 weeks were carefully noted as per protocol. Qualitatively and quantitatively distinct symptoms were elicited, comparable with effects of the crude substance. Compared to placebo, the homeopathic preparation produced significant symptoms in healthy human volunteers.

#### One model observational trial:

• Psoriasis study by Witt CM, 2009 [16]: In this prospective multicentre observational study, 82 patients suffering from psoriasis were evaluated over 2 years. Diagnoses and complaints severity improved markedly with large effect sizes (Cohen's d 1.02-2.09). QoL improved (SF-36 physical component score d=0.26, mental component score d=0.49), while conventional treatment and health service use were considerably reduced.

#### One model case series:

• Hay fever case series by Pandey V, 2016 [17]: Eight patients suffering from hay fever symptoms were treated with individualized homeopathy over a two-year period at a private clinic at Wimbledon during 2012-13. The average Measure Yourself Medical Outcome Profile (MYMOP) scores for the eyes, nose, activity and wellbeing had improved significantly after 2 wks and 4 wks (P<0.001). Thus, individualized homeopathic treatment was associated with significant alleviation of hay fever symptoms, enabling the reduction in use of conventional treatment.

#### One model case report:

· Scoliosis case report by Khuda-Buksh AR,

2016 [18]: A case of loss of lumbar lordosis with osteophytic lippings, disc desiccation, and protrusion, causing a narrowing of secondary spinal canal and a bilateral neural foramina, leading to vertebral column curvature with acute pain in an adolescent boy of 12 yrs age was treated successfully with different potencies of a single homeopathic drug, Calcarea phos. X-ray and MRI supported recovery and change in the skeletal curvature that was accompanied by removal of pain and other acute symptoms of the ailment.

#### **Documentation researches:**

- Mathie RT, 2006 [19]: The model for proper conduct of documentation research was first developed and put forward in this paper. Fourteen homeopathic physicians in England and Scotland collected clinical and outcomes data over a 6-month period in their practice setting. A specifically designed Excel spreadsheet enabled recording of consecutive appointments under clinical different headings. This study indicated that systematic recording of clinical data in homeopathy is both feasible and capable of informing future research. Similar study was replicated in dental practice setting further substantiating the model.
- Saha S, 2016 [20]: The model developed by Mathie RT, et al for documentation research was implemented to collect data for 3 months from the Obstetrics-Gynecology outpatient setting of The Calcutta Homeopathic Medical College and Hospital, West Bengal, India. This systematic recording catalogued the frequency and success rate of treating O&G conditions using homeopathy.
- Remarkable researches from preventive school:
- Leptospirosis trial by Bracho G, 2010 [21]: A homeoprophylactic formulation (Nosolep®) was prepared from dilutions of four circulating strains of Leptospirosis and administered orally to 2.3 million persons at high risk in an epidemic region in Cuba in 2007. A significant decrease of the disease incidence was observed in the intervention regions. No such modifications were documented in non-intervention regions. Thus the

- homeo-prophylactic approach was associated with a large reduction of disease incidence and control of the epidemic.
- Bryonia-Chikungunya trial by CCRH, 2014 [22]: A cluster- randomised, double-blind, placebo-controlled trial with was conducted Bryonia alba 30C in Kerala for prevention of chikungunya during the epidemic outbreak in August-September 2007 [Bryonia alba 30 C n = 19750; placebo n = 18479] with follow-up duration of 35 days. The findings showed that 2525 out of 19750 persons of Bryonia alba 30 C group suffered from chikungunya, compared to 2919 out of 18479 in placebo group [P=0.03]. The result reflects a 19.76% relative risk reduction by Bryonia alba 30C as compared to placebo.
- Oscillococcinum-Influenza review by Mathie RT, 2015 [23]: In this systematic review, all the published papers until 2014 on randomized, placebo-controlled trials of Oscillococcinum® in the prevention and/or treatment of influenza and influenza-like illness in adults or children were taken into account. Six studies were included: two prophylaxis trials (327 young to middle-aged adults in Russia) and four treatment trials (1196 teenagers and adults in France and Germany). The overall standard of trial reporting was poor and hence many important methodological aspects of the trials had unclear risk of bias. There was no statistically significant difference between the effects of Oscillococcinum® and placebo in the prevention of influenza-like illness (P=0.16); still, findings did not rule out the possibility that Oscillococcinum® could have a clinically useful treatment effect. There was no evidence of clinically important harms due to Oscillococcinum®.
- Dengue prophylaxis study by Marino R, 2008 [24]: A single prophylactic dose of Eupatorium perfoliatum 30cH was given to 40% of residents of São Paulo, Brazil in May 2001. Dengue incidence decreased by 81.5%, a highly significant decrease as compared with neighborhoods that did not receive homeopathic prophylaxis (P<0.0001). Between April and September 2007, a homeopathic complexcomposed of Eupatorium perfoliatum, Phosphorus and Crotalus horridus 30cH,

- was given to 20,000 city residents. This trial was aborted prematurely due to national political intervention. The results suggest that homeopathy may be effective in the prevention of Dengue epidemics.
- Vaccination survey by Eizayaga JE, 2016 [25]: An international online survey was conducted in 2015 with homeopathic doctors by means of an anonymous self-reported questionnaire. A total of 512 responses were obtained, 77.5% of respondents were from Latin American countries, 16.8% from Spain, with small numbers from several other countries. About 75.6% of the respondents considered vaccination safe, effective and necessary, while 12.5% stated they would not recommend vaccination under any circumstance. The variables significantly correlated with positive attitude towards vaccination were: working in the public health system (p = 0.04) and homeopathy not the main medical activity (P=0.005). Homeopaths from Brazil, where homeopathy is officially accredited, were more favorable to vaccination compared respondents from countries where homeopathy has inferior status (P<0.001). The results show that there is no contradiction between homeopathy and vaccination.

#### Prognostic research in homeopathy:

Homeopathic medicines are shortlisted in repertories for a given symptom or condition (rubric), based and graded (typeface) on absolute frequency of occurrence in proving and 'casual' clinical experience. This is a serious shortcoming of repertory, and great threat to its reliability as well [26]. The methodology is fundamentally problematic [27]. Bayesian method can solve this problem [28]. It usually applies to diagnostic research: a diagnostic test is better when it is positive more frequently in people with the disease than in other people. Its mathematical expression is Likelihood Ratio [LR; (a/a+c) / (b/b+d); i.e. sensitivity / 1 – specificity], i.e. the probability of a finding in patients with disease divided by probability of same finding in patients without disease. Higher is the LR, the test is better. Dr. Lex Rutten specializes in applying Bayes' theorem and LR in prognostic research of homeopathy [29] as under:



Diagnos	tic re	search	Prognostic research in homeopathy				
Disease present	Dis	ease absent	Medicine worked	Res	t of the population		
Test +ve	a	b	Symptom +ve	a	b		
Test -ve	С	d	Symptom –ve	С	d		
a+c		b+d	a+c		b+d		
Interpretation: A ter if it is +ve more with the disease the	freq	uently in people	<b>Interpretation:</b> A symptom is better indication for a medicine if found more frequently in 'medicine worked' population than in the rest of the population				

He suggests that grading should depend on LR, i.e. the difference between the medicine worked population and rest of the population. Thus LR provides a theoretical basis for translating experience into knowledge and generates reasonable certainty that the given medicine shall work in the given condition [30]. The choice of a homeopathic medicine is usually not based on one symptom. If symptoms are added, certainty about the curative effect of medicine will grow. So, Bayesian thinking may act as a perfect starting point for sequential update of posterior chance of selection of the most suitable medicine [31]. Overall, LR is a promising tool for accurate and quantitative description of strength of symptom, transparent differentiation among remedies by posterior chance, correction of repertorial misrepresentation, and finally controlling subjectivity in medicine selection. LR or prognostic factor research in homeopathy is getting momentum. Researchers are feeling the necessity to revamp and refine the homeopathic literature to improve the outcomes of controlled trials. Excerpts of the landmark LR researches are given below:

Prognostic research was carried out in 10 private practices in The Netherlands for 3.5 years using the Glasgow Homeopathic Hospital Outcome Scale (GHHOS; -4 to +4) as the outcome measure. Total 4072 prescriptions were analyzed; 6 rubrics were evaluated – diarrhea from anticipation, fear of death, grinding teeth during sleep, herpes lips, sensitivity to injustice, and loquacity. Drugs

- were enlisted; symptom prevalence, LR, and 95% CI were reported.
- Eizayaga JE, 2016 [33]: This retrospective research analyzed 752 records (202 Lyc. cases; 550 non-Lyc. cases) generated during last 21 years of practice. Overall, 22 symptoms were confirmed; 5 probable, 3 possible, and 5 contradictory symptoms were identified and arranged with their LR. Thus, retrospective assessment of prevalence and LR of symptoms in good responders might be a means for better selection of symptoms for prospective studies.
- Wassenhoven MV, 2004 [34]: In this retrospective research, 21,327 prescriptions generated over 16 years were analyzed. LR of Veratrum album symptoms related to mind, generalities, female genitalia, cough, mouth, stomach, perspiration, and sleep were reported. Recommendation was made to upgrade the value of the medicine in some rubrics.
- Koley M, 2016 [35]: This prospective research was conducted in 5 outpatients and 1 private practice in West Bengal for 1.5 years using GHHOS; 2039 and 4715 prescriptions were analyzed for thermal relations and desire/aversion for specific food items. 13 rubrics/symptoms were presented heat sensation of, aggravation heat and cold, heat vital lack of, desires cold and warm food, fish, egg, meat, sour/acids, spicy/pungent things, salt things, sweets, and bitter. Symptoms prevalence in the population with corresponding medicines and LRs was reported.



