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Role of Prakruti Sama Samaveta and Vikruti Visham Samaveta Siddhanta from Ayurveda in Pharmacovigilance.

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ABSTRACT: In the age of modern technology, scientific advancements, consumer awareness and the advent of evidence-based medicine, there is inadequate genuine clinical trial evidence supporting the efficacy and safety of Ayurveda drugs, except that this system is practised since hundreds of years. Another fact that supports it is the rarity of any adverse effect ever reported. Even the IEC guidelines for human trials take shelter under the fact that Ayurvedic drugs are time tested and require no evidence base of clinical safety data for approval of their use in humans. But this is a limitation which all along has interfered in acceptance of Ayurvedic medicines in developed world as a health care system. Further, a common misconception prevails among the masses and also a large population of practitioners is that Ayurveda drugs are safe and do not have any adverse reaction. Dravya is the entity which has been given with prime importance for its role in the prevention and treatment of different ailments. Generally, Dravya act according to Rasa, Guna, Virya and Vipaka. In some other conditions the action of Dravya cannot be expressed or explained with the help of Rasa, Guna, Virya and Vipaka. Diseases will be manifested because of the involvement of single Dosh or in combination with another Dosh or all three together. In such conditions concept of Vikruthi Visama Samavetha is helpful. Prakruti Sama Samaveta and Vikruti Vishama Samaveta are the two Siddhanta given by Acharya Charak while describing relation between Rasa-Dravya and Dosh-Vyadhi. This study is carried out with a view to know the applicability of this Siddhanta in understanding and prevention of ADR (Adverse Drug Reaction) and also to establish Pharmacovigilance in Ayurveda.

Key words: Ayurveda, Siddhanta, Prakruti, Sama, Samaveta, Vikruti, Visham, pharmacovigilance

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Introduction:

Pharmacovigilance can be projected as a great tool to help decision making with reference to adverse drug reactions in Ayurveda. A subsequent causality analysis would allow us to identify the possible underlying reason for the adverse effect in an Ayurvedic context and therefore ultimately to prevent such adverse reactions eventually. There is a major misconception among masses and also a large population of practitioners that Ayurveda drugs are safe and do not have any adverse reaction. Ancient texts clearly mention that if a drug is used without the knowledge of its proper action, it would certainly act as a poison¹. (Though it may seem to be a hypothesised statement, but its soul is vibrant with the concept of Pharmacovigilance. A recent survey conducted by the NCCAM in the USA showed that about 751 000 people in the United States had ever used Ayurveda and 154 000 people had used them within the past 12 months. Associated with this increasing use, there are growing concerns about the safety of Ayurvedic medicines also². There is very sparse evidence supporting the efficacy and safety of Ayurveda drugs, except that this system is in practice since hundreds of years. However, the Charaka Samhita, which is a classic text book of ayurveda, describes all the adverse reactions to medicines when they are prepared or used inappropriately. Attention is given to factors like the physical appearance of the part of the plant to be used (prakruti), its properties (guna), actions (karma; prabhava), habitat (desh), season in which it grows (ritu), harvesting conditions (grahitam), method of storage (nihitam) and pharmaceutical processing (upaskritam), which must be considered while selecting the starting material that goes to form the medicine³. Similarly, Charaka also describes, elegantly, several host-related factors to be considered when selecting medicines in order to minimize adverse reactions like the constitution of the patient (prakruti), age (vayam), disease

(vikruti), tolerance (previous exposure) (satmya), psychological state (satwa), digestive capacity (ahara-shakti), capacity for exercise (vyayama shakti), quality of tissues (Sara), physical proportions of the body (sahanan) and strength (bala)⁴. Also Prakruti Sama Samaveta and Vikruti Visham Samaveta Siddhant can be applicable to avoid ADR(Adverse Drug Reaction) to patient due to Ayurvedic drug. Prakruti Sama Samaveta and Vikruti Vishama Samaveta Siddhant are two important Siddhanta of Ayurveda given by Acharya Charak while describing the relation between Rasa- Dravya, Dosh-Vyadhi, the knowledge of which is beneficial for diagnosing and treating the patients without any hazard due to drug. This writing is therefore aim to bring to light, the basic tenets of the two Siddhant and their practical applicability in Pharmacovigilance.

