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An open labeled single arm clinical study to assess the effect of *Sadyovirechana* along with *Shivagutika* in the subjects of Stage IV Cancer

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Abstract

Background: Cancer is the gravest and tissue invasive disease which gradually hampers the quality of life and causes the decreased life expectancy. Ayurvedic classics were aware of malignant diseases; they referred to it as superficial swellings on the body (*Arbuda*) and *Gulma* (abdominal tumor) as internal or abdominal tumors. Also, other *asadhya* (not curable) conditions of diseases mentioned in the classics like *Kshataja* (cough due to injury) and *Kshayaja* (cough due to degeneration of tissues), *TridoshajaArshas* (advanced stage of hemorrhoids), *Yakritodara* (hepatomegaly) can be considered as advanced stages of cancer. At present the modern treatments for cancer are complex, unpleasant for patients and relatives as it requires long periods of treatment with risk of relapse. Also, in the advanced stage of this grave disease modern medicine has not seen beneficial in reducing the signs and symptoms and improving the quality of life. With this background the present proposal has been taken up to reduce the sufferings and to improve the quality of life in stage 4 cancer subjects.

Objectives: To assess the combined effect of *Sadyovirechana* (mild therapeutic purgation) along with *Shivagutika* (poly herbo-mineral preparation) in improving the quality of life in Subjects of Stage IV Cancer.

Methodology: 14 subjects of either gender diagnosed with Carcinoma of Stage IV were selected and administered three days *Sadyovirechana* with 20-30 ml of *Gandharvahastadierandataila* (processed castor oil) along with 10-20 ml of *Gomutra* (Cow's urine) after assessing the *Koshtha*. 5th day onwards *Shivagutika* 1 tablet three times a day for 3 months.

Result: The 'study treatment' has shown efficacy in relieving the symptoms on majority of the patients i.e., 10 subjects out of 14 subjects (71.42%) while 4 subjects (28.57%) were not responded to the treatment. 10 (71.42%) subjects showed improvement in performance status (general condition) noted on Karnofsky scales. While 4 (28.57%) of the patients were not shown any improvement in general condition.

Conclusion: The study treatment has proved to be of beneficial in improving the general condition and well-being of cancer patients as documented by the improvement in performance status noted on Karnofsky scales. Overall, it can be concluded that Ayurvedic treatment principles holds good in the management of advanced stage of cancer with respect to improvement in the quality of life, reducing the signs and symptoms, improving the general conditions and in providing the survival benefit to a great extent.

Keywords: *Sadyovirechana*, *Shivagutika*, *Arbuda*, Cancer, *Rasayana*

1. Introduction

By definition cancer is as a mass of tissue formed as a result of abnormal, excessive, uncoordinated, autonomous and purposeless proliferation of cells. ^[1] It is estimated that 19.3 million new cancer and almost 10.0 million cancer deaths occurred in 2020 worldwide. ^[2] The most common cancer diagnosed were Breast (47.8%) followed by cancer Lung (45.1%), Prostate (30.7%), Colorectal (30.1%) and Stomach (22.8%). The most common cause of death due to cancer was cancer lung, liver, stomach and breast. The projected incidence of patients with cancer in India as per ICMR report, among males was 679,421 (94.1 per 100,000) and among females 712,758 (103.6 per 100,000) for the year 2020. One in 68 males (lung cancer), 1 in 29 females (breast cancer), and 1 in 9 Indians will develop cancer during their lifetime. ^[3]

Ayurvedic classics were not unaware of malignant diseases; they referred to it as swellings anywhere on the body (*Arbuda*).

By definition *Arbuda* is a swelling occurring anywhere in the body due to vitiation of *tridoshas*, afflicting the *mamsadhātu*, which is circular, fixed and firm, slightly painful, big or wide spread, deep seated, slowly growing and non-suppurative. [4]

Regarding the treatment of *arbuda*, *acharyas* followed the line of treatment of '*shopha*' (oedema) and '*Granthi*' (tumor) which includes shaman (palliative), shodhana (systemic treatment), shastrakarma (Surgery) – *agnikarma* (cauterization) – *kshara karma* (alkali treatment) [5]. Hence *Arbuda* can be correlated with Cancer by definition, signs and symptoms and treatment.