#### CONCLUSION

The current landscape of clinical research in homeopathy is both promising and challenging. While there has been significant progress in recent years, there is still much work to be done to establish a robust scientific foundation for this alternative system of medicine.

The importance of clinical research in homeopathy cannot be overstated. It holds the key to validating the efficacy of homeopathic treatments and ensuring that they meet the rigorous standards expected of modern medical practices. Well-designed clinical trials can provide valuable insights into the therapeutic potential of homeopathy and help bridge the gap between traditional and evidence-based medicine.

Moreover, clinical research in homeopathy is essential for patient safety. Rigorous testing can identify any potential risks or adverse effects associated with homeopathic remedies, allowing healthcare providers to make informed decisions about their use in patient care.

Furthermore, as healthcare systems around the world strive to integrate complementary and alternative medicine into mainstream practice, robust clinical research becomes indispensable. It not only provides healthcare professionals with the evidence they need to make informed treatment choices but also fosters trust among patients and the broader medical community.

In a rapidly evolving healthcare landscape, clinical research in homeopathy plays a pivotal role in shaping the future of this field. It is a dynamic process that demands collaboration, innovation, and a commitment to scientific rigor. As we continue to unravel the mysteries of homeopathic medicine, let us remain steadfast in our dedication to conducting high-quality clinical research, for it is through this rigorous pursuit of knowledge that we can truly understand where we stand and chart a course toward a future where homeopathy can contribute meaningfully to healthcare worldwide.

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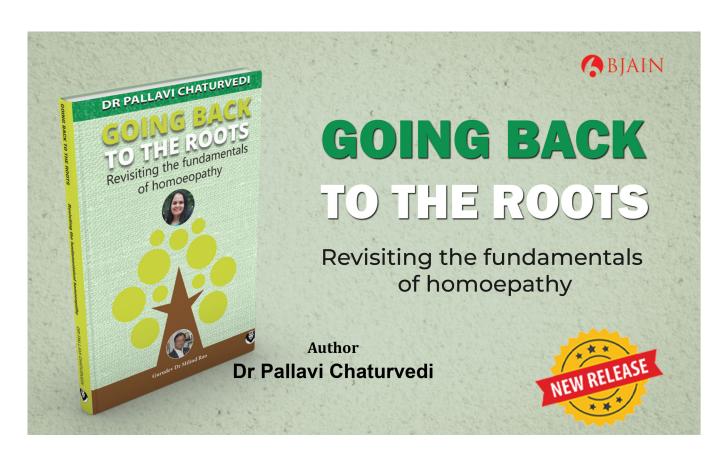


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# The Potency of the Anti-Oxidation Potential of Homeopathic Medicine Azadirachta Indica 6c and 200c in Accordance with the Protocol Given by Dr. Prieto's DPPH Microplate Protocol

Dr. Anand Pal Singh Kushwaha

#### ABSTRACT

The DPPH assay is a typical offline detection method, where the antioxidant activity is measured calorimetrically. The research was intended to Elicit the anti-oxidation effects of Azadirachta Indica 6C and 200C via calorimeter.

#### **AIM**

To Elicit the anti-oxidation effects of Azadirachta Indica 6C and 200C via calorimeter.

#### **OBJECTIVES**

- 1. To analyze the anti-oxidation potential of Azadirachta Indica 6C and 200C.
- 2. To observe the anti-oxidation effects of Azadirachta indica using a calorimeter.
- 3. To analyze Dr Prieto's DPPH Microplate Protocol, for the anti-oxidational property of Azadirachta indica 6C and 200C.

**Keywords:** Azadirachta Indica 6C and 200C, DPPH determination, Carcinogenesis, free radicals, antioxidants, anti-oxidation potential, calorimetrically, photoelectric calorimeter.

#### INTRODUCTION

Ceveral neoplasias can be prevented and treated Jusing Azadirachta Indica supplementation. The key anticancer effects of Neem components on malignant cells include inhibition of cell proliferation, induction of cell death, suppression of cancer angiogenesis, restoration of cellular reduction/oxidation (redox) balance. enhancement of the host immune responses against tumor cells. It has great potential for the prevention of cancer. Ovarian cancer represents about 5% of all women's cancers and breast neoplasia registered 55 new cases per 100,000 women annually. Azadirachta indica extracts sensitize cancer cells to immunotherapy and radiotherapy and enhance the efficacy of certain cancer chemotherapeutic agents.

This study is intended to present the collective

and critical analysis of the anti-oxidation of Azadirachta indica 6C and 200C.

#### **MATERIAL AND METHODS**

#### **STUDY DESIGN:**

DPPH Solution = 1 Particle of DPPH powder + 6ml of Methanol.

Control Solution= 5ml of DPPH solution + 0.005g of Ascorbic Acid.

**STUDY SETTING**: In the Pathology Department laboratory.

#### INVESTIGATIONAL MEDICINAL PROD-UCTS: Dr Prieto's DPPH Microplate Protocol. SELECTION OF MATERIALS:

Homeopathic drugs Azadirachta Indica



6C and 200C were purchased from GMP approved Homoeopathic pharmacy (Dr. Willmar Schwabe Pvt Ltd. Noida).

- DPPH Solution was purchased from Sisco Research Laboratories Private Limited.
- Methanol and Ascorbic acid were procured from CHEMDYES Laboratory.

#### Apparatus:

Multichannel pipette

Flat transparent 96-well plate with lid (may be reused if washed)

Spectrophotometer (plate reader)

High precision balance

Volumetric flask (500ml/50ml)

Beakers,

Photoelectric calorimeter

#### **Reagents:**

DPPH powder

Methanol (buffered or plain, HPLC grade)

Ultrafiltered (0.22  $\mu$ m), bi-distilled water (Mili Q system

#### **METHODS**

#### Dr. Prieto's DPPH Microplate Protocol

500ml of the DPPH is prepared by weighing 39.4mg of DPPH powder on a high precision balance preferably using an Eppendorf microcentrifuge tube, in which 1 ml of MeOH is added, the tube is closed and vortexed until complete dissolution. Spin down the tube in a centrifuge and transfer quantitatively to the 500ml Volumetric flask with the help of a micropipette and rinsing several times with MEOH. The volumetric flask is made up of the meniscus, with MeOH.

- 1. DPPH Solution = 1 Particle of DPPH powder + 6 ml of Methanol.
- 2. Control Solution= 5ml of DPPH solution + 0.005g of Ascorbic Acid.

#### **PROCEDURE**

Clean test tube 90 microliter of DPPH solution + 20 microliter of medicine + 3 ml of distilled water.

This solution is kept in the fridge wrapped in Aluminum foil when not in use, to reduce its degradation (light-induced).

• In the case of control ethanol = 20 microliters of medicines + 3 ml of distilled water.

The absorbance of control and medicine was measured using a photoelectric calorimeter after calibration.

The formula used for DPPH activity by,

The percentage of radical scavenging can be obtained using the formula:

% DPPH scavenging =  $100 \times [(Abs Sampled)-(Abs Sample Blank)]/[(Abs DPPH)-(Abs Solvent)]$ 

Table 1: Absorbance and anti-oxidant action of study and control groups						
	Absorbance	DPPH Radical scavenging action (%)				
Ascorbic acid	0.11					
Ethanol	0.05	0.11-0.05%0.11*100=54%				
Azadirachta indica 6C	0	0.11-0.00%0.11*100=100%				
Azadirachta indica 200C	0.02	0.11-0.02%0.11*100=81.8%				

#### DISCUSSION

Azadirachta indica 200C showed 81.8% antioxidation properties, and Azadirachta indica 6C showed 100% anti-oxidation property, in comparison to ascorbic acid.

The difference between both potency results is



about 18.2%.

#### CONCLUSION

As mentioned in the result 100% anti-oxidation property is present in Azadirachta indica 6C and 81.8% anti-oxidation property is present in Azadirachta indica 200C. An approach applying multiple assays in screening the antioxidant activity of Azadirachta indica 6C and 200C is highly advisable in the treatment of cancer and the data obtained by this improved method still need to be confirmed by an independent method.

