
Naturopathy module and its effect on biochemical parameters in patients suffering from hypothyroidism

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ABSTRACT

Introduction: Naturopathy may have a role in revitalizing thyroid gland. The aim was to investigate the effect of six months of Naturopathy intervention on hypothyroid patients.

Material & Methods: 100 hypothyroidism patients were recruited and 81 completed the trial (41 in control and 40 in Naturopathy group). The intervention groups received Naturopathy treatment for 56 sittings in six months. Levels of Thyroid, Liver, Kidney function tests, Muscle related enzyme, sugar fasting and HbA1c were estimated at baseline, after three and six months of intervention. Anti-thyroid peroxidase (Anti-TPO) antibodies was measured at baseline and after 6 months of treatment.

Results: In both groups there was significant increase in *ft4* level and significant decrease in TSH and Anti-TPO level. In the Control group the decreased TSH levels did not meet the clinical euthyroid range whereas in the Naturopathy group normal TSH range was achieved. Fasting blood sugar and LDH levels was found to decrease significantly in Naturopathy group. The amount of Thyroxine medicine taken by Control group increased significantly whereas increase in thyroxin medication seen in Naturopathy was less as compared to Control group.

Conclusions: Naturopathy as adjunct therapy was found more effective and can be used to prevent progression of disease to severity.

KEY WORDS: Anti-TPO antibody, *ft3*, *ft4*, Naturopathy, TSH.

INTRODUCTION

Thyroid hormone synthesis and secretion is regulated by a negative feedback system that involves the hypothalamus, pituitary, and the thyroid gland¹. Thyrotropin-releasing hormone secreted from hypothalamus stimulates anterior pituitary to release thyroid stimulating hormone (TSH) which further stimulates Thyroid gland to synthesize and

releases Triiodothyronine (T_3) and Thyroxine² (T_4). T_3 is the biologically active thyroid hormones that acts on nearly every cell in the body³. They increase the basal metabolic rate, affect protein synthesis, and are essential for proper development and differentiation of all cells of the human body. These hormones also regulate protein, fat, and carbohydrate metabolism.

Hypothyroidism is a clinical state resulting from under production of the thyroid hormones T_4 and T_3 ⁴. In India, thyroid disorders are most common among all endocrine disorders with state of hypothyroidism being more common than hyperthyroid and thyroid carcinoma state⁵. Prevalence of hypothyroidism in India is around 11%⁶. In hypothyroid patients, anti-TPO antibody positivity is an established marker of autoimmune thyroid disease⁷ and the percentage of adults testing anti-TPO antibody positive have been found to be 13.3%⁸.

Although treatment of hypothyroidism is considered simple but studies show that many patients on thyroid hormone replacement are either under treated or over treated. So Non-pharmacological interventions like Naturopathy is recommended for management of hypothyroidism. This is because Physical activity has been reported to affect endocrine functions⁹.

Naturopathy is an ancient form of physical activity that enhances blood circulation, tones up muscles, mobilize fat, reduce weight and bring down all the impurities to excretory channels and expel through sweat or urine. Beyond this, however, there are several secondary goals like increasing metabolism, improving physical health, treating depression and enhancing mental well-being and emotional balance. These have been practiced in Indian culture since ages but recently have received great deal of attention.

Our strategy for controlling hypothyroidism using Naturopathy modalities were focussed on stimulating thyroid gland so that it can help body in curing hypothyroidism. We wanted to learn if people with hypothyroidism can benefit from Naturopathy. Therefore, this study was planned to develop a healthy lifestyle program using Naturopathy modalities to combat the threat of hypothyroidism. The study was carried out to see the effect of Naturopathy on thyroid function tests and routine biochemical parameters, since there are only a few studies reporting such effects.

MATERIAL AND METHODS

The study was a prospective randomized control trial carried out at Bapu Nature Cure Hospital and Yogashram, Mayur Vihar Phase 1, Delhi. Duration of the study was two years (March 2017-March 2019) and study was conducted after due approval from the Ethical Committee of Bapu Nature Cure Hospital and Yogashram. Biochemical investigations were carried out at GIPMER, New Delhi.