At present the available Allopathic treatments for cancer are complex, unpleasant for patients and relatives, as it requires long period of treatment with the risk of relapse. Also, there is no significant or effective management of terminally ill patients in reducing the sufferings or in improving the quality of life. According to allied science, the maximum numbers of subjects of 'fourth stage' cancer may eventually become terminally ill where the prognosis is very bad.

So, the study is intended to cure the subject as far as possible, if not, give a maximum relief, so that subject can live with minimal sufferings. It is the need of the hour to care for this group of subjects who needs a careful observation and soothing relief.

1.1 Objective

To assess the combined effect of *Sadhyovirechana* along

Acharya	Qualities	Effect on Doshas	Other effects on the body
Charaka	Sweet	Decrease <i>Vata</i> , <i>Pitta</i> and <i>Kapha</i>	Wormicide, use in various skin disorders, beneficial in leprosy, itching and ascites
Shushruta	Pungent, sharp, hot, light, alkaline	Decrease <i>Vata</i> and <i>Kapha</i>	Promotes intellect and digestive power, beneficial in colic, digestive disorders, constipation, useful as purgative and for non-lubricant enema

Shivagutika [10, 11]: *Shivagutika* with *shilajith* as its main ingredient is indicated for various types of *yoniroga*, *arbuda*, *pradara* and considered as *rasayana*. Ingredients of *Shivagutika* 1. *Shilajith* (Bitumen) 640 gms 2. *Shunti* (Zingiber officinale) 80 gms 3. *Pippali* (Piper longum) 80 gms 4. *Katuka* (Picrorhiza kurroa) 80 gms 5. *Karkatashringi* (Pistacia integerrima) 80 gms 6. *Maricha* (Piper nigrum) 80 gms 7. *Vidarikanda* (Pueraria tuberosa) 40 gms 8. *Talisapatra* (Abies webbiana) 160 gms 9. *Vamshalochana* (Bambusa arundinacea) 20 gms 10. *Patra* (Cinnamomum zeylanicum) (leaves) 20 gms 11. *Twak* (Cinnamomum zeylanicum) (bark) 20 gms 12. *Nagakasara* (Mesua ferra) 20 gms 13. *Ela Eletharia cardamomum* 20 gms 14. Sesamum oil 80 ml 15. Sugar 640 gms 16. Ghee 160 gms 17. Honey 320 gms.

Source of Data: The subjects of either sex diagnosed with Carcinoma of Stage IV were selected from OPD of JSS Ayurveda Medical College and Hospital, Mysore, Preeti Cancer Centre, Mysore and JSS Hospital, Mysuru.

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Inclusion Criteria: All types of cancer subjects in stage IV and Either Gender

Exclusion Criteria: Subjects with systemic disorders which interfere the treatment, Pregnant and Lactating women and Children below 12 years of age

with *Shivagutika* in improving the quality of life in Subjects of Stage IV Cancer

2. Materials and methods

Details of the drugs

Gandharvahastadi eranda taila [6, 7]: The ingredients are *Gandharvahasta moola* (root of castor –ricinus communis), *Yava* (Barley-hordeum vulgare), *Nagara* (ginger – Zingifer officinalis- rhizome), water for decoction, *Ksheera* (Cow's milk) and *murchita eranda taila* (Castor oil). *Gandharvahastadi eranda tailam* is *Madhura* (sweet in taste) and *Kashayanurasam* (astringent sub- taste), *Madhura vipaka* (undergoes sweet taste conversion after digestion), *ushna* (hot in potency) *Vata – Kaphahara* (alleviate *vata* and *kapha*), *Pittala* (increase *pitta*), *Sookshma* (minute), *Teekshna* (piercing onto minute channels-penetrating action), *Sara* (smooth mobility) *Snigdha* (unctuousness), *Srotovishodhana* (cleanses body channels), *twachya* (improves skin quality) *vrushya* (aphrodisiac), *vayahsthaapi* (anti-ageing), *arogyakara* (promotes health), *Medhakara* (improves intelligence), *Smritikara* (improves memory), *Balakara* (improves immunity), *deepana* (improves digestion strength), *Vatodara* (useful in bloating), *Gulma hara* (anti- abdominal tumour), *vibandha hara* (alleviates constipation) and *Adhobhaga dosha hara* (expels vitiated doshas from lower part of the body – purgation) etc.

