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CRITICAL REVIEW OF MALAHARA- A TOPICAL DOSAGE FORM

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ABSTRACT

Very wide range of topical formulations are described in texts of Ayurveda. Malahara Kalpana is one of them. Malahara Kalpana is very convenient form of topical application. Tracing its historical evolution, it is revealed that Rasatarangini (2000 A.D) describes this dosage forms in detail. Malahara Kalpana is modified dosage form of other topical dosage forms like lepa, upanaha etc. Evolution of Malahara as dosage form from other primitive topical dosage forms is needed to be elaborated. Malahara has advantage over other topical dosage in terms of shelf life and applicability. Evolution of Malahara Kalpana with Pharmaceutical preparation methods, Standardization parameters, probable pharmacokinetics and pharmacodynamics is tried to elaborate through this review article.

KEYWORDS: Topical formulations from Ayurveda, Malahara Kalpana, Ointments, Standardization and mode of action of Malahara.

INTRODUCTION

Ayurveda, the ancient science of medicine has very wide range of topical formulations. Abhyanga, Lepa, Pralepa, Upanaha etc. are few examples of topical dosage forms described in the classical texts. Among above dosage forms ‘Malahara’ is one type of topical dosage form described in the later texts of Ayurveda.

The term ‘Malahara’ is being used by the text Yogaratnakara for the first time. Before that, term ‘Abhyanjana’ was used in classical texts for semi solid topical formulations. In the twentieth century, a Rasashastra treatise viz. Rasatarangini enumerated number of Malahara.

This dosage form is developed from its primitive dosage forms so as to improve its efficacy, application and shelf life.

Ointments, creams, gels & pastes can be correlated with Malahara by their mode of application and semi-solid consistency. Modifications were done in these topical dosage forms considering current lifestyle.

AIM: To review Malahara Kalpana critically.

OBJECTIVES

1. To study conceptual foundation of Malahara Kalpana.
2. To explore standardization parameters of Malahara Kalpana.
3. To propose probable pharmacokinetics of Malahara by Ayurvedic perspective.
4. To correlate Malahara Kalpana with the modern semi solid dosage forms.

MATERIALS AND METHODS

Classical Ayurvedic literature, modern pharmaceutics texts, journals and internet articles were searched for Malahara Kalpana. Compilation of information is done which is further processed.

Method

Compilation of relevant references→Scrutiny and classification of information→Categorical description→Discussion based on above points→relevant conclusion.

1. Definition of Malahara

Term 'Malahara' is derived from an Arabic word 'Maraham'.[1] While it is defined as,

मलं हरति इति मलहरः|

A formulation which cleanses the feculence or debris from site of action is called as Malahara.[1]

While modern pharmaceutics define parallel semi solid dosage forms on the basis of consistency as follows,

Ointments - Ointments are homogeneous, translucent, viscous, semisolid preparation intended for external application to skin or mucus membrane.

Creams - Creams are homogeneous, semisolid preparations consisting of opaque emulsion systems. Their consistency and rheological properties depend on the type of emulsion either water-in-oil (W/O) or Oil-in- Water (O/W) and on the nature of solids in the internal phase.

Gel - Gels are usually homogeneous, clear, semisolid preparations consisting of a liquid phase within a three dimensional polymeric matrix with physical or sometimes chemical cross linkage by means of suitable gelling agent.

Pastes - Pastes are stiffer preparations than ointment and contain a high proportion of powder dispersed in the fatty basis.[2]

2. Synonyms[1]

Sanskrit: Malahara	Gujarati: Malam
Latin: Unguentum	Marathi: Malam
English: Ointment	Arab: Maraham
Hindi: Malahara	Unani:Malaham

3. History and Development of Malahara

a) Vedic Period**:** The term Malahara is not used but the clear references in Vedas regarding the surgical procedures done by Ashwinau, denotes application of semisolid amalgamated substances for Sandhana (Plastic surgery) of head of Yagna, fixation of Visphalas artificial limbs etc. Also, the other forms like Lepena in the management of Vrana (wound) and Vidradhi (Abcess) are also quoted in Atharvaveda, which also signify the existence of topicaldosage form during Vedic period.

b) Samhita Period**:**In this period also Malahara term is not used but, Charaka has used the terminology 'Abhyanjana'. Sahastra dhauta Ghrita, Pinda taila etc are few examples of semisolid formulations having consistency like Malahara. Similarly, Sushrut Samhita and Ashtang Sangraha classified different lepa in various forms as per their therapeutic use.

c) Middle Period**:** Sharangadhara and Bhavaprakasha described and classified Lepa with broad spectrum effects with new methods of their preparations. Yogaratnakara introduced term 'Malahara' firstly.

d) Recent Period: Rasatarangini has introduced current Malahara Kalpana into Ayurveda. Text quotes various Malahara which are formulated based on modern principles.