Subjects and Study design: Hypothyroid-patients with TSH level >10 mIU/L and satisfying eligibility criteria, were recruited from various groups of society. 100 willing hypothyroidism patients in the age group 21-65 years were enrolled. Using random number table method the registered patients were divided randomly into

Groups of 50 each i.e. Group I (control group) and Group II (Naturopathy group). Out of the 100 hypothyroidism patients, 81 participants completed the trial (41 in control and 40 in naturopathy group). Patients were educated about the disease, associated risk factors and about the benefits of Naturopathy. Informed consent was obtained from patients and they were provided information sheet and a daily diary to record the compliance to the trial protocol and medicines. They had a medical examination and completed a health status questionnaire. Complete demographic details, clinical history, present and past medications were recorded for each patient at baseline.

Naturopathy interventions: Participants received 60 minutes sessions of Naturopathy treatment, thrice a week for first 2 months and twice in a week for next 4 months. The frequency of sessions was based on the earlier studies conducted at Bapu Nature Cure Hospital and Yogashram. Naturopathy sessions were scheduled between 6 am to 5 pm and at least three hours gap was maintained between meal and treatment session. Naturopathy interventions were provided by qualified therapists. Massage was done with non aromatic sesame oil which has anti inflammatory properties. Details of Naturopathy treatment given are mentioned in Table 1.

TABLE 1: Naturopathy treatments schedule for Group II hypothyroidism patients.

S.No.	Modality	Duration
1	Massage Legs - 8 min Hip -5 min Abdomen -7 min Neck -5 min	25 minutes
2	Steam Bath	10 minutes
3	Neck and Abdomen Pack	25 minutes
4	Total duration	60 minutes

Estimations: In this study thyroid function tests (fT3, fT4, TSH) and Anti-thyroid peroxidase (Anti-TPO) antibody estimation were performed using CLIA cobas-e411 analyzer. Fasting blood sugar (FBS), Liver function tests (Bilirubin, Aspartate transaminase (AST), Alanine Transaminase (ALT), Alkaline phosphatase (ALP), Protein and Albumin), Muscle related enzymes (Lactate Dehydrogenase (LDH), Creatine Kinase-MB (CK-MB), Kidney function tests (Urea, Creatinine, Uric acid), Lipid profile (Cholesterol, Triglyceride(TG), HDL-c) estimations were done using fully auto analyzer cobas-c501. HbA1c was estimated using HPLC system for HbA1C testing (Biorad D-10). All biochemical tests were blinded.

Statistical Analysis: The data was analyzed by an independent statistician, not related to the study. Blinding of data was followed during analysis. The data was analyzed using SPSS 16 version software. The statistical significance is considered at $p \leq 0.05$ levels for all

the parameters and the values are expressed as mean \pm SD.

RESULTS

Baseline characteristics of participants of Control (group I) and Naturopathy group (group II) were recorded (Table 2). The subjects were found to be matched for biochemical parameters and there was no statistical significant difference at baseline.

TABLE 2: Baseline comparison in Biochemical parameters within Control and Naturopathy group