Gomutra: Cow's urine [8, 9]

Diagnostic Criteria: Cytology / Biopsy proved malignancies & Radiological documented metastatic diseases.

Study Design: It is an open labeled single arm clinical study

Intervention: After obtaining consent from 14 subjects, three days *Sadhyovirechana* (mild therapeutic purgation) with 30 ml of *Gandharvahastadi erandataila* along with 20 ml of *Gomutra* (Cow's urine) was carried out. From 5th day onwards Tab. *Shivagutika* one trice daily for 3 months administered.

Assessment criteria

General condition – by using **Performance Status Karnofsky Scale**.

Documentation of the pain – in terms of severity

Measurement of weight in kilogram

Symptoms were graded in order of severity

The subjective parameters were assessed once in 30 days during the treatment period

Objective parameters: Hb%, TC, DC, ESR, RBS.

3. Observation and results

As present study was conducted on one group with small sample size of 14 different sites of cancers, it was not appropriate to apply major statistical measures to analyze the results. Hence descriptive statistics are used to assess the relief in clinical features, quality of life, life expectancy and


tumor size.

The 'study treatment' has shown efficacy in relieving the symptoms on majority of the subjects i.e., 10 patients out of 14 patients (71.42%) while 4 subjects (28.57%) were not responded to the treatment. 10 (71.42%) subjects showed improvement in performance status (general condition)

noted on Karnofsky scales. While 4 (28.57%) of the subjects were not shown any improvement in general condition. Out of 14 in 8 (57.14%) subjects, the tumor size not grown further during the treatment. Out of 14 subjects 7 subjects (50%) showed possible survival benefit compared to expected median survival as per the extent of disease.

Table 1: Showing the Incidence of Relief in Symptoms

S. No	Relief in Symptoms	No. of patients	Percentage (%)
01	Yes	10	71.42%
02	No	4	28.57%



The 'study treatment' has shown efficacy in relieving the symptoms on majority of the patients i.e., 10 patients out of

14 patients (71.42%) while 4 patients (28.57%) were not responded to the treatment.

Table 2: Showing the Improvement in Performance Status

S. No	Improvement in Performance Status	No. of patients	Percentage (%)
01	Yes	10	71.42%
02	No	4	28.57%


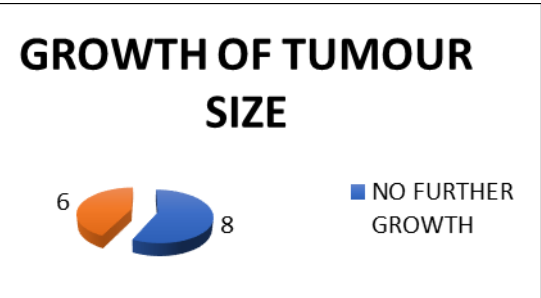


Table 3: Showing the Further Growth of Tumor Size

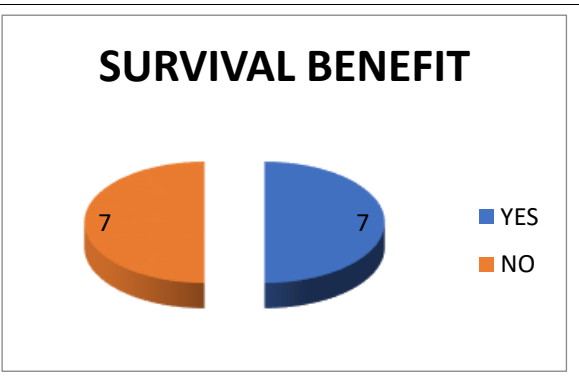
S. No	Further growth seen	No. of patients	Percentage (%)
1	No	8	57.14%
2	Yes	6	42.85%



In 8 (57.14%) patients the tumor size not grown further during the treatment.

Table 4: Showing the Survival Benefit

S. No	Survival Benefit	No. of patients	Percentage (%)
1	Yes	7	50%
2	No	7	50%



Out of 14 patients 7 patients (50%) showed possible survival benefit compared to expected median survival as per the extent of disease.

