

Efficacy of *Abhadi Ghanvati* versus Diclofenac Sodium in the Management of *Avabahuka* (Frozen Shoulder): A Research Protocol

SUDHA RANI VERMA¹, VINOD N ADE², MUKESH KUMAR BISEN³, DIVYA PATEL⁴

ABSTRACT

Introduction: *Avabahuka* is a disease of the shoulder joint characterised by *shoola* (pain), *stambha* (stiffness), and loss of *bahu praspandana* (decreased range of motion). This condition affects an individual's overall health, daily life, and ability to perform routine activities. The pathophysiology and clinical manifestations of *Avabahuka* and frozen shoulder are very similar.

Need of the study: Conventional treatments such as analgesics and corticosteroid injections often provide only temporary relief, and long-term use may be associated with side-effects or complications. *Abhadi Ghanvati* has shown promising results in managing *asthi-sandhigata vata* and *snayu-majja-gata vata*.

Aim: To evaluate and compare the efficacy of *Abhadi Ghanvati* versus a standard control (Diclofenac sodium) along with *Abhadi* oil in the management of *Avabahuka* (frozen shoulder).

Materials and Methods: A randomised, single-blind clinical trial will be conducted from October 2023 to August 2025 at Mahatma Gandhi Ayurveda College Hospital and Research Centre (MGACHRC), Salod Hirapur (H), Maharashtra, India. A total of 86 patients will be randomised into two groups: Group A (Intervention group): *Abhadi Ghanvati* 500 mg twice daily along with local *abhyanga* with *Abhadi taila*. Group B (Control group): Diclofenac sodium 50 mg twice daily along with local *abhyanga* with *Abhadi taila*. The duration of treatment will be 15 days. Assessment will be carried out on day 0, day 7, day 21, and day 30. Patients will be evaluated using objective parameters such as Range Of Motion (ROM) and subjective parameters such as shoulder joint stiffness and pain using the Visual Analogue Scale (VAS). Statistical analysis will be performed using paired and unpaired t-tests, along with the Chi-square test, with a statistically significant p-value <0.05.

Keywords: *Abhadi taila*, Range of movement, Shoulder pain

INTRODUCTION

Avabahuka, an *ansha-sandhi* (shoulder joint) disorder, is primarily caused by *vata dosha*. Although the term "*Avabahuka*" is not listed under *vata-nanatmaja vyadhi*, *Acharya Sushruta* and other scholars have classified it as a *vataja vikara* [1]. In modern medicine, *Avabahuka* is comparable to frozen shoulder, a condition characterised by shoulder pain, restricted movement, difficulty in performing daily activities, and discomfort while sleeping on the affected side. Frozen shoulder is also known as adhesive capsulitis [2].

The prevalence of frozen shoulder ranges from 2-5% [3], with females being four times more likely to be affected than males [4]. Among individuals with diabetes mellitus, the prevalence is significantly higher, between 10% and 22%, compared to the general population [5]. Early treatment options include analgesics, intra- and extra-capsular steroid injections, and pendulum exercises to improve shoulder mobility [6]. Diclofenac sodium, an analgesic, antipyretic, and anti-inflammatory drug, selectively inhibits prostaglandin synthesis and COX-2. It is well absorbed orally and is 99% protein-bound [5].

Vata vitiation can occur in two ways: directly, due to factors such as *ruksha* (dryness), *laghu* (lightness), and excessive load-bearing (*ati-bhara-vahana*); or indirectly, where *kapha-prokopaka nidanas* (excessively heavy or unctuous substances) lead to an increase in *vikruta kapha*, resulting in *kapha-avrita vayu*. In both situations, the aggravated *vata dosha* accumulates in the *srotas* (body channels) [1].

Various Ayurvedic texts describe numerous herbal formulations. *Acharya Yogaratnakar*, in *Vatavyadhi Chikitsa*, describes the *vata-kapha-hara* (*vata-kapha* balancing), *balya* (strengthening), *deepana*

(appetite-stimulating), *pachana* (digestive), *strotoshodhana* (channel-purifying), and *rasayana* (rejuvenating) properties of *Abhadi Ghanvati* (churna) [7]. This formulation is specifically indicated for *asthi-sandhigata vata* (bone and joint disorders), *snayu-majja-gata vata* (nervous system involvement), *katigraha* (lumbar stiffness), *gridhrasi* (sciatica), *manyastambha* (neck stiffness), and *hanugraha* (jaw stiffness) [8]. *Avabahuka* is one of the most prevalent *vatavyadhi* conditions and significantly impacts daily life. Although contemporary treatment options such as biopurification and physiotherapy are available, many individuals find it difficult to adhere to these regimens due to time constraints and demanding lifestyles [9].

