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## Review Article

## Ancient wisdom of ayurveda vis-à-vis contemporary aspect of materiovigilance

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## ABSTRACT

Materiovigilance is regulatory system to study and follow incidents that might result from using medical devices. To trail the occurrence of untoward effects associated with medical devices as well as to document and prevent their recurrence; the Indian Pharmacopoeia Commission initiated Materiovigilance program in India (MvPI) in 2015. Classical texts of Ayurveda include substantial description of devices intended for various therapeutic purposes such as *Panchakarm* (penta-bio purification procedures), Surgeries and for management of gynecological conditions etc. The implemented program of Materiovigilance does not include Ayurveda devices and thus there is need for documentation, systematic classification of Ayurveda devices and development of Ayurveda Materiovigilance (AMv).

In this review, relevant information from classical texts of Ayurveda, latest published information related to Materiovigilance and information of medical devices from classical texts of Ayurveda has been scrutinized along with systematic correlation and applied interpretation of the collected data. It is observed that Materiovigilance has been well documented in Ayurveda in context of twenty six surgical and diagnostic devices; eleven mostly utilized pharmaceutical instruments five *Panchakarma* instruments and five home devices. For regulation of quality of Ayurveda medical devices, their manufacturing, standard utilization, reporting and prevention of medical device associated errors; it is the need of hour to create and implement regulation in the form of AMv. The Ayurveda literature highlights that the ancient seers of Ayurveda were well aware regarding Materiovigilance in their own way. However in view of modern era and mainstreaming of Ayurveda heritage, critical revision, updating, systematically categorization of Ayurveda devices, development and implementation of AMv regulation is the need of hour.

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## 1. Introduction

A matter from which something can be created is known as material [1]. Various types of materials are an integral part of human civilization since human understood the use of stones for making crafts. The curious human mind has continued exploring different materials for creating different kinds of instruments based

on their intellect and thereby fulfilling requirements, from hunting to personal and social needs till current scenario of industrialization and advanced technologies. Subsequently, with rapidly increasing use, along with utilities and advantages, the drawbacks or harmful effects of these materials were noticed. Such drawbacks or harmful effects can be divided into two categories, one related to material itself (harmful effects of the material) and other related to improper use (incorrect and/or unskilled use). The harmful effects under the first category mostly occur when an inorganic material reaches the internal system in human body. For example the harmful effects observed due to the use of Lead metal for colouring

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toys and Lead poisoning [2]. On the other hand the drawbacks due to second category occur due to inappropriate use of instruments/equipment prepared from specific materials. These issues has brought attention of medical community and resulted in implementation of related regulations such as Medical Device Reporting (MDR) by United States of America. In India, the Medical Devices Rule (MDR) was introduced in 2017. As per this rule all the medical devices used in disease diagnosis, prevention, and treatment etc. and In vitro diagnostic kits are regulated currently under the Ministry of Health and Family Welfare, Government of India, and the Indian Pharmacopoeia Commission (IPC) has also initiated a program "Materiovigilance" in 2015 [3].

Materiovigilance specifically related to medical devices and the overall view may represent its beginning in middle of last decade; however the ancient seers of Ayurveda were considerably aware of both the aforementioned harmful effects and drawbacks. They set down the basis of Materiovigilance in Indian System of medicine (ISM) i.e. Ayurveda, Siddha, Unani and Yoga; Naturopathy and Homoeopathy. The end period of writing classical text of ISM is considered till 4th century AD and there is vast difference in technological development of ISM of that period with the current time. Therefore the ISM concepts such as Materiovigilance, which were well understood during that period, are now in need for up gradation with respect to the current classification system. In other words, the latest approaches towards categorization and systematization of information has created a need to update the classical information in a way which fits in this scientific era. In India, the increasing use of medical devices has highlighted the gaps regarding precision in monitoring of adverse events associated with medical device [4]. The IPC, which is designated as National Coordination Centre - Materiovigilance Programme in India (MvPI) has created a draft on Materiovigilance [5], however there is no such documentation where the Ayurveda aspects of Materiovigilance are systematically categorized in comparison to Materiovigilance draft of MvPI. In the view of rules and regulations imposed on modern medical device manufacturers, the Ayurveda device manufacturers do not have any specific regulations. The lacuna's such as systematic classification of Ayurveda devices in view of MvPI, information of their utility, highlighting the need of inclusion of pharmaceutical devices, home devices and increasing awareness regarding AMv, inspired for attempting the current work on ancient wisdom of Ayurveda vis-à-vis contemporary aspect of Materiovigilance which may further exercised in developing Ayurveda Materiovigilance (AMv).