Table 5: Significant parameters observed before and after treatment

Subject Number	Before treatment							After Treatment						
	Pain	KS	WT	Hb%	TC	ESR	RBS	Pain	KS	WT	Hb%	TC	ESR	RBS
1		20	85						80	82				
2														
3														
4														
5														
6														
7														
8														
9														
10														
11														
12														
13														
14														

4. Discussion

Criteria for selection of drugs: Selection of *Gandharvahastadierandataila* and *Gomutra* is based on following criteria

Gandarvahastadierandatailam: [6, 7] It derives its numerous health benefits from its unique phytonutrient composition. It includes various vitamins, minerals, carbohydrates, proteins, good fats, flavonoides, gingerol and other photochemical. These active ingredients have been shown to have anti-inflammatory and antioxidant properties. This allows the herbal oil to act as a natural removal, support for the body and support blood purification as well. It acts as Purgative in larger doses. It promotes digestive health by supporting regular bowel movements

Gomutra (Cow's urine): "Vishaghna" (Anti Poisonous) killer of all poisons and "Rasayan" (Rejuvenative) which can rejuvenate even old person and purify blood and cures all skin diseases. Cow urine destroys the diseases that are caused by poison (Toxin). Various poisonous chemicals can be purified with the help of cow urine. Cow urine increases the immunity power by increasing resistance power against diseases in human body

Anticancer Properties: [12] Studies shows that Cow urine therapy found that, it possesses anti-cancer properties and for that US granted patent in the field of cancer treatment by its virtues of bio-enhancing the activity of anti-cancer drugs Cow's urine has antioxidant properties and is a free radical and thus it neutralizes the oxidative stress. Cow's urine helps by repairing the damaged DNA and is therefore, effective as anti-cancer therapy [13] Chemopreventive potential of CU was observed in a study, which was conducted on 70 Swiss albino mice for 16 weeks. Papilloma were induced by 7, 12 dimethyl benzanthracene and later promoted by repeated application of croton oil. In mice treated with CU, the incidence of tumor (papilloma), tumor yield, and its burden was statistically less than the untreated group [14]. Effect of Cow Urine on various types of cancers was studied by Jain and his coworkers. Decrease in severity of various clinical symptoms (pain, inflammation, burning sensation, difficulty in swallowing, and irritation) was decreased from day 1 to day 8 with CU therapy. Percent of patients with severe symptoms decreased from 82.16 to 7.9 on day 8, patients with moderate symptoms increased from 15.8 to 55.3 and with mild symptoms, patients increased from 1.58 to 36.34. The severity of symptoms decreased

further with continued CU therapy [15] In the classics *gomutra* (cows' urine with selected drugs) has been mentioned in various advanced disorders like *Jalodara* (ascites), *Pandu* (anaemia), *Arshas* (haemorrhoids) etc. specially as *srotoshodhaka* because of its *kshara-ksharanaguna* (alkaline-scraping nature), *n ushnaveerya* (hot potency), *agnideepana* (improves digestion). [16]

The administration of *GandarvahastadiEradataila* along with *Gomutra* helps in *vatanulomana* which is very much essential in all the cancerous conditions as *vata* is abnormally deranged which in turn leads to the excessive proliferation of tissues. Both *GandrvaastadiEradataila* and *gomutra* are *srotoshodhaka* by virtue of its *rasa* (taste), *guna* (property), *veerya* (potency) and *karma* (action).

As per the classics *Shodhana* [17] therapy is a best practice before giving any *rasayanas* for its better absorption and action. Here the condition is an advanced case of different Carcinomas hence after assessing the *bala* of the patient a mild purificatory (*Mridu Shodhana*) therapy was given prior to the administration of the *Rasayana* drug – *Shivagutika*.

