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A CLINICAL STUDY TO EVALUATE THE EFFECT OF SIDHARTHAK LEPA, NIMB CHURNA AND AMALTAS FANT IN THE MANAGEMENT OF YUVANPIDIKA (W.S.R. TO ACNE VULGARIS)

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ABSTRACT

Aim: To evaluate the efficacy of ayurvedic drugs in the management of yuvanpidika (w.s.r. to acne vulgaris)". **Introduction:** Yuvan pidika or Acne vulgaris is believed to be the most common skin disease. It affects 70% of population during adolescence and early adult life. It can cause significant emotional distress and physical scarring if left untreated. **Settings and Design**: For the present clinical study 46 patients having Pitika resembling to shalmali-kantaka on face (papule/nodule), Ghana (thick hard or indurated) Medogarbha (comedones), Saruja (pain**),** Saraga (erythema), Daha (Burning sensation), Sopha (swelling) were selected in single group. **Materials and method:** We have selected **Shidharthaka lepa** for local application, which contains Sidharthaka (Brassica compestris), Vacha (Acorus calamus), Lodhra (Symplocos racemosa) and Sandhava lavana. **Nimb churna (*Azadirachta indica*)** and **Amaltas fant** (***Cassia fistula***) for internal administration. We adopted both bahya and abhyantara aushadhi prayoga for this study. Selection of regime is based on repeated recommendations of different Acharyas on Yuvan-Pidika. **Type of study:** Phase 2 single group study. **Statistical analysis used:** p value,

paired ‘t’ test, unpaired ‘t’ test, etc. **Results:** The trial drugs shows a significant results in terms of relieved & improvement in clinical parameters, out of 42 patients ***64***.28***%*** were relieved, ***28***.57***%*** patients were improved, 7.14***%*** had no response, and there is no case of worsened had been reported. **Conclusion:** Trial drugs were well accepted and tolerated with good positive response and no any side effect has been observed.

KEYWORDS: Yuvan pidika, Acne vulgaris, Sidharthak lepa, Nimba, Amaltas fant

INTRODUCTION

Ayurveda is an ancient science of indigenous medicine and its knowledge dates back to the era of Rigveda. Ayurveda provides a way to live healthy life & treatment for various diseases. It is a treasure of output & data obtained through various, continues observational research programs of many centuries. In the present scenario, the people are very much conscious about their health as well as beauty. Thus Health and beauty are the two faces of single coin. Face reflects the personality of person. It is saying that “Face is the index of mind”. The concern of face has taken first place in the present era.

In Ayurvedic texts the disease Yuvanapidika has not mentioned independently, Acharya Sushruta was 1st person, who described yuvanpidika under the heading of kshudrarogas.[1] There are 44 diseases under this group, Yuvana Pidaka is one of the diseases between them. The Shalmali thorn like eruptions on the face of adolescents, due to vitiation of kapha, vata and rakta are known as “Yuvanapidika” or “Tarunyapitika”.[2] These Pidikas destroy the beauty of the face and cause disfigurement of the face therefore they are also called as “Mukhadushika”.[3] Yuvan pidika characterized by Pitika (eruption like shalmali kantaka), Saruja (with pain), Ghana (thick, hard induration), Medogarbha (comedones), Yunamukha (eruption on the face), Daha (burning sensation) Kandu (itching), and Shoph (inflammation).[4] Yuvanpidika present the features which are similar to those of Acne vulgaris in modern medicine.

Acne vulgaris is believed to be the most common disease of the skin. The condition usually starts in adolescence, peaks at the ages of 14 to 19 years and frequently resolves by mid-twenties.[5] Acne vulgaris develops earlier in females than in males, which may reflect the earlier onset of puberty in females. The most severe forms of acne vulgaris occur more frequently in males, but the disease tends to be more persistent in females.[6]

Acne vulgaris is a chronic inflammatory disease of the pilosebaceous units. Acne manifests because of physiological disturbances during puberty, when the sebaceous glands grow in size and increase their production of sebum. Androgen from testis, ovaries and adrenal gland play the greatest role in stimulating sebaceous gland.[7] Acne occurs predominantly in sebaceous follicles that have been colonized by anaerobic bacteria Propionibacterium acnes contributes to the development of acne. Modern medicines give different options for treatment like topical therapy, antimicrobials, hormone, corticosteroids, UV eradication and intra lesion injections.[8] These are very expensive and they have different adverse effect.

