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A review on an Ayurvedic Approach for Cancer Treatment developed by Vaidya Balendu Prakash

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Abstract

Though many cancer alternative therapies are popular in India, however, few have been accepted by the convention oncology forum to be effective. The metal based Ayurvedic protocol developed by Vaidya Chandra Prakash and later popularised by his son Vaidya Balendu Prakash is one of such cancer alternative therapy. The first successful treatment of a Hodgkin's Lymphoma patient with bone metastasis was reported in 1960 with an Ayurvedic preparation called *Valipani* developed by Vaidya Chandra Prakash. *Valipani* contained processed mercury, sulphur, iron, harar (*Terminalia Chebula*) along with bhilava (*Semecarpus anacardium*), amla (*Emblica officinalis*), ginger and honey, which was primarily given to the patient to strengthen the bone marrow function. However, the results could not be repeated with the new batch of *Valipani*, may be because of some problems associated with the medicine preparation. Similar situation was also encountered with another metal based preparation called *Amar*. In 1980s a new metal based formulation called *Navjeevan* was prepared and it was found to be effective in the treatment of Myeloma and Lymphoma. In 1984 Vaidya Chandra Prakash passed away, it was then Vaidya Balendu Prakash who convinced the medical fraternity to accept his claims. Later, he patented his formulation and also present 13 successfully treated cancer patients for the 'Best Case Series' presentation in National Cancer Institute, USA. The evolution of this alternative metal based Ayurvedic therapy for cancer treatment is discussed.

Keywords: Ayurvedic cancer treatment, herbo-mineral, Bhasma, Vaidya Balendu

Introduction

India is a country with diverse societies with a variety of cultural beliefs and traditional medicine practices that have evolved over thousand of years¹. Ayurvedic medicine and some forms of herbal therapy to treat cancer are widespread in all corners of India². Modern oncology has systematically established on the basis of the cell/pathways involved in different cancers in most of the varieties^{3,4}. Although modern science has made some major strides in understanding cancer and its molecular basis the knowledge about how to prevent or treat cancer is still lagging behind⁵. In contrast to the critical analytical approach of western modern medicine, Ayurveda adopts a holistic approach and propounds a broad-based understanding of the entities of life, health, and disease⁶. Holistic treatment is the hallmark of Ayurvedic treatment⁷ Moreover, the principles of Ayurveda are universal but the practices are localised and individualised. This is a unique feature, which ensured sustainable utilisation of Ayurveda principles in providing health care universally⁸. Ayurvedic literature defines three body-control systems, viz., the nervous system (*Vata* or air), the venous system (*Pitta* or fire), and the arterial system (*Kapha* or water) which mutually coordinate to perform the normal function of the body^{9,10}. Any imbalance in these body-control systems can result in disease state. The fundamental aim of Ayurvedic therapy is to restore the balance between these three major body systems by using natural substances viz. herbal, plant & animal materials, and metals & minerals preparations. In this article, I describe the evolution of some metal based Ayurvedic formulations that was found to effective in the treatment of certain types of cancer. This alternative approach to treat cancer was first advocated by Vaidya Chandra Prakash of Meerut, later it was made popular by his son Vaidya Balendu Prakash.

Evolution: In the year 1960 Vaidya Chandra Prakash of Meerut was successful in treating few patients suffering from leukaemia with an Ayurvedic formulation called '*Valipani*'. This formulation contained processed mercury, sulphur, iron, harar (*Terminalia Chebula*) along with bhilava (*Semecarpus anacardium*), amla (*Embllica officinalis*), ginger and honey, which was primarily given to the patient to strengthen the bone marrow function. Incidentally, this formulation was first used by Guru Maharaj ji of Vaidya Chandra Prakash for the rejuvenation of his injured bony tissues. The success stories of treatment of cancer by Vaidya Chandra Prakash appeared in various newspapers and then Ministry of Health & Family Welfare, Government of India deputed a fact finding committee under Prof. V. Ramalingaswamy to investigate the matter. The committee did found that the patients were benefited but they did not endorse that the cure is due to Ayurvedic treatment. No efforts were made by the committee to understand how these patients had recovered ¹¹.

