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Review Article

# Concept of Materiovigilance in Ayurveda

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## ABSTRACT

*Incidents or any undesirable events occurring due to medical devices are being reported under Materiovigilance programme. Though concept of Materiovigilance are vibrant in various classical texts of Ayurveda, the ancient medical science, but a single hand information in this regard is lacking till date. Present paper deals with available evidence of use of various types of medical devices and view of ancient Ayurveda scholars about their safe uses.*

*Ayurveda Samhita records sample number of description about the safe use of medical devices in various context. Varieties of Shastra (Instruments), Anushastras (Devices used for para-surgical process) and Yantra (Equipments) etc. being used as medical devices in surgical, para-surgical, Panchakarma procedures. Some of the instruments and equipment are also reported for their use in daily regime as a Bhajana (container) and in the preparation of herbomineral drugs. Specific materials to be used for the preparation of these devises along with their specific measurements have also been recorded. Possible effects of container on the content were well versed to the ancient experts of Ayurveda and are well reflected with various textual references. Only need is awareness of its proper use and reporting of undesirable incidence to avoid any harm or loss in future and for the betterment of the system.*

***Key words:*** *Anushastra, Yantra, Shastra, Medical device, Safety*

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## INTRODUCTION

In a healthcare system, medical devices have an important role in the diagnosis, prevention, and treatment of different diseases. The se of medical devices can be well traced in any system of medicines, irrespective of its origin. In the recent health care delivery system, the role of medical devices has significantly increased due to many scientific innovations. These medical devices range from simple low cost ice bags and tongue depressors on one end of the continuum and very sophisticated high cost items such as cardiac pacemakers, magnetic resonance imaging machines and proton therapy devices on the other end. The World Health Organization has defined medical device as any "instrument, apparatus, implement, machine, appliance, implant, reagents for *in vitro* use, software, material or another similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life, control of conception, disinfection of medical devices providing information by means of *in vitro* examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the

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human body, but which may be assisted in its intended function by such means."[1]

Based on the function of the medical devices, it may be broadly classified as preventive care, assistive care, diagnostic and therapeutic device. These devices are now becoming an integral part of the health care systems and benefit the patients immensely. Besides their multiple usages, they also carry significant potential risks and there are unique challenges like safety concerns and diversity of products coupled with the sheer number of different devices in the market. Recently, defect detected in the devices or significant morbidity and mortality caused by the devices in the users are the major reasons to recollect it.[2-4]

Therefore, close monitoring of any undesirable performance or characteristic fluctuations of a medical device is highly essential for any health care system. For this purpose, a new system known as "Materiovigilance" has been evolved which is defined as the coordinated system of identification, collection, reporting, and analysis of any untoward occurrences associated with the use of medical devices and protection of patient's health by preventing its recurrences.[5]

In India, at present provisions related to import, manufacture, distribution and sale of only notified medical devices are covered under the Drugs and Cosmetics Act 1940 and Drugs and Cosmetics Rules,1945.

- Substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i);
- Substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii); and devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940;

Medical devises under the Medical Devices Rules, 2017 are classified as per Global harmony Task Force (GHTF) based on associated risk.[6]

1. Class A (low risk)
2. Class B (Low moderate risk)
3. Class C(moderate high risk)
4. Class D(high risk)

In India, among the traditional system of medicines, Ayurveda is considered to be the most practicing system of medicines with maximum number of registered practitioners, educational institutions, and hospitals. It has its own fundamental principles and is manly divided in to eight branches since its inception. The Central Council of Indian Medicine is imparting teaching in Ayurveda in 14 different specialities including surgery and procedural therapy namely *Panchakarma*. In other clinical practice too Ayurveda recommends the use of various devices.

Uses of surgical instruments and equipment have been extensively described in various classical texts of Ayurveda. Acharya Sushruta, the father of surgery, has enormously described the specification of the instruments and equipments used in various surgical procedures for different disease conditions which were further subdivided into different branches of Ayurveda like *Shalyatantra*(Surgery), *Shalakyatantra* (Eye and ENT), *Striroga and Prasutitantra* (Gynaecology and obstetrician) and *Kaumarbhritya* (Paediatrics). Other than these clinical branches, use of equipments, instruments, and apparatus are described expansively in *Panchakarma* (five procedural therapy of detoxification of body) and *Rasashastra* (branch of Ayurveda, that deals with the preparation of herbomineral medicines-Vedic Alchemy). Along with this, the use of specific material and metal is depicted for storage and preparation of specific food and medicines intended for the prevention of the diseases and wholesome effects of food.