Aim:

To review the two Siddhant Prakruti Sama Samaveta Siddhanta and Vikruti Vishama Samaveta Siddhanta described by Acharya Charak and its applied aspects regarding Pharmacovigilance.

Objectives:

- To review the concepts of Prakruti Sama Samaveta and Vikruti Visham Samaveta siddhant from Charak Samhita Viamanasthan first Adhyaya “Rasavimanam” with Chakrapani Teeka.
- To review the application of Prakruti Sama Samaveta and Vikruti Visham Samaveta in Pharmacovigilance.

Materials:

1. Charak samhita including Chakrapani Teeka.
2. Other samhita including Brihatrayees.
3. Related research articles from journals.
4. Other allied sources like websites and database.

Methodology:

1. Brief search is done to find out concept of Prakruti Sama Samaveta

and Vikruti Visham Samaveta siddhant from available material like Ayurvedic Samhita, database, websites.

2. Collected data is compiled and arranged to asses Pharmacovigilance in Ayurveda.
3. Also both Ayurvedic and Modern data are correlated to each other to asses role of Prakruti Sama Samaveta and Vikruti Visham Samaveta in Pharmacovigilance.

Discussion:

• Concept of Prakruti Sama Samaveta and Vikruti Visham Samveta:

The Adikarana of Ayurveda is “Puman” (Purusha)⁵. The Universe is made up of Panchamahabhuta including Purusha. Disease arises when there is vitiation in the Panchamahabhuta composition of body and the treatment comprises of effort trying to replenishment of the Panchamahabhuta⁶. The interaction between the Mahabhuta (in the form of Dosha) Purusha and the Mahabhuta (in terms of Rasa) of Loka forms the foundation of treatment⁷. Dravyas are also made up of Panchamahabhuta. The knowledge of effect of Rasa and its effect in Vyadhi and Aushadh is very much important to understand the main fundaments of Ayurveda.

One Dravya can be composed of many Rasa likewise in one particular disease more than one Dosha can be involved. So the relation of Rasa- Dravya and Dosa- Vyadhi should be known by the physician who is well explained by Prakruti Samasaveta and Viritvisamasaveta Siddhannta⁸.

Dosa	Aggravating Rasas	Alleviating Rasas
Vata	Katu, Tiktha, Kasaya	Madhura, Amla, Lavana
Pitta	Amla, Lavana, Katu	Madhura, Tikta, Kasaya

Kapha	Madhura, Amla, lavana	katu, Tiktha, Kasaya
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According to Prakruti samasamaveta siddhanta the results of the interaction between Rasa in Dravyas or Doshas in Vyadhi is similar to the Rasa and Dosha constituting them respectively⁹. E.g. wheat flour having Madhura (sweet) Rasa, Guru (heaviness) Guna (attribute) and Madhur vipaka (metabolic end effect) will have Vatahara (depletion of Vata) Karma (action)¹⁰. The effect we get according to the constituent of the Dravya. In case of Vyadhi there may be involvement of two or three Doshas and at the time of manifestation of disease symptoms arises according to the involved doses.

Prakruti Sama Samveta -

Component	Whole	Effect
Rasa	Dravya	Same
Dosha	Vyadhi	Same

According to Vikruti Vishama Samveta Siddhant concept the interaction between Rasa in a Dravya or Dosha in a Vyadhi results in an effect which is totally new and not similar to the individual Rasa and Doshas respectively. Where there is a substance having several Rasas or disorder having several Doshas one should first critically review analyse the role of Rasas or Doshas individually and then decide the effect of the substance or the disorder wholly¹¹.