Following initial successes, Vaidya Chandra Prakash made an attempt to prepare new batch of *Valipan* following similar methods of preparation, but the *Valipani* so developed did not yield the same success. Several attempts were made but none of the batches was that effective, though some were partially effective. In 1972 Vaidya Chandra Prakash prepared an experimental medicine using copper, mercury & sulphur following the concept of '*Gandhak Jarana*' described in the clinical text of '*Ras Shastra*'. This compound was named as '*Amar-72*' and was given to a patient who was diagnosed for advanced malignancy of pancreas. The patient miraculously recovered from his cancer. The *Amar-72* was also given to the patients of colon, bladder & skin cancer and many of them showed good recovery. In 1974 a fresh batch of *Amar-74* was prepared using old copper coins in place of copper available in the market. The methodology for the preparation of *Amar-74* was the same as *Amar-72* but none of the patients treated by this batch recovered. Vaidya Chandra Prakash formulated the *Amar* again by using same coins but could not change the results. The repeated failure with *Amar* disheartened him so much that he then diverted his attention to general practice ¹¹.

In December, 1980 Vaidya Chandra Prakash suffered an attack of paralysis and went into deep depression. At this juncture, his son Vaidya Balendu Prakash wanted his father's condition to improve and bring him back to normal life. Vaidya Balendu was interested in the cancer treatment with *Amar* as initially it gave good results. He then studied the personal diaries and notes of his father and discovered that the only difference between the two *Amar* preparations was of raw material. The pure copper turnings were used in the first preparation (*Amar-72*) and copper coins for the second preparation (*Amar-74*). He believed that there was some problem with the raw materials used for medicine preparation as the coins may have contained alloy of copper and not pure copper. When Vaidya Balendu Prakash discussed this issue with his father, immediately Vaidya Chandra Prakash wanted to make another batch of *Amar* with pure copper. After about one year of processing in 1982 a fresh batch of *Amar-82* was prepared. The preparation was then tried on a patient suffering from prostate cancer with bony metastasis. The patient completely recovered from cancer within 6 months. *Amar-82* also showed promising result in other patients. Vaidya Chandra Prakash then prepared another formulation consisting of processed and detoxified silver, mercury, sulphur and arsenic trioxide in (1:1:1:1) ratio along with some ayurvedic herbs like *Nirvishi* (*Delphinium denudatum*) and ground with rose, sandalwood, *Gajwan* (*Onosma bracteatum*), and *Lata kasturi* (*Hibiscus abelmoschus*) ark. The name given to this formulation was '*Navjeevan*'. This formulation when tried in patients was also found effective in the treatment of Myeloma and Lymphoma. Some successful stories were covered by different channels of media and then the Central Council for Research in Ayurveda and Siddha (CCRAS), Government of India, deputed another fact finding committee headed by Dr. Nautiyal in 1983. The Committee agreed that: "There is definitely some substance in the claim of Vaidya Chandra Prakash in the successful treatment of cancer and necessary research facilities should be provided to him" ¹¹. However, nothing fruitful resulted and no effort was made to study this Ayurvedic therapy in details. In

1984 Vaidya Chandra Prakash passed away. It was then Vaidya Balendu who carried forward the mission of cancer treatment with metal based preparation. He himself made a new metal based Ayurvedic formulation from mercury called *Valipani* in 1986. The mercury was first processed by *Shodhan* (Detoxification), *Bhavana* (Grinding/levigation), *Maran* (Incineration). The mercury so prepared turned into white powder dust and later on other ingredients was added to it. Vaidya Balendu observed that a considerable time was required to prepare the medicine as right type of preparation was the key to success. This preparation gave wonderful results in some terminally ill leukemia patients. One of the patients of Acute Lymphoblastic Leukemia (ALL) who had undergone chemotherapy, radiation and autograph bone marrow transplantation at Royal Marsden Hospital, London had a relapse of his disease and contacted Vaidya Balendu for help. As the disease relapsed after all types of conventional treatment possible, hence, the patient was declared a very poor patient of ALL. And his chance of recovery was very bleak. The patient made a remarkable recovery under the treatment of Vaidya Balendu. The unexpected recovery of the patient made his treating oncologist at UK, Dr. Simon Meller to visit India and to inquire about the treatment which his patient received. Dr. Simon Meller interviewed a number of patients who had been treated by Vaidya Balendu and recommended that there is a need for careful scientific investigations of the Ayurvedic medicines in collaboration with allopathic doctors. Another patient from London with Acute Megakaryoblastic Leukaemia (AML-M7) with poor prognosis was also immensely benefited with *Valipani*. He completely recovered with one year of treatment. In 1988 the then Science and Technology Minister, Shri K R Narayanan (who later became the 10th President of India) heard these success stories and tried to motivate Indian scientists and concerned Ministries to conduct more research in this area. On his initiative, Prime Minister's Office asked the Health Ministry to provide requisite support for further research. Health Ministry deputed another fact finding committee which confirmed the prima facie efficacy of Ayurvedic treatment in cancer patients and recommended immediate research in collaboration with CCRAS and Indian Council of Medical Research (ICMR). However, CCRAS expressed its inability to support the requisite research work due to lack of facilities and infrastructure. The matter was referred to ICMR. A detailed project proposal was prepared, but the initiation of the research study was not possible¹¹.