This narrative review is based on the classical texts of Ayurveda, latest published information related to Materiovigilance along with critical co-relational interpretation of both and summarizing them systematically in similar way to the draft of MvPI. Information from Ayurveda classical texts such as *Charaka Samhita*, *Sushruta Samhita*, *Ashtanga Sangraha* was scrutinized for the data collection as well as to verify the information narrated in related publications. Addition of instruments related references from classical texts has been intentionally avoided as such details are already available [6–8]. In Ayurveda, other than surgical devices; the devices used for body purification procedures, drug manufacturing as well as home utensils are also narrated to have specific effect on human body. Therefore, all these devices may be included in AMv. The categorization in comparison to MvPI was done based on similarity of devices as well as intended utilities of respective devices.

## 2. Correlational aspects

Like other countries, medical devices under the MvPI are divided into four categories viz. Class A (Low risk), Class B (Low moderate risk), Class C (Moderate high risk) and Class D (High risk)

based on purposes such as non-invasive, invasive, short term use and long term use (Table 1) [9]. These categories include surgical as well several as pharmaceutical materials. However, along with these categories the two additional categories such as devices used in *Panchakarma* (penta-bio purification measures) and home hold devices can be included in AMv. Twenty six surgical and diagnostic devices from *Sushruta Samhita* (excluding count of subtypes) (Table 2), 11 mostly utilized pharmaceutical instruments (Table 3), five *Panchakarma* instruments (Table 4) and 5 home devices (Table 5) can be included under AMv. The number of devices under category A, B, C and D are 21, 17, 08 and 01 respectively. It is also noted that AMv takes account of proper, specific manufacturing of devices/instruments, their sterilization and sufficient training to use them (8. Su Ch. 5/3) [10].

There are strong documented proofs of Materiovigilance in ISM such the Surgical instruments narrated by Sushruta, description related to health effect of metallic devices used for pharmaceutical purposes and utensils at home [11]. Almost all surgical devices narrated in *Sushruta Samhita* are currently utilized in modern surgery in more or less sophisticatedly developed form. This observation can be a base for inclusion of AMv under MvPI. It is observed that the ancient seers of ISM has emphasized on quality of instruments as well as quality and training of the physician to handle the instruments. This fact simply implies the need of inclusion of training to the concerned physicians who are intended to use the medical devices. The existing systems MvPI are developed for synthetic medical devices and medicines and require some modifications to address specific differences for ISM [11].

## 3. Discussion

The vigilance system is a regulation to access information regarding the use of medical devices or medical products as well as to assure patients safety in order to increase health benefits. Pharmacovigilance (PV) is a well-known system for reporting, management and control of adverse drug reactions due to consumption of medicines. It has been successfully implemented in Ayurveda since 29 September 2008 [12]. On the other hand, Materiovigilance is related to only medical devices or the devices which are used for diagnosis, prevention, monitoring and treatment of diseases. Like PV, implementation of Materiovigilance in Ayurveda has not been initiated as the ancient instruments now manufactured in modified forms and now must come under the Materiovigilance regulation. Since, there is no such claim/clarification observed in MvPI draft, it leaves a gap which results in uncontrolled manufacturing and non-recording of data related to quality and use of Ayurveda medical devices being used in Ayurveda.

