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PATHYAADI KWATHA " A HERBAL FORMULATION" FOR SHOTHA: A CLINICAL TRIAL

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ABSTRACT

In Ayurveda terms, swelling is called as Shotha or Shopha. Shotha (Odema or swelling) are of two types: Nija and Agantuja. Nija shotha is due to internal causes within the body i.e. vitiation of doshas first and then brings about pain. On the other hand Agaantuja Shotha is due to external factors and starts with pain first, then brings about the vitiation of doshas. Here emphasis was given on Nija Shotha. As per the aetiology of Shotha various fifteen diseases (vyadhis) described in Charaka Samhita sutra sthana Adhyaya 12 as the causative factor of Shotha are due to Agni vikruti and Srotorodha. Root cause of All these shotha causing diseases is Agnimandya which further leads to Srotorodha and Shotha utpatti. Hence a formulation having ushna, tikshna, laghu, rukshaguna, katutikta rasa, katuvipaka & ushnavirya. kaphavatashamaka, dipana, pachana, rochana, lekhana, srotovishodhana, shothahar, stholyahara and rasayana properties is effective in Samprapti Vighattan (breaking the pathogenesis) of Shotha. All the drugs/herbs mentioned in the Pathyaadikwatha taken from yogratnaakara (Shotha Chikitsa Prakarana Uttrardha) are having Deepana, Paachana, Shothahara, Stholyahara, Rasaayana, Ushana, Tikshana, Katutiktarasa, Agnivardhaka, Lekhana and Vatakaphashaamka

Key Words: Shotha, Agnimandya, Srotorodha, Pathyaadikwatha.

INTRODUCTION

Shotha has been described by all our ancient Acharyas in Brihat Trayee as well as in Laghutrayi. This shows how important shotha was at the ancient time too. In today's scientific world much researches have been done and many theories have been postulated out on Inflammation.

Shotha occupies a separate chapter in Sutra sthana as well as in Chikitsa sthana of Charaka Samhita.

In Ayurvedic terms, swelling is called as Shotha or Shopha. Shotha are of two types: Nija and $Agantuja^{I}$.

Nija shotha is due to internal causes within the body i.e. vitiation of doshas first and then brings about pain. On the other hand Agaantuja Shotha is due to external factors and starts with pain first, then brings about the vitiation of doshas. Here emphasis was given on Nija Shotha.

Aetiology of endogenous swellings i.e nija shotha²: Improper administration of oleation (Snehana), fomentation(swedana) ,emesis(vamana) ,purgation(virechana) , Asthapana and Anuvasana types of enema, elimination of doshas from the head ,adoption of improper post panchakarma program(samsarjana karma) excessive emaciation due to Chardi, Alsaka , Visuchika , Shwasa ,Kasa ,Atisara , Shosha , Pandu , Udara , Jwara , Bhagandara , Arsha, Kushtha, kandu, Vidhradi, vega dharana, when a person is emaciated due to panchakarma therepy / due to chronic disease / due to fasting or walking long distance, suddenly starts consuming exceedingly heavy, sour and salty food, alcohol, immature curd, intake of earth mud are etiological factors of Nija shotha or endogenous swellings.

Because of the above mentioned factors, Kapha, Asrika and Pitta enter the external

vessels (Bahya Siras) and afflict the vata dosha . As a result , the channel of circulation gets obstructed which spread to nearby areas leading to Shotha which is characterized by swelling³.

Various fifteen diseases (*vyadhis*) described as the causative factor of *Shotha* are due to *Agni vikrut*i and *Srotorodha*. Root cause of All these *shotha* causing diseases is *Agnimandya* which further leads to *Srotorodha* and *Shotha utpatt*i.

Hence a formulation having ushna, tikshna, laghu, rukshaguna, katutikta rasa, katuvipaka&ushnavirya.

kaphavatashamaka,dipana,pachana,rochan a,lekhana,srotovishodhana,shothahar ,sthol yahara and rasayana properties is effective in Samprapti Vighattan (breaking the pathogenesis) of Shotha.