Though direct references regarding Materiovigilance are not available in Ayurveda, one can interpret the data as evidence of Materiovigilance in many places. Medical devices used in the Ayurveda are described with its measurement, metal to be used, instructions and contraindications if any, for its appropriate use and safety. Present paper deals with available evidence of the use of various types of medical devices and aspects of Acharya for its use from various surgical branches/specialities of the Ayurveda i.e. *Shalyatantra* (Surgery), *Shalakyatantra* (Eye and ENT), *Striroga & Prasutitantra* (Gynaecology and obstetrician) and *Kaumarbhritya* (Paediatrics), instruments and equipment mentioned in the *Panchakarma*, for daily regime, and *Rasashatra* (Indian alchemy).

## OBSERVATIONAL REVIEW

In Ayurveda Medical devices are categorized as *Shastra* (Instruments), *Anu-Shastras* (devices used for para-surgical process), *Yantra* (Equipments) used in the preparation of herbomineral drugs, daily regime and *Panchakarma* procedures, and *Bhajana*(container).

**Medical devices used indaily regime:**

Selected metals such as *Swarna* (Gold), *Rajata*(Silver), *Tamra*(Copper), *Loha*(Iron), *Vanga* (Tin)are suggested for preparation of *Jihva Nirlekhana* (Tongue Scrappers) to be used in daily regime of oral hygiene.[8]

**Medical devices used in procedural therapy of *Panchakarma*:**

It has been emphasized for use of specific materials for preparation of *Yantra*(instruments/equipments) to be used for various *Panchakarma* procedures. (Table No.1)

Along with the specification of materials of instrument/equipment; detailing of measurement and shape is also well described in the classical textbooks. As per the textual references, urinary bladder of an animal or artificial *Bastiputaka* prepared from a thin skin of aquatic bird/goat or a wax coated cotton bag may be used as *Bastiputaka* for administration of the *Bastidravya*. *Bastinetra* is a tubular structure usually made up of brass, having a tapering end and a wider base, which resembles cow's tail. It has three rings on external surface called as *Karnika* (ridges), the last two at the bottom are used to fix the *Bastiputaka* with *Netra*. The length of *Bastinetra* is to be customised as per the age of the patient.

**Table No. 1: Showing textual references for the use of specific materials for preparation of instruments/equipments.**

| S.N | Devises | English term | Use of specific metals | References |
|---|---|---|---|---|
| 1. | *Anjanshalaka* | Collyrium rods | *Swarna, Rajata, Tamra, Loha* | *Sushrut Samhita Uttartantra* 18/62-63 |
| 2. | *Basti Netra Karnika Dravya* | Nozzle of enema pot | *Swarna, Rajata, Tamra, Loha, Riti* | *Charak Samhita Siddhisthana*3/7 |
| 3. | *Basti Netra* | The materials of enema tube | *Swarna, Rajata, Tamra, Kansya, Bamboo,* ivory, reed, hornor crystal | *Charak Samhita/Siddhisthana* 3/7 |
| 4. | *Uttarbastinetra* | vaginal douche catheter | *Swarna, Rajata* | *Charak Samhita Chikitsasthana* 30/6 |

The Materiovigilance concerns of these equipments are well explained with specific technical terms noted as *Bastinetradosha* (improper medical device) and *Bastidosha* (improper way of administration).[9,10] Like the *Bastinetra,* size of *Uttarbastinetra* (vaginal douche catheter) is also well explained in the textbooks.[11]

***Jaluka* (leech) as medical device**:

Bloodletting is one of the important procedures described for the treatment of *Raktaja Roga* (diseases caused by or affecting the tissues of blood). *Pracchana* (scrapping or scarification) and *Siravedha*(vein puncture)[12,13] are the two methods for bloodletting. *Shringa Avacharana* (wet cupping) and *Alabu Avacharana* (wet fire cupping) are also recommended as alternative methods. *Jalauka Avacharana* (medical leech therapy), considered as a surgical procedure is advised for the delicate patients, and its contraindications are also noted.[14,15] To avoid undesirable side effects it has been advocated to have selection of good quality of leech before application. On the basis of their breeding grounds, leeches are classified as *Savisha* (unfit for therapeutic purposes- poisonous nature) and *Nirvisha* (fit for therapeutic purposes- non-poisonous nature). Details of the fresh water *Jalauka* preservation, the pots to be used and feed etc. have been meticulously described in ancient text.[16]