Parameters	Group I Mean \pm SD	Group II Mean \pm SD	P-Value
fT3 (pg/ml)	2.9 \pm 0.44	2.68 \pm 0.58	0.07
fT4 (ng/dl)	1.04 \pm 0.23	1.06 \pm 0.24	0.70
Serum TSH (uIU/ml)	14.53 \pm 9.58	17.16 \pm 9.28	0.21
Anti TPO (IU/ml)	225.12 \pm 231.97	187.78 \pm 219.93	0.45
FBS (mg/dl)	91.51 \pm 14.46	97.03 \pm 15.40	0.10
HbA1C(%)	5.29 \pm 0.59	5.35 \pm 0.60	0.64
Cholesterol (mg/dl)	177.68 \pm 34.56	188.23 \pm 44.07	0.23
Triglyceride (mg/dl)	130.44 \pm 72.14	132.83 \pm 65.63	0.87
HDL (mg/dl)	53.22 \pm 16.26	51.93 \pm 14.80	0.71
Urea (mg/dl)	21.90 \pm 5.25	22.80 \pm 7.59	0.54
Creatinine (mg/dl)	0.74 \pm 0.16	0.74 \pm 0.14	0.84
Uric acid (mg/dl)	4.39 \pm 1.33	4.55 \pm 1.34	0.59
Total bilirubin (mg/dl)	0.47 \pm 0.24	0.42 \pm 0.18	0.22
Total protein (mg/dl)	7.54 \pm 0.63	7.48 \pm 0.68	0.68
Serum albumin (mg/dl)	4.45 \pm 0.36	4.40 \pm 0.29	0.31
ALP (U/L)	87.56 \pm 24.42	85.16 \pm 29.60	0.69
AST (U/L)	27.05 \pm 15.00	28.25 \pm 13.49	0.71
ALT (U/L)	23.39 \pm 11.66	26.18 \pm 14.37	0.34
LDH (U/L)	187.46 \pm 34.25	215.45 \pm 87.10	0.06
Ck- MB (U/L)	15.59 \pm 5.45	14.68 \pm 4.69	0.42

Table 3, Fig.1 and 2 shows changes in Biochemical parameters within Control and Naturopathy groups. The mean FBS in both the groups were within the normal range. There was no significant change in FBS in group I. But Naturopathy group II showed a significant decline in fasting blood sugar levels ($p = 0.02$) and in the levels of LDH ($p=0.02$). For other routine Biochemical parameters no significant changes were observed between pre and post intervention in Control group (Group I) or Naturopathy group (Group II) .

TABLE 3: Comparing changes in Biochemical parameters within Control and Naturopathy group

Parameters	Groups	Baseline	3 rd Month	6 th Month	RM ANOVA	
		Mean±SD	Mean±SD	Mean±SD	F-stat	P-Value
FBS (mg/dl)	I	91.51±14.46	91.15±13.23	89.76±12.22	0.40	0.63
	II	97.03±15.40	94.18±10.11	91.28±6.92	4.33	0.02*
HbA1C	I	5.29±0.59	5.23±0.62	5.30±0.42	0.30	0.73
	II	5.35±0.60	5.26±0.43	5.32±1.00	0.23	0.74
CHOL (mg/dl)	I	177.68±34.56	166.83±28.94	171.19±35.61	2.11	0.12
	II	188.23±44.07	184.20±40.31	180.10±38.86	1.05	0.34
TG (mg/dl)	I	130.44±72.14	132.32±66.06	126.34±50.40	0.188	0.81
	II	132.83±65.63	129.05±54.25	129.25±39.65	0.14	0.81
HDL (mg/dl)	I	53.22±16.26	48.83±12.82	52.93±29.00	0.59	0.49
	II	51.93±14.80	49.05±11.50	50.05±9.07	1.75	0.18
UREA (mg/dl)	I	21.90±5.25	21.93±6.65	21.16±8.06	0.29	0.70
	II	22.80±7.59	24.08±7.45	23.65±6.84	0.72	0.48
CRE (mg/dl)	I	0.74±0.16	0.74±0.14	1.38±2.39	2.94	0.09
	III	0.74±0.14	0.73±0.15	0.74±0.20	0.03	0.96
UA (mg/dl)	I	4.39±1.33	4.64±0.96	4.72±1.42	1.33	0.26
	II	4.55±1.34	4.64±1.44	4.89±1.23	2.04	1.41
T-BIL (mg/dl)	I	0.47±0.24	0.51±0.31	0.48±0.23	0.59	0.55
	II	0.42±0.18	0.37±0.17	0.42±0.20	2.76	0.07
TP (mg/dl)	I	7.54±0.63	7.69±0.47	7.67±0.56	1.15	0.31
	II	7.48±0.68	7.48±0.51	7.57±0.48	1.22	0.30
ALB	I	4.45±0.36	4.43±0.33	4.61±1.04	1.05	0.32

