

COMPARATIVE STUDY OF THE EFFICACY OF ARDRAKA AND SHUNTHI WITH GUDA IN THE MANAGEMENT OF SHITAPITTA WITH REFERENCE TO URTICARIA

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ABSTRACT

Purpose: comparative study of the efficacy of ardraka and shunthi with guda in the management of shitapitta with reference to urticaria

Design: Prospective, randomized, interventional, hospital based comparative study

Material & Methods: In present study 60 patients were randomly selected and divided into 2 groups, with 30 patients each. First group was treated with Ardraka swaras with guda as experimental group, Second group was treated with shunthi swaras with guda only as controlled group. Subjective parameters like Mandalotpatti, Kandu, Daha, Toda, Frequent of attacks, Associated symptoms like chhardi, aruchi, pipasa, jwar. And objective parameters like Mandalotpatti (Wheels) Length/Breadth in mm/cm were adopted. These were suitably graded to assess the results that were statistically

analyzed. **Results:** In present study out of 30 patients of group A, shows Mild change (25% – 49.9% relief) in 4, Moderate change (50% -74.9%) in 14 and Good change (75%- below 100%) in 12 patients. In Group B out of 30 patients, shows Mild change (25% – 49.9% relief) in 7, Moderate change (50% -74.9%) in 19 and Good change (75%- below 100%) in 4 patients. But according to the Mann-Whitney test (Z), the difference between both of above group was found no significant, as the calculated $p=0.164$. **Conclusion:** Comparison of the results of experimental group & control group shows that better relief in all the signs,

symptoms and overall improvement in Shitapitta but Comparatively Ardraka Swarasa was better than Shunthi Swarasa.

KEYWORDS: Shitapitta, Shunthi, Ardraka, Swarasa, urticaria.

INTRODUCTION

The 'Veda' word in Ayurveda proves that knowledge of Ayurveda has equal importance to the knowledge of Vedas. Vedas are known as root of all knowledge. Ayurveda is Upaveda of Atharva Veda. Whatever we are on this earth at this moment, we can see and feel how bad the impact of modern life is damaging the nature environment and our lives. As modern humans we also have an understanding that the quality of our health is affected by the negative impacts, such as air pollution, water, food and life style is not healthy.

Ayurveda is holistic life style system that teaches the practical details of the arrangement of food, body work, rest periods and work, which aims to achieve balance of body, mind and soul.

Ayurveda is not just medicine but a healthy life style. The basic principal of Ayurveda is to prevent diseases by balancing body, mind, soul and environment.

Skin is the most visible part of the body that reflects personality of a person and the first organ of the body interacting with the environmental agents like physical, chemical & biological agents.

In present busy and fast life, one can't follow the rules of "Dinacharya" and "Rutucharya" described in Ayurveda. Due to heavy Industrialization and Pollution, one constantly comes in contact with various pollutants. The spicy & fast food eaten now a days, which has very less nutritional values & also having similar properties to viruddhahara sevana, one becomes sensitive to allergens as well as antibodies and produces various types of allergic reactions, such as SHITAPITTA or Urticaria, which is very commonest allergic reaction.

According to Davidson 20th ED. large community prevalence studies has been between 20-30% of the population having various skin problems requiring attention.^[1] Urticaria affects 10% to 25% of population at some point in their life. (Henderson, Fleischer and Feldman, 2000).

Hives (Medically known as Urticaria) is very common, and most often its cause is elusive. Hives can change size rapidly and it's moves around, disappearing from one place and reappearing at other place, often in a matter of hours.

'Urticaria' is a disease characterized by itchy red rashes on skin on almost all over the body. The disease 'Shitapitta' is not a life threatening. It worries patient due to its appearance and frustrating condition because of severe itching.

Shitapitta is disorder in which vata and kapha are two doshas which are primarily disturbed due to doshprakopak hetu and in combination with pitta dosha cause Shitapitta. Vata dosha is dominant in Shitapitta which leads to formation of wheals, redness, itching over the skin.^[2]

Urticaria results from an immediate hyper sensitivity reaction between antigen and antibody, which causes increase in vascular permeability and edema (wheals).

In the Urticarial reaction Histamine is thought to be the most important biochemical mediator. It causes vasodilatation and enhances the capillary permeability for fluid and plasma proteins from blood into the affected tissues. So the accumulation of fluid with protein causes local edema.