**Medical Devices used in clinical management:**

There are different types of surgical procedures described in Ayurveda for which sharp instruments/equipments are recommended called as *Shastra.* Detailing of various types of *Shastra* are well explained in the Ayurveda along with their *Guna* (Properties) and *Dosha* (undesirable properties)[17]and advised to procure these instruments/equipments made up of hard iron (steel), prepared by skilled person.[18] This reflects the keen observations of the Acharya (expert) for selection of material and particularity for their preparation. Scissors made by *Swarna*(Gold), *Rajata*(Silver), *Tamra* (Copper), and *Loha* (Iron) are advised to be used for *Nabhi Kartana* (cutting umbilical cord),[19] whereas *Rajata, Tamra, Loha, Naga* (Lead), *Vanga* (Tin) are the metals used for rods of cauterization (*Shalaka Dahanopakaraṇa*). *Teekshna Soochi Shastra* (Sharp instruments) are advised to be used in labour room, for other purposes.[20]

**Devices used in culinary**

There are seventy-two references about the use of containers (of different materials that may alter the action of drug) for food and drug preparation and possible complications of its inappropriate use are also enumerated.

To bring about change in quality of *Ahara* (Food) or *Ausadhidravya* (Drug), Ayurveda recommends a process called as *Samskara*. Use of different containers / utensils (*Bhajana*) is one of such *Samskara*, intended to store, to serve and to prepare, specific food items or drug. These containers are also used for keeping the medicines required during operative or other procedural treatments. Uses of golden and silver containers have been recommended to enhance the quality of items. Specific use of iron vessel for the storage of *Rasayana Dravyas,*[21] suggesting the effect of *Bhajana* (Container) on its content i.e. food or drug or water. References of different containers reported for different food items are enlisted in table no.2

**Table No.2: Showing list of food items to be stored in specific container**

| S.N | Container | Food Item |
|---|---|---|
| 1. | *Tamrapatra*(Copper vessel), *Mruttika* (Mud vessel ) | Drinking water |
| 2. | *Krushnalouhapatra*(Black iron vessel), | *Ghrita*(Ghee) |
| 3. | *Rajatapatra*(Silver vessel) | *Peyapadartha*(drinks) mutton, boiled vegetables, pickles |
| 4. | *Kadali Patra* (Leaves of banana). | *Phala & Bhakshya* |
| 5. | *MrittikaPatra* (mud pots) | *Madya & Panaka* (alcoholic beverages) |
| 6. | *Vaidurya Patra* (Vessels made of precious stones) | *Ragashadava & Sattaka* (mostly sour preparations) |
| 7. | *Suvarna Patra* (Gold vessels) | Milk, Drinking water, syrup of boiled rice |
| 8. | *Kansya Patra* (Bronze vessels) | *Khala* (buttermilk boiled with sour substances, spices) |
| | | *Khatwara* (pungent , sour substances for licking) |
| | | *Kamblika*(Sour milk mixed whey) |

Similarly, there are also numerous references restricting the use of some specific materials for the storage of certain food and drugs like *Tamra* (copper vessel) for curd, metal vessels for pickles etc. Juice of *Drakshamla* (Grape wine) kept in brass or copper is incompatible,[22] *Ghee* kept in bronze vessel for more than ten days is toxic.[23]

**Devices used in *Rasashastra***:

*Yantras* are the apparatus used for the *Shodhana* (Purification), *Marana* (Incineration), *Swedana* (Steaming) etc. purposes of *Rasa* (Mercury), *Uparasa, Lohadi* (Minerals and Metals).[24,25] There are different categories of *Yantra*, like *Damaru Yantra, Kachapa Yantra* based on their shapes; *Swedani Yantra, Jarana Yantra* based on their functions; and *Lavana Yantra, Valuka Yantra* etc. are based on the material used.[26]Approximately there are 36 *Yantras* described in the various texts of *Rasashatra*, with specification of its measurement and material to be used. Iron is used for the making of *Ulukhala Yantra* used for the pounding process, and *Palika Yantra* which is used for *Gandhak Jarana* and extraction of oil.

During various *Samskaras* (processing) or hrebo-mineral preparations, the minerals and metals are proposed for heating where some metals require intense heating, according the requirement, crucible of specific shape and materials are designed. To sustain the heat and eliminate impurities, special designed "*Musha*" is described in the Ayurveda which help to takes away the *Dosha* from Rasa *Dravya*, avoid spilling of the content. Different varieties of *Musha* based on their shape, material used and purpose are depicted the classical textbooks[27]The basic materials used to make these *Mushas* were *Dagdhatusha* (ash of husks of grains), filamentous integuments of certain plants, ash powder, horse dung, *Lohakitta* (a type of Iron rust), black soil, wood ash etc. in different proportions.