(mg/dl)	II	4.40±0.29	4.31±0.29	4.29±0.32	1.19	0.30
ALP	I	87.56±24.42	85.85±23.91	87.56±22.49	0.17	0.81
(U/L)	II	85.16±29.60	88.05±31.26	83.10±26.41	1.19	0.30
AST	I	27.05±15.00	23.19±8.32	24.59±9.64	1.59	0.21
(U/L)	II	28.25±13.49	23.65±8.29	25.25±13.47	1.41	0.24
ALT	I	23.39±11.66	22.28±10.13	20.83±6.29	1.35	0.26
(U/L)	II	26.18±14.37	24.38±12.17	24.58±11.02	0.65	0.49
LDH	I	187.46±34.25	187.07±46.43	183.35±36.57	0.21	0.80
(U/L)	II	215.45±87.10	182.98±33.91	176.45±72.11	4.46	0.02*
CK-MB	I	15.59±5.45	14.71±6.59	15.66±6.90	0.35	0.69
(U/L)	II	14.68±4.69	12.83±4.72	14.02±10.57	0.76	0.41

* p≤0.05, ** p≤0.01, *** p≤0.001

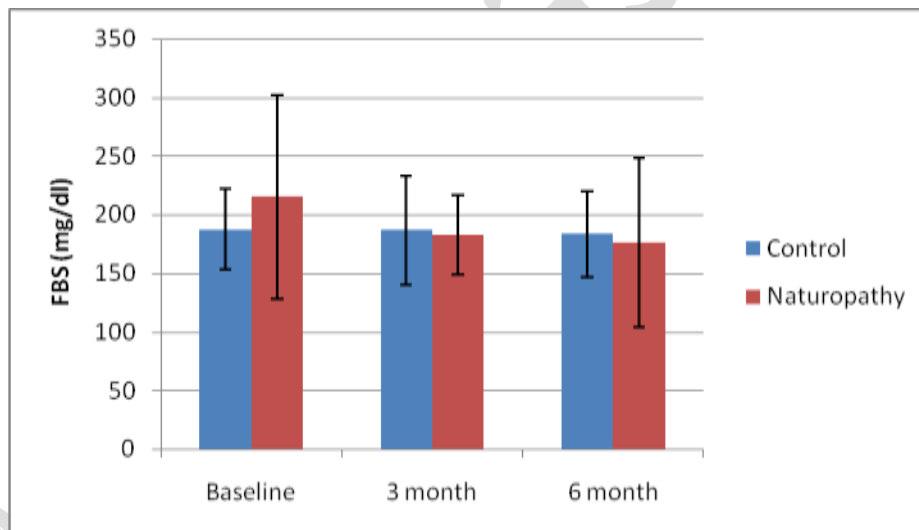


Fig 1: Changes in FBS in Control and Naturopathy groups

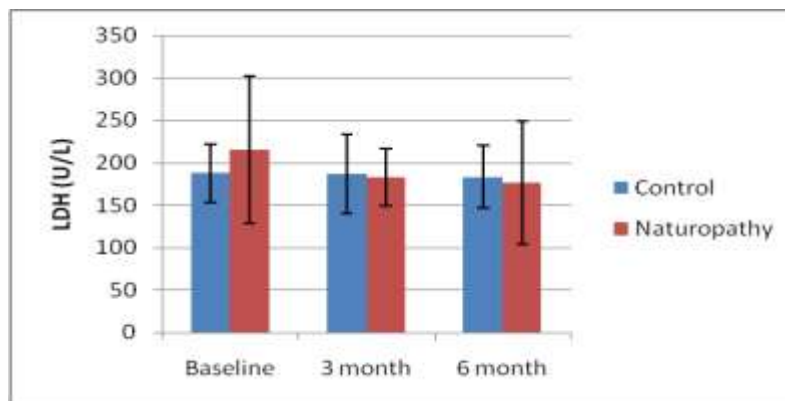


Fig 2: Changes in LDH activity in Control and Naturopathy groups

Table 4 shows changes in Thyroid function test within Control (Group I), Naturopathy group (Group II). No significant changes were observed in fT3, in any of the two groups. Post intervention there was significant improvement in fT4 levels in both groups ($p=0.001$ and $p = 0.003$ in control and naturopathy respectively) as shown in (Fig 3). At baseline level, the mean serum TSH concentrations of both groups were in the overt hypothyroid range. In both groups serum TSH concentration showed significant reduction ($p= 0.000$) after 3 and 6 months when compared to baseline.