In modern aspects of medicine antihistamines are mainly used along with Steroids which have so many side effects. Urticaria is mostly resistant to this treatment so far known to medical world. The present known treatment is still not an ideal one by any means. For the skin condition like Shitapitta both Shodhan and Shaman treatment is mentioned in Ayurvedic classics. The Shodhana procedure is laborious treatment procedure where the patient has to be hospitalized.

More over these Shodhana procedures are only indicated in patients having *uttama mamsa bala*. So the alternative Shamana oushadhi is selected for the present study. So emphasis was made to evaluate the efficacy of Ardraka Swarasa with Guda in comparison to Shunthi Swarasa with guda.

MATERIALS AND METHODS

For the rational treatment of any disease, knowledge of the mode of action of a drug, its effects on various body systems and the probable adverse effects is important, comparing pharmacological study provides such a basic.

Clinical trial is a carefully and ethically designed experiment with an aim to answer precisely framed question. It is a means to evaluate the efficacy and tolerability of a treatment in human beings.

This was 35 days clinical study. This comparative study was carried out in 60 patients of shitapitta. Out of these, 30 patients were treated with Ardraka swarasa and 30 with Shunthi swarasa.

Selection of Patients

Patient subjected to clinical trials were selected from OPD and IPD of kayachikitsa department and also from Medical camp.

CRITERIA FOR SELECTION OF PATIENT

A. INCLUSION CRITERIA

1. Patient in age group 16 to 60yrs of different socioeconomic status.
2. Sex-both sexes.
3. Patient with typical signs & symptoms of Shitapitta, which are explained in the Samhitas.

B. EXCLUSION CRITERIA

1. Age below 16 and above 60yrs patients.
2. Patients suffering from urticarial vasculitis, T.B., HIV, Viral infections, Diabetes, Carcinoma and other skin infections.
3. Patients who are taking other medications.

A) SUBJECTIVE PARAMETERS

1. Mandalotpatti
2. Kandū
3. Daha
4. Toda
5. Frequent of attacks
6. Associated symptoms like chhardi, aruchi, pipasa, jwar.

B) OBJECTIVE PARAMETERS

- Haematological tests—CBC, Absolute Eosinophil count, ESR Investigations of all patients were done before and after treatment.

- Measurement of mandal in mm_ cm. (length, bredth)
- Part of skin occupied by mandal in percentage. By using rule of nine

Grouping

After complete examination and investigations all patients were randomly divided into 2 groups.

Experimental group (Group A) – In this group 30 patients were treated with Andraka swarasa 12ml with Guda 4gm as anupana Twice a day.

Control Group (Group B) - In this group 30 patients were treated with Shunti swarasa 24ml with Guda 4gm as anupana Twice a day.

Type of Study- Clinical.

Duration of treatment- 35 days

Follow up- Every week

CASE PROFORMA

A special case proforma was prepared that comprised of all the Ayurvedic and Modern parameters essential for the assessment of the condition of Shitapitta patients before and after treatment.

CRITERIA FOR ASSESSMENT

Main signs and symptoms, associated complaints were giving different scores according to their severity. They were record before and after treatment.

A) SUBJECTIVE PARAMETERS

1. Mandalotpatti (Wheals)

0	No Mandal
1	Mandal on 25% of skin
2	Mandal on up to 50% of skin
3	Mandal on >50% of skin

1. Kandu, Toda, Daha

0	Nil
1	Patient can work easily.(mild)
2	Patient can not work easily.(moderate)
3	Patient can not concentrate on work.(severe)

2. Frequency of attacks

0	No attacks
1	Once in week
2	Once in alternate day
3	Once daily

3. Chhardi

0	No attacks
1	Mild (1 episode/week)
2	Moderate (2-3 episode/week)
3	Severe (>3 episode/week)

4. Jwara

0	Nil
1	Mild (99°-100° F)
2	Moderate (100°-102° F)
3	Severe (>102° F)

5. Aruchi

0	Nil
1	Mild
2	Moderate
3	Severe

2. Hrilhas

0	Nil
1	Mild
2	Moderate
3	Severe

B) OBJECTIVE PARAMETERS**1. Mandalotpatti (Wheals) Length/Breadth in mm/cm**

0	Nil
1	≤ 1cm
2	≥ 1cm but ≤ 3cm
3	≥ 3cm

2. Mandalotpatti (wheals) % of skin occupied by the rule of nine

0	No Mandal
1	Mandal on 25% of skin
2	Mandal on up to 50% of skin
3	Mandal on >50% of skin

OBSERVATIONS AND RESULTS**Symptoms Wise % of relief distribution of 60 patients of Shitapitta**