Vikruti Visham Samaveta -

Component	Whole	Effect
Rasa	Dravya	Not Same
Dosha	Vyadhi	Not Same

But this rule is not applicable universally because in case of disorders where the effect is not exactly in accordance with the

constituent it is not possible to decide the effect of the total drug or disease on the basis of the effect of individual Rasas or Doshas¹².

Reason Behind Concept of Vikruthi Vishama Samaveta -

Perverted combination of Rasas and Doshas:

- Nanatmakam
- Parasparen aupahatanam
- Anyoshchavikalpnairvikalpitanam

Vikruthi Vishama Samavetha can be understood under two headings-

- 1.Rasa-Dravya
- 2.Dosha -Vyadhi

Effect of Dravya in Vikruthi Vishama Samavetha Rasas are the Samavayi Karana of Dravya, however action of Dravya does not occur in line with the causative Rasa.

The unpredicted effect is explained with the following reasons:

- Difference in proportions of Rasa (Nanatmaka)
- The individual Rasas in a Dravya may suppress one another (Parasporeuaphata).
- Due to nature of various Samskaras (processing) like Svarasa etc (Anyaishevikalpanairvikalpit)¹³.

Application-

- Understanding the mechanism of the disease
- Understanding the mechanism of drug action

Understanding the Mechanism of Disease -

Here the combination is such that it shows symptoms which are entirely different, dissimilar to the participating Doshas. The physician will not be able to judge the combination of Doshas from the symptoms. Only such types are described in texts. Wherever the Lakshanas of Samsarga and Sannipata Vyadhis are mentioned it is clear that they follow the rule of Vikruti Vishama Samaveta concept.

Illustration-

Manifestation of Sannipata Jwara, the three Dosas like Vata, Pitta, Kapha may also combine in two different ways.

- 1.The combination may have manifestations similar to those of the individual Doshas.
- 2.The combination may have manifestation dissimilar to those of the individual Doshas.

Examples:

1. Understanding of Sannipata Jwara-manifested signs and symptoms are not in the tune with the signs and symptoms of the individual Dosas but these are the special ones caused by the combination of Dosas in a specific manner.
2. Appearance of Kota in Jwara having brown or red colour, has nothing to do with those of individual Doshas¹⁴.
3. Mrudbhakshana (eating mud) causing Mrudbhakshana Pandu¹⁵.
4. Seeing emptiness in the water reservoirs in dreams in Rajayakshma¹⁶.

Vyadhi Lakshana is a peculiar Lakshana respective to Vyadhi which cannot be explained on the basis of the Dosha involved which falls into the category of Vikruti Vishama Samaveta.

Example-

Kinchit Vibaddha-Kincit Drava Malam in Grahani¹⁷.

Upashaya-

Viparitarthakari means that, which though not opposite still produce the effect of the opposite¹⁸.

Hetu Viparitharthakari Ausadha

Applying hot poultice causing increase of pitta on a swelling of Pitta origin undergoing ripening.

Hetu Viparitharthakari Ahara

Use of foods which are Vidahi in swelling predominant of Pitta and undergoing ripening.

Vyadhi Viparitharthakari Aushadha

Use of Madhanaphala which produces vomiting in case of the disease vomiting.

Vyadhi Viparitharthakari Ahara

1. Use of milk which causes purgation in Atisara

2. Haritaki Prayoga in Atisara

Hetu Vyadhi Viparitharthakari Aushadha

In burns caused by fire application of paste of Aguru which is hot in potency and also curative for burns

Hetu Vyadhi Viparitharthakari Ahara

Use of wine which is intoxicating in alcoholic intoxication

Understanding the Mechanism of Drug Action- Illustrations-

1. Madhura Rasa in Tanduliyaka illustrates the perversion in combination. Normally Madhura Rasa Dravyas having Snigdha and Vrushya properties. But this taste in Tanduliyaka does not produce any such effect in the body.

2. Kashaya, Tiktha, Katu, Madhura Rasa of Tila also illustrate the irregular combination. When these Rasas are combined in equal proportion, then Tila should normally alleviate Pitta and Kapha. But actually it aggravates Pitta and Kapha.