For Yuvanapidika the line of treatment as described by different Acharyas may be summarised as lepa, Aushdhi prayog, vaman, shiravedha, nasya and abhyanga.[9,10,11,12] We adopted both bahya and abhyantara aushadhi prayoga for this study. **Shidharthaka lepa** for local application, which contains Sidharthaka (Brassica compestris), Vacha (Acorus calamus), Lodhra (Symplocos racemosa) & Sandhava lavana.[9,11] **Nimb churna** (Azadirachta indica) and **Amaltas fant** (Cassia fistula) for internal administration.

MATERIAL AND METHOD

Aims and objectives

1. To review the literature on Yuvanpidika w.s.r. Acne vulgaris.
2. To evaluate the effect of Sidharthaka lepa with internal application of Nimb-churna and Amaltas fant in the management of yuvan pidika.
3. To study any adverse effect of the trial drug.

Selection of cases: For the present clinical study patients were selected from OPD/IPD department of Kaya Chikitsa State Ayurvedic College & Hospital, Lucknow. Detailed clinical examination was performed as per the proforma which incorporates relevant data like symptomatology, physical signs, laboratory investigation reports as well as assessment criteria. The consent of the patient was taken before the clinical trial.

Inclusion criteria: For the present study, patients were randomly selected in between the age group of 15- 35 years irrespective of their sex, religion and occupation. Patients having 4 major criteria with or without minor criteria were selected for clinical trial.

Major criteria

1. Pitika resembling to shalmali kantaka on face (papule/nodule).

2. Ghana (thick hard or indurated)
3. Medogarbha (comedones)
4. Saruja (pain)

Minor criteria

1. Saraga (erythema)
2. Daha (Burning sensation)
3. Sopha (swelling)
4. Scar

Exclusion criteria

1. Patients did not fulfill inclusion criteria
2. Yuvanpidika other than face region i.e. –chest and back
3. Yuvanpidika with other systemic disorder like PCOD, Adrenal tumour etc.
4. Metabolic disturbance and any other skin disorder.

Investigation

Routine

Hematological investigation -T.L.C, D.L.C, E.S.R., Hb %, G.B.P

Urine: Routine & microscopic

Stool: Ova & cyst

Blood sugar: Fasting & P.P

R.F.T. & L.F.T

Specific: (if required)

1) Photography of lesion
2) Swab and/or scraping on acne spot for microbiological Examination.
3) Skin smear
4) Hormone test- Testosterone, Sex hormone binding globulin (SHBG), LH/FSH, A.C.T.H.
5) Imaging- X-ray/MRI/ CT (to rule out the adrenal tumor and ovarian Tumor)

Type of study: Phase-2, rational, single group study.

Treatment schedule with dose and duration

Sidharthak lepa- of 1/4 angula i.e.(4.5 mm) or the paste should be thick as enough to cover up the lesion and will be remove after 15 Minute or dry it at the night.

Nimb churna (fortified with nimb patra swaras)-1 gm 2 times in a day after meal with luke warm water (Capsule of 500 mg of nimb churna were form and give 2 capsule BD).

Amaltas fant

40 ml fant once in a day at night after meal (or as per patients kosth) for 60 days.

Follow up

Every fortnight during the administration of trial regimen up to 60 days and after the completion of trial 1 follow up was done (15 days after treatment).

Sample size

46 patient of yuvanpidika were registered for the present study in a single group, among these 4 patients were drop out.

Pathya & Apathya

1. Kapha pitta vardhak aahar such as oily & spicy food, Junk food, tea, coffee, non-veg and egg should be avoided.
2. Wash face at least twice a day with mild soap and warm water.
3. Don't scrub skin and squeeze pimples.
4. Don't use oil based make-up, hair products or lotion.

Criteria for assessment

All the sign and symptom are graded 0,1,2,3 on the basis of its intensity and severity given by patient on complained and confirmed by clinical examination before the trial drug.