Symptoms	% Relief	
	Group-A	Group-B
Mandalotpatti %	65.0	64.7
Mandalotpatti	65.0	64.7
Kandu	65.0	57.2
Toda	65.7	57.1
Daha	58.5	51.6
Frequency of attacks	64.8	61.0
Chardi	100.0	76.9
Jwara	100.0	58.8
Aruchi	100.0	51.9
Hrillhas	85.0	26.1
Total score	66.6	58.6

The above results shows relief in percentage,

a) Group – A – Mandalotpatti % of rule of nine (65%), Mandalotpatti in mm/cm (65%), Kandu (65%), Toda (65.7%), Daha (58.5%), Frequency of attacks (64.8%), Chardi (100%), Jwara (100%), Aruchi (100%), Hrillhas (85.0%).

b) Group – B -Mandalotpatti % of rule of nine (64.7%), Mandalotpatti in mm/cm (64.7%), Kandu (57.2%), Toda (57.1%), Daha (51.6%), Frequency of attacks (61%), Chardi (76.9%), Jwara (58.8%), Aruchi (51.9%), Hrillhas (26.6%).

Overall Effects of all Patients Wise distribution of 60 patients of Shitapitta

Overall Effect	No. of cases	
	Group-A	Group-B
No change (<25%)	0	0
Mild change (25% – 49.9%)	4	7
Moderate change (50% -74.9%)	14	19
Good change (75% +)	12	4

The above distribution shows that in group- A there were 12 patients got Good change, 14 patients got Moderate changes and 4 patients got Mild change, where as in the group-B there were 4 patients got Good changes, 19 patients got Moderate changes and 7 patients got Mild change in symptoms.

Total score Wise distribution of 60 patients of Shitapitta

Total score	BT		AT		% Relief	Wilcoxon Signed Ranks Test Z	P
	Mean score	Sd	Mean score	Sd			
Group-A	12.4667	2.2242	4.1667	2.2755	66.6	4.794	<0.001 HS
Group-B	12.4667	2.2242	5.1667	2.0858	58.6	4.803	<0.001 HS

Table shows that the Ardraka Swarasa provides highly significant relief ($p < 0.001$) i.e. 66.6% and Shunthi Swarasa also provides highly significant relief ($p < 0.001$) i.e. 58.6% in Total score of patients.

COMPARISON BETWEEN TRIAL GROUP AND CONTROL GROUP

According to the mann-whitney test (Z), the difference between both of above groups was found non significant, as the calculated. From this we can conclude that the treatment given to the both of the groups is equally effective on all symptoms.

Total Score

Total score	Mean difference score	Sd	Mann-Whitney Z	P
Group-A	8.3000	2.69290	1.393	0.164 NS
Group-B	7.3000	1.68462		

The mean difference score in the experimental group-A (8.3000) was found greater than the mean difference score of the control group-B (7.3000). This suggests that the treatment given to the experimental group-A is more effective for this Total Score compared to the control group.

But according to the mann-whitney test (Z), the difference between both of above groups was found non significant, as the calculated $p = 0.164$. From this we can conclude that the treatment given to the both of the groups is equally effective on this Total Score.

DISCUSSION

Urticaria (also known as hives, welts or nettle rash) is a raised, itchy rash that appears on the skin. The rash can be limited to one part of the body or spread across large areas of the body. Urticaria is a worldwide disease and may present at any age. The lifetime occurrence of urticaria in the general population ranges from 1% to 5%. Urticaria is classified as acute or

chronic. Urticaria consists of recurrent wheals that are usually pruritic, pink-to-red edematous plaques that often have pale centers. The wheals are transient, and in most types of urticaria last for <24 hours. The wheals range in size from a few mm to several cm in diameters. In some cases, the disorder is relatively mild, recurrent, and frustrating for both patient and physician. Shitapitta can be co-related with urticaria in Ayurveda, because it has same symptoms, like Kandu as itching, Daha as burning sensation, mandal as nettle rash, toda as pricking pain etc.

Shitapitta is disorder in which vata and kapha are two doshas which are primarily disturbed due to doshprakopak hetu and in combination with pitta dosha cause Shitapitta. Vata dosha is dominant in Shitapitta which leads to formation of wheals, redness, itching over the skin.

In this study 60 patients were registered & have completed their full course of treatment. In the previous chapter a record & statistical data of 60 patients of Shitapitta has been presented.