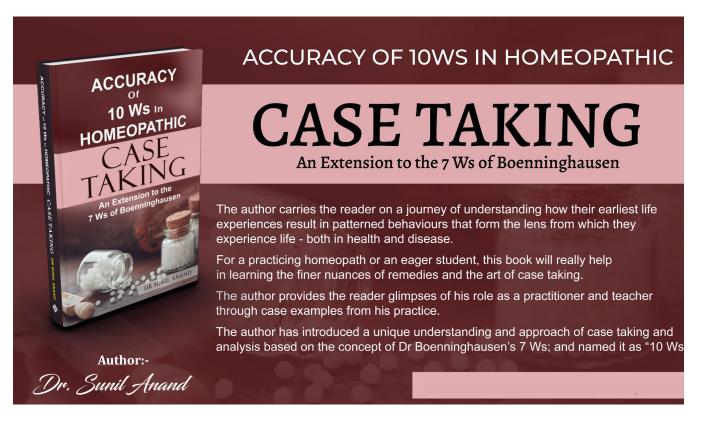
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# De-pigmentation Disorder (Pityriasis Versicolor) Treated with Lachesis - A Case Report

Dr. Smriti Pandey

#### **ABSTRACT**

Hypopigmentation refers to a reduction in the typical color of the skin, hair, mucous membranes, or nails due to a lack, deficiency, or unusual breakdown of the pigment melanin. Pityriasis versicolor, also known as tinea versicolor, is a common and harmless superficial fungal infection of the skin. Clinical manifestations of pityriasis versicolor can include either finely scaled patches with reduced pigmentation or increased pigmentation. The areas most frequently affected are the trunk, neck, and proximal extremities. This loss of pigmentation can be either partial, which may result from skin injury, or complete, as seen in conditions like vitiligo. It may also be temporary, as in the case of tinea versicolor, or permanent, as in albinism.

Keywords: Lachesis, Pityriasis versicolor, Individualised Homoeopathic Medicine

**Abbreviation:** T. versicolor- Tinea versicolor

#### INTRODUCTION

Skin pigmentation disorders encompass conditions that result in the skin either becoming lighter or darker than its usual color. Specifically, depigmentation disorders pertain to conditions that induce the loss of skin pigmentation.

There exist various factors that can lead to hypopigmentation, including:

- 1. Skin injury or damage, such as blistering or burns.
- 2. Inflammatory responses, often following an infection.
- 3. Impairment of melanocytes, the cells responsible for melanin production.
- 4. A reduced level of tyrosine, an amino acid critical for melanin synthesis.
- 5. Improperly conducted cosmetic skin treatments like chemical and laser peels, which may also provoke hypopigmentation.
- 6. Certain chronic or genetic conditions are known to be potential causes of hypopigmentation.<sup>(1)</sup>

#### Pityriasis versicolor

Pityriasis versicolor, also referred to as tinea versicolor, is a common and harmless superficial fungal infection of the skin that falls under the category of Malassezia-related diseases. Clinical characteristics of pityriasis versicolor encompass finely scaled patches with either increased or decreased pigmentation. The areas most commonly affected are the trunk, neck, and nearby extremities. Typically, the diagnosis of pityriasis versicolor is established primarily based on clinical observations.

The culprit behind pityriasis versicolor is Malassezia, a lipophilic fungus with a dimorphic nature, also known as Pityrosporum. This fungus is a natural component of the skin's flora. To date, there have been the identification of 14 different species of Malassezia.<sup>(2)</sup>

#### **Epidemiology**

Pityriasis versicolor is documented across the globe, yet its occurrence is more frequent in regions characterized by warm and humid climates.

Its prevalence can reach as high as 50% in tropical countries but drops to as low as 1.1% in colder regions like Sweden. This skin condition tends to manifest more often in adolescents and young adults, likely due to the heightened production of sebum by sebaceous glands, which creates a lipidrich environment conducive to the growth of Malassezia.

#### Histopathology

A skin biopsy is typically unnecessary to confirm a diagnosis, but if performed, histological observations reveal hyperkeratosis, acanthosis, and a mild superficial infiltrate near blood vessels in the dermis. Fungal elements are primarily located within the outermost layer of the skin, the stratum corneum, and are often visible even in hematoxylin-eosin stained sections. These elements, consisting of both spores and hyphae of Malassezia, are often likened to the appearance of spaghetti and meatballs. The use of a Periodic acid-Schiff stain may enhance the recognition of the fungus.

Individuals with pityriasis versicolor typically present with multiple, well-defined, oval-shaped patches or plaques that exhibit fine scaling. These skin lesions can vary in pigmentation, appearing either lighter or darker than the surrounding skin, and sometimes take on a reddish hue. In some cases, the lesions can merge and cover a larger area. While the fine scaling might not be readily noticeable on the patches, it becomes apparent when the affected skin is stretched or scraped.

The distribution of these affected skin areas reflects the preference of the fungus for lipid-rich regions, often involving seborrheic areas like the trunk, neck, and arms. The face, especially in children, may also be affected. Pityriasis versicolor skin lesions are generally asymptomatic or cause only mild itching. However, in very warm and humid conditions, severe itching can be present. Typically, the diagnosis of pityriasis versicolor is easily made based on its distinctive clinical presentation, characterized by patches or plaques with either increased or decreased pigmentation and fine scaling. The use of an ultraviolet black light (Wood lamp) can be helpful in revealing the characteristic coppery-orange fluorescence of pityriasis versicolor.<sup>(3)</sup>

#### **Albinism**

Albinism is a genetic condition arising from a mutation in one of the genes governing the production of melanin, leading to a decrease in melanin levels and the absence of skin pigmentation.

#### Vitiligo

Vitiligo is a persistent disorder characterized by the emergence of light-colored patches on the skin. While it can manifest on any body area, it typically appears most frequently on areas like the face, particularly around the eyes, the interior of the mouth, and the neck.

#### Pityriasis alba

An individual experiencing pityriasis alba will exhibit slightly raised, inflamed patches on their skin, which may gradually lose their pigment over time. Typically, these lesions tend to resolve themselves within a year. Other factors that can lead to reduced skin pigmentation include:

Lichen sclerosus, Psoriasis, Eczema, Laser skin resurfacing, Laser hair removal. Dermabrasion, Chemical peels.<sup>(4)</sup>

#### CASE REPORT

Mr. XX 13 year old school going male child presented to out patient department with Hypopigmentation on chest, abdomen, back, both upper limbs and lots of dandruff and itching on scalp for two years. Gradually started with complaints of 2-4 single circular hypopigmented areas on head and later on it spread all over back, chest and both upper limbs. White dandruff with dry hair and flakes that keep falling everywhere, small reddish eruptions with intense itching. Itching on hypopigmented areas with redness

**Past history** - malaria at the age of 9 years

**Family history** - father - hypertension, joint pain, mother - sinusitis



**Personal history** - took allopathic treatment for 2 month

#### Physical general

Outlook-lean and slim

Tongue - elongated

Teeth and gums - normal

Thirst - average

Perspiration - all over the body, especially on back

Thermal - hot

Desire - not specific

Aversion - not specific

Stool - normal,

Urine - normal, regular

Dreams - ns

Sleep - sound sleep Appetite - good

#### **MENTAL GENERAL**

A boy came to OPD while narrating his symptoms he was looking very confident and was talking to me without hesitation. His condition was very severe and bad, itching all over his body and

head, still he was smiling and confident. Wanting company and desire for lots of music and masti and did not want to study and do other household work. Sometimes he was caring, sometimes he was frivolous.

