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CONNECTIONS BETWEEN PARADIGUNA AND CLINICAL RESEARCH

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ABSTRACT

Ayurveda is an ancient health science. Primary sources of Knowledge of Ayurveda are Ayurveda Samhitas. Samhitas are written long back during the period of Samhita. Samhitas contain the roots of every science available. Research methods is the newly developed science. The roots of research methods can be traced in Samhitas too. Clinical research gains importance as it is in tandem with the objective of Ayurveda Viz maintenance of health and cure from diseases. Paradiguna are set of ten qualities told by Acharya Charaka for the success in treatment. This article analyses Paradigunas in the light of Clinical research.

Key words: Paradiguna, Clinical research, Ayurveda Research

INTRODUCTION:

Ayurveda is a unique science which details all about human life, health, disease, drugs and treatment strategies. From the origin of Ayurveda until now there has been growth and addition in the knowledge of Ayurveda. Addition of knowledge is because of research findings. Study of Ayurveda is essentially the study of Ayurveda Samhitas. Samhitas contain the information in a codified form. As the Samhitas contain information related to every aspect of human life either in brief or in details, the method of conducting clinical research should also be evident. Ayurveda is based on some fundamental principles that find applications in different ways. Guna Siddhanta is one such. Guna mean, nature, quality, property, characteristic feature, etc. Gunas are divided into various categories like Gurvadi, Paradi, Vishistha, Adhyatmika gunas. Among these gunas for the success of the treatment Paradigunas play a principal role. Paradigunas are the set of 10 guna that start from Para it includes Apara, Yukti, Sankhya, Samyoga, Vibhaga, Parimana, Prithaktwa, Samskara and Abhyasa. These properties are basically mentioned as useful in the success of the treatment. However, Ayurvedic concepts have far reaching implications and applications, there appears the utility of these in the process of clinical research.

PARADI GUNAS IN CLINICAL RESEARCH

PARA-APARA

Para is the first guna which means pradhana that is superior/ best/ primary when compared to another. Apara is opposite to para that is Apradhana which means inferior, worst, secondary when compared to another [1]. Charakacharya has given some criteria to understand the Paraparatva. Those are Deshs, Kala, Vaya, Mana, Paka, Virya, Rasa etc. Chakrapani added the terms Prakriti and Bala to Adi word. If Dehaprakriti is considered then Sama prakriti is Para when compared to Eka or Dvidoshajaprakriti. Among three types of Bala, Pravarabala is Para in relation to Avara and Madhyamabala. Similarly, many such examples from Samhita can be quoted. Like Agryadravya [2], Nityasevaniyadravya [3], Raktashali among Shuka dhanya [4] explained by Acharyas feature under Paraguna. Apara can be Ekadoshajaprakriti, Anupadesha, Pratyakshabhadaka bhava [5] etc. Paraguna is a

property which helps the body to maintain the *Dhatu samyata* whereas *Apara* disturbs the *Dhatusamyavastha*.

Parapara in the clinical research:

Para and apara plays an important role in clinical research. To determine the safety and effectiveness of the medication, devices, diagnostic products intended for human use, which may be used for diagnosis, treatment, prevention or for improving the quality of life in a disease. In comparative clinical research *Paraparatva* plays a role in selection of research topic which usually will be to compare one drug with another, dosage to see which dosage is effective, dosage form to see which dosage form is suitable to patient, Anupana to see which Anupana is suitable to both Roga and Rogi, Pathya to see which *Pathya* is good for patient to obtain significant result. *Paraparatva* in other words means to determine the superiority of the drug in terms of its dose, duration, appropriate to time, place, person. In considering the efficacy of Shamana over Shodhana treatment or vice versa in a particular disease *Paraparatva* has its role [6]. As the main purpose of the clinical research is to demonstrate the *Paraparatva* of drug, formulation, therapy, diagnostic tool and dietary supplements appropriate to achieve the *Dhatusamyata*. Obtaining *Apara* (negative/inferior) results is also important as it primarily help both scientists and researcher to pursue better and more novel methodologies. Thus, Paraparatva is very important in every step of clinical research process starting from the selection of the research problem till its preparation of summery in the form of document because it only becomes scientifically valid if it is designed superiorly.

YUKTI

Yukti comes under both *Guna* and *Pramana*. As *Guna* it helps to physician in planning the treatment [7] in terms of selection of *Dravya*, *Anupana*, *Aoushadha Sevana kala*. *Chakrapani* explains *Yukti* as a property helps for appropriate use of medicine on the basis of *Dosha Dushyadi* factors. Importance of *Yukti* is explained through following.

- Vaidya well versed with Yukti Guna is always superior to one who has Dravya Jnyana
 [8].
- Yukti can modify the poison into medicine and a good medicine into poison [9].

➤ *Chakrapani* comments that a treatment without logical reasoning is a waste like a person having worthless son [10].

