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EVALUATION OF EFFICACY OF AN *AYURVEDIC* TREATMENT PROTOCOL IN THE MANAGEMENT OF HYPOTHYROIDISM- A RANDOMIZED CLINICAL STUDY

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ABSTRACT:

Background: Hypothyroidism is a clinical syndrome resulting from the deficiency of thyroid hormones due to their insufficient synthesis which in turn results in a generalized showing down of metabolic processes. However, in *Ayurveda*, it is not clear how to interpret the pathogenesis of hypothyroidism which is a biochemically diagnosed disease. However certain pathogenesis phenomena e.g. *Kaphavrittvata* especially the *Udaan* and *Samaan*, *Dhatwagnimandhya*, and *Medodusti*, appear to have a role in disease manifestation. About 42 million people in India are suffering from thyroid disorders and India has a high prevalence of hypothyroidism. There is a need for safe, effective, and sustainable medicine for the management. **objectives** 1. To evaluate the clinical efficacy of *Ayurvedic* medicine- *Triphala Guggulu, Erand Tail Haritaki*, and *Varuna Kashaya* in hypothyroidism. 2. To find out an effective and safe ayurvedic treatment protocol to resist Hypothyroidism. **Study design –** Single-blind randomized Standard controlled clinical trial with the pre-and post-test performed. **Methodology –**Group A was administered with *Triphala Guggulu*, *Erand Tail Haritaki*, *Varuna Kashaya*. Thyroxin sodium was administered in the prescribed dose form among patients of Group B and the data was graded based on assessment criteria and was analyzed statistically. **Results –**The outcome of the treatment after 45 days was statistically extremely significant ($p<0.0001$) in the remission of the symptoms of hypothyroidism in most of the subjective, objective parameters and biochemical parameters. **Conclusion –** The Group A (Study group) treatment regimen was found to be effective in relieving the symptoms and sign was statistically extremely significant in muscle cramp, lethargy, dry skin and the result was very significant in edema, constipation, hair loss, BMI; however, it was significant in excessive sleep. The result obtained for the Sr. TSH value was statistically extremely significant.

Keywords – Hypothyroidism, *Triphala Guggulu, Erand Tail Haritaki, Varuna Kashaya.*

INTRODUCTION

Ayurvedic texts although, eight types of *Nindita Purushas* [1] can be described based on various hormonal disorders. Hypothyroidism is a clinical syndrome resulting from the deficiency of thyroid hormones due to their insufficient synthesis which in turn results in a generalized showing down of metabolic processes. Clinical features of hypothyroidism are weakness, malaise, lethargy, weight gain, peri-orbital puffiness, cold intolerance, loss of hair, dry and scaly skin, hoarseness of voice, constipation, muscle cramping, poor memory, menorrhagia dyspnea, etc. [2] Hypothyroidism is a major challenge both in developing as well as developed countries. In India, 42 million people are suffering from thyroid disorders, out of which hypothyroidism is the most common [3]. Hypothyroidism is the most common of thyroid disorders in India, affecting one in ten adults and its Global incidence is also increasing day by day. The prevalence of Hypothyroidism in India is 11% compared with only 2% in the UK and 4.6% in the USA [4] and is more prevalent among females with male to female ratio being 1:4 [5]. However, in *Ayurveda,* there are no guidelines about how to interpret the pathogenesis of hypothyroidism which is a biochemically diagnosed disease. However certain pathogenesis phenomena e.g. *Dhatwagnimandhya* [6], along with *Vatakaphaja Shotha* [7] and *Kaphavritavata* [8] especially the *Udana* [9] and *Samana* [10], appear to have a role in disease manifestation. The concept of *Galagand* a *Kaphaj Nanatmaja* [11] disorder has also partial resemblance in only limited cases. From the perspective of Hypothyroidism *Dosha Pratyaneeka Chikitsa* will also help to transact the position better. If the occlusion of Vayu by Kapha takes place, then drugs that alleviate *Kapha* and one which causes downward movement of *Vata* should be administered and *Srotoshodhana* is also an important line of management in *Avarana* [12] and to deal with *Medodusti*, drugs having *Lekhana* properties along with direct *Kaphavata Shamak* action may also bestow upon a significant treatment. For this purpose in one group of patients *Triphala Guggulu* [13], *Erand Tail Haritaki* [14], and *Varuna Kashaya* [15] were administered. In the second group, Thyroxine Sodium was administered for the same period. Taking all these points into consideration, this study was planned to evaluate the role of *Triphala Guggulu, Erand Tail Haritaki,* and *Varuna Kashaya* in the management of hypothyroidism. The ingredients of these drugs are also classically used for the management of *Galganda* in *Ayurveda*. *Triphala Guggulu* is selected which possesses *Kaphahara, Medohara*. It's having *laghu ruksha guna, ushna virya, katu vipaka* and *lekhana* property. *Erand tail haritaki* clearances by promoting bowel movement, *Yakrutta-uttejaka,* and *Shrotoshodhaka* improve the status of *Agni* and promote the power of digestion. *Varun Twak* is having *Laghu, Ruksha Guna, Ushna Virya, Katu Vipak*a, and *Kapha-Vata-Medohara properties*. Looking into its *Doshika* dominance, *Kapha* associated *Pitta Dushti* with vitiation of *Vayu* due to *Margavarana* and predominantly *Rasavaha* and *Medovaha Srotodushti* can be considered as the cause of the

disease. It is hoped that the results of this study will stimulate *Ayurvedic* scientists to take up this problem further on the basis of more sophisticated parameters and find out the definite cure for this disease from the wast materia medica of *Ayurveda*.