Modern medicine does not offer a specific cure for frozen shoulder, but Non Steroidal Anti-Inflammatory Drugs (NSAIDs) remain the primary line of management [10]. *Abhadi Churna*, a traditional Ayurvedic formulation, is commonly used for the management of pain. Its ingredients possess *vedana-sthāpana* (analgesic), *shotha-hara* (anti-inflammatory), *deepana* (digestive stimulant), *pachana* (digestive aid), *shula-prashamana* (pain-relieving), *sheeta-prashamana* (cooling), and *anulomaka* (bowel-regulating) properties, making it beneficial for *vata-vyadhis*. Herbs such as *Guduchi*, *Vridhdadaruka*, and *Shatavari* have *rasayana* (rejuvenating) and *balya* (strength-enhancing) properties, helping maintain balance between *doshas* and *dhatu* [11].

REVIEW OF LITERATURE

Acharya Yogaratnakar has recommended *Abhadi Churna* for the management of *Vatavyadhi* (neuromuscular disorders). This formulation contains several potent herbs, each contributing to its therapeutic efficacy. *Ashwagandha*, *Shatavari*, *Guduchi*, and *Vidhara* exhibit *rasayana* (rejuvenative) properties, making them highly

effective in conditions involving *dhatu kshaya* (tissue depletion or degeneration). *Shunthi*, *Ajmoda*, and *Shatpushpa* possess *deepana* (appetite-stimulating) and *pachana* (digestive) properties due to their *katu rasa* (pungent taste), aiding in the removal of *srotorodha* (obstruction of body channels). Additionally, *Rasna* enhances the formulation's analgesic effects.

Overall, *Abhadi Churna* demonstrates multiple therapeutic properties, including *shoolahara* (pain-relieving), *balya* (strength-promoting), *deepana*, *pachana*, and *rasayana*. Moreover, bioactive phenols derived from *Acacia arabica* have been shown to inhibit enzymes such as Cyclooxygenase (COX) and Lipoxygenase (LOX), thereby reducing the production of inflammatory mediators such as bradykinin, prostaglandins, and leukotrienes. This inhibition contributes to its analgesic, anti-inflammatory, and antipyretic effects [12].

Nishant K et al., conducted a comparative clinical study on the efficacy of *Abhadi Vati* and *Chinchadi Taila* in managing *Sandhivata* (osteoarthritis). Both formulations were beneficial, although *Chinchadi Taila* showed superior effectiveness compared to *Abhadi Vati* [7]. In another study, Priyanka et al., evaluated the effects of *Abhadi Churna*, *Mashabaladi Kwath Nasya*, and *Greeva Vasti* in patients with *Manyastambha*. Significant improvement was observed with *Abhadi Churna*, particularly on the first follow-up day post-treatment. Additionally, *Nasya* therapy with *Abhadi Churna* demonstrated better results than *Greeva Vasti* with *Abhadi Churna*, and the combination of *Greeva Vasti* and *Abhadi Churna* was found to be more effective than *Abhadi Churna* alone [13].

Wakte Swapnil D and Dhurve Sanjay A, compared *Nagaradi Churna* and *Abhadi Churna* in the management of *Janu Sandhivata* (osteoarthritis). *Nagaradi Churna* was found to be more effective in reducing joint pain (*sandhishoola*), swelling (*sandhishotha*), movement-related pain (*akunchana-prasaranajanya vedana*), improving ROM, and decreasing tenderness. However, *Abhadi Churna* was more effective in improving joint stability and functional ability [14].

Sarla B et al., assessed the efficacy of *Abhadi Churna* in conjunction with *pathya ahara* (dietary regimen) and *vihara* (lifestyle modifications) for *Gridhrasi* (sciatica). The study involved 60 patients, divided into two groups. Group A received *Abhadi Churna* (5 g twice daily with warm water), while Group B received the same treatment along with *pathya ahara* and *vihara* for 90 days. Assessments of pain, stiffness, pricking sensation, twitching, Straight Leg Raise (SLR) test results, standing time, and walking time revealed that Group B showed greater improvement than Group A [11].