#### PROVISIONAL DIAGNOSIS

#### PITYRIASIS VERSICOLOR

#### TOTALITY OF THE SYMPTOMS

- 1. Desire for company
- 2. Confident
- 3. Egotism
- 4. Like to wear shining and bright clothes.
- 5. Smiling face
- 6. Itchy scalp with crawling sensation
- 7. Itching increases after scratching
- 8. Itching at night,
- 9. Itching violent
- 10. Warmth of bed aggravate
- 11. Uncovering Aggravate
- 12. Warmth aggravate

#### ANALYSIS AND EVALUATION

MENTAL SYMPTOMS	EVALUATION
Company desire for	2+
Confident	3+
Egotism - children in	3+
Foppish	3+
Smiling	2+
PHYSICAL SYMPTOMS	
Skin- biting - scratching aggravate, after	3+
Skin- itching night	2+
Skin - itching violent	3+
Skin - itching - warmth - agg	2+

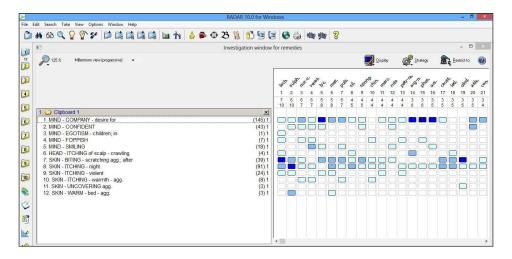
Skin- uncovering aggravate	1+
Skin- Warm - bed - agg.	2+
PARTICULAR SYMPTOM	
Head- Itching of scalp - crawling	2+

#### Symptoms converted into rubrics

Symptoms	Rubrics
Desire for company	Mind - Company desire for
Confident	Mind - confident
Egotism	Mind - Egotism , children in
Like to wear shining and bright clothes.	Mind - Foppish
Smiling face	Mind - Smiling
Itchy scalp with crawling sensation	Head - Itching of scalp - crawling
Itching increases after scratching	Skin - Biting scratching agg, after
Itching at night,	Skin- itching night
Itching violent	Skin itching violent
Warmth of bed aggravate	Skin - itching warmth agg.
Uncovering Aggravate	Skin - uncovering agg
warmth aggravate	Skin - warm bed , agg.

#### **REPERTORISATION**

Repertorisation done from Radar Opus using Synthesis repertory





#### Prescription

After case taking, based on repertorial totality and consultation of homoeopathic materia medica  $^{(5)}$  *LACHESIS MUTA 200C / 2 DOSE / 4 GLOBULES / Bd* was prescribed on date 06/06/2022

## Reasoning Behind Remedy And Choosen Potency

In repertorial analysis Lachesis Muta, Sulphur,

Nux Vomica cover all rubric, but Lachesis muta covered maximum number of symptoms, based on the repertorial totality and consultation of text books of materia medica<sup>(4)</sup>, Lachesis muta seemed to be the most suitable drug in this case and thus prescribed in 200C, two doses. The potency selection and repetition was based on the homoeopathic principles, susceptibility of the individual, and homoeopathic philosophy <sup>(6)</sup>

#### **BEFORE TREATMENT**

#### DATE- 06-06-2022







# AFTER TREATMENT DATE- 02-09-2022











Date of visit	Change of symptoms	Medicine/ dose/ potency	justification
26/06/22	Slight improvement, itching on scalp decreases.	Saccharum lactis 200c/1 dram/ bd/ 4 glb	To wait and allow the medicine to act
15/07/22	Mild improvement, hypopigmentation decreases	Lachesis 200C/one dose/4 globules	Condition remain standstill, same medicine repeated
15/08/22	Overall improvement	Saccharum lactis 200c/1 dram/ bd/ 4 glb	No new complaint
2/09/22	Skin colour getting normal, itching of scalp and body diminished.	Saccharum lactis 200c/1 dram/ bd/ 4 glb	Marked improvement

Table showing Follow up

#### CONCLUSION

Thereafter, the patient has been on placebo, till date, with continuous steady improvement and still under treatment. The improvement of the patient reaffirms the principles of single medicine, minimum dose and infrequent repetition as advocated by Hahnemann. This is a case, which speaks about the success of Homoeopathy in the management of hypopigmentation of skin.

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### **Anaemia Treatment in Homoeopathy**

Dr. Yasir Mirza, Dr Rubina Khanam

#### **ABSTRACT**

Anemia is defined as a condition in which the number of red blood cells (RBCs) and their oxygen-carrying capacity is insufficient to meet the body's physiological needs, which vary by age, sex, altitude, smoking, etc. Anemia is a major public health problem worldwide. Anemia affects an estimated 24.8 percent of the world's population. Anemia also negatively influences the social and economic development in countries with high prevalence of anemia. In general, it is assumed that 50% of the cases of anemia are due to iron deficiency. Iron deficiency anemia (IDA) is considered to be one of the top ten contributors to the global burden of disease. The prevalence of IDA varies among countries but is a major public health problem in the developing world. Iron deficiency is thought to be the most common cause of anemia globally, although other conditions, such as folate, vitamin B12 and vitamin A deficiencies, chronic inflammation, parasitic infections, and inherited disorders can all cause anemia. Homoeopathy is a holistic system of medicine that treats a person as wholehere a case report was a 25 years old female suffering from anaemia, on the basis of the totality of symptoms & individual peculiarity, prescribed homeopathic medicine Acid Phos. 30 & case was cured and quality of life became better.

**Keywords:** Anaemia, Iron, Hemoglobin, Homoeopathy, Acid Phos etc.

#### INTRODUCTION

nemia is a condition in which the number of red blood cells or their oxygen-carrying capacity is insufficient to meet physiological needs. It is a condition when the normal number of RBCs (<4.2 million/µl) or hemoglobin (Hb) level <12 g/ dl) in women and < 13 in men. Globally, anemia is the most common and inflexible nutritional problem affecting around 2 billion of the world's population having major impact on human health and social and economic development; and more than 89% of this burden occurred in developing countries. Accounting half of all cases, iron deficiency anemia is the most common cause of anemia. However, other conditions like nutritional deficiencies, acute and chronic inflammation, parasitic infections, growth spurt, increase in iron requirements, increased iron loss from the body during the menstruation, inherited or acquired disorders of hemoglobin synthesis, RBC production, or survival are also considered cause of anemia.

#### **Symptoms**

The most common symptom of anemia is feeling

of Fatigue and a Lack of Energy.

Other common symptoms may include:

- Shortness of breath
- Chest pain
- Headache
- Light-headedness & Lack of concentration
- Paleness of skin
- Fast or irregular heartbeat

#### Case Report-

Reg. no-8163/2019

Name - Mrs. A. S.

Age – 25 year

Sex - Female

Marital Status - Married

Address- Sri Ganganagar

Socioeconomic status-Poor



#### **Present Complaints**

Breathlessness since 15 days aggravation on exertion

Weakness – does not want to do any work

Headache since 14 days in occiput and vertex region

Palpitation of heart aggravate on exertion

#### **History of Present Complaints**

Patient comeS with a complaint of dyspnea when she do any heavy work, want to lie down always, husband is always beating and scolding her without any reason.

#### Past History of Illness with Treatment

Typhoid before 1 yrs.

#### **Family History**

Father-OA

Mother-DM II

Grand Father-BPH

#### Patient as a Person (Personal History)

#### **General Appearance**

- a) Built Normal
- b) Gait Normal
- c) Speech Normal
- d) Dress Sense Good
- e) Height 5'1"
- f) Weight 40 kg.

#### Diet

- a) Appetite Poor
- b) Thirst Normal
- c) Desires Juicy Thing
- d) Aversion Nothing

#### Discharges

a) Stool - Constipation

- b) Urine 4-5/0-1 D/N
- c) Abnormal Discharges NAD

**Thermal** - Chilly

Sleep -Sleepy but can't sleep

#### **Mental Generals**

Anger easily

Forgetfulness

Irritability

#### Gynecological/Obstetrical History

Menses: LMP-20.08.19

Time - 1-2 days, regular (28-30 days)

Character of blood - Bright red

Character of pain – Only 1st day

Obs. H/O- G1P1A0L1, FTND

#### **Physical Examination:**

Pulse - 68/min

Blood Pressure - 110/80 mm of hg

Anemia – Present

Eyes – Conjunctiva Pale

Tongue -Pale

Skin-Paleness

Cyanosis- Absent

#### **Systemic Examination:**

GIT –Abdomen soft non tender

**URINARY - NAD** 

CNS - Consciousness and Well Oriented

CVS - S1, S2 Heard

Respiratory - Bilateral Lung clear

**Investigation** –CBC, On date 31/08/19 Hb%- 6 mg/dl, MCV-60fl/red cell, MCHC-25gm/dl

#### Final Diagnosis - Iron deficiency Anemia

#### **Reportorial Analysis**

A) Repertorial Totality with Evaluation of Symptoms

#### **Symptoms Analysis**

- 1. Forgetfulness
- 2. Grief ailment from

- 3. Anger
- 4. Weakness
- 5. Desire Juicy Thing
- 6. Headache-Occiput and Vertex
- 7. Breathlessness on exertion/Respiration difficult
- 8. Chilly/General cold aggravation
- 9. Palpitation of heart aggravation on exertion
- 10. Anaemia

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		12 28	11 25	11 22	11 22	11 21	11 17	10 25	10 25	10 23
1. Clipboard 1	×									
1. MIND - FORGETFUL	(154) 1	3	2	2	1	1	1	3	2	1
2. MIND - GRIEF - ailments,from	(32) 1	3	3	2	1	2	-	-	-	1
3. MIND - ANGER irascibility	(137) 1	2	3	2	3	1	1	2	3	3
4. GENERALS - WEAKNESS, enervation - dayt	ime (23)1	1	2	1	1	-	1	1	2	-
5. STOMACH - DESIRES - juicy things	(8) 1	3	-	-	-	1	1	-	-	-
6. HEAD - PAIN, - Occiput	(231) 1	3	1	2	2	2	2	2	2	2
7. HEAD - PAIN, - Vertex	(157) 1	2	1	1	2	1	1	2	3	1
8. RESPIRATION - DIFFICULT	(259) 1	2	2	2	2	3	1	3	3	3
9. GENERALS - COLD - in general agg.	(134) 1	2	2	3	3	2	3	3	2	3
10. CHEST - PALPITATION heart	(203) 1	3	3	2	2	3	3	3	3	3
11. CHEST - PALPITATION heart - exertion	(57) 1	2	3	2	2	2	2	3	2	3
12. GENERALS - ANAEMIA	(89) 1	<								

#### **B. Analysis with Comments**

Out of six highest grading medicines. Acid Phos. is covering all the symptoms including thermal and desire also. So Acid Phos. becomes the ultimate choice of this patient.