AIM AND OBJECTIVES

1. To evaluate the efficacy of the designed treatment protocol comprising of ***Triphala Guggulu, Erand Tail Haritaki,*** and ***Varuna Kashaya*** in clinical signs and symptoms along with the thyroid profile of the patients suffering from Hypothyroidism.
2. To find out an effective and safe ayurvedic treatment protocol to resist Hypothyroidism.

MATERIAL AND METHODS:

In this study total of 40 patients with hypothyroidism were registered. Patients were randomly divided into two groups viz. Group A and Group B.

Sample Source

40 patients fulfilling the criteria of diagnosis as per the specially prepared proforma for the present study were admitted to the study from OPD and IPD of *Kayachikitsa* and *Panchakarma* department of Pt. Khushilal Sharma Govt. Ayurveda Hospital, Bhopal, and treated in two groups with equal no. of patients irrespective of their sex, caste, religion, etc.

Literary source

The information about the disease and the drugs was compiled from various Ayurveda Classics, Modern Medicine Books, Journals, Research Updates, and Websites.

Drug source

The formulations required for the clinical study were procured and prepared in the dept. of *Rasa Shastra* and *Bhaishajya Kalpana*, Pt. Khushilal Sharma Govt. *Ayurveda* Hospital, Bhopal under the guidance of connoisseurs.

Method of collection of data:

Study design

Randomized double arm, open labelled, parallel clinical study.

Grouping:

In this study total of 40 patients of Hypothyroidism were registered. Patients were randomly divided into two groups, i.e. Group A and Group B.

Group A - In this group, 20 patients of hypothyroidism were registered and treated with an *Ayurvedic* treatment regimen (*Triphala Guggulu* 2BD with lukewarm water for 45 days, *Erand tail Haritaki* 5gm+5ml HS with lukewarm water for initial 7 days and *Varuna Kashaya* 40 ml BD with *madhu* for 45 days*).*

Group B - This was the standard control group. In this group, 20 patients of hypothyroidism were registered and treated with thyroxin sodium (Dose as decided by modern physicians).

Table No. 1: Showing treatment regimen of Group-A (*Ayurvedic* treatment protocol)-

Drug	**Dosage form**	**Dose**	**ation**	***Anupana***

Group-A	*Erand tail haritaki*	*Churna +Oil*	5gm+5ml HS	7 Days (Initial 7 days only for Sroto-shodhana)	Lukewarm water
	Triphala guggulu	*Vati*	2BD (250mg of each tab)	8th day to 45th days	Luke warm water
	Varuna kashaya	*Kwath*	40 ml BD	8th day to 45th days	*Madhu*
Group-B	Thyroxine Sodium	Tablet form	As directed by the physician	45 Days	Water (Empty stomach in morning)

Study duration: 45days

Follow up:

- 15th. 30th, 45th day for clinical observation.
- 46th day for laboratory investigation.

Drug description -

Group - A

***Triphala guggulu* (*Yogaratnakar Galagand-gandmala-apchi-arbud-granthirogadhikar*/01) [16]**

Table no. 2: Showing contents of *Triphala guggulu* –

S. No.	Drug Name	Botanical Name	Quantity
1.	*Pippali*	*Piper longum*	2 Part
2.	*Marich*	*Piper nigrum*	2 Part
3.	*Shunthi*	*Zingiber officinale*	2 Part
4.	*Amlaki*	*Phyllanthus emblica*	2/3 Part
5.	*Haritaki*	*Terminalia chebula*	2/3 Part
6.	*Vibhitaki*	*Terminalia bellirica*	2/3 Part
7.	*Kanchanar*	*Bauhinia variegate*	12 Part
8.	*Guggulu*	*Commiphora mukul*	20 Part
9.	*Madhu*	*Honey*	100 Part

***Erand tail haritaki (Bhavprakash 26/51)* [17] –**

Table no. 3: Showing contents of *Erand tail haritaki* -

S. No.	Drug Name	Botanical Name	Quantity
1.	*Haritaki*	*Terminalia chebula*	5gm

2.	*Erand oil*	*Ricinus communis*	5ml

Varun kashaya (Bhavprakash 44/36) [18]

Table no. 4: Showing contents of *Varuna kashaya* –

S. No.	Drug Name	Botanical Name	Quantity
1.	*Varuna Mool*	*Crataeva Nurvula*	40ml

Figure no. 1: Showing *triphala guggulu*, *Erand tail haritaki* and *Varuna kashaya* ingredients

Criteria for selection of the patients:

1. Diagnostic criteria

As per diagnostic, inclusion, and exclusion criteria, patients were selected in this study.

- The diagnosis of hypothyroidism was based on the clinical signs and symptoms along with biochemical investigation.
- Laboratory investigation:
  - Serum TSH (0.4 - 4.12 microIU/ml)
  - T_3 (0.8 - 2.1ng/ml)
  - T_4 (5 – 15 micro.gm/dl)

2. Inclusion criteria

- Newly diagnosed cases of hypothyroidism.
- Patients aged between 16 to 56 years of either sex.
  - Based on thyroid profile elevated level of serum TSH or low level of serum T_3 & T_4. However, the cases in which T_3 and T_4 levels were within normal range and TSH level was high were also included.
- Patients who provided their written consent to participate in the study.

3. Exclusion criteria

- All complicated cases of Hypothyroidism Goiter, myxedema, severe mental illness, thyroid cancer, etc., and associated with other endocrine disorders.
- Patients having chronic systemic illness.
- Congenital hypothyroidism.
- Pregnant women and lactating mothers.
- Patients having undergone thyroid surgery. (However, the main diagnostic tool adopted was the thyroid profile.)