➤ Collection of medicine, purification, formulation and storage is done based on *Yukti*.

Yukti as a *Pramana* is the application of wisdom and intelligence to perceive true knowledge. It gives knowledge of *Trikala*-past, present, future and *Trivarga-Dharma* (righteousness in life), *Artha* (materialistic wealth), *Kama* (desires in life) [11].

Yukti in the Clinical research:

Clinical research starts with the proper planning of research protocol/ methodology. *Yukti* plays important role in,

Selecting and defining the research problem because the problem clearly stated is a problem half solved.

Formulating the hypothesis: Clearly stated hypothesis always keeps the researcher on right tract by indicating the type of data required and type of method of data analysis to be used.

➤ Defining the objectives of study: It facilitate the development of research methodology, orient the collection, analysis, interpretation and planning of the data.

➤ Sample designing, selecting sample size, grouping, deciding the duration of the study, selecting the diagnostic criteria, inclusion and exclusion criteria, applying statistical methods to test the significance of the study. So the procedural design of the research should be cleverly planned to yield results that are as objective as possible.

SAMKHYA

Samkhya means Ganita [12] denotes counting or calculation. Numbering is an essential part of Ayurveda as numbers are evident in Tridosha, Saptadhatu, Trimala, Panchamhabhuta, Shadrasa, Vimshatipramehaetc. Even for treatment Samkhya is very important, for deciding the dosage, its frequency and duration requires correct calculation. Also for planning the

Basti and other *Karma* one needs to calculate amount of *Kwata, Taila* etc to be prepared for a particular patient in a specific condition.

Sankhya in clinical research:

Sankhya refers to mathematics and expression in numericals. Statistics is *Sankhyashastra* which is the branch of mathematics dealing with the collection, analysis, interpretation and presentation of masses of numerical data. Samkhya can be understood as

- Medical statistics helps in finding efficacy of new drug and their comparison.
- Normal limits of various pathological and physiological condition can be determined through statistics.
- Standardising various Ayurvedic treatement according to Desha, Kala, Prakriti, Agni by applying various statistical procedures.
- ➤ Applying various statistical tests appropriate to collected data to draw level of significance in the form of P-value.

SAMYOGA

Union of two or more substances is known as *Samyoga* [13,14]. *Charakacharya* says *Samyoga* is of three types- *Dwandwakarmaja*, *Sarvakarmaja* and *Ekakarmaja* [15]. *Ekakarmaja* is ccombination of *Dravyas* where in only one remains active to produce the result. Eg – A crow sits on a tree, here crow alone takes part in *Samyoga*. Clinical example can be, *Erandapatra* is tied over the knee with the help of a bandage cloth to treat *Shotha*. Here *Erandapatra* and cloth come together, but it is only *Eranda* which relieves *Shotha*. *Dwandwakarmaja* is ccombination of two *Dravya* where in both take part actively towards the effect. Eg- Two goats fighting together. Clinically it can be understood as *Kumari* and *Haridra Lepa* for skin diseases where both drugs act to combat the disease. *Sarvakarmaja* is ccombination of more than two *Dravyas* where in all *Dravya* work to produce the effect. Eg-*Masha* kept in vessel which many in number, all will be converted into one particular preparation. Clinical example can be, *Trikatu Churna* in *kasa*, here all three drugs i.e. *Pippali, Maricha, Shunthi* together help to mitigate the *Kasa*.

Samyoga in the clinical research:

Samyoga in clinical research refers to combination of drug / formulation with body or combination of different drugs or therapies like *Shodhana* and *Shamana*. It can be understood as

- Combined effect of *Shamana* and *Shodhana* treatement.
- ➤ Effect of drug or formulation can only be observed after its *Samyoga* with human body.
- Combination of number of herbal or mineral drugs to prepare into a formulation.
- With the help of *Samyoga* synergistic effect of drugs can be studied.
- First step in statistical investigation is the collection of data from various sources like Experiments, surveys and records.

VIBHAGA

Vibhaga is opposite quality of Samyoga. Division of any combination is termed as Vibhaga [16]. Vibhaga has three words. Vibhakti which mean Cutting the Dravyas into pieces to prepare any formulations. E.g., Making coarse powder of kutaja bark to prepare kutaja Kashaya. Viyoga – It can be understood as losing its original qualities, i.e. when one drug is not included in any formulation like Hinguastaka Churna, the formulation may lose some qualities. Bhagashograha refers to considering the small portion of a preparation. E.g., while consuming the Rasayoga, making it into several divisions for proper therapeutic action.

Vibhaga in clinical research:

Vibhaga can be taken as the classification of data. It is the first step in analysis of data which leads to draw the conclusion in terms of significance. In clinical research *Vibhaga* finds its application in

- Understanding and analysing the individual effect of drug in a population.
- Dosage Dividing the dose according to *Vyadhi* and *Aturabala*.
- ➤ Dividing the study population into sample /groups and subjecting them to appropriate trial treatment.

