



An Open Label Single Arm Clinical Study to Evaluate the Efficacy of Vamana Karma with Nimba Kashaya Yoga in Sheetapitta WSR O Urticaria

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<i>Article History</i>	<i>Abstract</i>
<p>Received: 09 Jan 2024 Revised: 15 Feb 2024 Accepted: 07 March 2024</p> <p>CC License CC-BY-NC-SA 4.0</p>	<p>Present study is an observational clinical study carried out in 10 patients of Sheetapitta to evaluate the efficacy of Nimba Kashaya Yoga for Vamana. Sheetapitta disease explained in Ayurvedic classics shares similar aetiology, signs, and symptoms as that of Urticaria. Urticaria denotes the sudden appearance of hives and/or angioedema. Shodhana Chikitsa, mainly, Vamana or/ and Virechana is the main line of treatment advocated here to treat the disease. Special formulations are mentioned in classics for Vamana, which includes Patola Kashaya, Nimba Kashaya, Vasa Swarasa. Patients who fulfilled the diagnostic criteria were treated with Deepana Pachana, Snehana and Vamana with Nimba Kashaya Yoga. Assessment carried out using Urticaria Activity Score 7 showed marked improvement.</p> <p>Keywords: <i>Sheetapitta, Urticaria, Vamana, Nimba Yoga</i></p>

Introduction

Urticaria, commonly known as hives is a dermatological, allergic, vascular reaction. It is also an immunological condition which is characterised by skin rashes which are red, itchy wheals. They commonly occur following an infection or due to an allergic reaction. Urticaria may be acute (< 6weeks) or chronic (> 6 weeks). Chronic urticaria (CU) affects approximately 1% of the general population and around 20% of the population suffer from this condition once in their lifetime. It is characterized by the recurrence of hives (wheals) and/or angioedema for longer than 6 weeks. General line of treatment includes use of antihistamines. In severe cases, corticosteroids, leukotriene inhibitors and immunosuppressants are employed (Munjaj, 2012). Thus, educating patients, avoiding triggers, and using antihistamines forms the mainstay of therapy. Chronic cases can be difficult to treat and lead to significant disability, sometimes, even can be life threatening. Usually,

50% of patients of chronic urticaria will experience remission within 1 year. Systemic steroids and immunosuppressants have an extensive list of serious adverse effects such as adrenal suppression, weight gain, osteoporosis, hyperglycaemia, etc (Kim et al., 2013). Thus, need for alternate therapies to overcome the problem with much better clinical outcome has led to this study.

Sheetapitta disease explained in Ayurvedic classics shares similar aetiology, signs and symptoms as that of Urticaria. Due to excessive exposure to cold winds, Kapha and Vata doshas get aggravated, along with Pitta dosha vitiate Tvacha externally and Raktadi dhatus internally and produce Sheetapitta symptoms. They include Varati dashta samsthanavat shotha (swelling) over the skin, kandu (itching), toda (pricking pain), vidaha (burning sensation) (Sri Bhava Mishra, 2002).

Shodhana Chikitsa, mainly, Vamana or/ and Virechana is the main line of treatment advocated here to treat the disease. Shodhana therapies reduce the chance of remission, bring immunity in the body and provide a better outcome.

Vamana Chikitsa has been advised as the first line of treatment. Special formulations have been mentioned in classics for Vamana, which includes Patola Kashaya, Nimba Kashaya or Vasa swarasa (Sri Bhava Mishra, 2002). The current paper reports clinical study conducted in patients of Sheetapitta using Nimba Kashaya Yoga for Vamana. The objective of the present study is to evaluate the efficacy of Nimba Yoga for Vamana in Sheetapitta.

Materials and Methods

Study Design

This study was conducted in Sri Jayachamarajendra Institute of Indian Medicine Hospital, Bangaluru-09. Patients suffering from Sheetapitta were selected from the OPD and IPD of the hospital, irrespective of gender, religion, race, socio-economic status, and occupation. Random sampling technique was employed. Patients were assigned into a single group consisting of 10 patients. Written informed consent was obtained from all the patients before recording any data.

Inclusion Criteria

- Patients who are fulfilled diagnostic criteria, having symptoms of Sheetapitta.
- Medically diagnosed case of Urticaria.
- Patients between the age group of 18 and 50 years.
- Patients who were fit for Vamana Karma (Vagbhata, 2014a & b; Agnivesha a)

Exclusion Criteria

- Patients unfit for Vamana Karma (Vagbhata, 2014b).
- Pregnant and lactating women.
- Patients suffering from systemic diseases like Diabetes mellitus, Hypertension, Renal Failure, CVS, Malignancy etc.