#### Final Prescription -

Rx

Acid Phos 30/2 dose

PL 30 /BD 4 pills for 15 days

#### Mode of administration - Oral

Date - 31.08.2019

#### **General Management**

Advice to take medicine regularly. Take balanced diet, Fruits and green vegetables as much as take.



#### Treatment & Follow-Up:

	Date	Complaint	Prescription
1	15/09/19	Breathlessness decreased, weakness decreased, headache better, Patient feels mentally good	Acid Phos 30/ 2 dose PL 30 /BD for 15 days
2	30/09/19	Appetite improved, general condition improved, No breathlessness, Palpitation only on exertion, B. P 120/80 mmhg Hb%- 9.32mg/dl	Acid Phos. 200/ 2 dose PL 30 /BD for 15 days
3	14/10/19	No Palpitation on exertion, No episode of headache, No breathlessness, now they work, no weakness, appetite – good  B.P 120/80 mmhg	PL 30/BD for 15 days
4	30/10/19	Patient feels good, no complaint, Hb %- 12.8mg/dl	PL 30/BD for 15 days

of the complaint in detailed individual factors such as one's personal and family history while planning a treatment. Homeopathy is a holistic system of medicine, it treat person as a whole. It treats at a deeper level of immunity and enhances the healing capacity and proper assimilation of food in the body. This case shows that homeopathy is effective in case of Anemia, if we prescribe the medicine on the basis of totality of symptoms and individualization

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Opp. P.B.M. Hospital, Bikaner M: 7611000101, 9024474466

NAME - MRS. A.S.

DATE - 31-Aug-19

AGE - 25 YRS.

SEX - FEMALE

CONSULTANT - DR. YASHIR MIRZA

#### HAEMATOLOGY REPORT

TEST- NAME	RESULT	NORMAL	UNIT
Haemoglobin	6.0	12 – 18	gm / dl

dui

**TECHNICIAN** 

Dr. P.M. Sareen MD (PATHOLOGIST) RETD. PROF.&HEAD Dr. PUNIT SHARMA M.D., (RADIODIAGNOSIS) RMC No. 22730/9916

This is only Professional Opinion and not the Diagnosis. Kindly Correlate clinically.

This report is not valid of MLC Purpose. Subject to Bikaner Jurisdiction. Ph.: 0151-2242303





Opp. P.B.M. Hospital, Bikaner M: 7611000101, 9024474466

NAME - MRS. A.S

AGE - 25 YRS.

CONSULTANT - DR.YASHIR MIRZA

DATE - 30-Sep-19

SEX - FEMALE

#### **HAEMATOLOGY REPORT**

TEST- NAME	RESULT	NORMAL	UNIT
Haemoglobin	9.32	12 – 18	gm / dl

TECHNICIAN

Dr. P.M. Sareen
MD (PATHOLOGIST)
RETD. PROF.&HEAD

Dr. PUNIT SHARMA M.D., (RADIODIAGNOSIS) RMC No. 22730/9916

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Opp. P.B.M. Hospital, Bikaner M: 7611000101, 9024474466

NAME - MRS. A.S.

DATE - 30-Oct-19

AGE - 25 YRS.

SEX - FEMALE

CONSULTANT - DR.YASHIR MIRZA

#### HAEMATOLOGY REPORT

TEST- NAME	RESULT	NORMAL	UNIT
Haemoglobin	12.8	12 – 18	gm / dl

TECHNICIAN

Dr. P.M. Sareen MD (PATHOLOGIST) RETD. PROF.&HEAD Dr. PUNIT SHARMA M.D., (RADIODIAGNOSIS) RMC No. 22730/9916

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# Efficacy of Constitutional Homoeopathic Treatment in a Case of Dysfunctional Uterine Bleeding

Dr. A. Akshaya Tharankini

#### **ABSTRACT**

Psychosomatic disease refers to conditions that are influenced or exacerbated by psychological and emotional factors. Current awareness underscores the intricate interrelation between mind and body, revealing how emotions, stress, and psychological health can influence physiological processes, potentially fostering disease emergence or advancement. One such psychosomatic disease being dysfunctional uterine bleeding (DUB) caused by emotional disturbances. The condition is diagnosed when abnormal bleeding lacks a clear cause. This prevalent gynaecological condition occurs during a woman's reproductive years and is closely associated with emotional ailments. This article explores the uniqueness of homeopathy in treating psychosomatic diseases, particularly through the lens of a case involving Dysfunctional Uterine Bleeding (DUB) with irregular short menstrual cycles, profuse flow accompanied with lower back pain and cramps. As the cause is of mental plane, constitutional remedy has been administered. Few general symptoms which co-existed have also faded over treatment. The case report highlights how homeopathic remedies, tailored to individual constitutions, manifest unique capabilities in psychosomatic diseases.

**Keywords:** Dysfunctional uterine bleeding, Psychosomatic, *Ignatia amara* 

#### INTRODUCTION

The etymology of the term "psychosomatic" finds its roots in the Greek words "psyche" which means mind and "soma" meaning body [1]. Psychosomatic disease refers to conditions that are influenced or exacerbated by psychological and emotional factors. It is now widely understood that there is a complex interplay between the mind and body, where emotional states, stress, and psychological well-being can impact physiological processes and contribute to the development or progression of various diseases. These conditions often manifest when emotional distress triggers physiological responses, leading to new symptoms or exacerbations of dormant tendencies. This condition may involve dysfunction or structural impairment of bodily organs due to the improper activation of the involuntary nervous system and glands [2].

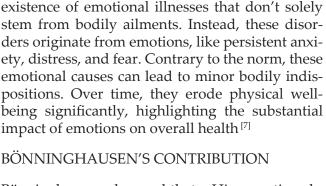
The earliest mention of the term "Psychisch-Somatisch" dates back to 1818 and is attributed to the German psychiatrist Johann Christian August Heinroth in his work "Lehrbuch."



"Psychisch-somatisch" (psychic-somatic) is introduced, showcasing early recognition of mentalphysical interplay. Heinroth's holistic approach links insomnia to both psychic and somatic factors, revealing an evolving understanding of the mind-body connection. The text highlights the complexities of early psychosomatic thought and its influence on medical comprehension of psycho-physical interactions [4]. Intricately woven, the Psyche-Soma interplay orchestrates feedback among nervous, endocrine, immune, and stress systems. Health embodies holistic well-being, not just the absence of illness. Addressing psychosomatic disorders necessitates the amalgamation of insights from diverse fields such as medicine, psychology, sociology, and various other disciplines [5]. In this context, Homoeopathy uniquely integrates mental facets into physical health. Many homeopathic stalwarts like Samuel Hahnemann, Bönninghausen and Kent emphasized the mind's role in illness, marking them as pioneers in the field of psychosomatic diseases. Homoeopathy underscores the inseparable interplay of mental and physical aspects in health and disease, encapsulating a comprehensive perspective of psychosomatic diseases and its treatment [6].

#### HAHNEMANN'S PHILOSOPHY

In Hahnemann's seminal work, "Organon of Medicine," specifically in Aphorism 210, Hahnemann addresses mental diseases. He asserts that these ailments are not a distinct category, as the disposition and mental state are invariably affected in all bodily diseases. For effective homeopathic treatment, understanding the patient's mental condition alongside their symptoms is crucial. Hahnemann underscores the significance of a holistic approach to accurately depict and treat diseases, aligning with the principles of homeopathy



In Aphorism 225, Hahnemann acknowledges the

Bönninghausen observed that a Hippocratic aphorism linked jaundice to emotional upheavals, with cases emerging soon after. Such jaundice responded swiftly to remedies such as Aconitum napellus, Chamomilla matricaria, Nux vomica, closely aligned with symptom patterns. This underscores the swift and effective action of treatments when tailored to individualized combination of physical and mental symptomatology [8]. Bönninghausen also proposed that certain chronic illnesses, including psychosomatic ones, stem from an innate, hereditary predisposition. He delineated distinct miasms—Psora, Sycosis, and Syphilis—each tethered to specific psychological and physical tendencies. This miasmatic framework offers a prism through which psychosomatic disorders can be holistically elucidated, encapsulating both the underlying disposition and the catalyst of emotional factors.