During ancient time, the medical devices belonged to ISM were not as sophisticated as those similar devices available today. However, the ancient seers of Ayurveda were well aware regarding the drawbacks and harmful effects caused by medical devices if expected qualities, parameters and precautions are not followed during device manufacturing, processing of medicines and their use in therapeutics. This perspective of AMv is discussed more clearly under the following headings.

### 3.1. Choice of metal

For manufacturing of medical devices, the commonly used metals and alloys are stainless steel, cobalt-chrome alloy, titanium, nickel-titanium alloy (nitinol), gold, platinum, silver, iridium, tantalum, and tungsten [13]. The choice of metal in modern aspect is based on stability, non-reactivity in acidic and basic mediums; degradation resistance, durability, dissolution resistance when in

**Table 1**  
Summarized categories of surgical devices as per MvPI.

| Category                     | Criteria for categorization of medical devices based on purpose  |   |   |  |
|------------------------------|--|---|---|--|
|                              | Non-Invasive   | Invasive  | Short term use  | Long term use  |
| Class A (Low risk)           | Medical device which comes into contact with injured skin, which is intended to be used as a mechanical barrier, for compression or for absorption of exudates only, for wounds which have not breached the dermis and can heal by primary intention.        | It is intended for transient use; and it is not intended to be connected to an active medical device; or it is intended to be connected to a Class A medical device only  | It is intended for use in an oral cavity as far as the pharynx or in an ear canal up to the ear drum or in a nasal cavity; and it is not liable to be absorbed by the mucous membrane | –  |
| Class B (Low moderate risk)  | Medical device which comes into contact with injured skin, which is intended to be used principally with wounds which have breached the dermis, or is principally intended for the management of the microenvironment of a wound                             | It is intended for use on the external surface of an eyeball; or it is liable to be absorbed by the mucous membrane.  | It is intended for short term use; and it is not intended to be connected to an active medical device; or it is intended to be connected to a Class A medical device only             | It is intended for use in oral cavity as far as the pharynx or in an ear canal up to the ear drum or in a nasal cavity; and it is not liable to be absorbed by the mucous membrane |
| Class C (Moderate high risk) | Medical device which comes into contact with injured skin, which is intended to be used principally with wounds which have breached the dermis and cannot heal by primary intention  | If it is intended to have a biological effect or to be wholly or mainly absorbed by the human body, if it is intended for the administration of any medicinal product by means of a delivery system and such administration is done in a manner that is potentially hazardous | –   | It is intended for long term use and, not intended to be connected to an active medical device or it is to be connected to a Class A medical device only                           |
| Class D (High risk)          | If it is intended to be used specifically in direct contact with the central nervous system or for the diagnosis, monitoring or correction of a defect of the heart or of the central circulatory system through direct contact with these parts of the body |   |   |  |

contact with human body, hardness and specific gravity. In Ayurveda, the preference is given to devices prepared from gold followed by silver, iron (steel), copper, zinc, tin and lead [14]. The ISM literature indicates that the first four attributes were considered in Ayurveda among the aforementioned qualities to choose metal for manufacturing of medical devices [15]. However the main focus to choose a specific device prepared from specific metal to treat specific disease type is based on physiological attributes of patient (*Prakriti*) and the aggravated pathological factor (*Dosha*). This view is clearly represented in context of use of different metals for cauterization [16]. Here as per Ayurveda point of view, it can be interpreted that even precise use of a well manufactured device can also result in unsatisfactory effects or untoward effect - if the aforementioned factors are not considered. In other words, AMv emphasises on consideration of type of metal and its relation with *Dosha*.