1. Saruja (pain)

S. N.	severity	nature	Grade
1	Nil	Absent	0
2	Mild	Occasionally present	1
3	Moderate	Tolerable pain	2
4	Severe	Intolerable pain	3

2. Daha (Burning sensation)

S.N.	Severity	Nature	Grade
1	Nil	Absent	0
2	Mild	Occasionally present	1
3	Moderate	Tolerable	2
4	Severe	Intolerable	3

3. Sopha (Swelling)

S. N.	Severity	Nature	Grade
1	Nil	Absent	0
2	Mild	Occasionally present	1
3	Moderate	Tolerable	2
4	Severe	intolerable	3

4. No. of lesion

No. of lesion	grade
No- lesion	0
1-5	1
6-12	2
More than 12	3

5. Medogarbha (Comedones)

Nature	grade
Absent	0
Present	1

6. Saraga (Erythema)

Nature	Grade
Absent	0
Occasionally present	1
Present in few lesion	2
Frequently present in almost all lesion	3

7. SCAR

Nature	Grade
Absent	0
Present	1

8. Ghana (Thick & hard induration)

Nature	Grade
Absent	0
Present	1

Total effect of therapy

The total effect of therapy of this trial have been grouped as followed.

1. Relieved - Patient has greater than 75% relief in terms of major and all minor symptoms and no recurrence of disease up to follow up period.

2. Improved - Patient having improvement between 40 -75% in terms of major and all minor symptoms and No recurrence of disease up to follow up period.

3. No response - Patient having improvement less than 40% in terms of major and minor symptoms.
4. Worsened - Patient having no improvement in terms of clinical symptoms or Disease may get worsened or symptom may increase.

Statistical analysis: The results are presented in mean ±SD and percentages. The Paired t-test was used to compare the continuous variables from before to after treatment. The Kendal's tau test was used to compare the categorical variables from Day 0 to subsequent time periods. Wilcoxon rank sum test was used to compare the symptom score from before to after treatment. Significance at the level of 0.1, 0.05, 0.02, 0.01, & 0.001 of p levels. All the analysis was carried out on SPSS 16.0 version (Chicago, Inc., USA).

The results were interpreted as

$p>0.05$ Non significant (N.S.)
$p< 0.05$ Significant (S.)
$p<0.01$ Moderate Significant (M.S.)
$p< 0.001$Highly Significant (H.S.)

RESULT AND OBSERVATION

In the present clinical trial, 46 Patients of yuvanpidika were registered in a single group. Out of them 42 patients have completed the full course of trial and 4 Patients did not complete the trial period because of some genuine reason, hence dropped out. Therefore demographic & clinical observation was made on 46 patients and therapeutic observations on 42 patients.

Demographic observation

In the present clinical study, it was found that the age group of (20-24) year i.e. comprises the maximum number of patients 17 (36.95%) patients. According to sex 37 (80.44%) patients were female and 9 (19.56%) patients were male. Maximum number of patients 33(71.73%) were Hindu according to religion. According to educational status 46 cases (100%) were literate. Maximum number of patients 36 (78.26%) were student. Maximum number of patients 32 (69.56%) were vegetarian. Maximum number of the patients 26 (56.52%) belonged to upper middle class and 16(34.78%) patients belonged to lower middle class. According to marital status maximum number of patients 38 (82.6%) were unmarried. Majority of the patients 36 (78.26%) were from urban area. maximum number of patients were addicted to tea i.e. 40 (86.95%) patients. According to Deha Prakriti, Vata-Pittaja was

found in most of the patients i.e. 22 (47.82%) patients, Vata-Kaphaj in 16 (34.78%) patients and Pitta-kaphaj found only in 8 (17.39%) patients. According to Agni, Mandagni was observed in 18 (39.13%) patients. History of dandruff was present in 18 (39.13%) patients, occasionally present in 16 (34.78%) patients. Duration of illness were maximum 28 (60.86%) between 1-5 year. Maximum number of patients 23(50%) were of krura koshtha. 32 (69.56%) patients were having family history of the disease. Regarding causative factors (nidana) explained by ayurvedic acharyas 22 patients were having the history of viruddha aahara, 13 (28.26%) were having for Vyayama ati Bhuktavopsevinanam (Excessive work done just after the food), Vega Dharana (Suppresion of natural urges) in 32 (69.56%), Diva Shayana in 14 (30.43%).

Clinical observations

It was observed that before use of trial patients showed Pitika resembling to shalmalikantaka on face, medogarbha, Ghana, saruja, were present in all the registered patients i.e 46(100%) followed by saraga in 33 patients (78.57%), scar in 22 patients (47.61%), shoph in 16 patients (38.09%), daha in 15 patients (35.71%).