Diagnostic Criteria

- Patients with Sheetapitta lakshanas.

VARATIDASHTA SAMSTHANA SHOTHA

AMOUNT	SCORE
None	0
Mild	1
Moderate	2
Severe	3

KANDU

AMOUNT	SCORE
None	0
Mild	1
Moderate	2
Severe	3

VIDAHA

AMOUNT	SCORE
None	0
Mild	1
Moderate	2
Severe	3

Patients fulfilling UAS7 (Urticaria Activity Score for 7days) (CSU, 2017; Zuberbier at al., 2013).

WHEAL

AMOUNT	SCORE
None	0
Mild: < 20 wheals over 24hours	1
Moderate: 20-50 wheals over 24 hours	2
Intense: >50 wheals over 24 hours or large areas of wheals that blend into one	3

PRURITIS (ITCH)

AMOUNT	SCORE
None	0
Mild: Present but not annoying or troublesome	1
Moderate: Troublesome but do not interfere with normal daily activity or sleep	2
Intense: Severe itch, which is sufficiently troublesome to interfere with normal daily activity or sleep	3

Investigations Blood:

- CBC with ESR
- AEC (Absolute Eosinophil Count)

Intervention

It is an Open label single arm clinical study with patients suffering from Sheetapitta as per proforma prepared for the study after fulfilling inclusion and exclusion criteria.

Vamana Karma was conducted as follows:

1. Deepana and Pachana was done with Chitrakadi vati (Agnivesh b) 500mg three times a day before food with ushnajala for 3-5 days till the appearance of nirama lakshanas.
2. Snehapana was done with Murchita ghrita (Govind Sen a) starting with the hrasiyasimatra of 25-30ml and depending on the digestion of sneha, dose of sneha increased in arohana krama for 3- 7 days till the appearance of Samyak snigdha lakshanas (Vagbhata, 2014c).
3. Sarvanga abhyanga was done with Murchita tila taila (Govind Sen b) followed by Ushna jala snana (hot water bath) during vishrama kaala (resting day).
4. Kaphakara ahara was advised for doshotkleshana on the day of Vishramakala (Vagbhata, 2014d).
5. Vamana was conducted on the next day of Vishrama kaala, early morning between 6am to 8am. Yavagu, approximately 200-400gms was administered to all patients before giving Vamana Yoga. Nimba Kashaya as Vamaka Yoga and Yashtimadhu Kashaya & Lavana jala as Vamanopaga were used to conduct Vamana until Pittanta or Samyak Shuddhi lakshanas appeared (Agnivesha c).
6. Salt water gargling and inhalation of Haridra dhuma was performed as Paschat Karma (Agnivesha d).
7. Peyadi Samsarjana Krama (Agnivesha e) was followed based on the Shuddhi.

Study Outcome Measures

The outcome of the study was assessed before treatment and after treatment using the following scales:

1. UAS7 (Urticaria Activity Score for 7days): UAS is a scoring system to evaluate signs and symptoms of Urticaria. It involves scoring of wheals and pruritis separately on a scale of 0 to 3 for 7 days.
2. Sheetapitta lakshanas such as, Varatidashta samsthanavat shotha, Kandu, and Vidaha were scored from 0 to 3 for 7 days.

Total Study Duration: 21days

Statistical Analysis

Paired 't' test and Wilcoxon signed rank test was used for Statistical analysis.

Level of Significance:

Insignificant – $P > 0.05$

Significant – $P < 0.05$

Highly Significant – $P < 0.003$ and $P < 0.001$

Results

The present study was carried out in 10 patients. Demographic and Personal Data is as follows:

Table No.1 Distribution of patients according to Gender

		Gender			
		Frequency	Percent	Valid Percent	Cumulative Percent
	Male	4	40.0	40.0	40.0
	Female	6	60.0	60.0	100.0
	Total	10	100.0	100.0	

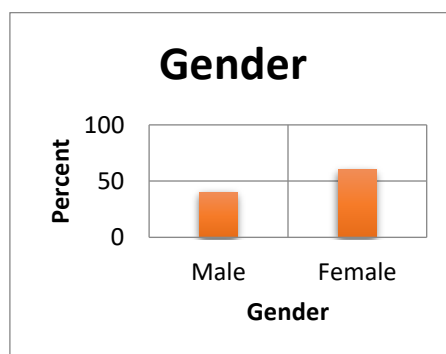


Table No.2 Distribution of patients according to age

Age		
	N	%
20-24	1	10.0%
25-30	2	20.0%
31-35	2	20.0%
36-40	1	10.0%
41-45	2	20.0%
46-50	2	20.0%