For the present study, a herbal formulation '' *Pathyadi Kwatha*" ⁴ was selected with the help of textural reference of *YOGARATNAAKARA UTTARARDHA SHOTHA CHIKITSA ADHYAYA PATHYAADI KWATHA* (Page no 128)

Pathya amruta bharangi punarnava agni darvi nisha daru mahaaushadhaanam / Kwatho

nipitodarapaanipaadvaktraashritam hantichirena shopham || 1||

All the drugs/herbs mentioned in the *pathyaadikwatha* taken from *yogratnaakara* (Shotha Chikitsa Prakarana Uttrardha) are having Deepana, Paachana, Shothahara, Stholyahara, Rasaayana, Ushana, Tikshana, Katutiktarasa, Agnivardhaka, Lekhana and Vatakaphashaamka

As per the principles of *Ayurveda* symptomatology as well as the pathogenesis of Hypothyroidism is due to *Agnimandya* which has been proven by many studies. Thus for the present study patients of Hypothyroidism having shotha (swelling) as prominent clinical feature were selected.

QUALITY STANDARDIZATION OF THE DRUG

The raw drugs for the proposed preparation were provided from the institute itself

(Ayurvedic and Unani Tibbia College, Karol Bagh) through proper channel and certified from the institutional lab.

Method of Preparation of Pathyadi Kwatha⁵

(On the basis of Kwatha Perparation) mentioned in **AFI part 2 Vol 1** Pathyaadi Kwatha was prepared with the following ingredients in the ratio given below:-

Drugs	Latin Name	Part Used	Part	
Haritaki	Terminalia Chebula	Fruit	One Part	
Guduchi	Tinospora Cordifolia	Stembark	One Part	
Bharangi	Clerodendrum Serratum	Root Bark	One Part	
Punarnana	Boerhavia Diffusa	Panchang	One Part	
Chitraka	Plumbago Zeylanica	Root Bark	One Part	
Devdaru	Cedrus Deodara	Stem Bark	One Part	
Haridra	Curcuma Longa	Rhizome	One Part	
Daruharidra	Berberis aristata	Root Bark	One Part	
Shunthi	Zingiber Officianle	Rhizome	One Part	

All the drugs were cleaned and dried. They were coarsely powdered (Yavakuta), weighed (20gms) as per formula, and then mixed well. Then they were boiled in 16 times water (320 ml) and reduced to $1/4^{th}$ (80ml). Then it was filtered.

Dose: 40 ml twice a day orally before lunch and dinner.

DESCRIPTION OF DRUGS OF PATHYAADI KWATHA⁶

DRUG	BOTANICAL NAME	FAMILY	RASA	GUNA	VIRYA	VIPAK A	PRAYOJY ANGA	CHEMICAL CONSTITION
Haritaki (API Part 1VOL 1)	Terminalia chebula Retz.	Combretaceae	Kashaayap radhaana	LaghuRuks ha	Ushna	Madhura	Fruit	Chebulinic acid chebulagic acid corilagin
Guduchi (API part 1 VOL 1)	[Tinospora cordifolia (Willd) Miers ex Hook .f. and Thoms]	Menispermac eae	Tiktakasha aya	Guru snigdha	Ushna	Madhura	Kaanda (Stem)	BerberinGiloin

Bharangi (API part 1VOL 3)	[Clerodendru m serratum (Linn.) Moon.]	Verbenaceae	TiktaKatu	LaghuRuks ha	Ushna	Katu	Root bark	Sapponin antihistaminic activity in ghansatva
Punarnava (API part 1 VOL 3)	Boerhavia diffusa (Linn.)	Nyctaginacea e	Madhurak ashaayatik ta	LaghuRuks ha	Ushna	Madhura	Panchaanga (wholeplant)	Punarnavine
Chitraka (API part 1 VOL 1)	Plumbago zeylanica (Linn.)	Plumbaginace ae	Katu	Laghuruks hatikshna	Ushna	Katu	Root bark	Plumbagin
Devdaru (API part 1 VOL 4)	[Cedrus deodara (Roxb.) Loud]	Pinaceae	Tikta	Laghusnigd ha	Ushna	Katu	KaandaSaar a (stem)	Sesquiterpene
Haridra (API part 1 VOL 1)	Curcuma longa (Linn.)	Zingiberaceae	Tiktakatu	RukshaLag hu	Ushna	Katu	Rhizome	Curcumine
Daruharidra (API part 1VOL 2)	Berberisaristat a DC	Berberidaceae	Tiktakasha aya	Laghuruks ha	Ushna	Katu	Root, stem bark	Berberin, occiacrenthin
Shunthi (API part1VOL 2)	Zingiber officinale(Ros c.)	Zingiberaceae	Katu	Laghusnigd ha	Ushna	Madhura	Rhizome	Zingiberene, zingiberol, gingerin, shogaol