Therapeutical observations

The Comparative study of the Symptomatology as well as the pathological investigation were performed before and after treatment provided following results. The drug regimen has shown their effect in almost all the symptomatology as shown in table no.1.

Table no. 1: Showing the assessment of clinical features across time intervals in cases of yuvanpidika.

Symptoms	Before treatment mean±SD	After treatment mean±SD	Mean change	p-value	% Improvement
Pidika	1.62±.66	.38±.62	1.24±.04	<.0001	69.16%
Medogarbha	1±00	.24±.43	.76±.57	<.0001	76.19%
Ghana	1±.00	.24±.43	.76±.57	<.0001	76.19%
Saruja	1.62±.49	.21±.42	1.41±.07	<.0001	78.57%
Daha	.50±.74	.10±.30	.40±.44	.0015	73.3%
Shoph	.60±.83	.19±.40	.39±.43	.0054	50%
Saraga	1.62±1.13	.36±.62	1.26±.51	<.0001	63.63%
Scar	.48±.51	.36±.48	.12±.03	.2740	25%

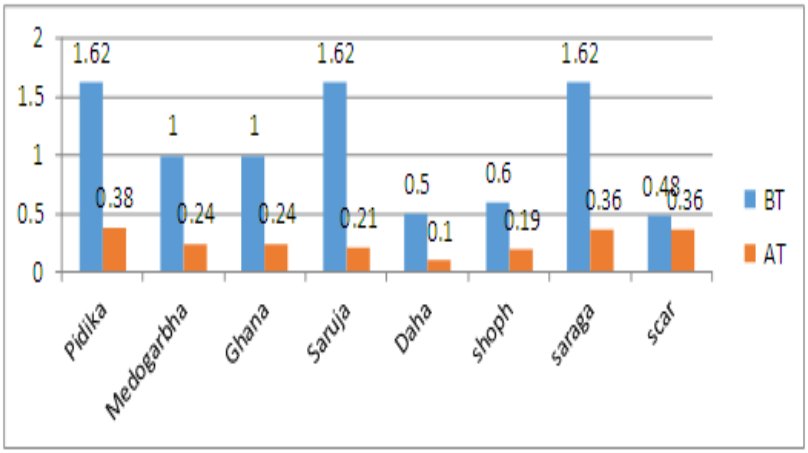

Figure No: ***Shows the change of clinical features across time intervals (BT & AT)in cases of yuvanpidika.***

Table no. ***Comparison of biochemical parameters across time intervals in cases of yuvanpidika (n=42).***

Biochemical parameters	Mean±SD BT	Mean±SD AT	Mean change	p-value[1]
Hb%	11.27±.958	11.524±.698	.250±.260	.034
TLC (cell/cmm)	7470.00±1589.09	7450.00±1589.07	20.00±1114.14	0.14
ESR(mm /1st hour)	20.81±3.67	17.83±2..47	2.98±1.2	.0032
B. sugar (F) gm/dl	83.34±9.11	83.07±9.22	0.29±0.95	0.23
B. sugar (PP) gm/dl	124.35±14.06	120.15±22.00	4.20±1.25	0.13
Bilirubin(mg/ dl)	0.40±0.20	0.38±0.14	0.02±0.14	0.34
SGOT (U/L)	27.930±6.96	27.75±6.30	0.18±2.03	0.47
SGPT (U/L)	25.08±6.96	25.58±6.16	0.50±2.58	0.13
Alkaline phosphatase(U/L)	162.85±17.19	161.93±16.01	0.93±7.20	0.067
Blood urea	23.68±5.82	23.28±5.41	0.4±2.81	0.54
Serum Creatinine	0.83±0.15	0.82±0.07	0.01±0.14	0.85

There was no significant ($p>0.05$) change in all parameters from before to after treatment.

Table 3: Showing Over all Effect of Therapy.

Result	No. of Patients (N=42)	Percentage
Relieved (>75%)	27	64%
Improved (between 40-75%)	12	28%
No response (<40%)	3	8%
Worsened	0	0

During the trial of treatment no any side effect has been observed. Regarding to the total effect of therapy, out of 42 patients, 64% were relieved, 28% patients were improved and 8% were unchanged, and no worsened case was registered during the trial. Statistical data shows that significantly improvement ($P<0.001$) in symptoms.