(Fig 4) In Naturopathy group euthyroid range was achieved whereas in Control group mean level was more than the normal range

TABLE 4 : Comparison of changes in Thyroid function test within Control (Group I), Naturopathy group (Group II)

Parameters	Groups	Baseline	3 rd Month	6 th Month	RM ANOVA	
		Mean \pm SD	Mean \pm SD	Mean \pm SD	F-stat	P-Value
fT3 (pg/ml)	I	2.90 \pm 0.44	3.01 \pm 0.79	2.97 \pm 0.42	0.42	0.61
	II	2.68 \pm 0.58	2.82 \pm 0.50	2.84 \pm 0.42	1.81	1.72
fT4 (ng/dl)	I	1.04 \pm 0.23	1.18 \pm 0.24	1.19 \pm 0.25	7.48	0.001**
	II	1.06 \pm 0.24	1.16 \pm 0.22	1.24 \pm 0.24	7.40	0.003**
TSH (uIU/ml)	I	14.53 \pm 9.58	7.33 \pm 8.35	7.74 \pm 8.08	26.38	0.000***
	II	17.16 \pm 9.28	4.98 \pm 2.97	3.93 \pm 2.75	62.29	0.000***

* $p<0.05$, ** $p<0.01$, *** $p<0.001$

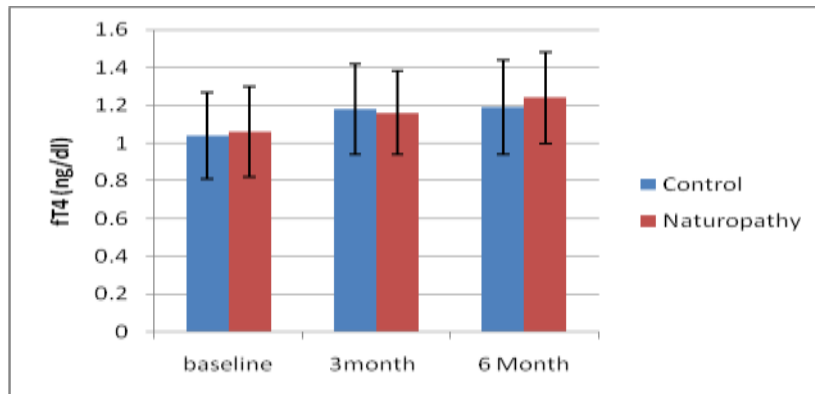


Fig 3: Comparison of fT4 levels after 3 months and 6 months between Control and Naturopathy groups

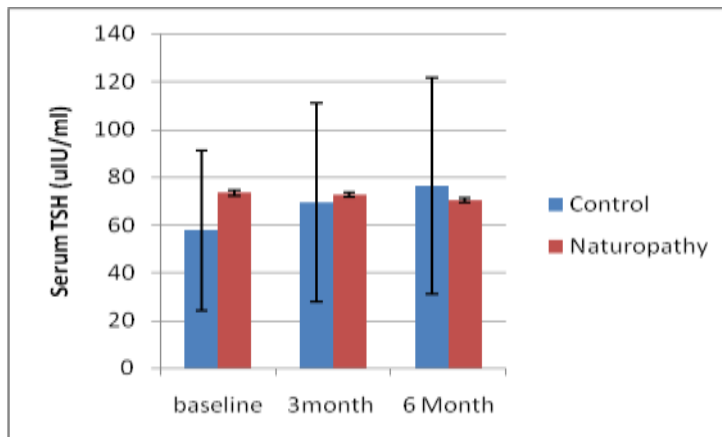


Fig 4: Comparison of serum TSH concentration between Control and Naturopathy groups at baseline, after 3 months and after 6 months.