AIMS & OBJECTIVES

- 1. To study the concept of *Shotha* as per the principles of *Ayurveda*.
- 2. To evaluate the efficacy of *Pathyadi kwatha* in the management of *Shotha* .

MATERIALS & METHODS

Patients diagnosed with fulfilling the diagnostic criteria were selected for the present study from O.P.D. and I.P.D. of A and U Tibbia College and Hospital, Delhi irrespective of sex ,caste ,race ,religion .All the selected patients after the registration

with necessary information and taking the informed consent were studied.

STUDY DESGIN

It is a prospective, randomized type of clinical trial.

Study type--- Interventional

Purpose --- Treatment

Masking --- Open label

Number of groups- There was one group.

Sample size: There were total 30 patients.

Duration of study: 3 months.

Source of Drug

The drugs were provided by the institute itself through proper channel and **certified** from the institutional lab.

DIAGNOSTIC CRITERIA

The patients were diagnosed on the basis of signs and symptoms as described for hypothyroidism in modern text and standard scientific grounds involving symptomatology, Laboratory investigations and clinical conformation.

INCLUSION CRITERIA

- 1.Age between 16-60 years (including both sexes).
- 2.Patients fulfilling the diagnostic criterias of Hypothyroidism having Shotha/ Oedema as the prominent clinical feature.
- 3. Patients able to participate in the study and ready to follow the instructions and sign the consent form for the 3 months

EXCLUSION CRITERIA

- 1.Age below 16 yrs. and above 60 years.
- 2.Pregnant and lactating mothers.
- 3.All complicated cases of hypothyroidism or associated with other endocrine disorders like Euthyroidism, hyperthyroidism, diabetes mellitus.

- 4.Patients associated with any other systemic diseases, like Neuromuscular disorders, any cardiovascular disorder , Hepatic disorders , autoimmune disorders and renal disorders.
- 5.Patient who is suffering from hypothyroidism for more than 10 yrs.
- 6.Patient taking antibiotic therapy for any systemic illness within 2 months.
- 7.Patient who fail to give consent.
- 8.H/O hypersensitivity of any trial drug.

WITHDRAWL CRITERIA

- 1. Failure to consume less than 70% of drugs.
- 2. Failure to come for follow up
- 3. Any adverse drug reaction of the therapy developing in the subject.
- 4.If thyroid level is getting further raised with the trial drug.

The patients were called for regular followup at an interval of two weeks to evaluate their clinical status and to observe the adverse effect of the treatment. *Shotha* was assessed on the basis of grading and was recorded.

Criteria for Assessment

Following score pattern was adopted for the assessment which is as follows:

Grade	Score						
Absent	0						
Mild	1						
Moderate	2						
Severe	3						

Clinical grading of *Shotha* (Generalized swelling / Shotha)

chinear grading of Stroma (Generalized Swelling / Shotha)	
No swelling.	0
Swelling on lower/upper extremities/ face	1
Swelling on both upper and lower extremities.	2
Swelling all over the body .	3

INVESTIGATIONS

Following investigations were performed in all the registered patients of study:-

Hb, TLC, DLC, ESR, L.F.T., K.F.T., Lipid profile , Blood Sugar, Thyroid Profile (Sr. T_3 , Sr . T_4 , Sr. TSH) ,Anti—TPO (Thyroperoxidse) , RA factor ,CRP , ASO titre.