3. Varthaka acts as Vatahara even though it is having Katu, Tiktha Rasas. These indicates that there is some irregularity in the combination in as much as some of these rasas are manifested while others or not¹⁹.

Prabhava- Vikruti Vishama Samaveta

Susrutha Acharya has explained Prabhava through the concept of Achinthy Virya. He is of the opinion that the Prabhava Janya Karma is un-predictable (Achinthy) and un-questionable (Amimamsya)²⁰. It is the property which is characterised by specific actions of substances which cannot be explained in terms of pharmacological actions. Chakrapani also quoted Virya as Chintya and Achinthy. The Achintya Virya is considered as Prabhava²¹. Charaka Acharya has mentioned certain Rasa Virudha Viryas. They are examples of Vikruthi Visama Samavetha.

- Anupamamsa-Madhura, Kashaya, Tiktha-Ushna Virya

- Saindhavalavana-Lavana Rasa, SeethaVirya
- Amalaki-Amla Rasa-Seetha Virya

Vikruti Vishama Samaveta - Vichitra Pratyarabdha –

Basically there is no difference between Samanya Pratyarabda and Prakruti Sama Samaveta. But Vikruti Vishama Samaveta differs from Vichitra Pratyarabda. Vichitra Pratyarabda Dravya are which do not have structural similarity among the constituents, it means structurally dissimilar but functionally similar. In Vikruti Vishama Samaveta structurally similar but functionally dissimilar.

Concept of Pharmacovigilance in Ayurveda:

Etymology-

Pharmaco – Drug,

Vigilance - To be awake/ alert

Definition –

It is the pharmacologically related science related to the detection, collection, assessment, understanding, and prevention of adverse effects particularly long-term, and short-term side effects of Medicine.

Some Technical Terms Used –

ADR – Adverse Drug Reaction – A response to a drug that is noxious and unintended, and which occurs at doses normally used in man.

SE - Side Effect – Any unintended effect of a pharmacological product occurring at doses normally used in man.

SAE – Serious Adverse Event – Any fatal adverse event which is fatal, life-threatening, permanently disabling, or which results in hospitalization.

Pharmacovigilance, also known as Drug Safety, is the pharmacological science relating to the collection, detection, assessment, monitoring and prevention of adverse effects with pharmaceutical products. Vigilance means to be more careful, especially in order to notice possible danger or difficulties. As per Ayurveda, any

drug/management/procedure that, when administered, produces any untoward effect other than expected beneficial action is not considered a perfect treatment. Not only this, the promotion of health and prevention of disease is the first approach in Ayurveda. Before starting any treatment, multifaceted analysis of the status of the patient is mandatory so that the possibility of untoward symptoms due to error in diagnosis and planning of treatment is negligible. A possibility to consider environmental factors along with psychological status further adds evidence that Ayurveda incorporates such concepts of being vigilant in the treatment.

Adverse Drug Reactions (ADR) are defined as any response to a drug which is noxious and unintended, including lack of efficacy, which occurs at doses normally used for prophylaxis, diagnosis or therapy of disease or for modification of physiological function in the body. However, the term Pharmacovigilance does not figure in the Ayurvedic texts, but its concept is vibrant across all texts of Ayurveda. Ayurveda has described situations of drugs not utilized optimally (according to their order, proportion, combinations, or indication required as per the individual needs)²². The Charaka Samhita beautifully elaborates three essential points to ensure safe use of medicines, including knowledge about the name of the drug, its physical identification, and its properties. We all know that these points remain relevant to ensure a drug safety in whatever system of medicine. Besides the knowledge about drug identification and properties, Ayurveda puts further stress upon its use in clinical situations. While describing rational medicine use Ayurveda mandates knowledge of yoga (a single drug or a combination of more than one) and mana (dose) and its individualization as per patient's needs²³. Yukti (tactful use of medicine as per individual needs also called yuktivyapasharaya chikitsa)²⁴ is possibly the biggest tool of Ayurveda which renders a safe and effective use of a medicine possible in routine clinical

practice. Ayurveda provides flexibility about the choice of drugs, their doses, combinations, and duration of therapy according to the patient's sensitivity to a drug as well as the seriousness of the disease. Hence, practising Ayurveda in the way it is taught in the classical texts can minimize adverse reactions greatly.