Criteria for assessment:

A clinical proforma was prepared incorporating the clinical signs and symptoms of Hypothyroidism and a scoring pattern was adopted for the assessment of the clinical improvement.

Subjective criteria for assessment

- Excessive sleep
- Muscle cramp
- Edema
- Dry skin
- Constipation
- Lethargy
- Hair Fall
- Menstrual irregularities

Objective criteria for assessment

- BMI
- Complete Thyroid Profile- T_3, T_4, TSH

Grading:

Table no. 5: The improvement in the clinical signs and symptoms will be assessed by adopting the following scale.

S. no.	Parameters	*Criteria*	*Grade*
1.	**Excessive sleep**	6 to 7 hrs/day	**0**
		8 to 9 hrs/day	**1**
		10 hrs/day	**2**
		More than 10 hrs/day	**3**
2.	**Muscle cramps**	Not present	**0**
		Patient like to stand in comparison to walk	**1**
		Patient like to sit in comparison with stand	

		Patient like to lie in comparison with sitting Patient like to sleep in comparison with lying down	**2** **3** **4**
3.	**Oedema**	No Oedema Oedema on lower/upper extremities Oedema on upper & lower extremities Oedema on all over the body	**0** **1** **2** **3**
4.	**Dry skin**	No dryness Dryness after bath only Dryness the whole day but relieved by oil application Dryness the whole day and not relieved by oil application	**0** **1** **2** **3**
5.	**Constipation**	No constipation Motion once in a day without complete evacuation Motion once in two days Motion once in more than two days with hard stool	**0** **1** **2** **3**
6.	**Lethargy**	Doing work satisfactorily with proper vigor on time Doing work without desire, unsatisfactorily but in time Doing work without desire, unsatisfactorily, with a lot of mental pressure, and not in time Not starting any work in his/her own responsibility, doing little work very slow	**0** **1** **2** **3**
7.	**Hair loss**	Absent	**0**

		Hair Fall on washing Hair Fall on combing Hair Fall on simple stretching	**1** **2** **3**
8.	**Menstrual Disturbances**		
	Menorrhagia	Normal Menstruation Bleeding for longer than a week Passing blood clots larger than a quarter Restricting daily activities due to heavy menstrual flow	**0** **1** **2** **3**
	The interval between two cycles	24-34 days 35-39 days 40-45 days >45 days	**0** **1** **2** **3**

Laboratory investigations –

1. Serum TSH, T_3, T_4

Results

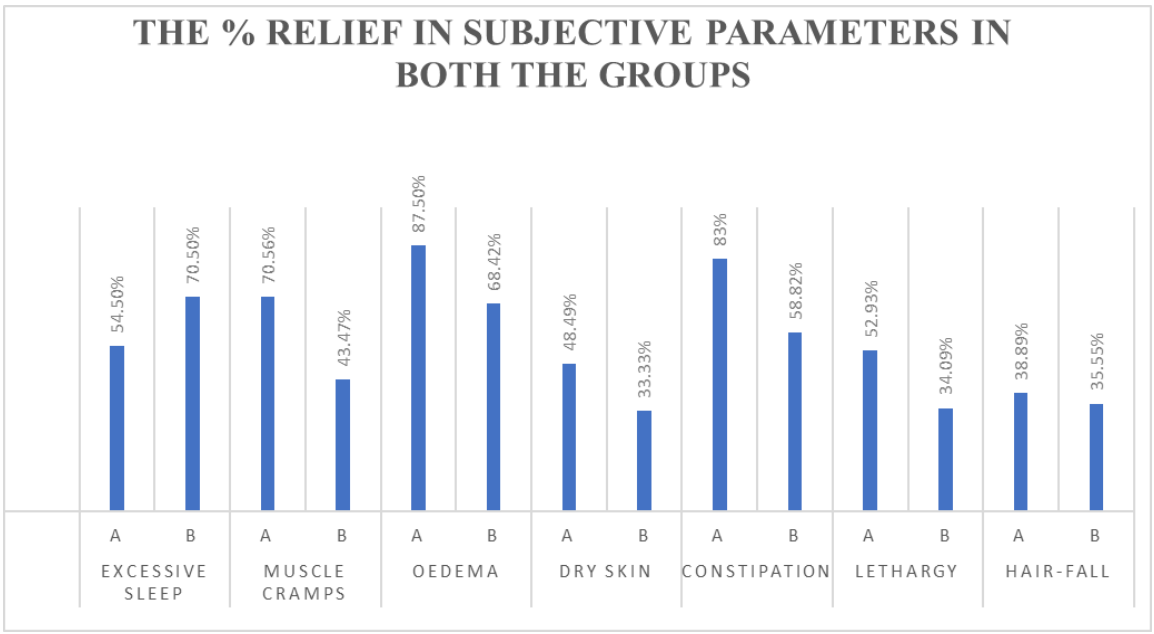
All the results are calculated using the software: Graph Pad Prism 5. To evaluate the effect of treatment on individual parameters in Group A and Group B Wilcoxon Sum Rank Test was applied and in Inter-group comparison Mann-Whitney Test was applied. The result of this study is given in Tables 6-8 with their graphical presentation.