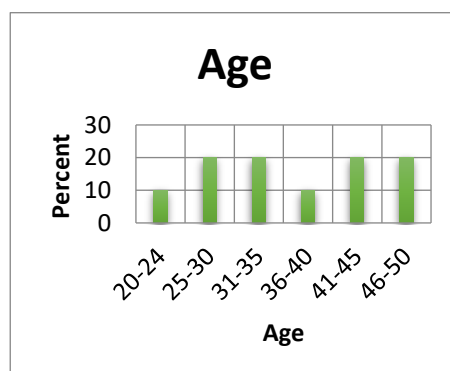
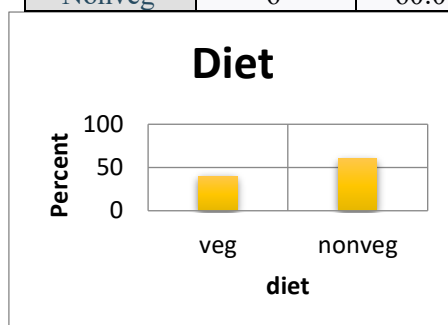
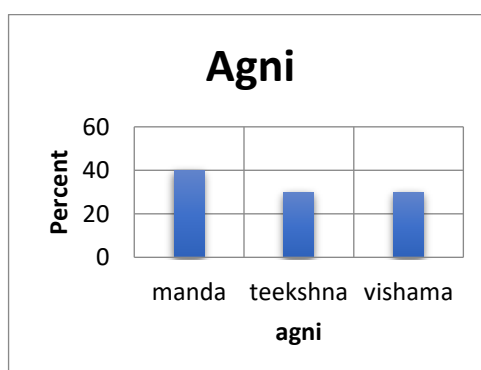


Table No.3 Distribution of patients according to Diet

Diet		
	N	%
Veg	4	40.0%
Nonveg	6	60.0%

**Table No. 4** Distribution of patients according to Agni

Agni		
	N	%
Manda	4	40.0%
Teekshna	3	30.0%
Vishama	3	30.0%

**Table No. 5** Distribution of patients according to Koshta

Koshta		
	N	%
Mrudu	2	20.0%
Madyama	5	50.0%
Krura	3	30.0%

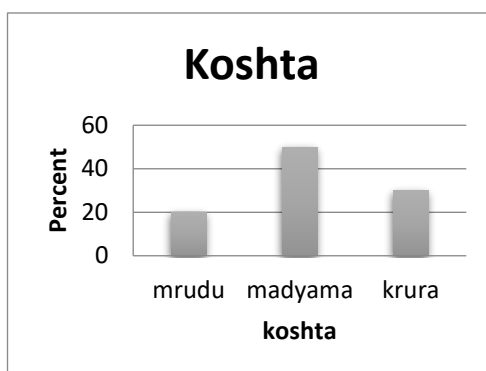


Table No. 6 Distribution of patients according to Prakruti:

Prakruti		
	N	%
VP	2	20.0%
VK	3	30.0%
PK	3	30.0%
PV	1	10.0%
KP	1	10.0%

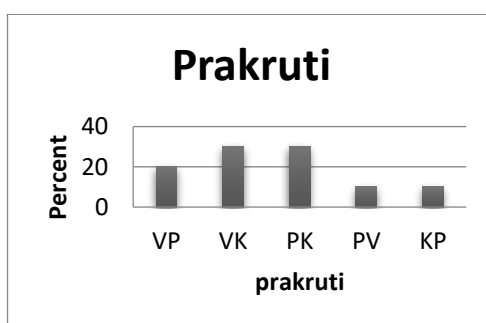


Table No. 7 Overall effect of Nimba Yoga for Vamana in Sheetapitta on subjective criteria (n=10)

Parameter	Mean BT	Mean AT	Mean difference	SD	SE	t	P
Wheals	18.80	4.60	14.200	3.584	1.133	12.529	<.001
Itch	19.80	1.50	18.300	1.494	.473	38.723	<.001
Varatidashta samsthanavat Shotha	18.80	4.60	14.200	3.584	1.133	12.529	<.001
Vidaha	11.20	2.50	8.700	6.929	2.191	3.971	<.003
Kandu	19.80	1.50	18.300	1.494	.473	38.723	<.001