#### KENT'S ILLUMINATION

Kent believed that the mind served as the core of the entire functioning of the organism, and it also acted as the pivotal point from which the process of disease initiation began. Kent's viewpoint was that before delving into the treatment, the mental symptoms had to be thoroughly understood using the conventional approach. This allowed for the identification of remedies that aligned with the patient's mental state. Once this compilation of suitable remedies was established, typically comprising five to ten options or more if needed, the next step involved comparing these remedies with the remaining symptoms of the case. Kent made specific mention of Chamomilla matricaria. He noted that it was effective in addressing sore throats primarily in individuals with irritable constitutions. The mental state characteristic of the drug was the determining factor for deciding

when to administer it for a sore throat [9-11].

#### **RECENT RESEARCH:**

Bagadia et al., 2023, studied Essential Hypertension (EHT) related to the challenges of blood pressure control. The study delved into EHT's psychosomatic and genetic connections and explored homeopathy's holistic approach. With 172 subjects involved, the research showcased significant reductions in both anger and blood pressure variables across both groups. Remarkably, the treatment group exhibited more pronounced reductions, suggesting the potential efficacy of individualized homeopathy as a complementary strategy for managing anger and hypertension simultaneously [12].

Tanveer et al., 2023, examined the societal impact of alcohol by investigating its cultural and economic influence under their research "Efficacy of homeopathic treatment in the wives of alcoholic addict male patients". This research delved into the disruptions within families caused by alcoholism, specifically focusing on wives of alcoholic addicts. The study aimed to evaluate the efficacy of Homoeopathic treatment in addressing emotional well-being. Through a two-part approach involving extensive literature review and practical analysis of data from 101 patients' wives, the research showcased positive outcomes. The study's conclusion highlights the effectiveness of homoeopathic treatment on psychological wellbeing. It emphasizes the substantial role of proper counselling and the careful selection of remedies based on the totality of symptoms in the treatment process [13].

Meenakshi et al., 2023, addressed the substantial health impact of leucorrhoea, particularly in developing nations like India, affecting individuals' quality of life. Non-pathological leucorrhea, characterized by excessive vaginal discharge, itching, and psychosomatic symptoms, was studied retrospectively with 30 cases. Treatment was guided by patient miasms, aiming to alleviate symptoms in young unmarried females. Predominantly affecting the 15-19 age group from urban, middle-economic backgrounds with nuclear families, the study highlighted sycotic miasm prevalence. Pulsatilla nigricans emerged as a common remedy, mainly in 200th potency. Symptomatic improve-

ments were evident, enhancing patients' quality of life [14].

#### DYSFUNCTIONAL UTERINE BLEEDING

#### Definition:

Dysfunctional uterine bleeding (DUB) is diagnosed when no clear cause can be found for the abnormal bleeding. It occurs in both ovulatory and anovulatory cycles. It is a common gynaecological disorder occurring in a woman's reproductive years. It is diagnosed through exclusion and requires a systematic assessment to rule out other causes of abnormal bleeding. Often linked to oestrogen withdrawal during transitional phases like puberty and perimenopause. Treating bleeding aims to stop current bleeding, prevent future occurrences, and avoid complications, usually using medical approaches like pregestational agents. Conventional treatments encompass nonsteroidal anti-inflammatory drugs, oral contraceptives, progestins, danazol, GnRH agonists, and antifibrinolytic drugs. Endometrial ablation and hysterectomy are debated, while newer techniques offer alternatives [15]. Surgical options may be considered if medical treatments are ineffective, demanding further evaluation if needed [16].

#### Prevalence in India:

Dysfunctional uterine bleeding (DUB) constitutes a prevalent gynaecological issue in India, impacting a considerable female population. Its occurrence is notably pronounced among women of reproductive age, with prevalence influenced by diverse factors including regional location, socioeconomic circumstances, and cultural norms. Geographical disparities and varied access to healthcare contribute to differing rates of diagnosis and management.

#### **Clinical Features:**

Women experiencing DUB may present with a range of clinical features. These include unpredictable menstrual cycles, heavy or prolonged bleeding, intermenstrual spotting, and even occasional episodes of amenorrhea (absence of menstruation). The severity of symptoms can vary, impacting a woman's physical and emotional well-being. Dysfunctional uterine bleeding is

managed with medical therapy, levonorgestrel-releasing IUD, endometrial ablation, or hysterectomy. In the Netherlands, medical therapy is usually favoured, despite a significant difference in an RCT comparing it to endometrial ablation [17].

#### Diagnosis and management:

Accurate diagnosis of DUB involves a comprehensive approach. Medical history, including menstrual patterns, is essential, along with a thorough physical examination. Diagnostic tests may include blood tests to assess hormone levels, ultrasound to evaluate uterine and ovarian structures, and endometrial sampling to rule out other potential causes of abnormal bleeding. The treatment of DUB aims to alleviate symptoms, restore normal menstrual patterns, and improve overall quality of life.

#### Psychosomatic Correlation:

DUB may be associated with psychosomatic factors, highlighting the complex interplay between the mind and body. Stress, emotional disturbances, and psychological factors can influence hormonal balance and exacerbate abnormal bleeding. Integrating psychosocial support, stress management, and counselling into the treatment plan can contribute to more comprehensive care. Examining adolescents with dysfunctional uterine bleeding, this retrospective study covered a decade (1981-1991) at Montreal pediatric hospitals. Medical therapy showed efficacy for most cases (93.4%), with only a minority (8.2%) needing dilation and curettage. The findings emphasized the connection between immature hypothalamicpituitary-ovarian axis and such bleeding during adolescence, underscoring successful medical management. [18].

#### **CASE HISTORY**

#### PERSONAL DATA

Patient name: Mrs. X	Age: 29 years
UID: 2123	Gender: Female
Occupation: Housewife	Religion: Hindu
Marital Status: Married	Socio-economic status: Moderate
Address: Xyz	Contact number: 987654321

#### PRESENTING COMPLAINTS

Date: 25/04/2023

Chief complaints: Menstrual irregularities

Symptoms	Location	Sensation & Pathology	Modalities (< & >)	Concomitant	Treatment
Menstrual	Female repro-	- Menstrual	A/F,	Pain in lower back	
irregularities	ductive sys-	cycle irregu-	After deliv-	and abdomen	
and profuse	tem,	lar	ery	with cramps dur-	
flow			or	ing flow.	
	Since 2 years,	- Short cycle	Husband's		
	Increased 6 months.	length 15 - 17 days	affair		
		- Profuse flow on some days			
		(3 pads/day)			



Headache	Head, whole,	Occasional	Unspecified	Heavy sensation	OTC drugs
	location un-	headache			
	specified,				
				Sleep disturbed	
				1	
	Since 1 year.				

#### PAST HISTORY

History	Disease/Operation/Injury	Age/Year of oc- currence	Treatment taken	Outcome
Past H/O	Nil	-	-	-
Family H/O	Mother – Diabetic and Hyper- tensive	Above 45 years of age	Modern medicine	Values under control

#### PERSONAL HISTORY:

- Diet & Food Habits: Non vegetarian
- **Economic status:** Moderate
- Sexual history: No contraception needed; condoms whenever necessary. Rare sexual activities but not satisfactory, thoughts on mind during the act.
- **Vaccination:** Mostly done as per schedule.

#### GYNAECOLOGICAL HISTORY

- **Menarche**: 13 years Dark bleed at start and then normal
- LMP: 27/03/2023 & 15/04/2023
- Cycle length:

Before complaints 28-29 days

Present 15-17 days

- **Menstruation:** 4-5 days
- Nature of flow: Colour red, no major clots, non-staining.
- Quantity:

Before complaints

- Day 1 and 2: 2-3 pads/ day
- Day 3: 1-2 pads/ day
- Day 4 and 5: 1 pad unfilled/day

- Discharge: No H/O abnormal discharges
- **Accompaniments:** Pain in lower back and abdomen, severe to moderate cramps.