Table 01: Examples of Malahara with broad spectrum therapeutic application.

Sr. No	Malahara	Therapeutic Use	Reference
1	SahastraDhauta Ghrita	Jwar, Daha	Cha. Chi. 3/257
2	Lashunadya Ghrita	Unmad	Cha. Chi. 9/51
3	Palankashadi Taila	Apasmara	Cha. Chi.10/36
4	Varaha Vasa	Arsha	Cha. Chi.14/48
5	Pinda Tailam	Jwara, Daha, Arati	Cha. Chi. 29/122,123
6	Vranamruta Malahara	Vrana Upadansha	Rasatantrasara page no.433
7	Vranamuta shweta	Shuddha Vrana	Rasatantrasara page no.433
8	Gulabi Malhara	Vipadika	Rasatantrasara page no.433

Historical background reveals that, evolution in the preparation of Malahara have taken place from Vedic period to modern period. Malahara Kalpana can be correlated with ointment and it plays an important role in topical route of management of skin lesions. During Vedic period, simple paste of drugs was used for application over affected site. In Samhita period, bases like Taila, Ghrita, Madhucchistha, Sarjarasa etc. have been used. For example, in Charaka Samhita Vatarakta Chikitsa has prescribed Pinda Taila, which is to be prepared with certain drugs. It includes Sarjarasa and Madhucchishta to develop a semi-solid consistency to the finished drug.[3] Similarly, Sushruta Samhita describes siddha Ghrita containing Madhucchishta and Sarjarasa prepared for therapeutic use in Agnidagdha in Agnikarma Vidhi Adhyaya of Sutrasthana.[4] These are semi solid preparations which can be considered as the primary stages of Malahara Kalpana.

4. Composition of Malahara[1,2]

A) Aushadhi/ Medicine: Medicinal drug which is going to be administered should be in the form of Siddha Sneha (Medicated oils/ ghee), Kwatha/ Swaras (decoction/ juice), Powder (Mesh Size 120 to 150) etc.

It can be divided as follows on the basis of origin:

a) Metals and Minerals: Mercury, Arsenic, Lead, Zinc. Etc.

b) Herbal Origin: Various powders, Raisins, Seed Oils etc.

c) Animal Origin: Medicated animal fat, Harts etc.

B) Base materials: Sarjarasa, Urna Meda (Wool Fat), Siktha, Kokum butter, Hydrogenated Oils, Ghrita etc.

As per Ayurvedic perspective, base Materials can classified as follows:

Table 02: Types of Base materials as per Ayurvedic perspective.

Basis of Classification	Types of Bases with Examples
Source	1. Mineral: Vaseline, Paraffin etc. 2. Herbal: Kokum butter, Hydrogenated oils etc. 3. Animal: Bees Wax, Ghee, Butter, Wool Fat etc.
Consistency	1. Solid: Vaseline, Kokum Butter, Bees Wax etc. 2. Semi solid: Ghee, Butter, Hydrogenated Oil etc. 3. Liquid: Liquid Paraffin, Oils, Emulsions etc.
Heat Stability	1. Heat Stable: Vaseline, Kokum Butter, Bees Wax etc. 2. Heat Unstable: Butter, Ghee etc.

Base Materials from modern pharmaceutics:[2]

On the basis of their nature and chemical composition these are classified into four groups:

a) Oleaginous Bases- Ceresin, Paraffin b) Absorption Bases- Wool Alcohol, Liquid Paraffin

c) Emulsion Bases- Stearic Acid, Glycerin d) Hydrophilic Bases- Carbopol, PEGs.

Good qualities of base materials are as follows

i. It should be inert.
ii. It should be stable with change in temperature in the container.
iii. It should melt on body temperature.
iv. It should be absorbable through skin.
v. It should not cause any kind of irritation to body tissues.