Often because of this, the need for Pharmacovigilance in Ayurveda is questioned. The view is that if Ayurvedic medicines are used as described there will not be any ADRs. The adverse reactions, if noted, are believed to be due to improper use or poor quality of medicines²⁵. It is in this context that Pharmacovigilance, in the way it is applied in contemporary medicine, is considered to be neither essential nor applicable to the basic needs of Ayurveda.

- **Need of the Pharmacovigilance in Ayurveda:**

In ancient times, the Ayurvedic physicians prepared medicines themselves for their patients. Today, only a handful of practitioners follow this practice and production and sale of Ayurvedic drugs has become formalized into a thriving industry. Manufacture and marketing of Ayurvedic drugs is covered by the Drugs and Cosmetics Act, 1940. Hence two categories of medicines labeled as "Ayurvedic" are available in the market: classical Ayurvedic formulations and patent and proprietary formulations. Moreover, with increased use of drugs of these systems, the chance for adulteration, preparation of counterfeit drugs and development of formulations which do not have conceptual basis in these systems has increased. Further cultivation of medicinal plants with laboratory generated species is being attempted on the basis of chemical composition and is likely to be used in increased manner for commercial purpose. These changes may have profound impact on the safety and efficacy of the ASU drugs in the market. In short Pharmacovigilance in Ayurveda is needed -

- To ensure safety of drugs, so as to minimize adverse effects, if any.
- To maintain efficacy of drug, so as to provide maximum benefit to the patient.

Application of Prakruti Sama Samaveta and Vikruti Visham Samveta in Pharmacovigilance:

National Pharmacovigilance Program (NPP) encouraged reporting of all suspected ADRs, but number of reports related to Ayurvedic / herbal drugs is abnormally low. Concepts & terminologies related to ADR monitoring are not covered in the Ayurvedic curriculum. Methods to study drug safety problems have not evolved adequately in Ayurveda. Information related to medicines is in the form of shlokas in the texts, it is not easily available to the general public. Signal detection is difficult because of the inherent belief that Ayurvedic medicines are safe. Patients often use medicines from different systems of medicine concomitantly - difficulty in assigning causality. There is lack of quality assurance and control in the manufacture of Ayurvedic medicine.

Most Ayurvedic formulations are multi-ingredient. We should strengthen the basic idea which has led us to think and discuss this issue. The clinicians of Ayurveda should be given training regarding close monitoring of all drug prescriptions. For adequate knowledge of Pharmacovigilance in Ayurveda the physician must go through application of basic principle like Prakruti Sama Samaveta and Vikruti Visham Samaveta. According to Vikruti Vishama Samaveta concept, the interaction between Rasas in a Dravya or Doshas in a Vyadhi results in an effect which is totally new and not similar to the individual Rasa and Dosha respectively. Therefore this new and unpredicted effect cannot be inferred from the cause. Eg: Brihat Panchamulas Ushna Virya even though it has Kashaya, Tikta Rasa. Hence by understanding and analysing the future effect of combine medicine the physician will be able to

conquer Adverse Drug Reaction of that particular medicine. Also prescription of Ayurveda drugs along with modern drugs should be avoided so that the effect of drugs on the human body can be analysed.

Conclusion:

Prakruti Sama Samaveta and Vikruti Vishama Samaveta are such principles which form the framework of Ayurveda which has been used in Ayurveda with a modification so as to suit the purpose of treatment. These two concepts form the base of diagnostic– treatment principle in Ayurveda. So understanding of perverted combination of Rasas and Doshas, Need for ascertaining the total effect is very important. Using the above basic principle the physician can avoid Adverse Drug Reaction of combine medicine.

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