The *Shivagutika* is a polyherbomineral formulation mentioned in *Rasayana Prakarana* of *BhaishajyaRatnavali*. [18] The main ingredient is *Shilajitu* (Black Bitumen) along with more than 50 herbal drugs like *Triphala*, *Dashamula*, *Guduchi*, *Patola*, *Bala*, *Yastimadhu*, *Gomutra* (cow's urine), *Gokshira* (cow's milk), *Kakolyadigana drugs*, *Shatavari*, *Narikela*, *Karkatasringi*, *Trikatu*, *Talisapatra*, *Vidari*, *Vamsalocana*, *Trijata*, *Nagakasara*, *Tilataila*, *Ghrita* (cow's ghee), *Madhu* (honey). It is a *Rasayana* (Rejuvenative) drug, having a wide range of benefits in chronic and advanced diseases like *vatarakta* (gouty arthritis), *rajayakshma* (chronic respiratory disorders), *jwara* (chronic fever), *pleeharoga* (disorders of spleen), *arshas* (haemorrhoids), *pandu* (anaemia), *hidroga* (cardiac ailments), *grahani* (IBS/Sprue syndrome), *gulma* (abdominal tumors), *hikka* (hiccough), *kasa* (chronic cough), *swasa* (dyspnoea), *udara* (ascites), *kushtha* (chronic skin ailments), *switra* (leukoderma), *kshaya* (phthisis), *shosha* (emaciation), *unmade* (mental disorders), *apasmara* (epilepsy), *mukharogas* (oral cavity diseases), *shiroroga* (diseases related to the head), *atisara* (loose stools), *asrigdhara* (menorrhagia), *kamala* (jaundice), *prameha* (diabetes mellitus), *yakritodara* (liver disorders), *arbuda* (cancerous conditions), *vidradhi* (abscess), *atishoulya* (obesity), *sleepada* (elephantiasis). Also alleviates different types of poisonous effects from the body. It promotes the strength, aphrodisiac, power, virility and lusture. It improves

memory, intellect, immunity, clarity of sense organs and provides maximum longevity.

Shivagutika ^[19, 20, 21] is a polyherbal formulation can cure the morbid factor with oral medicine, nourishment and enhance the immunity (*Ojas*). It acts as an antibiotic, anti-diabetic, anti-venomous, anti-hypolipidaemic, anti-inflammatory, analgesic, immuno-modulatory, antiviral, antimicrobial and antioxidant agents. In addition, it is also believed to increase the skin tone (*Varna Prasadana*), strengthen the body (*Balya*), scrapes off unwanted tissues, splits and expels the morbid matters from the body. *Shiva Gutika* is also responsible for the gain in body weight, counter-acting the symptoms and improvisation of the blood. It further ameliorates the body from maladies like tuberculosis, gout, diarrhea, jaundice, piles, anemia, and fever. Furthermore, it is also believed to have a positive effect on reproductive system diseases, fever, splenic disorders, vomiting, distension of abdomen, cough, dyspnoea, tastelessness, weakness, and diseases related with mouth, eyes, and head.

Shilajatu, the main ingredient of shiva gutika has *kashaya* (astringent), *amla rasa* (sour taste), *katu vipaka* (pungent in biotransformation), *anushnasheeta veerya* (not to cold in potency)⁷. It is useful in alleviating *tridoshas* (three humours). It possesses *rasayana* (rejuvenation), *vrishya* properties (aphrodisiac). It is useful in the treatment of *prameha* (diabetes mellitus), *pandu* (anemia), *gulma* (tumour), *pleeharoga* (spleen disorders), *sthaulya* (obesity), *shotha* (swelling), *jvara* (fever) etc. It is said that there is no such disease which cannot be cured with *shilajatu*.

Studies revealed that *Shilajit* and its combined constituents also elicited and activated, in different degrees, murine peritoneal macrophages and activated splenocytes of tumor-bearing animals at early and later stages (unresponsive) of tumor growth ^[22].

5. Conclusion

1. The study treatment has proved to be of beneficial in improving the general condition and well-being of cancer patients as documented by the improvement in performance status noted on Karnofsky scales.
2. The same combinations of drugs have been used to treat cancers of different sites taking only 'cancer' as the basic common factor. The study treatment has shown some efficacy in majority of patients (10 out of 14), showing effectiveness in malignancies in general.
3. The study treatment has been effective in reducing symptom produced by cancer in 10 out of 14 patients. Showing its possible effectiveness as a palliative care treatment. Seven patients have shown a possible survival benefit compared to expected median survival as per extent of disease.
4. Another interesting feature is that, in 8 patients out of 14, the tumors have not grown in size during the period of observation, showing possibility of some anti-tumor activity.
5. Overall, it can be concluded that Ayurvedic treatment principles holds good in the management of advanced stage of cancer with respect to improvement in the quality of life, reducing the signs and symptoms, improving the general conditions and in providing the survival benefit to a great extent.

6. Scope and recommendations

Randomized controlled clinical trials can be conducted to

evaluate the effect of *Sadyovirechana (Mridu Shodhana)* followed by *Rasayana* Therapy.

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