#### **OBSTETRIC HISTORY**

G1 P1 A0 L1 D0

Labour: Full term - Normal vaginal delivery

Lactation: Insufficient

#### LIFE SPACE INVESTIGATION

- Perinatal: All the milestones were achieved normally, no known event during mother's pregnancy.
- **Childhood:** Raised by strict parents; calm and introverted; limited social interactions.
- Education: Holds B.A degree; reserved during college, maintained good grades, interested in arts, writes in curvy style, occasional anger issues in college.
- Occupation: Housewife, happily managing household responsibilities.
- Marital history: Arranged marriage; initial year filled with happiness, both had good understanding till their daughter born, after that turbulent relationship till now, husband had extra-marital affair with sister's daughter,

always used to compare her with his sister's daughter in all aspect, she discovered husband's affair which caused an immense sadness and much stress, loves husband so much but also hates him. Aversion to even see him at times. Frequent bouts of anger and arguments. Husband's affair had a deep impact, leading to emotional turmoil. Went out of home in anger and a brief stay at

- mother's home; persuaded by sister-in-law to return, which resulted in increased affection for sister-in-law's support.
- Children: One daughter, full term vaginal delivery, attached to her, afraid about her future due to husband's affair.
- **Current:** This affair and health issue affecting her much.

#### MENTAL AND PHYSICAL GENERALS

Mental Generals	Physical Generals
Company: Usually desires company	Stool: Regular [Once/day]
Consolation: Aggravation	Urine: Regular [No difficulty]
Contradiction: Not related	Sweat: Profuse, increased around genitals
Desire: Nothing peculiar	Thirst: Normal [1-2 litre/day]
Aversion: cold	Appetite: 2-3 times/day
Tendency: Nil	Sleep: Disturbed
Dreams: Disturbing	Discharge: Nil

#### **DESIRES AND AVERSION**

Thermal: Cold aggravation in general	Climate: Summer, aversion to winter
Fanning: Desire	Covering: Desire
Bathing: Normal room temperature water	Food: Not specific, likes sweets
Posture: N/A	Motion: N/A

#### GENERAL EXAMINATION

Built & nutrition: Moderate	Height: 150 cm
Weight: 66 kg	BMI: 29.3 kg/m <sup>2</sup>
Gait: Steady	Anaemia: Mild pallor
Jaundice: No icterus	Cyanosis: Nil
Oedema: No oedema	Clubbing: Nil
Skin pigmentation: Nil	Hair distribution: Normal
Warts: Nil	Nails: Normal
Lymphadenopathy: Nil	BP: 112/70 mm Hg
Pulse: 86 /minute	Temperature: N/A
RR: 20/minute	SpO <sub>2</sub> : N/A

#### LAB INVESTIGATIONS

18/03/2023 – USG Abdomen and Pelvis – No uterine fibroids or endometrial abnormalities Previous report shows TSH to be normal



#### **DIAGNOSIS**

**Provisional diagnosis:** Dysfunctional uterine bleeding

#### Differential diagnosis

1. Uterine fibroids, or leiomyomas, are benign smooth muscle tumours originating from the myometrium of the uterus. They can induce irregularities in uterine contractions, leading to dysfunctional uterine bleeding (DUB).

- These growths can distort the endometrial cavity and lead to menorrhagia (excessive menstrual bleeding), as well as metrorrhagia (intermenstrual bleeding).
- 2. Polycystic ovary syndrome complex endocrine disorder marked by hyperandrogenism, anovulation, and polycystic ovaries. Intermenstrual bleeding, often owing unstable endometrial to shedding, can occur. Hyperinsulinemia and insulin resistance further exacerbate hormonal imbalances leading to other symptoms.

#### **CASE ANALYSIS**

Common symptoms	Uncommon symptoms
<ul> <li>- Menstrual cycle irregular</li> <li>- Short cycle length 15 - 17 days</li> <li>- Profuse flow on some days</li> <li>- Pain in lower back</li> </ul>	<ul> <li>- Ailments from, After delivery</li> <li>- Husband's affair</li> <li>- Headache, whole, location unspecified</li> <li>- Consolation: Aggravation</li> </ul>
<ul> <li>- Pain in abdomen</li> <li>- Menstrual cramps</li> <li>- Mother – Diabetic and Hypertensive</li> <li>- Sleep: Disturbed</li> </ul>	- Thermal: Cold aggravation in general - Sweat: Profuse, increased around genitals

#### **PRESCRIPTION**

#### Rx

- 1. Ignatia amara 0/1 in water 10 drops BD / 30 days
- 2. Sac lac 3 pills BD / 30 days
- 3. Ferrum phosphoricum 6X / 30 days

#### Selection of medicine:

Mode – Constitutional remedy

Homeopathic Psychology by Philip M. Bailey

He calls *Ignatia amara* as the "emotional roller-coaster". At first her defensive wall is expressed as anger and indignation, which wells up whenever

the Ignatia individual feels that she has been rejected, let down or neglected. She has been abandoned once, and dare not risk it a second time by seeking comfort from another. At times, however, she feels much worse when alone, especially in the acute stages of grief. Any constitutional type can enter into an Ignatia state following a bereavement, or a separation from a loved one.

Materia Medica by James Tyler Kent

A woman has undergone a **controversy at home**. She has been disturbed, is excited, and **goes into cramps, trembles and quivers. Goes to bed with a headache. Is sick. Ignatia will be her remedy.** Nervous affections and troubles of all sorts come on at the menstrual period.

William Boericke

It is especially adapted to the nervous temperament-women of sensitive, easily excited nature, dark, mild disposition, quick to perceive, rapid in execution. Rapid change of mental and physical condition, opposite to each other. Great contradictions. Female - Menses, black, too early, too profuse. During menses great languor, with spasmodic pains in stomach and abdomen.

#### **FOLLOW UP**

#### 26/05/2023

- LMP: 10-05-2023
- Less cramping and lower back pain
- Bleeding profuse (3 pads/day for day 1 & 2)
- Sleep better
- Headache slightly better but persists

#### Rx

- 1. Sac lac in water 10 drops BD / 30 days
- 2. Sac lac 3 pills BD / 30 days
- 3. Ferrum phosphoricum 6X / 30 days

#### 09/06/2023

- LMP: 03-06-2023
- Stressed due to husband's nephew visited home
- Mild cramping
- Body ache with back ache, leg pain
- Sleep disturbed
- Headache slightly better but persists

#### Rx

- 1. Ignatia amara 0/3 in water 10 drops BD / 30 days
- 2. Sac lac 3 pills BD / 30 days
- 3. Ferrum phosphoricum 6X / 30 days

#### 14/07/2023

- LMP: 07-07-2023
- Mild cramping on day 1
- No back pain or leg pain

- Sleep better but disturbing dreams
- Headache better but persists

#### Rx

- 1. Ignatia amara 0/3 in water 5 drops BD / 30 days
- 2. Sac lac 3 pills BD / 30 days
- 3. Sac disc 6X / 30 days

#### 10/08/2023

- LMP: 06-08-2023
- Mild cramps on day 1
- No back pain or leg pain
- Sleep better with less dreams
- Headache occasional, once in this month

#### Rx

- Ignatia amara 0/3 in water 5 drops BD / 30 days
- 2. Sac lac 3 pills BD / 30 days
- 3. Sac disc 6X / 30 days

#### CONCLUSION

Homeopathy exhibits distinctive capacities in addressing psychosomatic ailments. This case report underscores the effectiveness of meticulously chosen constitutional homoeopathic remedies in treating female bleeding disorders arising from emotional causes. For a more comprehensive comprehension, the need arises for additional case series and studies featuring larger sample sizes. Such endeavours can contribute to a deeper understanding of homeopathy's potential in managing similar conditions.

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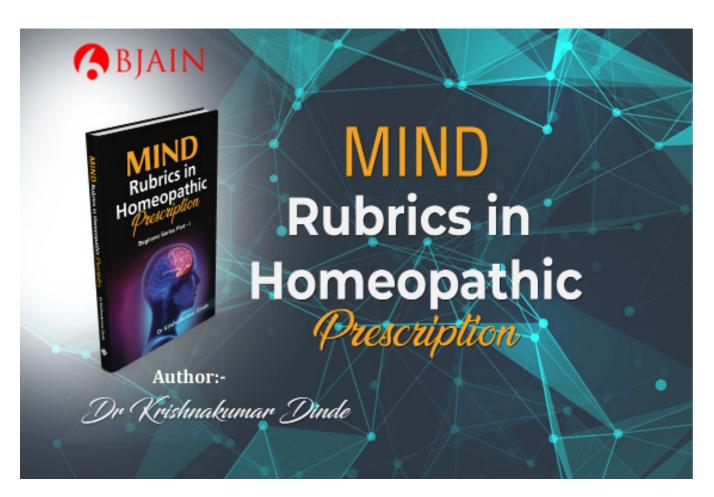
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Dr. A. Akshaya Tharankini





### The Essence of Various Groups

# (The main features of different elements discussed with practical case examples)

Review by- Dr. Niharika Jain

#### **About the Reviewer**



Dr Niharika Jain B.H.M.S. (M.D.)

Associate editor, The HomoeopathicHeritage Currently working at the Central Council for Research in Homoeopathy in New

Delhi as a senior research fellow, **Dr. Nihari-ka Jain** is the founder of the Vigyan School of Homoeopathy. She has been awarded the "Young Researcher Award" in 2022 and the "Homoeopathy Gouray Samaan" in 2023.