Table no. 6: Effect of therapy on subjective parameters. (Wilcoxon Sum Rank Test)

Variable	Group	Mean		Mean Diff.	% Relief	P value	Result
		BT	AT				
Excessive Sleep	A	0.6111	0.2778	0.3333	54.5%	0.0313	S
	B	0.8500	0.2500	0.6000	70.5%	0.01	ES
Mann-Whitney test p>0.05, U=138, Considered not significant.							
Muscle Cramps	A	1.889	0.5556	1.333	70.5%	0.0001	ES
	B	2.300	1.300	1.000	43.4%	0.0005	ES
Mann-Whitney test p>0.05, U=136, Considered not significant.							
Oedema	A	0.8889	0.111	0.7778	87.5%	0.0020	VS
	B	0.9500	0.3000	0.6500	68.4%	0.0078	VS

Mann-Whitney test p>0.05, U=167, Considered not significant.							
Dry Skin	A	1.833	0.9444	0.8889	48.4%	0.0005	ES
	B	1.950	1.300	0.6500	33.3%	0.0010	ES
Mann-Whitney test p>0.05, U=153.50, Considered not significant.							
Constipation	A	0.6667	0.1111	0.5556	83%	0.0032	VS
	B	0.8500	0.3500	0.5000	58.8%	0.0177	VS
Mann-Whitney test p>0.05, U=172, Considered not significant.							
Lethargy	A	1.889	0.8889	1.00	52.9%	0.0002	ES
	B	2.200	1.450	0.7500	34 %	0.0005	ES
Mann-Whitney test p>0.05, U=156, Considered not significant.							
Hair-fall	A	2.000	1.222	0.7778	38.8%	0.002	VS
	B	2.250	1.450	0.8000	35.5%	0.0001	ES
Mann-Whitney test p>0.05, U=161, Considered not significant.							

BT: Before Treatment, AT: After Treatment, ES: Extremely Significant, VS: Very Significant, S: Significant, NS: Not-Significant

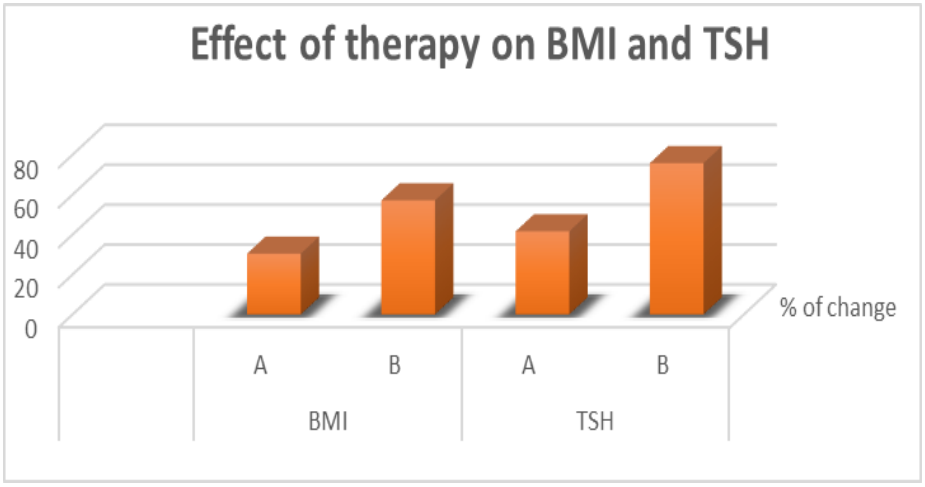


Graph 1: Effect of therapy on subjective parameters.

Table no. 7: Effect of therapy on BMI and TSH (objective parameters)

Variable	Group	Mean		Mean Diff.	% Relief	SD	SE	P	t value	S
		BT	AT							
BMI	A	1.150	0.8000	0.35	30.43	0.6156	0.1376	0.0047	3.199	VS
	B	1.400	0.6000	0.8	57.14	0.5982	0.1338	0.0001	5.812	ES
Unpaired t-test p>0.05, t=1.042, Considered not significant.										
TSH	A	7.387	4.312	3.0	41.62	3.805	0.8509	<0.0001	5.425	ES
	B	8.796	2.129	6.667	75.79	1.426	0.3188	<0.0001	8.159	ES
Unpaired t test p>0.05, t=2.403 Considered not significant.										

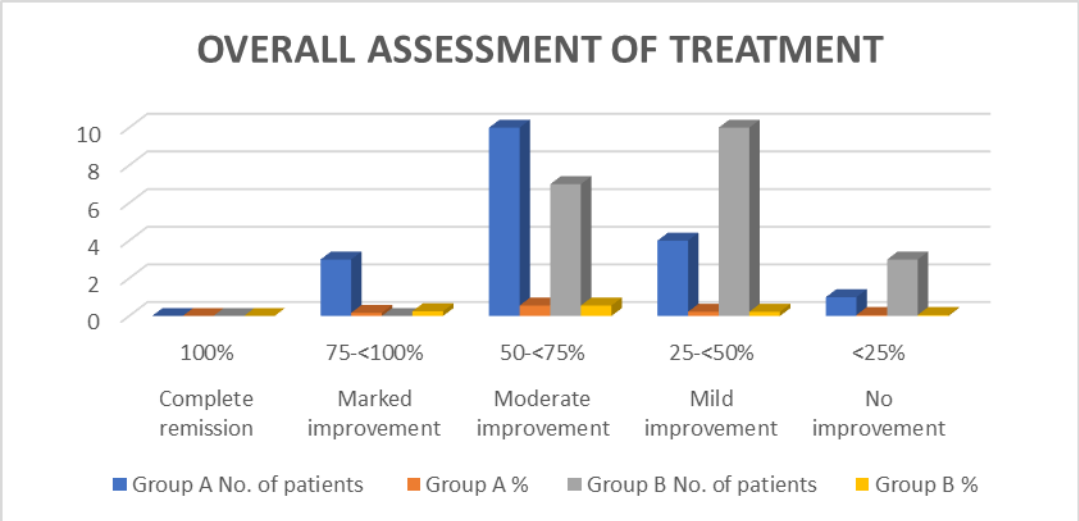
BT: Before Treatment, AT: After Treatment, ES: Extremely Significant, VS: Very Significant, S: Significant, NS: Non-Significant



Graph 2: Effect of therapy on objective parameters.

