ejpmr, 2019,6(9), 309-313

SJIF Impact Factor 4.897

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Research Article

ISSN 2394-3211

EJPMR

A CLINICAL EVALUATION TEJOVAHATYADI CHURNA PRATISARNA AND GOMUTRA SIDH HARITAKAYADI VATI IN THE MANAGEMENT OF SARVASARA ROGA(MUKHA PAKA) W.S.R. TO APHTHOUS ULCER

Dr. Seema Rani*[1], Dr. Satish Sharma[2], Dr. Vijayant Bhardwaj[3] and Dr. Swati Singh[4]

[1, 4]M.S. (ENT), Shalakya Tantra, R.G.G.P.G. Ayu. College and Hospital, Paprola, HP.
[2,3]Reader, R.G.G.P.G. Ayu. College and Hospital, Paprola, HP, India.

***Corresponding Author: Dr Seema Rani**

M.S. (ENT), Shalakya Tantra, R.G.G.P.G. Ayu. College and Hospital, Paprola, Hp.

Article Received on 26/06/2019 **Article Revised on 17/07/2019** **Article Accepted on 06/08/2019**

ABSTRACT

Ayurveda is the God gifted very ancient and the first medical science and composed by the originator Brahma and treated as Panchama Veda. Mukhapaka is kapha pitta predominant disease. It can be correlated with aphthous ulcer according to symptoms. Tejovahatyadi churna and Gomutra sidh haritakyadi vati having Kapha Shamak properties is taken as the drug of choice to control Sarvasar roga. Aim and objectives were to evaluate the efficacy of Tejovahatyadi churna and Gomutra Sidh Haritakyadi Vati on Sarvasara roga. All the selected patients fulfilling the criteria were taken in single group (10 patients) and was advised to take Tehovahatyadi churna for pratisarna and Gomutra Sidh haritakyadi vati for oral use for seven days. All patients completed their trial out of which two patients showed moderately relief. Eight patients were reported with complete cure of the disease.

KEYWORDS: Mukhapaka, Tejovahatyadi churna, Gomutra sidh Haritakyadi vati, Pratisarna.

INTRODUCTION

Ayurveda, The science of life offers a natural care for the protection of health and prevention of diseases.[1] In the past two millennia of human history, the world of medicine has completed a full cycle of development. The art and science of healing started from centuries went through eras of modernisation and revolutionary development and has come back to the ways of nature. The present century perhaps the green era in the history of modern man for the solution to the ever complicating, undiagnosed/syndromes. The entire world is focussing on alternative and traditional systems of medicine and diseases occurring again and again. The international health regulatory bodies are eagerly looking forward to traditional systems of medicine, where Ayurveda holds a key position.

Ayurveda, the life science renowned from time immemorial.[2] The research work is integral part of the science dealing with health and disease.

The concept of mouth ulcer has been dealt in ayurveda under the heading of Sarvasar or Mukhpaka roga.[3]

The etiology of chronic recurrent oral aphthous ulcers is still unclear.[4] In recent years there has been significant change in life style, dietary patterns. Due to growing affluence, rapid industrialization, and socio-economic development there is increase in stress and strain.[5] These factors have led to the increased prevalence of the disease; Aphthous ulcer i.e. upto 25% in general population. Autoimmune mechanism is believed to be the root cause of Aphthous ulcers.[6] Chronic recurrent oral aphthous ulcers are the most common inflammatory disease of the oral mucosa.[7]

Due to AU, patient finds it difficult to eat solid or liquid food, depending upon the severity of the disease. Food in any form is essential for the growth of body and for maintenance of health and restriction of food by any reason is responsible for reduction of immunity and so patient becomes prone to many diseases. It may develop into severity and chronicity if it is not treated properly as early as possible.

The Recurrence of disease also leads to a sense of frustration both in patient and clinician. Still no significant treatment regime is available which can effectively combat this malady. A meticulous approach is the need of the time for the cure of this particular disease.[8]

AIMS AND OBJECTIVES

- To study the MukhaPaka roga according to Ayurvedic concept.
- To study the Aphthous ulcer in light of modern concept and to avail latest information related with research as possible.

- ❖ To study the efficacy of formulation Tejovahatyadi churna[9] combined with Gomutra Sidh Haritakayadi vati[10] in the context of Aphthous ulcer.
- ❖ To promote complete ulcer healing within the short period of time.
  To avoid its complication or sequel and to study any side effect of the therapy.

MATERIAL AND METHODS

Plan of study

To meet the objectives of present research work, the study was planned under two headings as

- Literary study
- Clinical study

Literary study

All Ayurvedic and modern texts were reviewed in detail regarding the disease undertaken for the trial. Detailed review of the related drugs under trial was done.