The specification of MvPI regulations recommends that the medical devices manufacturing and utilization for intended purposes should not compromise the patients' health [17]. Ayurveda has also been dedicated for the same purpose. However Ayurveda health related approach consider almost all common major as well as minor routine of an individual life such as when to wake up, how to clean teeth's, how to batch, what and how much meal is to be taken according to digestive capacity, what should be done after meal, how to seat, how to walk etc till going to bed. Hence it can be interpreted that the view of Ayurveda is much more subtle as it emphasizes controlling health related factors at individual level in the form of guidelines such as lifestyle, daily regimen and seasonal regimen (16. Su Ch. 3/3–40) [18]. Similarly the AMv is also made subtle by including home devices (instruments and equipment) used for daily purposes such as plates for meal, vessels to store drinkable water, bath tubs, etc. Few researches have also highlighted the health benefits of home devices made from gold, silver and copper [19,20]. Some of such devices are depicted in Table 5 based in view of AMv. Home equipments are also types of devices

but considering the wide range of home devices, at least the type of metal for specific purpose can be included in Materiovigilance.

### 3.2. Device dimension and design

There are no specification details regarding device dimension and design in MDR 2017. This is because of different types of devices as well as the dependency of dimension and design based on intended use and preference by physicians. On the other hand, there is a vivid description of device dimensions and designs in Ayurveda. Such details are not included in the tables because the dimensions are narrated in ancient measurements and their standardization in view of metric measurements is still awaited. Further the size of instrument (both sharp and blunt) are sometimes out of context in this modern era and thus such devices may need re-designing for utility precision in terms of body control of present time. For example, the currently used probing device is thin at the blade as well as shank and slightly thick at the handle; however the *Shalaka* (probe) mentioned in Sushruta Samhita for *Bhagandara* (fistula in ano) is finer at the tip and gradually increasing in diameter at the end. This instrument if used as per text may increase risk of perforation and artificial opening. In other words, it can be claimed that few Ayurveda devices were primitive which need through revision for replacing them with similar more suitable modern devices. Similarly the devices which are out of context today, can also be identified and discarded to increase precision of Ayurveda surgical devices as per current need. In modern medicine, there are an estimated 2 million different kinds of medical devices on the world market, categorized into more than 7000 generic devices groups [21]. This observation indicates that there should be regulations to maintain device dimension and design as it is almost impossible to include all devices under Materiovigilance to understand and maintain record of their risk. In comparison to it, the classical guidelines for Ayurveda devices are specific and thus can be reviewed, modified and then included in AMv, which may prove