Table no. 8: Overall effect of therapy in Group A and Group B

Overall assessment of treatment		Group A		Group B	
		No. of patients	%	No. of patients	%
Complete remission	**100%**	00	00	00	00
Marked improvement	**75-<100%**	03	16.66%	00	25%
Moderate improvement	**50-<75%**	10	55.55%	07	55.55%
Mild improvement	**25-<50%**	04	22.22%	10	22.22%
No improvement	**<25%**	01	5.55%	03	5.55%



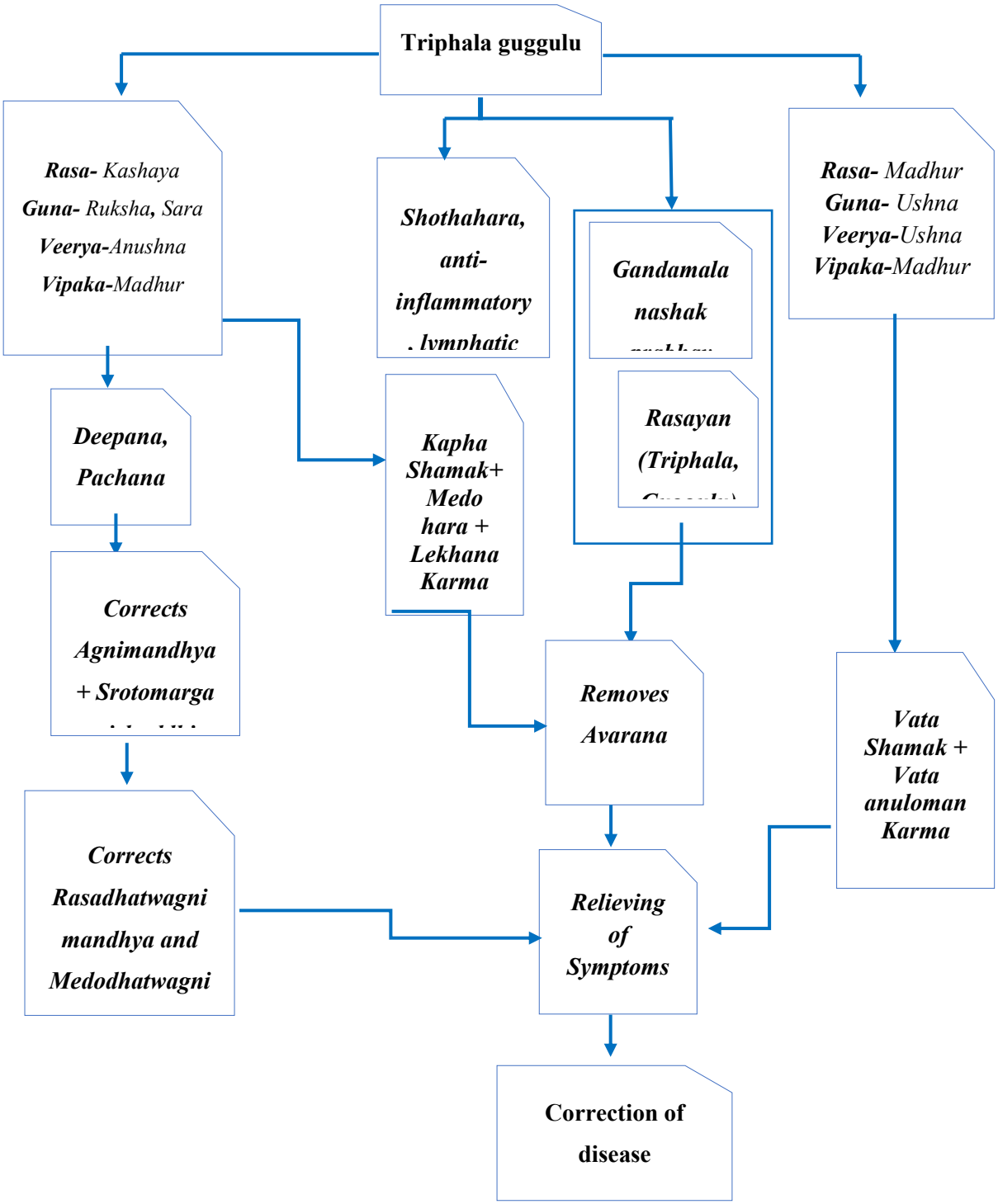
Graph 3: Overall effect of therapy in both groups