EFFECT OF THERAPY

Effect on Mandalotpatti % by rule of nine

It was reduced to 0.57 from the initial score 1.63 with 65% relief and highly significant result ($p < 0.001$) in group-A. In group-B it was reduced to 0.60 from the initial score 1.70 with 64.7% relief. It is obviously showed that the effect of group-A was quite better than group-B therapy in the Mandalotpatti This was probably due to kaphaghna, Shothahara, Aamapachaka properties of both drugs.

Effect on Mandalotpatti mm/cm

It was reduced to 0.57 from the initial score 1.63 with 65% relief and highly significant result ($p < 0.001$) in group-A. In group-B it was reduced to 0.60 from the initial score 1.70 with 64.7% relief. It is obviously showed that the effect of group-A was quit better than group-B therapy in the Mandalotpatti. This was probably due to kaphaghna, Shothahara, Aamapachaka properties of both drugs.

Effect on Kandu

The initial score of kandu was 1.80 which was reduced to 0.63 with 65% relief with highly significant result ($p < 0.001$) in group-A. In group-B the symptom was reduced to 0.77 from the initial score 1.80 with 57.2% relief. This may be because of kapha- pittaghna, Raktashodhak, Dipana, Pachana property of drugs.

Effect on Daha

The initial score of Daha was 2.00 which was reduced to 0.83 with 58.5% relief with highly significant result ($p < 0.001$) in group-A. In group-B the symptom was reduced to 1.03 from the initial score 2.13 with 51.6% relief. This may be because of kapha- pittaghna, Raktashodhak, Dipana, Pachana, Sheeta Prashamana property of drugs.

Effect on Toda

The initial score of Daha was 2.13 which was reduced to 0.73 with 65.7% relief with highly significant result ($p < 0.001$) in group-A. In group-B the symptom was reduced to 0.90 from the initial score 2.10 with 57.1% relief. Toda is also one of the important symptoms produced by vitiation of vata. This showed both drugs can provide better relief in Toda probably due to vatashamak property of drugs.

Effect on Frequency of attack

Frequency of attack was decreased to 0.80 from 2.27 in group-A with 64.8% relief & statistically highly significant result ($p < 0.001$). In group-B initial score of frequency of attack was 2.23 which decreased to 0.87 with 61.0% relief with statistically highly insignificant result ($p < 0.001$).

Frequency of attack may be due to muhuschhari & ashukari guna of vata. Frequency of attack decreases probably because of Vataghna property of drugs.

ASSOCIATED SYMPTOMS**Effect on Chardi**

Chardi was decreased to 0.00 from 0.17 in group-A with 100% relief & statistically non significant result ($p = 0.059$). In group-B initial score of Chardi was 0.13 which decreased to 0.18 with 76.9% relief with statistically non insignificant result ($p = 0.083$). This showed Ardraka Swarasa can provide better relief in Chhardi than Shunthi Swarasa, may be because of its Deepana, Pachana, kapha-pittaghna, Jwaraghna property.

Effect on jwar

Jwar was decreased to 0.00 from 0.30 in group-A with 100% relief & statistically significant result ($p = 0.024$). In group-B initial score of Jwar was 0.17 which decreased to 0.07 with 58.8% relief with statistically non significant result ($p = 0.083$). This showed Ardraka Swarasa can provide better relief in Jwar than Shunthi Swarasa probably due to Pittaghna property.

Effect on Aruchi

Aruchi was decreased to 0.00 from 0.23 in group-A with 100% relief & statistically significant result ($p=0.020$). In group-B initial score of Aruchi was 0.27 which decreased to 0.13 with 51.9% relief with statistically significant result ($p=0.046$). This showed both can provide better relief in Aruchi may be because of its Deepan, pachana, Rochana & Triptighna property of drugs.

Effect on Hrillhas

Hrillhas was decreased to 0.03 from 0.20 in group-A with 85% relief & statistically significant result ($p=0.025$). In group-B initial score of Hrillhas was 0.23 which decreased to 0.17 with 26.1% relief with statistically non significant result ($p=0.046$). This showed both drugs act probably because of Kaphaghna & Deepan, Pachana property.

Effect on ESR

The initial score of ESR was 25.47 which was reduced to 16.77 with highly significant result ($p<0.001$) in group-A. In group-B the ESR was reduced to 16.13 from the initial score 26.17 with highly significant result ($p<0.001$) in group-B.

Effect on AEC

The initial score of AEC was 423.00 which was reduced to 300.67 with highly significant result ($p<0.001$) in group-A. In group-B the AEC was reduced to 326.33 from the initial score 431.67 with highly significant result ($p<0.001$) in group-B.