Types of Malahara[1]

It can be divided into three types based on medicament used in the prepared Malahara:

1. Prepared from Medicinal Powder: Powders incorporated into base material to form Malahara.
2. Prepared from Medicated ghee and oil: Medicated oils and ghee mixed with suitable base material to achieve ointment like semisolid consistency.
3. Prepared from Volatile oils: Volatile oils were added to melted base materials then allowed to cool to form ointment.

Based on requirement of Agni it can also be divided as,

1. Agni Sadhit: Requires heat to mix medicament with base material. This kind of Malahara can be prepared by fusion process.
2. Anagni Sadhit: Does not require heat for preparation. This kind of Malahara can be prepared by triturating medicaments with base material.

Pharmaceutical preparation of Malahara[2]

In the texts of Charak Samhita, few medicated oils and ghee were explained which has semisolid consistency e.g., Pinda Taila, Shatdhauta Ghrita. Pinda Taila contains Sarjarasa (*Raisin of Shorea robusta*) and Siktha (Bees Wax) which provides semisolid consistency to the formulation. While, Shatadhauta Ghrita needs vigorous trituration in the water to form semisolid consistency. In this formulation, water in oil emulsion is formed between molecules of water and ghee.

Rasatarangini described various Malahara prepared by mixing medicament with bees wax.[6] In Rasatantrasara, Sarjarasa dissolved in oil is triturated in the solution of Tuttha and water to form semi solid, soft Malahar.[7] Wide range of pharmaceutical processes to prepare Malahara are described in various Ayurvedic texts.

Methods of preparation of Malahara can be described in two types according to modern pharmaceutics[2]

A) Trituration B) Fusion

Table 03: Pharmaceutical methods of preparation.

A) Trituration:	**B) Fusion:**
Medicaments which are to be incorporated into bases are generally insoluble in it.	Bases are needed to be melted and melting of these materials should be done with decreasing order of their melting points.
In this method Trituration slates used for this process.	Highest melting point substances should be melted firstly and then other substances with lower melting point should be added.
Shatadhauta/ Sahastra dhauta ghrita are the examples of this kind of Malahara.	Yashadamrit Malahara, Gulabi Malahara are the examples of Malahara prepared by this Malahara

7. Standardization parameters for Malahara.[8]

The book viz., General guidelines for drug development of Ayurvedic formulations describes standardization parameters as follows:

1. Description
2. Colour
3. Odour
4. Viscosity (If in the form of flowing material)
5. Rancidity test
6. Microscopy (if powdered drugs incorporated)

7. Particle size (if powdered drugs incorporated)of the ingredients
8. Total acidity
9. TLC/HPTLC/GC/GC-M S/HPLC (any one or all)
10. Assay (Wherever possible)
11. Uniformity of content
12. *pH*
13. Thermal stability
14. Total fat content
15. Loss on drying at 105^{O}C/Moisture content
16. Spreadibility
17. Test for heavy/toxic metals

Lead, Cadmium, Mercury, Arsenic

(Limits as per ASU Pharmacopoeia)

18. Pesticide residue

Organo chlorine pesticides,

Organophosphorus pesticides,

Pyrethroids. (Limits as per ASU Pharmacopoeia)

19. Microbial contamination:

Total viable aerobic count

Enterobacteriaceae

Total fungal count

(Limits as per ASU Pharmacopoeia)

20. Test for specific pathogen

Escherichia coli,

Salmonella spp.,

Staphyloccocus aureus,

Pseudomonas aeruginosa (Limits as per ASU Pharmacopoeia)

21. Aflatoxins (Limits as per ASU Pharmacopoeia)

(B1, B2, G1, G2)

22. Shelf life

8. Shelf Life (Stability) of Malahara[9]

Definition: It is defined as the extent to which a product retains within specified limits and throughout its period of storage and use (Shelf-life), the same properties and characteristics that it possessed at the time of manufacturing.

Factors that affect product stability are Temperature, Light, pH level, Humidity, Precautions during manufacturing.

Table 04: Shelf Life For Semisolids As Per I.C.H. Guidelines.