A case study conducted by Gugale Pooja S and More Mukund M, demonstrated that *Abhadi Churna* significantly improved symptoms such as lower back pain, bilateral buttock pain, tingling sensation, and anterior flexion range. The patient was treated with *Abhadi Churna* (4 g twice daily) for 21 days [15].

Tanmane CS and Khan AY, conducted a randomised controlled trial evaluating *Indravarunimuladi Churna* in *Sandhigatavata* (osteoarthritis). Patients were divided into two groups: Group A received *Indravarunimuladi Churna* (5 g twice daily), while Group B received *Abhadi Churna* (5 g twice daily) for four weeks. Group B showed superior results in general knee function, VAS scores, and WOMAC index, whereas Group A was more effective in improving ROM and reducing joint stiffness (*sandhishthambha*) [16].

This study aims to evaluate and compare the efficacy of *Abhadi Ghanvati* with the standard control, Diclofenac sodium, in the management of *Avabahuka* (frozen shoulder).

Objectives

1. To study the efficacy of *Abhadi Ghanvati* in *Avabahuka* (frozen shoulder).
2. To study the efficacy of Diclofenac sodium in *Avabahuka* (frozen shoulder).

3. To compare the efficacy of *Abhadi Ghanvati* and Diclofenac sodium in the management of *Avabahuka* (frozen shoulder).

Null Hypothesis (H_0)

Abhadi Ghanvati will be equally or less efficacious than Diclofenac sodium in *Avabahuka* (frozen shoulder).

Alternative Hypothesis (H_1)

Abhadi Ghanvati will be more efficacious than Diclofenac sodium in *Avabahuka* (frozen shoulder).

MATERIALS AND METHODS

A randomised, single-blind, clinical trial will be conducted from October 2023 to August 2025 at the Department of Kayachikitsa and Panchakarma, Mahatma Gandhi Ayurveda College Hospital and Research Centre (MGACHRC), Salod Hirapur (H), Maharashtra, India. Institutional Ethics Committee approval has been obtained (registration number: MGACHRC/IEC/MAY/2022/482). After obtaining written informed consent from each patient, the study will commence. The trial has been registered on the Clinical Trials Registry - India (CTRI) web portal with registration number CTRI/2023/10/058877. The ethics committee will monitor the progress of the trial and determine outcomes. Any adverse events will be evaluated by the researcher and reported to the ethics committee. Patient confidentiality and privacy will be maintained throughout the study.

Inclusion criteria: Patients willing to provide written informed consent, patients of both sexes aged between 21 and 60 years, and patients presenting with classical clinical symptoms of Grade I frozen shoulder [17] will be included in the study.

Exclusion criteria: Patients with systemic disorders such as hepatic or renal failure, patients with a fracture or dislocation of the affected limb, and patients with a history of adverse drug reactions to Diclofenac sodium will be excluded from the study.

Withdrawal criteria:

1. Patient unwilling to continue treatment
2. Development of any adverse effect

Screening investigation:

1. X-ray of the shoulder {Anteroposterior (AP) and lateral views}
2. Renal function test
3. Liver function test

Sample size calculation: The sample size (n) for comparing two independent means will be calculated using the formula:

$$n \geq \frac{((Z_{1-\alpha/2} + Z_{1-\beta})^2 \times (\sigma_1^2 + \sigma_2^2/r))}{(\mu_1 - \mu_2)^2}$$

Alpha (α) = 0.01

Beta (β) = 0.01 (Power = 0.99)

Mean of Internal rotation before diclofenac treatment (μ_1) = 26, Mean of Internal rotation after diclofenac treatment (μ_2) = 43 [18].

Standard Deviation before (σ_1)=12, Standard Deviation in after (σ_2)=17.