Table 5, Fig 5 shows Anti TPO antibody levels at baseline and after 6 months of intervention. Paired t-test comparison between the mean anti-thyroid peroxidase antibodies concentrations at baseline and after 6 months intervention, showed significant decrease in both groups ($p=0.002$ and $p=0.009$ in control and Naturopathy group respectively). However, the mean Anti-TPO antibody concentration did not reach the normal range (< 34) in any of the groups.

TABLE 5. Comparison of Anti TPO antibody(IU/ml) of Control and Naturopathy group at baseline and after 6 months of treatment.

Group	Baseline	6 Month	t value	P value
Control	320.20 ± 223.83	239.6 ± 231.23	3.05	0.002**
Naturop	344.37± 200.13	229.11 ± 205.88	2.82	0.009**

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* $p \leq 0.05$, ** $p \leq 0.01$, *** $p \leq 0.001$

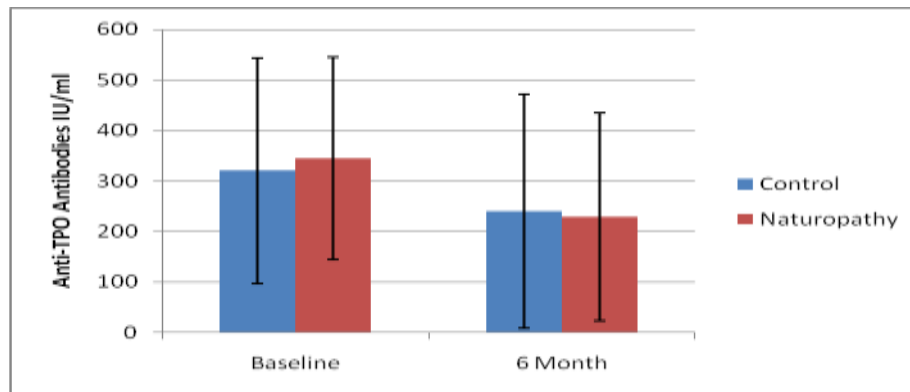


Fig 5: Comparison of serum Anti-TPO antibody concentration between Control and Naturopathy groups at baseline and after 6 months.

Mean dose of Thyroxine medication increased significantly among group I (Control patients) ($P=0.000$). In group II Naturopathy patients, there was less increase in Thyroxine dose intake and was also less significant ($p=0.032$) (Table 6, Fig 6).

TABLE 6: Change in Thyroxine medication dose in the three groups

Group	Baseline	3 rd month	6 th month	F-value	P value
Gp I	57.81±33.45	69.37±41.59	76.26±45.19	18.83	0.000***
Gp II	61.22±33.29	66.67±38.29	65.06±34.79	3.59	0.032*