Clinical study

A total number of 10 patients were selected from ShalakyaTantra OPD of hospital affiliated to R.G.G.P.G.Ayu.College, Paprola after obtaining their consent .Case study was random and patients were selected irrespective of sex, caste, religion, etc. History of all the patients was recorded according to the proforma. All the patients were followed up after commencement of trial.

Criteria for selection of patients

I) Inclusive Criteria

i) Patients having ulcer in oral cavity (lasting less than 1 month).
ii) Patient presenting with signs and symptoms of Aphthous ulcer (AU as an autoimmune process)
iii) Age above 5 years irrespective of sex.

II) Exclusive Criteria

i) Ulcer formed due to malignancy, seropositive patients.
ii) Patients below 5 years of age.
iii) Ulcer due to viral infection, secondary bacterial infection.
iv) Associated symptoms i.e. fever, malaise and tender lymphadenopathy.
v) Associated with autoimmune disorders i.e. Bechat`s syndrome, Reiter syndrome, IBS, SLE.
vi) Trauma induced, dermatological origin.
vii) Drug induced ulcer, ulcer due to nutritional deficiency.

METHODS OF STUDY

After careful examination, 10 patients were selected from the OPD of ShalakyaTantra of R.G.G.P.G. Ayu. Hospital, Paprola and treated in single trial group.

Trial group and Trial drug

In this group both Gomutra sidh Haritakyadi vati and Tejovahatyadi churna were given to the 10 patients as a trial drugs combination.

Mode of administration and dose of trial drug in trial group

- ❖ Tejovahatyadi churna - 5gm BD for pratisarna (Charak chikitisa 26/190)
- ❖ Gomutra sidh Haritakayadi vati - 500 mg tablets BD with lukewarm water after food. (Chakradatt)

Duration of trial - 7 days
Follow up - 2 follow up at weekly interval
1 follow up in the last of month

Criteria for assessment of result

- Subjective
- Objective

1. **Subjective** - Grading and scoring system was adopted for assessing each symptom before the commencement of trial and after completion of trial.

The overall score of each symptom was recorded as:

Sr. No.	Symptoms	0	1	2	3
1	Pain in the affected area	No Pain	Mild pain on touch	Moderate-pain without touch	Pain causing difficulty in opening mouth
2	Burning sensation	No complaint	Mild- with hot beverages	Moderate-felt on taking spicy and acidic, salty food	Severe-throughout the day without any aggravating factor
3	Difficulty in chewing/ingestion	Can eat easily	Mild- can eat solid food	Moderate-can eat liquid food only	Severe- cannot eat liquid as well as solid food
4	Excessive salivation	No complaint	Complaining of salivation	Has to spit saliva	Dribbling of saliva
5.	Inflammation	No hyperemia	At ulcer margin only	Floor of ulcer	Centre of ulcer necrosed/ slough seen
6.	Size (degree) of ulceration	No ulceration	<3mm	3mm - <1cm	>1cm
7.	No. of ulceration	No ulceration	<1	2-10	>10
8.	Site of ulceration	Nil	<1	2-5	>5

viii) **Objective Criteria:-** Haematological parameters - Hb%, TLC, DLC, ESR, Blood sugar, VDRL, HIV I and II (if required for, diabetic and hypertensive patients.

Drugs
Tejovahatyadi churna
Gomutra sidh Haritakayadi vati

Ingredients of Drug Used
Tejovahatyadi Churna

Sr.no.	Name of plant	Botanical name	Family	Part used	Quantity
1.	Tejovaha	Zanthoxylum alatum	Rutaceae	Bark	1 part
2.	Haritaki	Terminalia chebula Retz.	Combretaceae	Fruit pericarp	1 part
3.	Ela	Elettaria cardimomum	Zingiberaceae	Seeds	1 part
4.	Manjistha	Rubia cordifolia Linn.	Rubiaceae	Root	1 part
5.	Kutki	Picrorrhiza kurroa	Scrophulriaceae	Root	1 part
6.	Motha	Cyperus rotundus Linn.	Cyperaceae	Rhizome	1 part
7.	Patha	Cissampleos parietal Linn.	Menispermaceae	Root	1 part
8.	Jyotishmati	Celastrus panniculatus	Celastraceae	Seeds	1 part
9.	Lodhra	Symplocos racemosa	Symplocaceae	Bark	1 part
10.	Daruharidra	Beriberis aristata	Zingiberaceae	Root	1 part
11.	Kustha	Saussurea lappa	Compositae	Root	1 part

Method of preparation
All the ingredients were collected in equal parts and fine powder was made and kept in container.