Ratio (Group-2 /Group-1) = 1

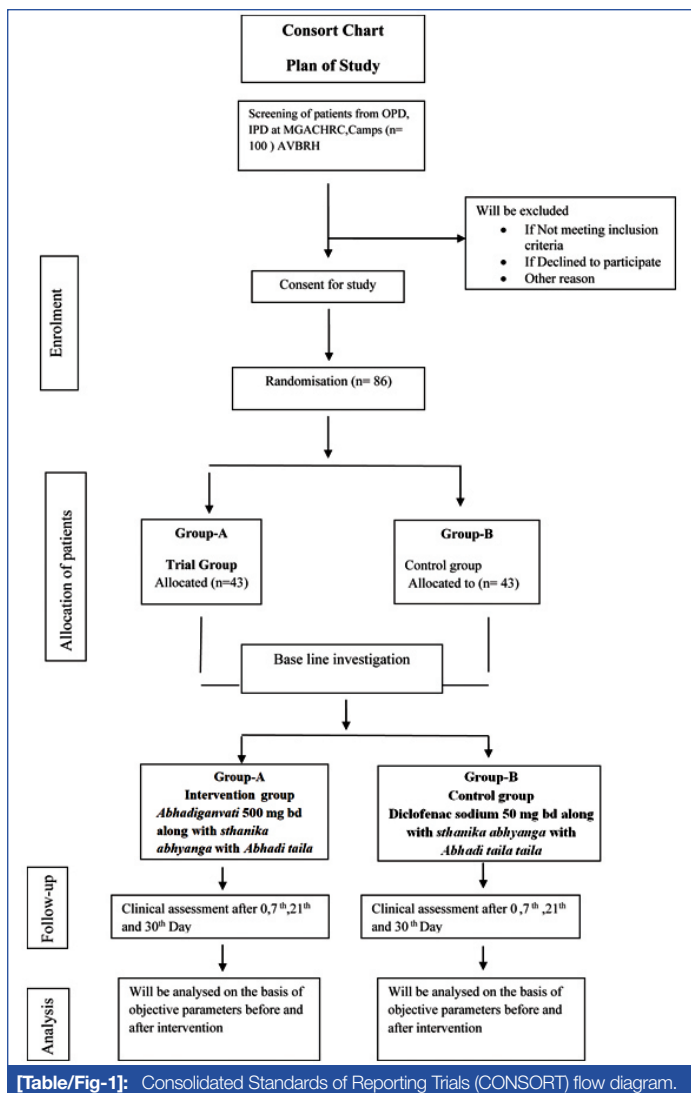
$Z_{1-\alpha/2} = Z_{0.995} = 2.5758$, $Z_{1-\beta} = Z_{0.99} = 2.3263$

$n \geq (24.0313 \times 433)/289 = 10405.57/289 = 36.01$

Minimum sample size needed per group = 37 considering 20% dropout =37+6 =43 per Group

Total minimum sample size needed = 86.

Participants (N=86) will be randomly allocated into two equal groups (n=43 each) using a computer-generated randomisation sequence. Allocation concealment will be ensured using Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) prepared by an independent researcher not involved in participant recruitment or assessment [Table/Fig-1].



Group A (Intervention group): *Abhadi Ghanvati* 500 mg twice daily along with *sthanika abhyanga* using *Abhadi taila* (n=43).

Group B (Control group): Tablet Diclofenac sodium 50 mg twice daily along with *sthanika abhyanga* using *Abhadi taila* (n=43).

All raw materials for the drug will be procured from the local market and authenticated by a *Dravyaguna* expert. The medicine will be prepared at the *Rasashala*, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha [Table/Fig-2] [19-29].

Method of Preparation of *Abhadighanvati*

All raw drugs mentioned in [Table/Fig-2] will be taken in equal proportions. After drying, they will be ground into a coarse powder, and a decoction will be prepared using eight parts of water over a moderate flame until it reduces to one-fourth of its original volume. The prepared decoction will then be filtered through a thin, clean cloth. The filtrate will be boiled again to achieve a thick, semi-solid consistency suitable for granulation. The granules will be punched into tablets and preserved in airtight packets [Table/Fig-3] [30].



[Table/Fig-3]: *Abhadighanvati*.

Method of Preparation of *Abhadi Oil*

Tila taila will be taken in a stainless-steel container and heated until free from froth. All the *murchchhit dravyas* will be taken in powdered form, each in equal parts. The powdered *murchchhit dravyas* will be mixed with *tila taila*, and the prepared *kalka* from [Table/Fig-2] will be added. The oil will then be heated, adding four times water at a moderate temperature. The consistency will be monitored continuously until the appearance of the fourth stage, when the *kalka* is ready for *varti* formation. The oil will then be filtered using a muslin cloth and allowed to cool [Table/Fig-4] [31]. Diclofenac sodium tablet IP 50 mg will be purchased from - Lifestyle pharmacy (MGAC) (Medicine and Drug supply), AVBRH campus, Sawangi (Meghe) Wardha, India (there will be no conflict of interest).