Even the heating appliances and procedures in which amount of fuel are specified for qualitative and quantitative measures of heating to beget the quality end product is explained well. Eg: *Mahaputa, Gajaputa,Varaha Puta, Kukkuta Puta, Kapotha Puta*
Thus it can be inferred that, ancient Ayurveda scholars were well versed about the interaction between instruments/equipment and medicine. Therefore specific materials of equipment were recommended for specific metallic preparation, along with its present measurement to ensure the safety of products and manufacturer.

## DISCUSSION

Materiovigilance program is meant to analyze, scrutinize, and prevent the recurrence of harmful effects that occurs due to use of medical devices. After the start of the Materiovigilance programme in July 2015, more than 1931 medical device adverse events are received by the Indian Pharmacopoeia.[28] Increased awareness and user-friendly reporting of the adverse events increased the number of reported cases.
Finding of the present review of the classical literature of Ayurveda concerning the safe use of medical devices, specification of their measurements and material to be used signifies the vigilance concern of the authors of various ancient Ayurvedic texts. These classical instructions about measurement of the instruments, equipment and selection of specific metals and minerals enabled Ayurvedic physicians to improve the quality of medical devices and ensure the safety of users and patients. It is observed that many of the surgical instruments available in present era are made according to the description made in Sushruta Samhita dignified the ancient knowledge. With the advancement in science, many modifications are also being carried out in the field of medical devices and their materials, as per the availability and feasibility. Disposable and reusable kit needs proper monitoring, whereas reusable *Shalaka* (probe) and surgical instrument need proper sterilization before reuse.
With the advancement, equipment and instruments used for *Panchakarma* procedure are also modified by using sophisticated materials. Multipurpose massage table, adjustable *Snehana* table, oil heating machine, cups and rings for *Kati* and *Janu Basti*, automatic *Shirodhara* machine etc. are available which are having many benefits[29] These modified and customised equipments are available in the market for sale without proper certification of authorised body. Nowadays, *Basti* administration is often done using enema-can or douche-set, but it was reported that the classical method of preparation of devices is proven better as compared to the novel method,[30] as fundamental concept of active homogenous pressure is fulfilled by traditional method only. Therefore, specifications of equipments mentioned in the classical textbooks and fundamental concept behind that need to be noticed while upgrading the medical devices in present era.
Leech therapy is also needed to be monitored properly to avoid any undesirable effects. Various toxic symptoms due to therapeutic use or accidental bite of poisonous one along with their management have been well noted in the classical texts of Ayurveda.[31] Food and Drug Administration (FDA) on June 21, 2004, certified the medicinal leech (*H.medicinalis*) as a medical device.[32] *Jalauka* (leech) used for *Raktamokshana* (bloodletting) can be reused only after proper cleaning of the non-poisonous species. Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other sharp object used for bloodletting should be disposable or properly sterilize.
Considering patient safety at utmost priority Materiovigilance should be adopted in Ayurveda. Complications reported during bloodletting (*Raktamokshana),* and *Panchakarma* procedures like burning during *Swedana* or *Snehana* due to faulty devices or improper handling, ADR reported due to defective instrument like defective enema pot, unsterilized, unhygienic equipment, need to scrutinize and report. *Agnikarma* (Cauterization) to be practised with utmost care by selecting proper instruments. Recent development of various instruments for the measurement of *Nadi* (pulse) also needs to be well monitored and standardized. Instruments used in the manufacturing units also require periodic inspection to ensure its hygiene, maintenance, and safety of users. Likewise, there is a need to explore the effect of different container on storage of food in terms of its safety to avoid ominous effects of unhealthy packaging material like plastic, aluminium, lead, Teflon and evaluate the reported classical references.[33]

## CONCLUSION

Materiovigilance Programme of India launched by Drug Controller General of India is an effort to ensure safety of medical devices. Review of the classical Ayurvedic books also revealed about a well-documented concept about safe use of medical devices in the these ancient texts. So, to ensure the safety of users and patient, there is requirement of adequate knowledge of documented references, availability of trained staff in handling instruments, proper training of health-care professionals in terms of device safety, alertness and attentive for the fundamental concept of its traditional purpose. Ayurveda science is welcoming the upgradation of many of these traditional devices. An awareness about the Materiovigilance among the Ayurvedic practitioners for reporting of undesirable incidence is need of the time. This may lead to avoid any harm or loss in future and help for providing quality and safe treatment to the society.

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