**Table 2**  
Categories of Ayurveda surgical devices.

| Sr. | Instrument subtype and total number                    |        | Category       | Use   |
|-----|--|--------|----------------|---|
|     | Sanskrit Name (Modern name)                            | Number |                |   |
| 1.  | <i>Svastika yantras</i> (Cruciform instruments)        | 24     | <b>Class A</b> | They resemble the mouths of beasts or birds. They are mainly used for extracting thorn or foreign bodies embedded in bones  |
| 2.  | <i>Sandansha yantras</i> (Dissecting forceps or tongs) | 2      | <b>Class A</b> | The <i>Sandansha yantras</i> are divided into two classes and are with or without locks. They are used for extracting foreign bodies from skin, muscles, blood vessels and ligaments  |
| 3.  | <i>Tala yantras</i> (Spoon shaped instruments)         | 2      | <b>Class A</b> | <i>Tala yantras</i> have one or two surfaces resembling the scale of a fish. They are used for extracting foreign bodies from the ear, nose or a sinus  |
| 4.  | <i>Nadi yantras</i> (Tubular instruments)              | 20     | <b>Class C</b> | Used for removing foreign bodies and inspection and treatment of disease spots of external orifices. For example, <i>Arsho yantra</i> (rectal speculum for piles), <i>Bhagandara yantra</i> (rectal speculum for fistula in ano) and <i>Yoni vranekshanam</i> (vaginal speculum)  |
| 5.  | <i>Shalaka yantras</i> (Rod like instruments)          | 20     | <b>Class B</b> | Used for different purposes having lengths and circumferences depending on the site of application. They are used for probing, retraction, separation, extracting foreign bodies from passages, wound cleaning, cauterization, removing nasal polyps. Applying collyrium and cleaning urethra   |
| 6.  | <i>Upa yantras</i> (Accessory instruments)             | 25     | <b>Class A</b> | These are rope, intertwined thread, bandages, leather straps, bark, creeper, linen cloth, round pebble, stone, hammer, palm and sole, finger, tongue, teeth, nail, mouth, hair, ring of a horse's bridle, twig of a tree, spittoon, evacuating, exhilaration, magnetic stone, caustic, fire cautery and drugs. Mostly useful as supportive accessories during surgery |
| 7.  | <i>Mandalagra sastra</i> (Circular knife)              | –      | <b>Class B</b> | Sharp to blunt dissection, Excision and Scrapping,  |
| 8.  | <i>Karapatra</i> (Bone saw)                            | –      | <b>Class C</b> | Used to cut or remove bones, to provide accurate, measurable cuts, e.g. in knee surgery   |
| 9.  | <i>Vrdhipatra</i> (Scalpel)                            | –      | <b>Class B</b> | Used for surgery, anatomical dissection, podiatry etc. Scalpels may be single-use disposable or re-useable.   |
| 10. | <i>Nakha sastra</i> (Nail parer)                       | –      | <b>Class A</b> | Paring the fingernails or toenails  |
| 11. | <i>Mudrika</i> (Ring knife)                            | –      | <b>Class B</b> | Sharp to blunt dissection, Excision and Scrapping,  |
| 12. | <i>Utpala patra</i> (Lancet)                           | –      | <b>Class A</b> | Used to make punctures, such as a fingerstick, to obtain small blood specimens  |
| 13. | <i>Ardha dhara</i> (Single edged knife)                | –      | <b>Class B</b> | Sharp to blunt dissection, Excision and Scrapping,  |
| 14. | <i>Suci sastra</i> (Suturing needle)                   | –      | <b>Class B</b> | Drainage, puncturing, and suture tissues that are easy to penetrate   |
| 15. | <i>Kusa patra</i> (Bistoury)                           | –      | <b>Class B</b> | Opening abscesses, slitting up sinuses and fistulas   |
| 16. | <i>Ati mukha</i> (Hawkbill scissors)                   | –      | <b>Class B</b> | Drainage, to cut soft tissues at the surface or inside the human body   |
| 17. | <i>Sarari mukha</i> (Scissors)                         | –      | <b>Class B</b> | Drainage, to cut soft tissues at the surface or inside the human body   |
| 18. | <i>Amtara mukha</i> (Curved bistoury)                  | –      | <b>Class B</b> | Opening abscesses, slitting up sinuses and fistulas   |
| 19. | <i>Trikurcaka</i> (Three edged knife)                  | –      | <b>Class B</b> | Drainage, to cut soft tissues at the surface or inside the human body   |
| 20. | <i>Kutharika</i> (Chisel)                              | –      | <b>Class D</b> | A cutting instrument used mainly in orthopedic, ENT and in neurosurgery   |
| 21. | <i>Vrihi mukha</i> (Trocar)                            | –      | <b>Class B</b> | Puncturing, as a portal for the subsequent placement of other instruments, such as graspers, scissors, staplers etc.  |
| 22. | <i>Ara</i> (Awl)                                       | –      | <b>Class C</b> | Creating or enlarging holes in bone   |
| 23. | <i>Vetasa patraka</i> (Scalpel of different type)      | –      | <b>Class B</b> | Used for surgery, anatomical dissection, podiatry etc. Scalpels may be single-use disposable or re-useable.   |
| 24. | <i>Badisa</i> (Sharp hook)                             | –      | <b>Class C</b> | Extraction of foreign bodies, exploration and the manipulation and retraction of tissues, nerves, vessels, and bone   |
| 25. | <i>Danta sanku</i> (Tooth scaler)                      | –      | <b>Class B</b> | Extraction of foreign bodies specially used together with periodontal curettes, periodontal scalers are used to remove calculus from teeth  |
| 26. | <i>Esani sastra</i> (Sharp probe)                      | –      | <b>Class C</b> | To dissect, incise, separate, or excise tissue, Probing and as a director   |