Sr.No.	Packing	Creams	Ointments
1.	Tubes	3-Months	6-Months
2.	Jars/Pots	1-Month	3-Months
3.	Diluted Commercial Preparation	2-Weeks	4-Weeks
4.	Extemporaneously Prepared in a suitable base	4-Weeks	8-weeks

Characteristics of ideal Malahara

1. It should be chemically and physically stable.
2. It should be smooth and free from grittiness.
3. It should be melt or soften at body temperature and be easily applied.
4. The base should be non-irritating and should have no therapeutics action.
5. The medicament must be finely divided and uniformly distributed throughout the base.

9. DISCUSSION

A. Pharmacokinetics of Malahara

Probable Pharmacokinetics by Ayurvedic Perspective:

Before coming to Pharmacokinetics Rachana and Kriya Sharira of the Twacha is needed to be explored as follows.

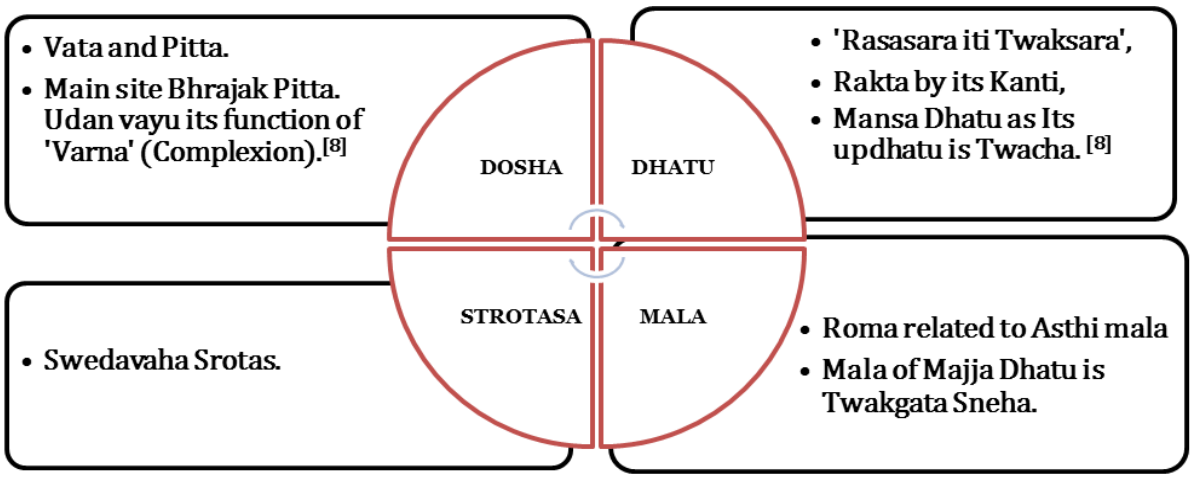

Diagram 01: Representation of Dosha, Dhatu and Mala associated with skin.

Skin Rachana and Kriya Sharira[10]

a. Skin is Dosha Sthana of Vata and Pitta. Also, Main site for Bhrajak Pitta. For complexion of skin Udan Vayu is responsible.[10]

b. Dhatu related to skin are Rasa- 'Rasasar iti Twaksara', Rakt by its Kanti, Mansa Dhatu as Its updhatu is Twacha.

c. Skin is mulasthana of Swedavaha Srotas.

d. Mala of Majja Dhatu is Twakgata Sneha.

e. Roma which are related to Asthi mala are reside on the skin.

f. Panchbhautika Sanghatana of Skin is Prithvi mahabhuta pradhan.

Seven Layers of Skin as per Sushruta Samhita[4, 11]

Table 05: layers of skin and diseases.[11]

S. No.	Skin layer	Functions	Diseases
1.	Avabhasini	Reflecting the health of the individual and maintaining health of deeper layers and of the interstitial, nutrient fluid called rasa dhatu Illuminates all shades of the skin	Pityriasis vesicular (Sidhma) and padmakantak considered as papilloma
2.	Lohita	Supporting the outer layer and indicates the quality of blood	Nonelevated mole (Tilakalaka), Naevi (Nyacha) and capillary angioma (vyanga)
3.	Shweta	Balancing the color of the skin	Charmadala, Ajagallika and mashaka
4.	Tamra	Nurturing and protecting the upper layers	Leprosy (Kushtha) and erysipelas (visarpa)
5.	Vedini	Sensation	Leprosy (Kushtha) and Vitiligo (Kilasa)
6.	Rohini	Healing and regeneration	Sebaceous cyst (Granthi), lymphadenitis (apachi), tumor (arbuda), filariasis (shlipada) and goiter (galaganda)
7.	Mansadhara	Skin to appear firm and supple	Fistula (Bhagandar), abscess (vidradhi) and Piles (arsha roga)

Skin is Vata and Pitta Sthana so due to Ruksha Guna of Vata and Ushna Guna of Pitta skin craves for the Snigdha Guna to maintain balance of dosha and hence Oleaginous or Lipophilic substances show maximum penetration through skin.