DISCUSSION

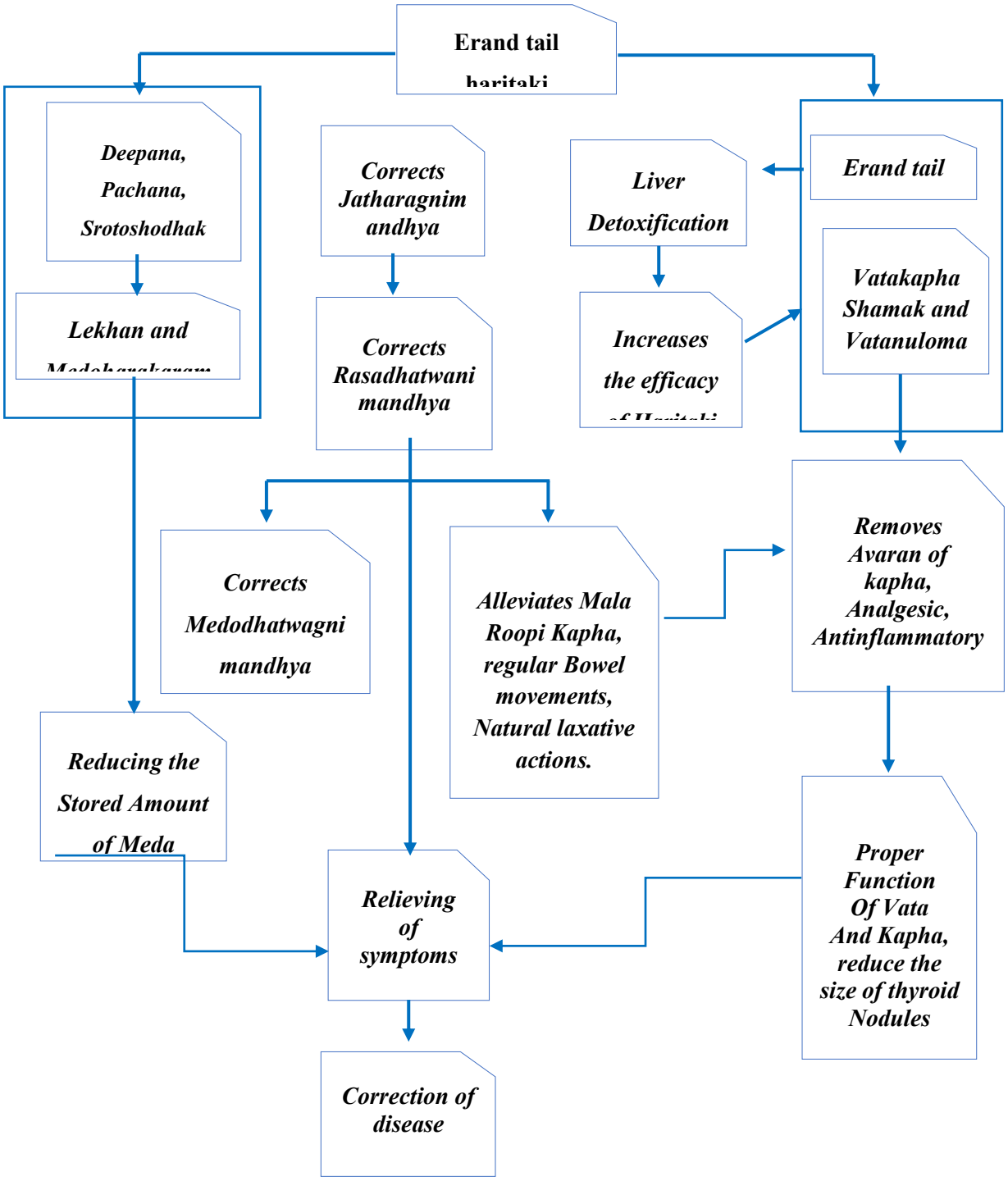
Hypothyroidism is the most common form of thyroid disorder and a commonly encountered problem in clinical practice, it is also the second most prevalent endocrine disorder [19] worldwide and India is not an exception. In *Ayurveda* although there is no specific terminology or clinical entity described as such, probably because the disease is biochemically diagnosed and not just only the basis of symptomatology. Pathogenesis of hypothyroidism according to the principles of *Ayurveda* can be interpreted as dysfunctioning of the *Agni,* particularly *Dhatwagni, Ama,* and *Avarana*.

- *Erand Tail Haritaki* was indicated for the purpose of *Nitya virechana (Srotoshodhana)*. Hypothyroidism is *Vata kaphaja* disorder but with *Pitta dusti*, since there is hypo secretion of hormones *pitta* is to be considered as a hormone and perhaps *Pitta* needs to be regularized, hence combination was made. *Katu, Tikta, Kashaya Rasa pradhanya , Laghu, Ruksha, Tikshna, Ushna Guna pradhanya* and *Ushna Virya* are indicative of *Kaphashamaka* effect of the *Eranda Tail Haritaki*. Hence it improves the *Agni,* helps in the removal of *Ama* and *Avarana* from the body and clears the channel. *Haritaki* is *Srotovibandhahara* and *Rasayan*. *Rasayana* property helps to produce good quality of *Rasa*.
- *Triphala Guggulu* is considered a drug of choice for all kinds of *Granthi Vikaras, Galgand, Apachi, Arbuda,* and *Gandmala*. It contains *Amalaki, Haritaki, Vibhitaki, Kanchanar, Pippali, Marich, Shunthi, Guggulu* and *Madhu*. This combination of herbs is primarily used to reduce or break down the deep-seated *Kapha* and to support digestive fire.
- *Varuna Kashaya* has *Kapha-Vata Shamaka, Deepana, Pachana, Rechana, Vatanulomana,* and *Shothhara* properties, it is also very well indicated in *Gandamala*. It cures different types of edemas and constipation caused by *kapha* and *Vayu* and stimulates digestion and metabolism *(Agni)*. With *anupana* of *Madhu possesses kapha-pitta shamaka, lekhana, kapha vilayana, chhedana, srotovishodhana, marganusari, yogvahi and Deepana.*