Dose dependent action – Analysing the dose dependent action of the single drug or formulation in a population.

PARIMANA

The quality which aids in measurement is called as *Parimana/Mana* [17]. *Anu, Dirgha, Mahat, Hrswa* are some types of measurements. In *Ayurveda* based on *Desha, Kalinga* and *Magadhamana* are explained. *Amarakosha* [18] explains three types of *Mana* as

- 1. *Pautava mana* (measuring the weight)
- 2. *Druvaya mana* (measures volume)
- 3. Payya mana (measures length)

Parimana in the clinical research:

These are measurement tools for assessment of the reliability, validity and responsiveness of clinical trials in the form of collecting the demographic data and outcome. In the clinical research various scales of measurements are used such as scale of measurements for Blood Pressure, Heart Rate, Respiratory Rate, body weight, hight, BMI, pain, temp, PASI score in psoriasis, blood sugar levels in Diabetes etc before and after the clinical trial.

PRATHAKTWA

The uniqueness of substance by which it differentiates from others is called *Prathakatwa* [19[. *Chakrapani* comments saying that *Ghata* and *Pata* is different because of their unique qualities E.g *Dhattura* is different from *Haritaki*. *Prathaktwa* is of three types- *Asamyoga*, *Vailakshyanyam*, *Anekata*. *Asamyoga* mean the differentiation between the two substances which cannot be combined together. E.g.- *Meru* and *Himalaya Parvata* cannot be brought together. *Vailakshyanya* refers to the difference between two substance which belongs to single category but still are separate due to their distinct character (*Vishishtalakshana*). E.g. *Shatavari* and *Vacha* are herbal drugs, but each have clear character to differentiate. *Anekata* is Difference between the substance of the same class. E.g. *Masha* grains belong to same *Jati* but each *Masha* grain varies from its size or colour.

Prathaktwa in clinical research:

Prithakatva is the assessing the distinct features/characters/results among the same population.

- Expecting the distinct outcome in a population having similar disease. It might be obvious because of *Pratipurusha Siddhanta*.
- To detect the level of *Vyadhi Kshamatva* by exposing population to some trail drug to produce distinct effect.
- After classification of data observing and assessing the distinct features to draw an appropriate conclusion.

SAMSKARA

The factors which import/modifies the qualities of a substance is called the *Samskara* [20]. Qualities of a substance is influenced due to various factors like *Jala, Shoucha, Agni Sannikarsha, Manthana, Desha, Kala, Vasana, Bhavana, Kalaprakarsha, Bhhajana* [21]. Right from collection of the medicine up to its preparation, storage and usage every where *Samskara* play significant role which enable the drug to perform its anticipated action. Thus, *Samskara* can be aptly utilised for treatment to enhance the qualities of the medicine and thereby for a successful treatment.

Samskara in clinical research:

Samakara refers to processing, which imparts, modifies the qualities of a substance. Role of samskara in research can be understood as

- ➤ The prepared research proposal is subjected time to time correction, verification, clarification of quarries, inclusion of better/new ideas or protocol so that it becomes scientifically valid document.
- ➤ Protocol deviation: Accidental or unintentional changes to, or non-compliance with the research protocol that does not increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data [22]. It happens because of *Samskara*.
- ➤ Efficacy of a drug is determined in its raw form and also processing it with other drugs and making it into a formulation.

➤ Collected data is also undergoes various samskara in terms of statistical tests and finally suitable conclusion is drawn.

ABHYASA

Regular usage of a substance/ practice is called the *Abhyasa* [23]. This very relevant to treatment because for successful relief from a disease, continuous usage of medicaments and practices are very essential. Treatment of *Yapya* diseases is through regular usage of *Pathyaahara* and *Vihara*.

Abhyasa in clinical research:

Reproducibility of result is the hallmark of any good research. Reproducibility requires repetition. Repetition is *abhyasa* and practice leads to perfection. Research itself is a continuous process where in researcher continuously thinks about the research project by doing so it adds some knowledge, enables better fast thinking and analysing capacity.

- ➤ Multicentric research trial executing the same research protocol at multiple centres by various researcher results in obtaining the clinically and statistically and strong outcome.
- ➤ Drug discovery and development In clinical research novel drug only comes into market after passing through multiple stages of testing and getting approved by the relevant regulatory authority.

CONCLUSION:

There is no separate manual on how to do research in *Ayurveda* as manuals or books available today. Though there are various references available which tells about evidence of various kinds of research process in *Ayurveda* but they are scattered. So, it is very essential for a researcher of *Ayurveda* to have a proper understanding of fundamentals and their application in research process. Thus, *Paradigunas* being one among the fundamental principles helps in conducting clinical research in scientific way to discover a novel drug, treatment or diagnostic methods.

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