Discussion

Discussion on Disease

The present open label single arm clinical study was taken up to evaluate the efficacy of Vamana using Nimba Yoga in Sheetapitta. The aetiology of Sheetapitta may be traced back to intake of sour, spicy, salty food, day sleeping habit found in most of the subjects. Profession of two subjects was to work in the field which led to exposure of cold wind. The study has been conducted in Bengaluru, Karnataka where the seasonal changes are very much evident. These causative factors have led to the vitiation of all the three doshas- Vata, Pitta and Kapha. Vitiated Kapha and Pitta have circulated all over the body along with Vata dosha targeting Rasa and Rakta Dhatus by taking shelter in Twacha or skin, thus producing the symptoms. They include Varatidamsha samsthanavat shotha, kandu, vidaha. Sheetapitta term has been mentioned in laghutrayee, while Charaka mentions as Pitaka, Kota, Kandu as bahu dosha lakshanas (Agnivesha f). These symptoms may be compared with the signs and symptoms of modern day Urticaria.

Samprapti Ghataka

Dosha- Tridosha

Available online at: <https://jazindia.com>

Dooshya- Rasa, Rakta,
 Agni-Jataragni and Dhatwagnimandya
 Aama-Jataragni and Dhatwagnimandyajanya
 Srotas- Rasavaha, Raktavaha
 Srothodushti prakara- Sanga, Vimarga gamana
 Udbhavasthana-Amashaya
 Sancharasthana– Sarvashareera
 Vyaktasthana- Sarvashareera vyapta twak

Discussion on Treatment

Acharya Charaka has advised Shodhana either Vamana and/or Virechana, based on dosha predominance as the line of treatment for Bahu dosha lakshanas (when vitiated doshas are excessively aggravated). Medieval period authors also opine that Shodhana in the form of Vamana and/or Virechana as the first line of treatment. Because, it is an undebatable topic that Shodhana eliminates doshas from the root and chances of reoccurrence of the disease are rare. Vamana Chikitsa has been selected here as Sheetapitta is an amashaya samutta vyadhi with Kapha predominance. Special drugs like Patola, Nimba, Vasa have been specifically mentioned for Vamana in Sheetapitta -Udarda-Kota condition. They have a crucial role in Samprapti Vighatana or to break down the pathogenesis. These drugs possess Tikta, Katu rasa which help to relieve the symptoms significantly. In the present study, Nimba Kashaya was used as Vamaka Dravya. The dose (Pandita, 2000) was decided based on the Koshta of the patient. Approximately 2 litres in Krura Koshta, 1.5litres in Madya Koshta and 1 litre in Mrudu Koshta was used. Due to Kashaya rasa, Katu Vipaka, Laghu, Ruksha Gunas present in Nimba, Kapha chedhana followed by Kapha vilayana and nirharana takes place in Sheetapitta. Pitta dosha was eliminated by Tikta Rasa and Sheeta Veerya present in Nimba while, Vata dosha is taken care by Katu vipaka (Sri Bhava Mishra, 2002). Hence, using Nimba Kashaya for Vamana as Dosha Shodhana Dravya is scientifically evident which is mentioned in the classics.

Discussion on Result

Paired 't' test and Wilcoxon signed rank test was used for Statistical analysis. Highly significant result was found in UAS7 Scale and when other parameters were compared before treatment and after treatment.

Conclusion

Shodhana Karma is ideal therapy in bahudosha avastha conditions. Hence, Vamana therapy was selected here using Nimba Kashaya specifically mentioned for Sheetapitta which was able to bring significant outcome in all the subjects. Also, Nimba is a commonly available drug which may be used for Vamana compared to other Vamaka dravyas. It is observed that, patients having Pitta lakshanas along with Kapha dosha may need Virechana Karma after Vamana. Vamana treatment bestows promising results and the same study may be carried out in larger population.

Conflict of Interest: None

Source of support: Nil

References

1. YP Munjal. API Text Book of Medicine, Association of Physicians India, 9th edition; 2012, 491-492.
2. Kim S, Baek S, Shin B, Yoon SY, Park SY, Lee T, Lee YS, Bae YJ, Kwon HS, Cho YS, Moon HB, Kim TB (2013). "Influence of initial treatment modality on long-term control of chronic idiopathic urticaria. 2013, PLoS ONE, 8(7):e69345
3. Sri Bhava Misra. Bhavaprakasa, Chowkambha Sanskrit Series Office, Varanasi, 2nd edition; 2002, Chikitsa prakaranam, 54/1,3, Sheetapitta Udarda Kota Utkotadhikara, 518-519.
4. Sri Bhava Misra. Bhavaprakasa, Chowkambha Sanskrit Series Office, Varanasi, 2nd edition; 2002, Chikitsa prakaranam, 54/ 7, Sheetapitta Udarda Kota Utkotadhikara, 519.
5. Vagbhata, Ashtanga Hrudaya with Sarvangasundara commentary of Arunadatta and Ayurveda Rasayana commentary of Hemadri edited by Pandit Hari Sadashiva Sastri Paradakara, Varanasi; Chaukambha Sanskrit Sansthan ; reprint 2014 sutrasthana 18/1-6, 260.