Urine: – Routine and Microscopic Examination.

STATISTICAL ANALYSIS

The data of the therapeutic assessments were analysed statistically in the terms of percentage (%), mean score (x), standard deviation (SD) and paired t test.

The results were interpreted at p <0.05, p<0.01 and p <0.001 significance levels.

Non-significant : P>0.05 Significant : P<0.05

Highly significant: P<0.01, P<0.001,

P<0.0001

RESULT

Effect of drug on *Shotha* (generalized swelling / oedema)

The mean **BT** (before treatment) Generalized Swelling score was 2 which declined to 0.36 AT (after treatment) which indicates 82% improvement or relief. The statistical analysis shows that it is highly significant result at p<0.01.

Number	BT	AT	Improvement	% of	S.D	S.E	t-	p-	Result
of	(Average)	(Average)	(Average)	Improvement			value	value	accept
patients									at
30	2	0.36	1.63	82	0.71	0.13	12.45	< 0.01	99%
									(HS)

DISCUSSION

Shotha (Generalized swelling) : Clinical study showed 82% improvement in Shotha . Puffiness is due to accumulation of hyaluronic acid in the tissues which is related to loss of inhibitory effect of thyroid hormones on hyaluronate, fibronectin and deposition collagen. Increased connective tissues like hvaluronic acid,glycosaminoglycans and other polysaccharides leads to non pitting boggy oedema in Hypothyroidism⁷.

As per Aacharya Charaka when vitiated doshas due to mithya Aahara or Vihara

causes obstruction of *srotas* or channels which hampers the normal movement of *vata* i.e *vayumargaavarodha*, leads to *Shotha utpatti* ⁸.

Amarasa is formed by the Amaanna or apakva anna due to Agnimaandya. This Ama rasa produces kleda and obstruction in dhatu and srotas which further hampers the nourishment and leads to Amarupi or malarupi dhatu vridhi. Due to rasa dhatu dushti by Ama Rasadhatvagnimandya occurs. Now prasaadansha of previous dhatu which is Amarupi here with the help of respective Dhatvagni which is manda here i.e Dhatvagnimandya dushita rakta dhatu is produced.Other dhatus are also affected due to Derranged uttarottara dhatu poshana krama. On the whole this type of

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srotorodha and dhatudushti leads to vayumarga avarodha, which further vitiates the whole process and leads to the Shotha utpatti.

Swelling of face especially eyelids, hands and feet result due to accumulation of hydrophilic mucopolysaccharides subcutaneously which is nothing but *Aam rupi or malrupi Dhatu* due to *Dhatvagnimandya*.

Pathyadikwatha is having *ushna*, *tikshna*, *laghu*, *rukshaguna*, *katutikta rasa*, *katuvipaka&ushnavirya*. Hence it exhibits

kaphavatashamaka,dipana,pachana,rochan a,lekhana,srotovishodhana,shothahara and rasayana properties. So acts on the pathogenesis of Shotha as per Ayurveda principles.

CONCLUSION

Inthe recent years interest in medicinal plants has increased considerably .Apart from the reliance on therapeutic values described in ancient texts and current interpretations by specialists in the field of ayurveda,laboratories in several countries have initiated analytical studies scientifically determine the efficacy of better known medicinal plants in the treatment of Pathogenesis diseases. and of hypothyroidirm symptomatology similar to that of AGNIMANDYA / DHAATVAGNIMAANDYA and SHOTHA . When we go through the classical text, we see that all these disorders arise due to agnimaandya and srotoavarodha. Chikitsa is SAMPRAAPTI VIGHATTAN. Chikitsa of all these three disorders is same which includes LANGHAN. DEEPAN. PAACHANA. AGNIVARDHAKA. KAPHAVATASHAAMKA. SHOTHAHARA STHOLYAHARA and

RASAYANA. Pathyaadi kwatha possesses

all these qualities and hence acts very well on the pathogenesis of Shotha as evidenced by the present study.

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