In 1989, a cancer research institute was set up at Dehradun in memory of Vaidya Chandra Prakash (Vaidya Chandra Prakash Cancer Research Foundation). It was a public charitable trust to promote research on metal based formulations and to develop treatment protocols for various forms of cancer, chronic inflammatory and immunological disorders. With the help of public charity, a laboratory and other research facilities were also set up.

Scientific Evaluation of Ayurvedic Formulation: For many years, CCRAS had asked Vaidya Balendu for the literary basis of his work so that a project work could be initiated. In spite of many meetings and dialogues with CCRAS nothing fruitful resulted. Ultimately, the impasse was broken when Mr. Saleem I Sherwani took charge of the Minister of State (Independent Charge), Health & Family Welfare, Government of India. Two of his relatives who were diagnosed with acute myeloid leukemia earlier were immensely benefited with the Ayurvedic therapy of Vaidya Balendu. So under the chairmanship of Mr. Sherwani a Cancer Research Sub-Committee (CRSC) was set up in CCRAS to take up a scientific research study of the metal based Ayurvedic medicine in the treatment of cancer. Finally, in 1997 a project entitled: 'Effect of metal based Ayurvedic formulations in patients of Acute Promyelocytic Leukemia (APL) – A pilot study', was undertaken. The Cancer Research Committee was headed by Dr. Dinesh Chandra, Professor and Head, Department of Pharmacology, Maulana Azad Medical College, Delhi. The other members of the committee were Haematologist and Oncologist from All India Institute of Medical Sciences and experts from ICMR and CCRAS. The aim of the study was to note the therapeutic effect of the Ayurvedic approach in the treatment of APL in 90 days¹¹.

A total of 15 patients were enrolled for this study. All the patients had to avoid *Pittavardhak Aahar* (food which aggravates pitta) during Ayurvedic treatment. Therefore, patients were strictly not allowed to take tea, coffee, aerated drink, reheated and aluminium cooked food, red meat, shell fish, yolk of egg, and *Guru Aahar* (Heavy food). As APL has high morbidity due to hemorrhage and infection. Hence, a strict isolation and complete rest was prescribed to all the patients till they achieved hematological remission. Later, they were advised to follow regulated life style with controlled dietary items. After the completion of the treatment, patients were allowed to lead normal diet and life style. The bone marrow slides before and after the Ayurvedic treatment was done and evaluated from department of laboratory Oncology, Institute Rotary Cancer Hospital, All India Institute of Medical Sciences, New Delhi. The slides were also cross reviewed from other cancer institutes. Three Ayurvedic medicines *Navjeevan*, *Kamdudha Ras*, *Kehruba Pisthi* and *Leucas aspeca* root were used for treatment of APL patients. The idea of using these Ayurvedic medicines was to restore the homeostasis and reversing the proliferation of neoplastic cells in bone marrow¹². The compositions of various Ayurvedic formulations were as follows:

Composition of Navjeevan***Anupan: Water**

Traditional Name	English /Scientific Name	Proportion
Rajat Bhasma	Silver bhasma	1 part
Jaharmohra	Serpentine stone	1 part
Nirvisha	<i>Delphinium denudatum</i>	1 part
Taruni, gulab	<i>Rosa centifolia</i>	1 part
Chandan	<i>Santalum album</i>	1 part
Gajwan	<i>Onosma bracteatum</i>	1 part
Lata kasturi	<i>Hibiscus abelmoschus</i>	1 part