Malahara Kalpana is intended for its penetration through the skin for its therapeutic action. Even in case of Varnya Action of few Malahara, permeable base material is required which will help to balance Udan Vayu. Applied Malahara undergoes Pachana by Bhrajak Pitta.

Thereafter, Udan Vayu facilitates penetration of that Malahara from outer surface of the skin to the Sira.

For understanding of systemic absorption through skin, rachana sharir from sushruta is needed to be explored. Sushruta described Tiryakgami Sira are four in number and further divided into small branches, these small branches of Sira are beneath the skin. Essential elements from Abyanga, Parisheka, Avagaha, Lepan after metabolized by Bhrajaka Pitta are transported from applied site to the desired organ system by these branches of Tiryakgami Sira.

In Sushrut samhita seven layers of skin are explained where layer wise diseases of skin are explained. Considering this, topical dosage forms can be designed as per duration of preparation, mode of application and absorption time.

B. Applicability (Broad Spectrum advantages of Malahara)[5]

1. It is very convenient form of topical application.
2. Vast scope for its therapeutic action.
3. It provides a medium for topical drug delivery and bypasses other systems for absorption for its therapeutic action.
4. Malahara delivers drug exactly at the desired site with minimal risk of hypersensitivity and other such complications when prepared with proper precautions.
5. It is used not only in the skin diseases but also for cardiovascular and psychiatric disorders.

CONCLUSION

1. Topical dosage forms undergone evolution to evolve as Malahara.
2. Malahara has improved shelf life which eases availability and applicability.
3. Malahara should be prepared and standardized as per general drug development guidelines by CCRAS.
4. Malahara is having wide range of therapeutic action yet simple, easier for administration and cost effective.
5. Development in the current form is still going on for sustained drug release.

REFERENCES

1. Dhamankar PV, Ayurvediya Aushadhikaran (Agama ani Pratyaksha) 2ed. Mumbai: Shri Dhootpapeshwar Ayurved Vidyalaya Samiti, 1964.
2. Leon Lachman, Herbert Lieberman, Joseph Kanig. The Theory and Practice of Industrial Pharmacy. Mumbai: Varghese Publishing House, 1990.
3. Tripathi B. Charaka Samhita. Varanasi: Chaukhamba Surbharati Prakashan, 2014; 2.
4. Shastri A. Sushruta Samhita. Varanasi: Chaukhamba Sanskrit Sansthan, 2013; 1.
5. J Poonam Bhojak Et Al: Malahara Kalpana – An Ancient and Modern Pharmaceutical Approach. International Ayurvedic Medical Journal {online} 2017 {cited April, 2017} Available from: http://www.iamj.in/posts/images/upload/1182_1189.pdf
6. Dr. Dubey Somil.Review of Malahara Kalpana of Rasa Tarangani. J Ayurveda Integr Med Sci., 2019; 2: 79-84. http://dx.doi.org/10.21760/jaims.4.215
7. Anonymous. Rasatantrasaar & Siddhaprayog Sangraha. 22nd ed. Kaleda (Rajasthan): Krishna Gopal Ayurved Bhavan (D.T.), 2013.
8. https://www.ayush.gov.in/docs/guideline-drug-development.pdf Ministry of AYUSH: Delhi.
9. R A Lowe. Storage, Stability and in use Shelf life guidelines for non-sterile medicines: London; NHS, 2001.
10. Tripathi B. Charaka Samhita. Varanasi: Chaukhamba Surbharati Prakashan, 2012; 1.
11. Balkrishna A, Telles S, Gupta RK. The Anatomy of the skin: Concepts from Ayurveda and computational modelling. Indian Journal of Clinical Anatomy and Physiology, January-March, 2018; 5(1): 150-153.