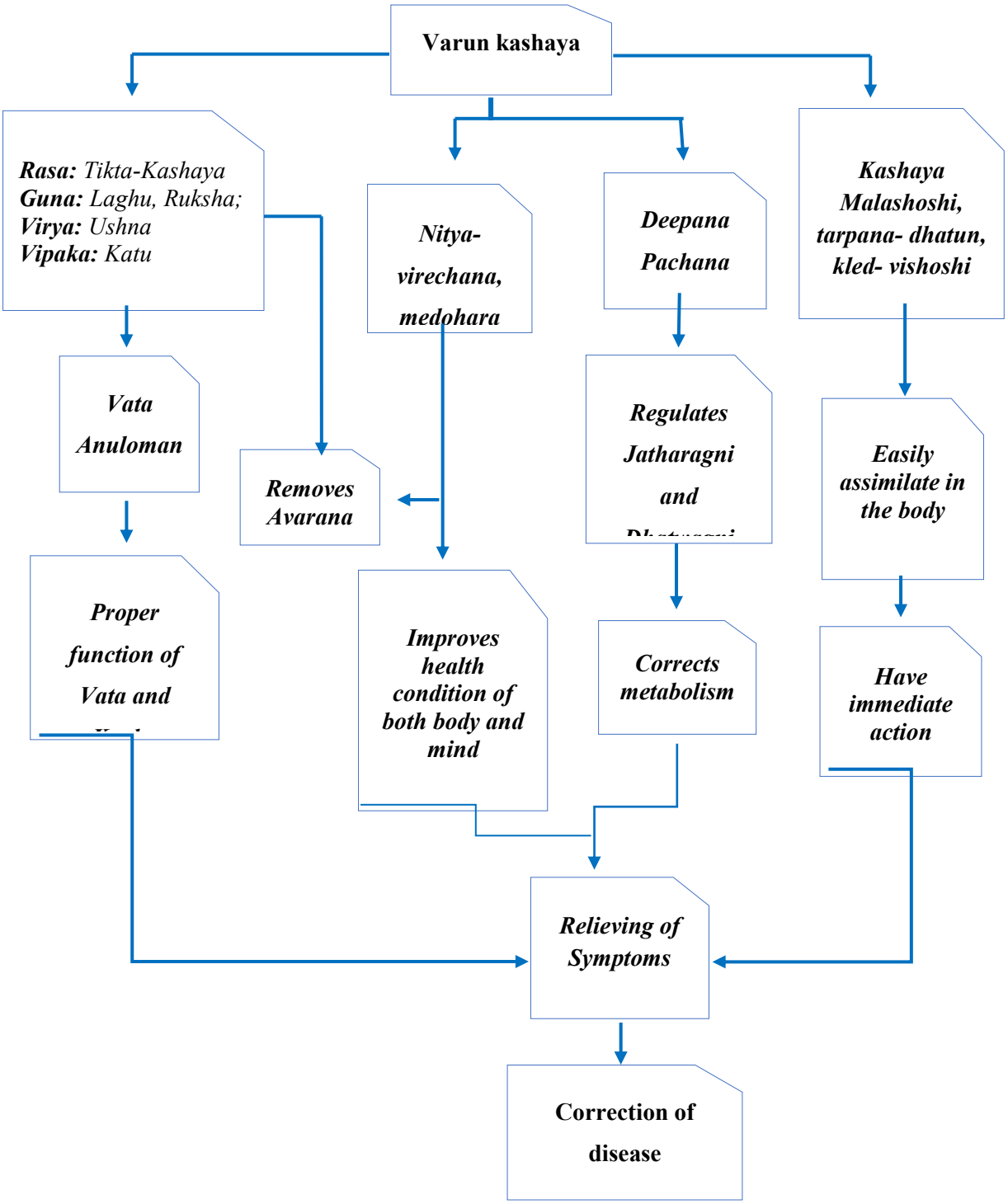
Flow chart no. 1*:* Showing probable mode of action of *Triphala guggulu*



Flow chart no. 2: Showing probable mode of action of *Erand tail haritaki*



Flow chart no. 3: Showing probable mode of action of *Varuna kashaya*



A total of 40 patients were registered in the study, out of which 38 patients completed the course of the treatment with complete follow up and 2 patients discontinued the treatment. Female to male ratio observed in the study was 3:1 (Females 72.5%). The female preponderance of thyroid autoimmunity is most likely due to sex steroid effects on the immune response, but an X-chromosome related genetic factor is