*Proprietary Ayurvedic medicine

Composition of Kamadudha Rasa**Anupan: Mishri**

Traditional Name	English /Scientific Name	Proportion
Mauktik Pisthi	<i>Mytilus margaritiferus</i> preparation	1 part
Pravala pisti	<i>Corallium rubrum</i> preparation	1 part
Mukta sukta pisti	<i>Mytilus margaritiferus</i>	1 part
Kapardika bhasma	Calcinated and purified <i>Cypraea moneta</i> shells	1 part
Sankha bhasma	Calcinated and purified <i>Turbinella rapa</i> shells	1 part
Svarna gairika	Calcinated and purified Ochre	1 part
Amrta satva	<i>Tinospora cordifolia</i> extract	1 part

Composition of Keharuba Pisthi:

Trinakanta Mani churna – 1 part

Gulab arka - Q. S. (for mardana)

Dose and administration of drug:

1. Navjeevan tablet:

First three months – 250 mg tablet three times daily

Next nine months – 125 mg tablet three times daily

2. Kamdudha Ras (250 mg) + Kehruba Pisthi (125 mg)

First three months – four times daily mixed with honey

Next nine months – Only Kamdudha (250 mg) three times daily

3. Dronapushpi (*Leucas aspeca*) root as supportive medicine for initial 40 days.

Out of the 15 patients, 11 patients could complete the treatment and 10 showed complete remission of the disease. Four patients could not complete the treatment and expired at day 4, 7, 16 and 30, respectively after the start of treatment. One patient showed complete remission in peripheral blood. Probably this was the first time in India when such an impressive

success of APL could be achieved with Ayurvedic treatment which was scrutinized by allopathic doctors and scientifically documented. The project was initially sanctioned for 90 days, later; the tenure of the project was extended for 3 years. However, no financial assistance was given to the patients for the procurement of medicines and lab investigation charges. Out of 11 patients 3 patients discontinued treatment after 90 days due to financial constraints and died. However, the other 8 patients who continued the treatment survived. The follow up evaluation of renal and hepatic parameters were carried out in most of the patients at varying time intervals. Most of them indicated that the values remain within limits or were not clinically significant, however, in one patient the creatinine level increased to 2.1 mg/dl ¹².

Rational for using Ayurvedic Medicines: Acute promyelocytic leukemia is a sub classification of Acute Myeloid Leukemia (AML). Diagnosis of APL is based on specific cell morphology. Molecular markers are studied for specific identification of this disease ¹³. However, Ayurvedic literature has no direct reference for the diagnosis of leukemia or its sub classification. Some scholars have interpreted present day leukemia with *Raktarbuda/Raktapitta* since certain symptoms of leukemia resemble with these diseases ¹². Leukemia is clonal, neoplastic proliferation of immature cells of haemopoetic system, which are classified by aberrant or arrested differentiation. Leukemic cells rapidly accumulate in bone marrow cavity replacing most of normal haemopoetic cells thus resulting in signs and symptoms of disease ¹⁴.

Ayurveda emphasizes on *Hetu* (etiological factors) in diagnosis and treatment of disease. *Hetu* is further characterized as *Sannikrishta* (root cause) and *Viprakrishta* (associated cause). Therefore, the proliferated cells coming into blood stream making it as *Sannikrishta Hetu* causes haemorrhage and anaemia, but *Viprakrishta Hetu* lays in the proliferated neoplastic cells present in bone marrow. Ayurveda is based on the principle of *Dosha*, *Dhatu* and *Mala* (Waste products of the body). Gold, silver, lead, copper, tin, iron and zinc are also termed as *Dhatu* in Ayurvedic texts. There is a interlinking between *Khanij Dhatu* (Natural element) to *Sharir Dhatu* (Body element). It is said that these *Khanij Dhatu* are present in *Sharir Dhatu* in different concentrations either in single or in combination of one or more. Any imbalance of these *Dhatu*s in *Sharir Dhatu* leads to disturb body metabolism and cause the disease¹².

Rajat (Silver) is present in *Asthi* (Bone), *Majja* (Bone marrow), epithelium of intestine, endodermis, lungs, epithelium of skin, epithelium of blood cells, meninges, vestibular part of ear, and endothelium of nasal septum. That is why there is special effect of *Rajat* on these parts of the body. *Rajat* is moderately toxic in crude form (*Ashuddha*). Silver is available commercially in 99.9% purity. But as per Ayurvedic parameter, *Rajat* in this form is *Ashuddha* and may cause hyperthermia, weakness, constipation, and whole body ache. Therefore, silver has to undergo *Shodhan Sanskar* (Purification process) and *Maran Sanskar* (Incineration) and converted into *Rajat Bhasma*. *Navjeevan* is aimed to restore the homeostasis thus reversing the proliferation of neoplastic cells in bone marrow ¹².