Gomutra Sidh Haritakaydi Vati

Sr.no.	Name of plant	Botanical name	Family	Part used	Quantity
1.	Tagar	Valeriana wallichii	Valerianaceae	Rhizome	1 part
2.	Haritaki	Terminalia chebula	Combretaceae	Fruit pericarp	1 part
3.	Kustha	Saussurea lappa	Compositae	Root	1 part
4.	Saunf	Foeniculum vulgare	Umbelliferae	Fruit	1 part
5.	Gomutra				SOS

Method of preparation
Haritaki was kept in gomutra overnight while other ingredients were powdered, than haritaki with gomutra was mixed with powdered material and mixed. After sometime vati was made with that paste and dried in heat.

Criteria for Final Assessment of Results
The total effect of therapy was assessed in five groups:-

Cured	100% relief in signs and symptoms and no recurrence during follow up study have been considered as cured.
Marked Improvement	75% - <100% improvement in signs and symptoms has been considered as marked improvement
Moderately improvement	50% - <75% improvement in signs and symptoms has been recorded as moderate improvement
Mild improvement	25% -<50% improvement in signs and symptoms has been considered as mild improvement
Unchanged	Up to 25% reduction in signs and symptoms was noted as unchanged

Effect of Therapy

The efficacy of both the therapies i.e.Tejovahatyadi churn and Gomutra Sidh Haritakayadi vati in combination was adjudged in 10 patients on various parameters and results were derived after execution of statistical methodology.

Sr. No.	Symptoms	N	Mean		X	% relief	S.D. +	S.E. +	't'	P
			B.T.	A.T						
1.	Pain in affected area	10	2.3	0.7	1.60	69.56	0.516	0.163	9.798	<0.001
2.	Burning sensation	7	1.3	0.3	1.00	76.92	0.816	0.258	3.873	>0.001
3.	Difficulty in chewing /ingestion	5	1.1	0.2	0.90	81.81	0.994	0.314	2.862	>0.01
4.	Excessive salivation	2	0.40	0.1	0.30	75	0.675	0.213	1.406	>0.1
5.	Inflammation	8	1.8	0.6	1.2	66.67	0.789	0.249	4.811	<0.001
6.	Degree (size) 0f ulceration	10	1.8	0.3	1.5	83.33	0.527	0.167	9.000	<0.001
7.	No. of ulceration	10	1.4	0.2	1.2	85.71	0.422	0.133	9.00	<0.001
8.	Site of ulceration	10	1.7	0.2	1.5	88.23	0.527	0.167	9.00	<0.001

1. Pain in affected area

The initial score of pain in affected was 2.3 which was reduced to 0.7 after the treatment. The %age of relief was 69.56% which is highly significant statistically at the level of p<0.001(t=9.798).

2. Burning Sensation

The initial score of burning sensation was 1.3 which was reduced to 0.3 after the treatment. The %age of relief was 76.92% which is significant statistically at the level of p>0.01(t=3.873).

3. Difficulty in Chewing

The initial score of difficulty in chewing was 1.1 which was reduced to 0.2 after the treatment. The %age of relief was 81.81% which is significant statistically at the level of p>0.01(t=2.862).

4. Excessive Salivation

The initial score of excessive salivation was 0.4 which was reduced to 0.1 after the treatment. The %age of relief was 75% which is non-significant statistically at the level of p>0.1(t=1.406).

5. Inflammation

The initial score of inflammation was 1.8 which was reduced to 0.6 after the treatment. The %age of relief was 66.67% which is highly significant statistically at the level of p<0.001(t=4.811).

6. Degree (size) of ulceration

The initial score of size of ulceration was 1.8 which was reduced to 0.3 after the treatment. The %age of relief was 83.33% which is highly significant statistically at the level of p<0.001(t=9.000).

7. No. of ulceration

The initial score of size of ulceration was 1.4 which was reduced to 0.2 after the treatment. The %age of relief was 85.71% which is highly significant statistically at the level of p<0.001(t=9.00).

8. Site of ulceration

The initial score of size of ulceration was 1.6 which was reduced to 0.2 after the treatment. The %age of relief was 88.23% which is highly significant statistically at the level of p<0.001(t=9.000).

OBSERVATION

Total 10 patients in single group were registered. It was found that maximum number of patients 4 (40%) were between the age group 51-60 years. Maximum registered patients 5 (50%) were females and were Hindu 10 (100%) religion wise. As per socio-economic group upper middle class patients were obtain 8 (80%). As per occupation maximum number of patients were employees 5 (50%). Maximum no. of patients were of Kaphaja Prakriti 4 (40%) and were having mandagni 8 (80%). Maximum patients had Madhyam Satva 5 (50%) and Tamsik Prakriti 8 (80%). Maximum patients were having satisfactory sleep 7(70%).