\***Class A** - Low risk, **Class B**- Low moderate risk, **Class C** - Moderate high risk, **Class D** - High risk.**Table 3**  
Categories of Ayurveda pharmaceutical devices based on the risk parameters.

| Sr. | Device name(s)  | Mede up of                                 | Risk category* | Intended use   |
|-----|---|--|----------------|--|
| 1.  | Mortar and Pestle<br>( <i>Khalva yantra</i> )             | Stone, Iron, Porcelain                     | Class A        | Trituration/mixing of herbs, metals, minerals, powdering and levigation                                    |
| 2.  | Crucibles   | Basically Soil and Iron                    | Class A        | Melting, extraction, preparing alloys of metals, Processing of mercury                                     |
| 3.  | Bottles   | Glass, Silver, Gold, Iron, Soil            | Class A        | <i>Kupipakwa kalpa</i> preparation, storage of fermented medicaments                                       |
| 4.  | Specific Jars   | Glass, Silver, Gold, Iron, Soil, porcelain | Class A        | Raw drug and prepared medicine storage, for preparation of fermented medicine                              |
| 5.  | Knife   | Iron, copper, Silver, Gold                 | Class B        | Cutting plant parts  |
| 6.  | <i>Tula yantra</i><br>(weighing machine)                  | Iron, copper, Bronze                       | Class A        | Weighing of medicines and other materials  |
| 7.  | Sieves (according to particle size)                       | Wood, Iron, Copper, Cotton                 | Class A        | Sieving of powdered materials  |
| 8.  | <i>Bhatti</i> (stove/gas fire)                            | Mud and Iron                               | Class C        | Mild, moderate to intense heating  |
| 9.  | <i>Ulukhal yantra</i><br>(hammer mill)                    | Wood, Iron                                 | Class A        | Powdering of dry herbs, pounding of metals   |
| 10. | <i>Palika yantra</i> (big spoon with vertical handle)     | Wood, Iron, Copper                         | Class A        | Formulation preparation from mercury and sulphur, extraction of liquid from tank, purification of sulphur. |
| 11. | <i>Darvi yantra</i> (Big mouth and long handle big spoon) | Wood, Iron, Copper                         | Class A        | Melting and purification of metals   |

\***Class A**- Low risk, **Class B**- Low moderate risk, **Class C** - Moderate high risk, **Class D**- High risk.

**Table 4**  
Categories of Ayurveda Panchakarma devices based on the risk parameters.

| Sr. | Device name(s)   | Mede up of                                    | Risk category* | Intended use                           |
|-----|--|---|----------------|--|
| 1.  | <i>Basti yantra</i> (insertion part of enema tube)         | Gold, Silver, Copper, Tin, Bronze, Iron, Bone | Class B        | Enema                                  |
| 2.  | <i>Uttarbasti netra</i> (insertion part of vaginal douche) | Iron, Copper, Gold, Bronze, Bamboo            | Class B        | Vaginal douche                         |
| 3.  | <i>Nadi Swedana yantra</i> (fomentation tube)              | Iron, Copper, Bronze, Bamboo                  | Class A        | Whole body fomentation                 |
| 4.  | <i>Agni karma shalaka</i> (rods for cauterization)         | Gold, Silver, Copper, Iron                    | Class C        | Cauterization at specific part on body |
| 5.  | <i>Dhuma netra</i> (tube of instrument used for smoking)   | Gold, Silver, Copper, Iron                    | Class A        | Smoking of medicated fumes             |

a milestone to regulate the uncontrolled manufacturing and sell of Ayurveda related devices.