Ayurveda is based on *Dosa*, *Dushya Siddhanta* (capable of being disturbed by the doshas). Similarly, *Dushi-Visha* (Weak and slow poison) is one of the important etiology factors for the disease process in the body. *Nirvishi* and *Jawahar mohra* are organic material; both have potent *Vishaghna* (Detoxifying) *Prabhava* (Effect) thus eliminating *Dushi-Visha* from the patient's body. Most of the symptoms of leukemia can be incorporated with the characteristics of *Rakta-pitta*. All ingredient of *Navjeevan* had *Pitta shamak* (destroyer of pitta) property, as *Rajat* and *Jawahar mohra* are *Kashaya* (Astringent) *rasa* and *Nirvishi* is *Tikta* (Bitter) *rasa*, rose, sandalwood and Lata kasturi, are also *Kashaya rasa*. Thus, *Navjeevan* predominant is *Kashaya rasa*. APL is biologically distinct from the other subtype of AML, because of the coagulopathy associated with the disease. *Kehruba pisti* and *Kamdudha Rasa* are classic Ayurvedic preparations known for their haemostatic properties. Hence, they were given to all patients to prevent hemorrhage. APL patients have lower immunity and usually present with

the symptoms of intermittent fever while there is no sign of any infection or bacterial growth in urine, blood and stool culture thus resembling the symptoms of *Visamjwara* (similar to Malaria). *Dronapushpi* roots have strong *Visamjwaraghna* and *Visaghna* (Poison killing or destroying) properties. Hence, it was given to patients to control the intermittent fever as a supportive medicine for initial 40 days ¹².

Recognition: Recognizing the efforts made by Vaidya Balendu in the treatment of certain form of blood cancers with Ayurvedic medicines, Government of Indian awarded him *Padma Shri* in 1999 ¹⁵.

Patent: Efforts was then made to patent the proprietary Ayurvedic formulation [*Navjeevan*], in India, American and European. The Indian patent was granted in 2000 ¹⁶, the European patent was granted in 2003 ¹⁷ and in September 6, 2005, the American patent was granted ^{18, 19, 20}.

Best Case Series Presentation: A Best Case Series (BCS) review process has been used at the US National Cancer Institute (NCI) to assess the available case report documentation of unconventional cancer approaches ²¹. Program is used as a vehicle to evaluate retrospective case reports of cancer patients treated with unconventional therapies. The Office of Cancer Complementary and Alternative Medicine (OCCAM) in National Cancer Institute is now exclusively responsible to carry out the evaluation work. The essential requirements for the BSC are: i) cases have a pathologic confirmation of cancer, evidence of tumor regression, absence of confounders, and confirmation that the patient used the unconventional therapy in question, which is designated as “persuasive” (P); ii) all the above criteria except that the tumor response is stable at best, which is designated as “supportive” (S), and iii) when all the data especially the histopathology slide is not available then the case becomes a not evaluable (NE). A compilation of 13 cancer patients who were benefited with the Ayurvedic therapy of Vaidya Balendu was presented to the OCCAM for the Best Case Series in 2009. It was my idea to go for a BSC presentation following the OCCAM guidelines ²². Out of the 13 cases, 9 were leukemia cases; and most of the cases were treatment failure patients. Some successfully treated patients were followed-up for over 12 years ²³. Out of the 13 cases submitted for evaluation 8 were found to be persuasive and 2 were supportive. The 3 cases that were not evaluable were due to the fact that the initial biopsy slide could not be submitted for evaluation. The details of the patients are presented in table 1. Based of these reports Vaidya Balendu was invited to NCI, Bethesda, USA for discussion about his Ayurvedic approach to treat cancer ²⁴.