6. Agnivesha. Charaka Samhita, annotated by Charaka and redacted by Dridhabala with the ayurvedadipika commentary of chakrapanidatta, edited by Yadavaji Trikamji Acharya. Siddhisthana 2/9, 688.
7. Vagbhata, Ashtanga Hrudaya with Sarvangasundara commentary of Arunadatta and Ayurveda Rasayana commentary of Hemadri edited by Pandit Hari Sadashiva Sastri Paradakara, Varanasi; Chaukambha Sanskrit Sansthan; reprint 2014 Nidanasthana 4/7, 8, 473.
8. Australasian Society of Clinical Immunology and Allergy. ASCIA Chronic Spontaneous Urticaria (CSU) Guidelines, 2015.
9. Zuberbier T et al. The EAACI/GA2LEN/EDF/WAO Guideline for the definition, classification, diagnosis, and management of urticaria: the 2013 revision and update. Allergy 2014; 69: 868– 887.
10. Agnivesha. Charaka Samhita, annotated by Charaka and redacted by Dridhabala with the ayurvedadipika commentary of chakrapanidatta, edited by Yadavaji Trikamji Acharya. Chikitsa sthana 15/96-97, 520.
11. Govind Das Sen. Bhaishajya Ratnavali, with Vidyotini Hindi Vyakhya by Kaviraja Ambikadattashastri, Varanasi, Chowkambha Sanskrit series office, 16/1, 329.
12. Vagbhata, Ashtanga Hrudaya with Sarvangasundara commentary of Arunadatta and Ayurveda Rasayana commentary of Hemadri edited by Pandit Hari Sadashiva Sastri Paradakara, Varanasi; Chaukambha Sanskrit Sansthan; reprint 2014 sutrasthana, 16/29-31, 249-250.
13. Govind das sen. BhaishajyaRatnavali, with Vidyotini Hindi Vyakhya by Kaviraja Ambikadattashastri, Varanasi, Chowkambha Sanskrit series office, 5/1286-87.
14. Vagbhata, Ashtanga Hrudaya with Sarvangasundara commentary of Arunadatta and Ayurveda Rasayana commentary of Hemadri edited by Pandit Hari Sadashiva Sastri Paradakara, Varanasi; reprint 2014 sutrasthana 18/12, 262.
15. Agnivesha. Charaka Samhita, annotated by Charaka and redacted by Dridhabala with the Ayurveda dipika commentary of chakrapanidatta, edited by Yadavaji Trikamji Acharya; Chaukambha Surabharati Prakashan; Sutrasthana 15/9-12, 94.
16. Agnivesha. Charaka Samhita, annotated by Charaka and redacted by Dridhabala with the ayurvedadipika commentary of chakrapanidatta, edited by Yadavaji Trikamji Acharya: Chaukambha Sanskrit Sansthan; Sutra sthana 15/14, 95.
17. Agnivesha. Charaka Samhita, annotated by Charaka and redacted by Dridhabala with the Ayurveda dipika commentary of chakrapanidatta, edited by Yadavaji Trikamji Acharya: Chaukambha Sanskrit Sansthan: Siddhi sthana 1/11, 678.
18. Agnivesha. Charaka Samhita, annotated by Charaka and redacted by Dridhabala with the Ayurveda dipika commentary of chakrapanidatta, edited by Yadavaji Trikamji Acharya. Sutra sthana 16/13-16, 97.
19. Pandita Sharngadharacharya. Sarangadhara Samhita with the commentaries Adhamalla's Dipika and Kasirama's Gudhartha-Dipika, edited by Pt. Parashuram Shastri Vidyasagar: Krishnadas Academy, Varanasi: reprint 2000: Uttarakhanda 3/14, 306.
20. Sri Bhava Misra. Bhavaprakasa: Chowkambha Sanskrit Series Office, Varanasi, 2nd edition; 2002, Purva Khanda, Varga prakaranam,6/94, 294.