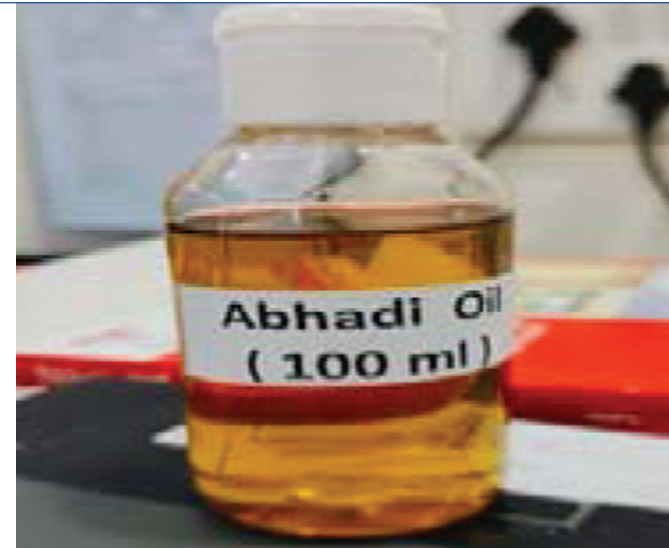
The intervention details for Group A and Group B are summarised in [Table/Fig-5].

Outcomes: The range of motion of the shoulder joint will be assessed using a Goniometer (Physioactive Goniometer) [Table/Fig-6] [9].

S. No.	Name of the drugs/Botanical name	Rasa	Guna	Veerya	Vipaka	Karma
1.	<i>Babbula</i> (<i>Acacia nilotica</i>) [19]	Kashaya	Guru, Ruksa	Shita	Katu	<i>Kaphahara</i> (<i>Nirysa-pitta-vatahara</i>), <i>Lekhana</i> , <i>Grahi</i>
2.	<i>Rasna</i> (<i>Alpinia officinarum</i>) [20]	Tikta	Guru	Ushna	Katu	<i>Kaphavatahara</i> , <i>vayahsthapana</i>
3.	<i>Guduchi</i> (<i>Tinospora cordifolia</i> Willd) [21]	Tikta, Kashaya	Guru, Snigdha	Ushna	Madhura	<i>Tridosha samaka</i> , <i>Medhya</i> , <i>Rasayan</i> , <i>Depaniya</i> , <i>Grahi</i> , <i>Medohara</i> , <i>Kandughna</i> , <i>Jwara hara</i> , <i>Daha-Prasamana</i>
4.	<i>Shatavari</i> (<i>Asparagus recemosus</i> Willd) [22]	Madhur, Tikta	Guru, Snigdha	Shita	Madhura	<i>Vata-pittahara</i> , <i>Rasayana</i> , <i>Vrsya</i> , <i>Stanyajanana</i> .
5.	<i>Shunthi</i> (<i>Zingiber officinale</i>) [23]	Katu	Guru, Ruksa, Tiktsna	Ushna	Madhura	<i>Vata-kaphahara</i> , <i>Dipana</i> , <i>Bhedana</i>
6.	<i>Shatapushpa</i> (<i>Anethum sowa</i>) [24]	Katu, tikta	Laghu, tiksna	Ushna	Katu	<i>Vata-kaph hara</i> , <i>Dipana</i>
7.	<i>Ashwagandha</i> (<i>Withania somnifera</i> Dunal) [25]	Katu, tikta, kashaya	Snigdha, Laghu	Ushna	Katu	<i>Vata-kaphahara</i> , <i>Balya</i> , <i>Rasayana</i> , <i>Sukrala</i>
8.	<i>Hapusha</i> (<i>Juniperus communis</i> Linn) [26]	Katu, Tikta	Guru	Ushna	Katu	<i>Vata kapha hara</i> , <i>Dipana</i>
9.	<i>Vruddhadaru</i> (<i>Argyrea speciosa</i>) [27]	Kashaya, katu, tikta	Laghu, snigdha	Ushna	Madhura	<i>Vata kaphahara</i> , <i>Rasayana</i> , <i>Vrsya</i>
10.	<i>Yavani</i> (<i>Carum copticum</i>) [28]	Katu	Laghu, ruksa, tiksna	Ushna	Katu	<i>Kapha vatahara</i> , <i>sukrahara</i> , <i>dipanapachana</i>
11.	<i>Ajamoda</i> (<i>Apium graveolens</i>) [29]	Katu, Tikta	Laghu, ruksa, tiksna	Ushna	Katu	<i>Kapha-vatahara</i> , <i>vidahi</i> , <i>dipana</i> , <i>hrdya</i> , <i>balya</i> , <i>vrsya</i>

[Table/Fig-2]: Illustrating the ingredients and properties of *Abhadi Ghanvati* [19-29].