Table 1: Details case reports presented for Best Case Series

Patient	Age / Gender	Cancer Type	Prior Conventional Treatment	NCI/ OCCAM Report
01	55/F	Chronic lymphocytic leukemia	No	P
02	23/F	Acute myeloid leukemia	Yes	P
03	17/M	Acute lymphoblastic leukemia	Yes	P
04	36/M	Acute promyelocytic leukemia	Yes	P
05	51/M	Non-Hodgkin's lymphoma	Yes	S
06	16/M	Acute myeloid leukemia	Yes	P
07	47/M	Acute myeloid leukemia	Yes	P
08	33/M	Promyelocytic leukemia	Yes	P
09	22/F	Acute lymphoblastic leukemia (L2)	Yes	P
10	3/M	Wilms's tumor	Yes	NE
11	74/F	Adenocarcinoma stomach	Yes	S
12	75/F	Breast cancer	No	NE
13	9/F	Acute lymphoblastic leukemia (L2)	Yes	NE

Abbreviations: M, male; F, female; NE, not evaluable; S, supportive; P, persuasive.

Discussion

The work of Vaidya Balendu proves without any doubt that metal based Ayurvedic preparations are not only effective in the treatment of some terminal cancer patients, but also was quite safe. Over the last 15 years over 100 blood cancer patients are treated with his metal-based preparations with good response rate ²⁵. Traditionally, many Ayurvedic doctors have been using herbo-mineral preparations for the treatment of chronic ailments. Although no systematic pre-clinical and clinical studies on the efficacy and toxicity of these preparations are published, they are considered to be safe in view of clinical experience as recorded in the ancient Ayurvedic documents ²⁶. However, it has been repeatedly argued that adverse effects may occur because of Ayurvedic drug consumption if such agents are not properly processed or consumed ²⁷. Saper et al. ²⁸, ²⁹ documented significantly high levels of heavy metals, beyond permissible limits, in some Ayurvedic herbal preparations exported from India and those manufactured in the USA. Following his publication, Government of India through the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha (AYUSH), and CCRAS, began scientific studies to characterize the herbo-mineral preparations, (Bhasmas and other heavy metal containing formulations) being used in India and that are exported. Investigations were carried out to study the genotoxic potential of various herbo-minerals formulations/*Bhasmas* viz. *Manikya Ras*, *Abhrak Bhasam*, *Mandur Bhasma*, *Tamra Bhasma* and *Kajjali Bhasma*, *Swas Kuthar Ras*, *Smrit Sagar Ras* etc., in Wistar rats by Micronucleus assay and Comet assay. The results revealed lack of induction of micronuclei or DNA damage as evidenced by the Comet assay, despite the presence of traces of transformed toxic heavy metals in these formulations ^{30,26}.

In the Ayurvedic description, several metallic preparations are in clinical use since 12th century AD ³¹. *Rasa-Shastra* is the Ayurvedic Science that deals with the processing and different preparations of mercury and other metals. *Rasa*, or mercury, is used for its *Yogavahi* or vehicular properties in a variety of preparations. *Bhasmas* including mercury, lead and arsenic, besides other valuable metals like gold, silver, copper, and minerals like sulphur, pearl, coral and gems etc., are described in the ancient Ayurvedic literature. There are certain Ayurvedic formulations containing heavy metals, like mercury (*Rasa*), that have to be thoroughly processed many times to result in a non-toxic, easily absorbable active compound. The process of purification consists of *Shodhana* (purification/potentiating), *Bhavana* (impregnation/levigation), and *Marana* (incineration/calcinations) according to *Rasa-Shastra* which acclimatize the toxic mineral/metal to effective remedies known as *Rasaoushadhies* of Ayurveda ³². Metals or minerals are made by hammering into coarse powder, which are then subjected to *Shodhana*, wherein metals or minerals are heated to red hot or melted and quenched in particular liquid media for specified times. *Shodhita* materials are then mixed with specific drugs for incineration (*Maraka Dravyas*) and are levigated (*Bhavana*) by particular liquid media for specified times. *Bhavana* is a process of wet grinding, in which materials are ground with particular liquid media for a specific period. From levigated doughy mass, *Chakrikas* (Pellets) are prepared and taken into earthen crucibles faced together; and junction is sealed by mud smeared clothes. This apparatus (*Sarava Samputam*) is subjected for heating in traditional *Puti* (heating grade) or electric muffle furnace. Heating of materials continue to this apparatus is called as *Putapaka* in parlance of Ayurveda. Burning is continued for specific time limit and when cooled down, apparatus (*Sarava Samputa*) is taken out and opened to get incinerated powder. These procedures are repeated for particular time and finally prepared *Bhasma* (incinerated metals) is collected ^[33]. The processed metallic Ayurvedic medicines so obtained then pass through even more verification steps before they are declared fit for internal use. For example, the Iron in *Loha Bhasma* should not rust when kept outside. Each time before burning, the metallic powders are processed with fresh herb juices to neutralize their toxicity. Some of the heavy metals are burnt up to one hundred times to make sure that the heaviness or toxic effect of the metal is nullified. ³⁴.