RESULT

Sr. no.	Assessment	No. of patients	% age
1.	Cured	8	80%
2.	Markedly improved	2	20%
3.	Moderately improved	0	0
4.	Slightly improved	0	0
5.	Unimproved	0	0

DISCUSSION

Rasa Panchak of Tejovahatyadi churna having Ushan Virya (54.4%), katu vipaka(90.1%), Tikta ras(81.8%), laghu guna(81.8%) and Kaphapitta shamak property (45.4%). Tejovaha and kutki having stomachic and digestive property. So Tejovahatyadi churna is used for local application. The ingredients of Gomutra Sidh Haritakyadi vati consists of katu Rasa (100%), laghu Guna (100%), Ushna Virya (80%) and katu vipaka(60%). Haritaki act as a rasayan. It improves the general condition of the body and acts as a rejuvenator of the body. Ingrdients of Gomutra Sidh Haritakyadi vati, by their antioxidant properties removes toxic free

radicals(Ama i.e. root cause of disease). Thus helps in the Samprapti Vighatana of the Mukhapaka.

Pobable Mode of action

- The probable mode of action of drug can be attributed to the annexed effect of the pharmaco therapeutic properties of various constituents of the trial drug. To sketch the mode of action it is imperative to look into the Raspanchaka as it is fundamental of pharmaco therapeutic of Ayurvedic management.
- As told by Acharyas the diseases which occurs in mukha Pradesh are mainly due to vitiation of kapha dosha.
- Although the exact aetiology of Aphthous ulcer is not known, they are considered to be an autoimmune disease.
- Tejovahatayadi churna is having dominance of tikta rasa (81.8%), katu rasa (63.6%) respectively, laghu guna (81.8%), ruksa guna(63.6%), ushna veerya (54.4%), katuvipaka (90.1%) and kapha pitta samaka (45.4%), tridoshahar(27.2%), kaphvata hara (27.2%) properties.
- Whereas Gomutra sidh Haritakyadi vati is having dominance of katu rasa(100%), tikta rasa (80%) respectively, laghu guna (100%), ushna veerya (80%), katu vipaka (60%) and kapha vata hara properties (40%) due to which it is stomachic and improves digestion. It also pacify the vitiation of kapha dosha which is the responsible for the disease resulting in amoutpatti.

CONCLUSION

- Analysis of the study reveals that Mukhapaka is a disease which mostly affects the people who are having Mandagni and incidence increases with age.
- This disease is more common in middle class and literate people who are more attentive towards their mental and physical health, because aphthous ulcer affects the mental status of a person.
- Regarding aetiological factors it is confirmed that poor nutrition, Patients of Kaphaja and Tamsik prakriti are more common to this disease.
- Drugs used in single group, in which result of Tejovahatyadi churna and Gomutra sidh Haritakyadi vati was highly significant.

Present study requires to be repeated on large samples and observation of results should be done for longer period to assess duration of the effect and side effects of the drugs if any, so that drugs can be established for treatment of Mukhapaka.

REFERENCE

1. Pt. Kashinathshastri and Dr.Gorakhanathchaturvedi, Charaka Samhita of charaka with Vidyotini Hindi Commentary, Sutrasthana Reprint edition; 2009 chapter 30 versus 12 Varanasi: Chaukhambhabharati academy, 2009; 587.
2. Pt.Kashinathshastri and Dr.Gorakhanathchaturvedi, Charaka Samhita of charaka with Vidyotini Hindi Commentary, Chikitsasthana Reprint edition; 2009 chapter 15 versus 12 Varanasi: Chaukhambhabharati academy, 2009; 466.
3. AmbikadattShastri, Sushruta Samhita of Sushruta with Ayurveda TatvaSandipika Hindi Commentary, nidanasthna, Reprint edition; 2012, chapter 16 versus 36, Varanasi: Chaukhambha Sanskrit Sansthana, 2012; 391.
4. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4215084/
5. Scully C, Porter S. Oral mucosal disease: Recurrent aphthous stomatitis. Br J Oral Maxillofac Surg, 2008; 46: 198–206.
6. Shulman JD, Beach MM, Rivera-Hidalgo F. The prevalence of oral mucosal lesions in U.S. adults: data from the Third National Health and Nutrition Examination Survey, 1988-1994. J Am Dent Assoc, 2004; 135: 1279–86.
7. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4215084/
8. Cowan MM. Plant products as antimicrobial agents. ClinMicrobiol Rev., 1999; 12: 564–82.
9. Pt. kashinathshastri and Dr.Gorakh nath chaturvedi,charaka samhita of charaka with vidyotini Hindi Commentary, Chikitsa sthana Reprint edition, 2009; 26(190): 49.
10. Srichakrapani krita Chakradutt Vaidyaprabha Hindi commentary by Dr. Indradeva Tripathi, Chaukhamba Sanskrit Sansthana, Varanasi, Mukhroga Chikitsa, 56/24: 333.