Diclofenac sodium tablet IP 50 mg will be purchased from - Lifestyle pharmacy (MGAC) (Medicine & Drug supply), AVBRH campus, Sawangi (Meghe) Wardha; Conflict of interest - there will be no conflict of interest.



[Table/Fig-4]: Abhadi oil.

	Group A	Group B
Drug	<i>Abhadi Ghanavati</i>	Tab. Diclofenac Sodium
Dose	500 mg BD	50 mg BD
Aushadhi Sevana kala	Along with <i>Sthanika abhayanga</i> with <i>Abhadi Tail</i>	Along with <i>Sthanika abhayanga</i> with <i>Abhadi Tail</i>
Anupan	100 mL Lukewarm water	100 mL Lukewarm water
Route of administration	Orally	Orally
Duration	15 days	15 days
Follow-up period	0, 7, 21, 30 days	0, 7, 21, 30 days

[Table/Fig-5]: Grouping and posology.

Subjective criteria:

- Pain will be assessed using a Visual Analogue Scale (VAS).
- Joint stiffness will be assessed using a graded scale [Table/ Fig-7] [9].

Painful/restricted up- per limb movements using goniometer	Observation in degree	Grading	Clinical assessment			
Shoulder			0 th day	07 th day	15 th day	30 th day
Flexion	161-180	0				
	141-160	1				
	121-140	2				
	<120	3				
Extension	51-60	0				
	41-50	1				
	31-40	2				
	<30	3				
Abduction	161-180	0				
	141-160	1				
	121-140	2				
	<120	3				
Adduction	40-50	0				
	30-40	1				
	20-30	2				
	10-20	3				
	0-10	4				
Internal rotation	71-90	0				
	51-70	1				
	31-50	2				
	<30	3				

External rotation	71-90	0				
	51-70	1				
	31-50	2				
	<30	3				

[Table/Fig-6]: Range of Motion (ROM) of shoulder joint [9].

Stiffness	Description	Grading	Clinical assessment			
			0 th day	07 th day	15 th day	30 th day
None	No stiffness	0				
Mild	Mild stiffness on movement of shoulder joint	1				
Moderate	Moderate stiffness, on movement of joint or rest; interfering the daily activities	2				
Severe	Severe stiffness, very difficult movements and also rest, inability to sleep, disturbs all daily activities	3				

[Table/Fig-7]: Normal grading of stiffness [9].

STATISTICAL ANALYSIS

Statistical Package for the Social Sciences (SPSS) software (version 27.0) will be utilised for statistical analysis. The Chi-square test will be applied for subjective parameters, while the paired t-test will be used for objective parameters. For intergroup comparison, the unpaired t-test will be employed. A p-value of ≤0.05 will be considered statistically significant.

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PARTICULARS OF CONTRIBUTORS:

1. PhD Scholar, Department of Kayachikitsa, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Datta Meghe Institute of Higher Education and Research (Deemed to be University), Wardha, Maharashtra, India.
2. Professor, Department of Panchkarma, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Datta Meghe Institute of Higher Education and Research (Deemed to be University), Wardha, Maharashtra, India.
3. PhD Scholar, Department of Kayachikitsa, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Datta Meghe Institute of Higher Education and Research (Deemed to be University), Wardha, Maharashtra, India.
4. PhD Scholar, Department of Rachna Sharir, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Datta Meghe Institute of Higher Education and Research (Deemed to be University), Wardha, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Sudha Rani Verma,
PhD Scholar, Department of Kayachikitsa, Mahatma Gandhi Ayurved College,
Hospital and Research Centre, Datta Meghe Institute of Higher Education and
Research (Deemed to be University), Wardha, Maharashtra, India.
E-mail: dr.sudharani2012@gmail.com

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