Metals and minerals are used as medicine in Ayurveda since Samhita period in form of fine powder called as 'Ayaskriti.' Later, with the development of *Marana* technique the metal and minerals were converted even to finer state, absorbable and non toxic form of medicine known as *Bhasma*³⁵. When various *Bhasmas* viz. *Swarna bhasma*, *Makshika bhasma*, *Abhrak bhasma*, *Tamra bhasma* and *Louha bhasma* were subjected to analysis under electron microscope it was found that they were similar to nanocrystalline materials possessing similar physico-chemical properties^{33, 36}. The therapeutic effect of *Bhasma* may be attributed to large surface area of materials and small particle size by which they can easily transported into cell nucleus and to specific target sites as desired. Due to the classic process of repeated incineration and grinding with herbal juice the basic characteristic of the metals/minerals gets completely altered. It is mainly due to change in electrical, thermal, inorganic, optical, chemical and biological behaviour of the nano size particles³⁷. From the observation of Vaidya Balendu it can be inferred that right type of ingredients and preparation methodology was the key for his success. The processing period of some of his metallic preparations took over one year. What happens to metals during the process of preparation of *Bhasma* for Ayurvedic medicine is still a matter of considerable academic and research interest. However, it is necessary to ensure that there is no toxicity resulting from the addition of metals in large quantities in herbo-mineral preparations³⁸.

There is a great deal of discussion about the controversy surrounding the use of heavy metals in Ayurvedic preparations and the potential toxicity of these metals^{39, 40, 41}. The possibility of toxicity affecting liver and renal functions is of particular importance. However, except one, none of the 8 APL patients treated by Vaidya Balendu who took long term metal based therapy showed any hepatic or renal toxicity. In a recent report⁴² a patient of gall bladder cancer with liver metastasis treated with *Yakrita-pleehari lauha*, an Ayurvedic herbo-mineral preparation along with Ursodeoxycholic acid for 10 days improved the clinical condition of the patient. The liver function test viz. serum bilirubin, Alanine Aminotransferase (SGPT), and alkaline phosphatase of the patients done at regular interval of 4 days for 15 days also indicated that there was considerable improvement of the liver function. This indicates that proper scientific evaluation of various Ayurvedic herbo-mineral/metal preparations should be urgently undertaken in a comprehensive manner. More importantly, the research findings should be published and made available to all stake holders. Also, there is little literature available on treatment of terminal cancer patients with Ayurvedic therapy. As a considerable number of cancer patients with advanced disease are opting for Ayurvedic therapy, hence, a national/international convention on 'Palliative cancer care with Ayurvedic therapy,' should be convened to address this issue and formulate guidelines.

The Indian traditional medicine industry has come a long way from the times when it was considered unnecessary to test these herbo-mineral/ metallic formulations prior to use, to the introduction of Good Manufacturing Practice (GMP) guidelines for the industry⁴³. However, we still have a long way to go. The conflict between the traditional practitioners and the purists demanding evidence of safety and efficacy needs to be addressed. Manufacturers of Ayurvedic medicines are now facing many problems such as low quality raw material, lack of authentication of raw material, non-availability of standards, lack of proper standardization methodologies of single drugs and formulations and lack of quality control parameters⁴⁴. Use of inferior grade of raw material, adulteration and deviations in standard manufacturing practice either intentionally or unintentionally, leads to the production of inferior quality products, which not only rise the concern over the efficacy but also the safety⁴⁵. Recent reports of gross inconsistency of five marketed formulation of a popular Ayurvedic herbo-mineral preparation *Naga Bhasma* indicated that these formulations were not prepared as per the guidelines mentioned in the Ayurvedic text. Hence, enforcement of strict regulatory guidelines is strongly warranted before launching Ayurvedic medicines into the market⁴⁶. Because of wide spread use of Ayurvedic medicines it has become necessary to lay down stringent parameters to ensure batch to batch consistency and reproducibility⁴⁷. There is an urgent need for the practitioners

of Ayurveda, scientific research institutions and the industry to work together to optimise the risk-benefit profile of these herbo-mineral/metal based medicines.

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