also possible [20]. Patients (47.5%) were found between the ages of 31 to 45 years of age. It is a lifestyle disorder, people in this age group are under strong working pressure in today's modern life style and remain busy which leads to irregular *Dincharya, Ritucharya*, etc. It may lead to vitiation of the *Doshas*. Thus, people in this age group are more prone to get inflicted by diseases caused due to derangement of *Agni*. Prevalence of Hypothyroidism increases with age [21]. Maximum (90%) patients were reported to be married. In married patients, lack of exercise, family- responsibilities and various types of stress may lead to *Rasavaha Sroto Dushti* [22]. But marital status does not have any direct relationship with the disease. According to American Thyroid Association, incidence of hypothyroidism increases after pregnancy [23]. Maximum (80%) patients were reported from Hindu religion, (97.5%) belonged to urban habitat and (55%) were educated up to college level. Maximum (52.5%) patients were reported homemakers. This high incidence may be due to responsibility of the more house hold work, *Diwaswapa* and day to day family stress with some of gynecological problems, which vitiate the *Dosha*, leading to *Agni* vitiation and subsequent *Ama* formation. Maximum (67.5%) belonged to middle-class section of society. Maximum (60%) patients were taking a mixed diet, Maximum (65%) patients reported *Kroora kostha*. Maximum patients were having poor appetite (62.5%). Loss of appetite is a common symptom of hypothyroidism; it is due to *Kapha vriddhi, pitta kshaya* [24]*, rasadhatudushti* [25] and *Manda* status of *Agni* due to *kaphaavrutta Samana Vata* [26]. Generally, thyroxine increases the appetite and food intake. So, hyposecretion of thyroxine causes loss of appetite [27]. Maximum (67.5%) were having irregular bowel habits. Thyroxine increases the secretions and movements of GI tract. So, lack of thyroxine causes constipation [28]. Maximum (55%) patients were suffering from *Mandagni. Rasa Dushti* and *Sama Kapha Vruddhi* occurs due to *Agni Vikruti,* which is the main cause in the pathogenesis. *Mandagni* is the root cause of all the disease and so in hypothyroidism [29]. Hypothyroidism was positive in 22.5% patients. As with most autoimmune disorders, susceptibility to autoimmune hypothyroidism is determined by a combination of genetic and environmental factors and the risk of autoimmune hypothyroidism is increased among siblings. HLA-DR polymorphisms are the best documented genetic risk factors for autoimmune hypothyroidism [30]. In this study 37.5% patients were overweight (BMI between 25-29.9) and 20% patients were obese (BMI > 30). It can be considered that the majority of patients were overweight and obese, *Medodhatvagnimandya* resulting in *Medo Dhatu Vriddhi* leading to *Sthaulyata*. These findings suggest that the *Dushti* of *Meda Dhatu* occur in hypothyroid patients. Thyroxine decreases the fat storage by mobilizing it from adipose tissues and depots. Decrease in thyroxine secretion increases the body weight (despite poor appetite) due to decreased metabolic rate and fat deposition [31]. In this study out of 40 patients, 29 were females amongst them maximum (37.93%) were having menopause history, while (34.4%) of patients were having normal menstrual blood flow, 20.6% of patients were having heavy menstrual cycle while 6.45% of patients were having scanty menstrual cycle. Also, idea may be put that *Artava dushti* is seen because of *Vata Vikruti* and *Sama Avastha* of *Rasa* i.e. vitiated *Rasa*

dhatu leads to vitiation of its *Updhatu Artava* causing above menifestation. In early stages it is due to the fall in progesterone levels and endometrial proliferation resulting in exccesive menstruation. In later stages, there is suppression of pituitary functions leading to ovarian atrophy and amenorrhoea. In the present study, lethargy was present in 95% of patients followed by muscle cramps in 85% of patients. Hair loss was found in 82.50% of patients while dry skin was observed in 80% of patients. Weight gain was present in 65% of patients while constipation was found in 57.50% of patients. Oedema was observed in 55% of patients and excessive sleep was observed in 48% of patients. These are common manifestations of hypothyroidism that resemble the *lakshanas* of *Kaphavritta Vata,* especially *Kaphavritta Udana Vata* and *Kaphavritta Samana Vata*. This gives an idea about the involvement of *Avarana* in the pathogenesis of hypothyroidism and *doshika* dominance of the disease, in which *Kapha dosha* is the main culprit associated with *Pitta Kshaya* and *Margavaranjanya Vata dushti*. So, from the above discussion, the probable effect of *Triphala Guggulu, Eranda Tail Haritaki,* and *Varuna Kashaya* might be as below:

1. To remove *Avaran* of *Kapha* and to do *Vatanulomana.*
2. To augment the *Agni* and digest the *Ama,*
3. To break the obstruction of *Srotasa*
4. To correct *Rasadhatwagni mandhya* and *Medodhatwagni mandhya*.

CONCLUSION

The trial drugs *Triphala Guggulu, Erand tail Haritaki,* and *Varuna Kashaya* used in the present study are having *Kapha Shamaka, Vatanulomaka, Deepana, Pachana, Srotoshodhana, Shothaghna*, *Lekhana, Rasayana* and *Yakruta-uttejaka, Medohara*, *Medhya, Balya* properties. All these properties are helpful in *Samprapti Vighatana* of Hypothyroidism. Hence, they are helpful in relieving symptoms like Excessive sleep, Muscle Cramps, edema, dry skin, constipation, lethargy, and Hair fall. Overall effect of assessment reveals that 16.66% patients showed marked improvement, 55.55% moderate improvement in group A while marked and moderate improvement observed in Group B was 0% and 35% respectively. On the basis of % relief study group (*Triphala guggulu, Erand tail haritaki and Varuna Kashaya*) provided better improvement (62.2%) in clinical signs and symptoms of hypothyroidism than control group (Thyroxine sodium) (49.16%). On intra-group comparison, both groups A (Study Group) and B (Control group) show significant results statistically. However, on intergroup comparison, the result was not significant. On the basis of the above result, it could be concluded that both groups were effective in the management of Hypothyroidism. However, Group A showed better efficacy in the management of hypothyroidism as compared to Group B.

Adverse drug reaction (ADR): No adverse drug reactions were reported during the course of the study.

Limitations of the study:

- The study area was limited to Bhopal city although some of the patients also belonged to the nearby areas.
- The sample size was too small to generalize the results for all populations. Only newly diagnosed cases were selected for this study.
- The present study was conducted in a limited time with limited facilities.

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