* $p \leq 0.05$, ** $p \leq 0.01$, *** $p \leq 0.001$

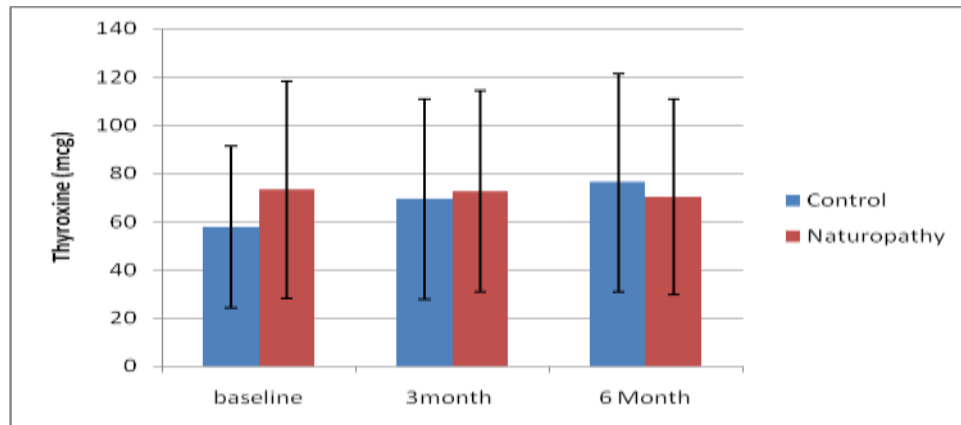


Fig 6: Changes in Thyroxine dose in Control and Naturopathy groups

DISCUSSION

In recent times there has been an increase in awareness about the use of non conventional therapies along with modern medicine, especially for non communicable diseases. There is growing clinical evidence of the use of Naturopathy in chronic non-communicable degenerative disorders¹⁰. Mechanism of action of Naturopathy is to rejuvenate the sluggish thyroid and adrenal glands. It is beneficial not only for hypothyroidism but also for the health of the endocrine system.

Naturopathy believes that build up of toxins in the body interferes with the endocrine functioning; therefore, detoxification is the natural first step in the treatment. A detoxification can be done with the help of fasting, massages, enema and mud therapy etc. In case of heavy metal, toxicity chelation can be done. Detoxification would ensure that all the accumulated toxins are removed from the body. In our study we have used massage, steam bath and neck and abdomen packs. Unlike Allopathy that solves just the symptoms of hypothyroidism by prescribing artificial hormones, naturopathy tries to remove the root cause.

Thyroid hormones are crucial for development, growth, differentiation, metabolism and thermogenesis in the body. Thyroid hormones are important regulators of energy metabolism¹¹. Studies show that thyroid hormones play a role in development and function of cardiovascular, nervous, immune and reproductive system¹². Also adequate thyroid function is essential for normal development and retention of cognitive function throughout life¹³. Many of the thyroid disorders occur due to excessive stress. Naturopathy may be useful in alleviating stress and anxiety to a great extent and may be used to prevent and treat thyroid gland dysfunction.

Aim of the present study was to evaluate the effects of 6 months of Naturopathy treatment on thyroid function. It was observed that in both control and intervention groups there was significant increase in fT4 level and a significant decrease in TSH level. In Anti-TPO level also significant decrease was seen although normal value was not attained in any of the groups. As per the AACE recommendations, the effective treatment of Hypothyroidism is

restoring the higher serum TSH to the normal physiological range¹⁴. In the Control group mean TSH levels did not meet the clinical euthyroid range, whereas in the Naturopathy group TSH level reached normal range after 6 months of intervention. We found that during the period of study, the amount of Thyroxine medicine taken by control group increased significantly but there was less increase in dose intake in Naturopathy group. A long-term intake of artificial hormones by the body eventually results in reduced functional capacity of thyroid gland and over a period increases its dependence on artificial hormones. The effectiveness of Naturopathy intervention in our study is in accordance with earlier studies wherein a decrease in the elevated serum TSH level associated with primary hypothyroidism was induced by increase in body temperature¹⁵. Another study reported decrease in serum TSH after sauna bath¹⁶. There are reports of increase in serum cortisol levels after steam bath treatment. Since increased serum cortisol level suppresses TSH this could be a plausible explanation for significant lowering of TSH by naturopathy treatment¹⁷. The treatments used in our study were steam bath along with massage and mud packs. All these could have worked in further lowering of TSH levels over a period of 6 months. Proper absorption of orally administered Thyroxine in the intestine is a critical step. It is also possible that naturopathy modalities may have improved absorption of ingested Thyroxine medicine which may have resulted in better control of serum TSH levels.