She did the "Master Course Program" from the well-known "The Other Song International Academy" in Mumbai in 2018–2019.

She presented a research paper on "Innovative Score for Assessment of Respiratory Ailments in Post-COVID-19 Patients" at the All India Postgraduate Homoeopathic Conference in Kolkata and the Heilkunst-Erhellen International Conference in Germany in April 2023. She was invited to speak at the HOMCON Agra 2023 National Conference.

At the Vigyan School of Homeopathy, which she founded, she imparts knowledge and techniques for effective homeopathic clinical practice. She engages in educational outreach by conducting webinars and instructing students in India and abroad.

With her publications including various articles and research papers in peer-reviewed national and international journals, she is actively involved in research covering a wide spectrum of health conditions, including post-COVID patients' respiratory complaints, skin disorders, Polycystic Ovarian Syndrome, autoimmune disorders, and non-communicable diseases. Her dedication to advancing homeopathic medicine is evident through her multifaceted contributions and commitment to excellence in the field.

The Essence of Various Groups
The Main Features of Different Elements discussed with Practical Case Examples

Roger Morrison Nancy Herrick

In the contemporary landscape of homeopathic practice, it is evident that the teachings of esteemed homeopathic pioneers often go overlooked amidst the proliferation of modern homeopathic gurus and their doctrines. These classic works authored by the old masters of homeopathy are nothing short of literary gems, offering invaluable clinical insights and practical tips that can significantly enhance one's proficiency in homeopathic practice. It is imperative to bridge this gap and acquaint aspiring homeopaths and homeopathic students with these timeless treasures.

The purpose of this endeavor is to introduce a remarkable book from the chronological record of homeopathic literature to the next generation of homeopathic practitioners and scholars. By delving into the wisdom contained within these classic texts, we can tap into a profound reservoir of clinical knowledge honed through decades of practical experience and thus invigorate our contemporary homeopathic practice with a deep understanding of its historical foundations.

This is the complete transcript of Roger Morrison's seminar, presented in September 1988 in Burgh-Haamstede, the Netherlands. The book has been compiled into two parts. The first part is about the main features of the different elements, and the second part is the Materia medica along with cases.

#### Type of book:

#### Part I -Elements (Groups)

An inherent identity of this scholarly work lies in its close literary coherence and seamlessly coordinated content, which make clear the distinctive characteristics of the individual groups of Materia medica. In this book, the authors have depicted the essence of 18 groups like acid, calcium, magnesium, and many others. The author covers all the important aspects of the groups, like the main indications, mental general, physical general, and particular symptoms. This book attempts to provide a comprehensive and practical understanding of the many Materia medica groups. The book provides precise similarities and dissimilarities between different groups while emphasizing the

essential qualities that characterize them.

#### Part II - Materia Medica Along with Cases

Many medicines are compared with other closely related medicines having similar symptoms. The comparison of the essences of various related medicines helps a lot in choosing a remedy. In The Essence of Various Groups, the authors have painted the essence of 60 remedies. While reading every remedy, a clear portrait of the patient with minute details comes out in front of you. Of particular note is the comprehensive study of allied remedies, which provides valuable insights into the similarities and disparities in their properties. The author additionally provides descriptions of numerous barely noticeable and rarely used medicines in this book, and many of the usual medicines have been given additional uses. This work presents an invaluable means of comprehending the unique characteristics of each remedy. Importantly, it serves as a pivotal tool in mitigating the potential for prescription errors. Acknowledged as a classical exemplar in the field of drug comparison, this text is essential reading for practitioners aspiring to achieve precision and assurance in their prescription practices.

After Materia medica, the author gives 41 very interesting examples of cases, showing how two elements come into play in cases. If we clearly understand the characteristics of elements (groups), our prescription becomes very effective.

#### The Objectives of This Book Are As Follows:

The foremost objective of this literary work is to provide a thorough and extremely comprehensive explanation of the major groupings within the Materia Medica field. Additionally, it carefully compares these groupings, providing a compact and precise understanding of each group's characteristics. This work fills an enormous vacuum in the literature by highlighting the unique characteristics of diverse Materia Medica groups and permitting their comparative analysis with unprecedented precision. It is a unique and authoritative resource.

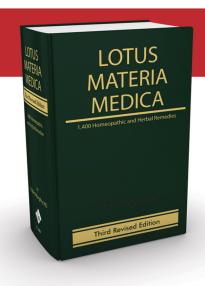
#### Structural Layout and Organization of The Book:

Notably, this book adopts a highly accessible and conversational writing style, making it easily absorbable for readers. Within its pages, the authors undertake an exhaustive analysis of the group-based Materia Medica, presenting a novel and well-reasoned perspective. This innovative approach breathes new life into the longstanding concept of group study in Materia Medica, rendering it more comprehensible and elucidative. A hallmark of this work is its unique compilation, offering readers a schematic overview of the systematic study of drugs as categorized within the homeopathic Materia Medica. This book sur-

passes others within the same thematic category, representing exceptional value for its price.

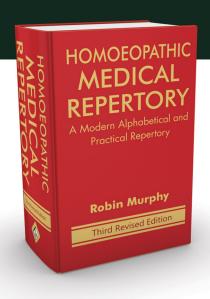
#### Conclusion

In conclusion, this book provides clear and thorough insights, making it an invaluable resource for postgraduates, PhD scholars, practitioners, and researchers in the field of homeopathy. Overall, this book is a testament to the author's dedication to the advancement of homeopathic knowledge and practice. It is an absolute privilege to write a review for this extraordinary publication.



## **Highlights**

- 1400 remedies
- Addition of modern terminology, cross references and corrected errors
- Combined homeopathic and herbal Materia Medica
- Covers historical uses, folklore, legends, case histories, therapeutics, toxicology, provings, and pharmacy of many homeopathic and herbal remedies.



## **Highlights**

- 20,000 new rubrics
- 100,000 new additions
- Expanded cross-references, remedy list and word index
- Hundreds of new remedies
- Large new clinical chapter and nine other new chapters

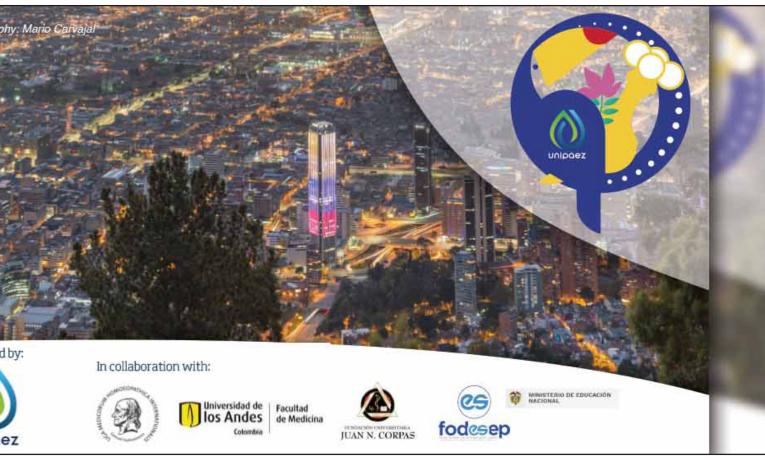
# Highlights







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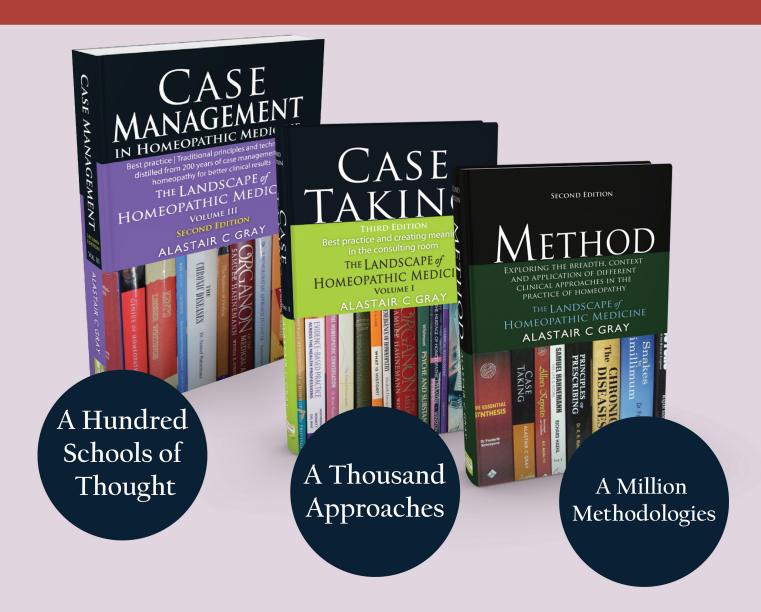
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