DISCUSSION

Discussion is a process that is carried out to interpret the observation made during the study in order to derive out proper conclusion. Yuvanpidika is one of such disease which massacres the beauty of a person. The site and Age of the occurrence of this disease are face and adolescent respectively. The beauty consciousness of a person is at its peak at adolescent and the site of this disease i.e face is such that it cannot be kept covered all the time.

Yuvanpidika present the features which are similar to those of Acne vulgaris in modern medicine. The cause of the disease is the disturbance in the equilibrium of Vata, Kapha and Rakta Doshas due to unbalanced dietary regimen and altered mode of life style. These vitiated Doshas circulate in the body and get locate under the skin surface, especially of the face. Vata makes the vitiated Kapha dried in the Srotas and transform into the small & hard swellings with itching on the mouths of these Srotas (1^{st} and 2^{nd} grade). Sometimes this swelling becomes inflamed & suppurated by the Rakta and Pitta (3^{rd} & 4^{th} grade).

This disease is more common in age group of 20-24 year of life and more persistently in female but severity more in male patients. In Charaka Samhita the age between 16- 30 years is Vivardhmana dhatu guna avsatha, specially the starting period of functional state of Shukra dhatu (Abhivyakti & Vriddhi) and this is also the age of predominance of Pitta dosha. In Modern medicine hormonal imbalance, specifically of androgens is one of the important causative factors, which in turn stimulates the sebaceous glands to produced excess sebum. In females, due to major hormonal changes during menarche, the occurrence of this disorder may be a little bit earlier than the males.

During the study it was observed that maximum no. of Pidikas were on Ganda and Lalata Pradesha, along with Chibuka, Nasika etc. It is because of the maximum number of sebaceous glands found on this site and also the size of the glands is comparatively large. The disease yuvanpidika more common in vegetarians. Any specific correlation between vegetarian diet and incidence of yuvanpidika may not be established as the sample size is small. This study showed that stressful life may be precursor or stimulator for acne. The stress causes excess secretion of androgens and subsequently leads to Acne.

In this study we have selected sidharthak lepa consisting sidharthak, lodhra, vacha & sandhav lavana for external use with internal application of nimb churna as raktashodhak and Amaltash Fant as kosthshodhan. Sidharthak has kapha vata shamak, kushthgna, kandughna,

Krimighna properties.[13] Its lepa or oil is used as varnya (lightening the skin colour) so helpful in post acne hyperpigmentation. Lodhra in powder form used externally in inflammatory skin disorder and bleeding wound. It also has anti androgenic effect on internal use and showed a significant anti-inflammatory action.[14] Vacha is kapha-vata shamak and its root extract exhibit antimicrobial property.[15]

Nimb has tikta and kasaya rasa, it acts as raktashodhak[16] as the rakta is pradhan dushya in yuvanpidika. The antimicrobial activity of different part of nimb's extract is well documented.[17] Its Bark extract also produced significant anti-inflammatory activity.[18] Amaltas acts as mild purgative and I have use it for kosth-shodhan because krura koshtha (patients having tendency of constipation) was observed in 23 (50%) patients. Due to shitavirya and madhur rasa it is pitta samaka also.[19,20]

CONCLUSION

On the basis of present clinical trial following conclusion have been drawn. According to aetiology, pathogenesis, clinical features and treatment of yuvanpidika and acne vulgaris are quite similar and resembles to great extent with each other. This disease is more common in age group of 20-24 year of life and more persistently in female but severity more in male patients. Disease show a higher risk in unmarried ones. Disease affected more to people who are student because they belong to a particular age group when hormonal changes takes place. These findings further propagate that stressful life may be precursor for acne. Vata-pitta and Vata-Kapha prakriti individuals show greater risk and affinity towards the disease. No any biochemical abnormalities have been observed in registered cases after completion of trial. The patients who had registered with mild and moderate features of disease improved and relieved earlier than severe grade patients. The regimen was well tolerated and did not show any side effects except the lepa had some burnining sensation in initially just after applying on the face may be because of sandhav lavana but it was seen only in few patients. Thus the regimen should be tested on large scale for longer duration of trial to look for other beneficiary sides of drug.

CONFLICT OF INTEREST: Nil.

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