The concentration of serum Anti-TPO antibodies showed significant decrease in both groups although it did not reach the normal level in any of the groups. Higher concentration of Anti-TPO antibodies indicates presence of autoimmune thyroid disease. Reasons for the increase in anti-TPO positivity remain unclear; the underlying pathogenesis may involve a complex interplay of genetic, environmental and endogenous factors^{18, 19, 20}.

Liver, muscle and kidney metabolizes thyroid hormones and regulates their systemic endocrine effects; which suggests thyroid dysfunction may disturb liver, muscle, other organ function and vice versa²¹. So effect was seen on LFT, KFT, Muscle related enzymes and Lipid Profile. Earlier studies have reported reduction in serum cholesterol and other lipid profile components in normal population following naturopathy modalities like steam bath^{22, 23}. We speculate that in our study decrease in lipid profile in patients might be difficult owing to reduced cellular metabolism in hypothyroid patients.

It has been observed in a study that hypothyroidism is associated with insulin resistance²⁴. In our study normal FBG levels were observed but in post Naturopathy intervention group there was significant reduction in FBG. Since our Naturopathy intervention consisted of massage, neck and abdomen pack and steam bath it is difficult to decide if this reduction in FBS is a result of a particular treatment or a combined effect of all the treatments. In our study mechanism behind lowering of fasting blood glucose may be better overall metabolism because of improved thyroid function as a result of Naturopathy. Few earlier studies have also reported reduction in fasting glucose following treatment using specific naturopathy modalities, such as, massage, steam bath, abdomen pack^{25,26,27}.

In this study it was observed that muscle related enzyme LDH levels decreased in Naturopathy group. All tissues contain various amounts of the [LDH](#) isoenzymes; however, muscle, liver, and red blood cells are the major sources. LDH is a measure of the membrane integrity and its elevations are seen as an early indicator of tissue damage. The level of [LDH](#) is more in damaged cells compared to normal cells. Various conditions can raise the LDH levels including hypothyroidism²⁸. This is because thyroid hormones are essential for

normal growth, development and basal metabolic rate of all cells, so its alteration can affect the entire metabolism and can alter the activity of serum enzymes. The elevated LDH levels in Hypothyroidism could reflect increased release and/or decreased clearance of LDH from the liver²⁹. In our study LFT, KFT were in normal range and so were levels of LDH. But there was a significant decrease in LDH in Hypothyroid patients undergoing Naturopathy. In Skeletal muscle Thyroid hormones influence contractile function, muscle repair and myogenesis³⁰. In Hypothyroidism less Thyroid hormone may have affected muscle repair work resulting in more anaerobic glycolysis and high LDH value. As we recruited Hypothyroid patients and not the normal one so we did not have their basal LDH level. It was observed that because of Naturopathy TSH levels decreased to euthyroid range, which could have resulted in normalization of metabolism and lowering of LDH subsequently.

Naturopathy modalities seem to have a positive effect on the entire body metabolism as evident from decreased levels of TSH, and increased levels of fT4. Naturopathy modalities were not only helpful in the management of hypothyroid condition but also helped prevent further tissue damage as evident from decreased LDH activity. Decrease in Fasting Blood sugar also indicates the holistic effect of naturopathy based interventions. This user-friendly, healthy lifestyle program of Naturopathy cure planned in our study can further result in more benefits if it is followed for longer duration with a high degree of compliance. This study will be helpful to motivate patients to take up responsibilities of their own health.

CONCLUSION

Effect of Naturopathy treatments resulted in the rejuvenation of thyroid gland and increased fT4 levels. This would have resulted in better metabolic control (e.g. myogenesis and muscle repair) as is reflected by decreased LDH levels. Naturopathy, as an adjunct intervention therapy, has been found to be effective, safe and beneficial intervention for management of hypothyroidism. Also the dependence on artificial hormones was reduced as compared to control group.

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