### 3.3. Device quality management and awareness regarding materiovigilance

Number of potential device-related injuries and potential device-related deaths registered in 2006 in USA were 116086 and 2830, respectively. However the report shows that only 4146 recall actions were registered from 2000 to 2006 [22]. A survey conducted in Australia in 2012 reported 6812 incidents involving medical devices to the Australian Therapeutic Goods Administration (TGA) which includes 295 deaths and 2357 serious injuries during the period of January 2000 to December 2011. However, during the same time period, there were only 35 medical device recalls and 34 medical device alerts issued by the TGA [23]. The overall aspect of these and similar reports highlights the concern regarding device quality management and awareness regarding Materiovigilance. The situation is worrisome in context of AMv as the guideline for devices is not established and thus there is no regulation to maintain quality of Ayurveda medical devices excluding those devices which are now replaced by modern devices. Another concern is regarding awareness of Materiovigilance in Ayurveda community. Like PV, Materiovigilance is neither a part of academic curriculum nor there is any awareness activity related to it. However, large numbers of devices are being utilized by Ayurveda practitioners especially by Ayurveda surgeons, Panchakarma practitioners and drug manufacturers. The practice of medical devices in Ayurveda pharmaceuticals and therapeutics without sufficient knowledge of device error; is indicative of critical need to bring forth essential regulatory measures for Ayurveda devices quality management as well as competent plans for increasing awareness regarding Materiovigilance along with AMv aspect.

**Table 5**  
Categories of Ayurveda home useable devices based on the risk parameters.

| Sr. | Device name(s)   | Mede up of                                      | Risk category* | Intended use  |
|-----|--|---|----------------|---|
| 1.  | <i>Anjana shalaka</i> (rods for application of Collyrium for eyes) | Gold, Silver, Copper, Iron                      | Class C        | Application of collyrium at eyes  |
| 2.  | <i>Jivha nirlekhana</i> (tongue cleaner)                           | Gold, Silver, Copper, Tin, Bronze, Iron         | Class A        | Cleaning tongue   |
| 3.  | <i>Snana patra</i> (vessels for bath/tub batch)                    | Copper, Bronze, Lead, earthen pots              | Class A        | Boiling water and for bath  |
| 4.  | <i>Udaka patra</i> (vessels to store potable water)                | Copper, earthen pots                            | Class A        | Storage of boiled and cooled drinkable water                            |
| 5.  | <i>Bhojana patra</i> (Utensils for meal)                           | Gold, Silver, Copper, Bronze, Iron, Mud vessels | Class A        | For storage of food, plates for taking meal, glasses for drinking water |

### 3.4. Pharmaceutico-materiovigilance (PhMv) and docere-materiovigilance (DoMv)

The terms PhMv and DoMv are not narrated before and are designed based on the relation of Materiovigilance to pharmaceutical industry and physician, respectively. The medical devices and pharmaceutical devices do not require national permissions for marketing which is must criteria in context of medicine. Medical devices are controlled under Materiovigilance but there is no control on the quality of devices used to manufacture medicines by pharmaceutical industries. Most Ayurveda physicians have mini pharmacy with necessary devices to prepare the required medicines themselves. Such common pharmaceutical instruments are depicted in Table 3. Medicine manufacturing related regulations of Food and Drug Administration (FDA) and Good Manufacturing Practices (GMP) are not applicable for such physicians. Norms such as GMP have strict regulations regarding several pharmaceutical requirements (e.g. instrument, equipment, raw materials, analytical laboratory, packaging materials etc.) and documentations (e.g. Labels, specifications and testing procedures, for starting and packaging materials and for finished product; master formula etc.) However, excluding handling and cleaning of devices, guidelines regarding type, quality of metal and its effect on medicine are lacking. In context of drugs for therapeutic emesis and purgation, Charaka, author of Charaka Samhita has mentioned that factors such as geographical location, season, devices used for drug processing and storage contributes in pharmacodynamic action of drug (22. Ka 1/11) [24]. In other words, the ancient seers of Ayurveda by experience discovered that the instruments used for medicine preparation, processing and storage have synergistic or antagonistic impact on the attributes of the medicine. The claim may not be applicable to manufacturing of all medicines but still it holds ground for manufacturing several Ayurveda medicines specially medicines of mercury and fermented preparations. Therefore, a brief guideline under PhMv can be made as an update for enhancing precision of GMP.