CBC was done only to r/o infective pathology.

Effect on all Symptoms

In the sample of 60 patients of Shitapitta, it was observed Maximum no. of patients registered i.e. 100% were having Tikta amla udgar with Hrid-kanth daha in 95% of patients, Utklesh in 93.33% of patients, Vanti in 88.33% of patients, Shiroruja in 75% of patients, Aruchi in 88.33% of patients, sarvanga daha in 25% of patients and Kandu in 15% of patients. Shows that most patients of Amlapitta suffer from Tikta Amlaudgar, Hrid-kanth daha and Utklesh.

Effect on Total Score

The over all effect of each therapy was assessed on the basis of improvement in individual patients.

Group A (ARDRAKA SWARASA)

The treatment was found effective and showed Mild change (25% – 49.9% relief) in 4, Moderate change (50% -74.9%) in 14 and Good change (75%- below 100%) in 12 patients.

Group B (SHUNTHI SWARASA)

The treatment was found effective and showed Mild change (25% – 49.9% relief) in 7, Moderate change (50% -74.9%) in 19 and Good change (75%- below 100%) in 4 patients.

The overall effect of Ardraka Swarasa is better in comparison to Shunthi Swarasa.

Probable Action of the Drug**Ardraka Swarasa**

- Vata shaman due to Ushna Guna of drug which reduces the Toda.
- Kapha shaman due to Katu, Ushna, Ruksha, Tikshna Guna which reduces the Kandū.
- Pitta shaman due to Madhura Vipaka and Guru Guna which reduces the Daha.
- Aampachana due to Ushna Virya and Katu Rasa.
- Rasa-Rakta shudhikar due to Katu Rasa.
- Jwaraghna due to Jwaraghna and Shitaprashamana Guna of Ardraka.
- Chhardigna due to Vatanulomana Guna.
- Twak vaigunya reduced due to Vata-Pittaj Guna.
- Rochan.^[3]

Shunthi Swarasa

- Vata shaman due to Snighdha, Ushna Guna and Madhura Vipaka of drug which reduced the Toda.
- Kapha shaman^[4] due to Katu, Ushna, Laghu Guna which reduced the Kandū.
- Pitta shaman due to Madhura Vipaka which reduced the Daha.
- Agnideepana due to Katu Rasa and Ushna Virya which reduced the Aruchi, Hrillhas.
- Aampachana due to Ushna Virya and Katu Rasa.
- Rasa-Rakta shudhikar due to Katu Rasa.
- Jwaraghna.
- Chhardigna due to Vatanulomana Guna.
- Twak vaigunya reduced due to Vata-Pittaj Guna.
- Truptighna^[5]-Aruchinashak
- Trushnanighraha^[6]

- Shitaprashaman^[7]
- Shulprashaman^[8]

CONCLUSION

- After analyzing all the data and the observations, it was found that most of the Nidanas explained in Ayurvedic classics have described that vitiation of vata dosha, is the main cause in the disease Shitapitta, kapha is the anubandhi dosha and Pitta dosha samsarg.
- In the present study the predominance of the disease is more in the Vata-Pittaj and Pitta-Vataj Prakruti.
- The study also shows that the disease is more seen in the persons taking Non-Veg diet, because of their more intake of high protein diet.
- The study also shows that the Age group above 30- below 40 yrs (50%) and above 40- below 50 yrs was more prone i.e. middle aged peoples were more vulnerable to Shitapitta.
- The study also shows that the Females were more prone to Shitapitta.
- In present study it was found that in addition, consumption of Tea is around 78.3%, smoking 8.3%, Tobacco 15% and 20% non-addicted.
- One of the aims of this study was that whether Ardraka Swarasa & Shunthi Swarasa really plays any role in the management of the disease. For that it was planned to administer it. The elaborate analysis of the result of this study showed that Ardraka Swarasa and Shunthi Swarasa was administered, the improvement rate was better in both groups.
- Comparison of the results of experimental group & control group showed that better relief in all the signs, symptoms and overall improvement in Shitapitta but comparatively Ardraka Swarasa was better than Shunthi Swarasa.
- By statistical analysis it is concluded that Ardraka swarasa (66.6% relief) and Shunthi swarasa (58.6% relief) shows significant results in reducing all of signs and symptoms of Shitapitta.
- During the present study, it can be noted that the drugs Ardraka, Shunthi and the Guda can be well tolerated by the patients without any side effects.

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