In Latin, Docero means “Physician” or “Doctor”. The term DoMv is created to separately emphasize role of physician under Materiovigilance. Keen knowledge of all surgical instruments is also a must quality of surgeons in Ayurveda surgery too [25]. No matter how preciously the medical device has been made, the safety of the device equally depend on user and his purpose of exercise. Here knowledge regarding types of devices, their use and physicians training are three key factors to insure safety of medical devices. Insuring this knowledge and training through specially designed vigilance questionnaire and initiating mandatory feedback after purchasing a medical device by a physician is expected under DoMv. There are over 500,000 different types of devices worldwide available [26]. The current global market of medical devices is enormous that the pre-marketing review process is unable to detect all possible malfunctions, ease and difficulties in use of all different medical devices [27]. The DoMv will provide data regarding the benefit of all such devices in clinical evaluations as well as it may also generate guidelines regarding standard methods

of handling a device in specific condition/disease. Another advantage of DoMv is that it can serve as a trial unit for approval of devices pre-marketing. Practically accessing advantage, limitations and drawbacks (potential risk and benefit) of devices can also be achieved through implementation of DoMv.

### 3.5. Scope and limitations of AMv

The Ayurveda literature indicates substantial information on Materiovigilance specially in Sushruta Samhita which is main Ayurveda textbook of Surgery. However as a matter of fact, the instruments such as *Nadi Yantra* are now replaced by proctoscope and gastroscopy etc. Similar concepts such as usage of ant for the suturing of anastomosed edges of intestines in abdominal surgeries is indicating towards absorbable suturing material but not the same can be used in current times. It is also understandable that many instruments were designed to remove the foreign bodies borne out of the warfare like arrows, swords, poisonous sticks etc and now such instruments have limited usages. At the same time, the positive aspects such as use of disposable instruments made from specific woods, plant parts, mud and glasses to avoid cross contamination are appreciable. Establishing quality specification of such devices is important especially for those which are useable on daily basis. It is also observed that the AMv aspect in classical texts of Ayurveda is scattered in different chapters and under different headings. Thus complete conceptualization of AMv with respect to MvPI is complicated task. In comparison to global market of modern devices, the trading of Ayurveda devices is far less and almost limited to India. However Ayurveda as ISM is serving major health need in India and recently has attracted attention of medical community at global platform. The current regulation, which is under implementation by Government of India (GOI), relates to grant permission to Ayurveda surgeons to perform 58 surgical procedures; is a revolutionary amendment [28]. This regulation may draw attention of device manufacturing industries towards Ayurveda medical devices and developing their modified forms. Large numbers of Ayurveda devices specially related to *Panchakarma* are already in market and there is no guideline to control their quality standards. The same situation is about pharmaceutical devices. Elaboration, standardization and implementation of AMv along with PhMv and DoMv can prove a contributing strategy for regulation of Ayurveda related devices at pre-market approval and creating post market vigilance framework.

## 4. Conclusion

Documentation and regulations for AMv is in undeveloped stage and there is need and scope for its implementation. Compared to PV, the awareness regarding Materiovigilance is very much limited which necessitate to formulate strategies for its implementation. The information from classical text of Ayurveda highlights satisfactory awareness towards Materiovigilance, however this aspect need to be updated systematically for implementation and thereby betterment and mainstreaming of Ayurveda heritage.

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