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An open-label, interventional study to evaluate the efficacy of homoeopathic medicines in the treatment of hypothyroidism

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ABSTRACT

Objectives: Hypothyroidism is a thyroid hormone deficiency that affects age groups. The incidence of hypothyroidism is on the rise; conventional treatment comprises life-long hormone replacement therapy (levothyroxine). Missing doses lead to the recurrence of symptoms. Homoeopathic medicines are prescribed based on individualisation and are said to be beneficial in treating such conditions. The objectives of the study were to ascertain the role of homoeopathic medicines in the treatment of hypothyroidism.

Materials and Methods: An open-label, interventional study on 30 patients was carried out in the Outpatient and Inpatient Departments of Mahesh Bhattacharyya Homoeopathic Medical College, Howrah. The patients were evaluated for 1½ years. Thyroid-stimulating hormone (TSH) level and Zulewski's clinical score were recorded at baseline and after 6 months of treatment for assessing the primary and secondary outcomes. Medicines were prescribed based on strict homoeopathic principles.

Results: The result showed that the mean ± standard deviation serum TSH level decreased from 18.18 ± 16.58 to 7.68 ± 8.51 ($P < 0.0004$) and the mean value of Zulewski's clinical score also decreased from 7.30 ± 1.39 to 3.60 ± 1.87 ($P < 0.0001$) after 6 months of treatment.

Conclusion: The outcome of individualised homoeopathic treatment was found satisfactory with evidence of overall improvement in patients.

Keywords: Individualisation, Homoeopathic principles, Hypothyroidism, Serum thyroid-stimulating hormone level, Zulewski's clinical score

INTRODUCTION

Thyroid disease is arguably among the most common endocrine disorders worldwide; India is no exception. An estimated 42 million people in India have thyroid disease.[1,2] The word hypothyroidism is derived from the Greek 'hypo' meaning 'reduced', 'thyreos' meaning 'shield' and 'eidos' meaning 'form'. In hypothyroidism, also called underactive thyroid or low thyroid, the thyroid gland does not produce sufficient thyroid hormone (T3 and T4). Reduced thyroid activity is usually primary, caused by thyroid disease, or secondary, due to hypothalamic-pituitary disease leading to reduced production of thyroid-stimulating hormone (TSH).[3,4] The prevalence of primary hypothyroidism is 1:100 but increases to 5:100 if patients with subclinical hypothyroidism (normal T3 and T4, raised TSH) are included. The female-to-male ratio is approximately 6:1.[5]

Hashimoto's thyroiditis is the most common cause of hypothyroidism in countries with sufficient dietary iodine.[6]

Iodine deficiency remains a common cause of hypothyroidism worldwide. In areas of iodine sufficiency, autoimmune disease (Hashimoto's thyroiditis) and iatrogenic causes (treatment of hyperthyroidism) are most common.[7] Other common causes of hypothyroidism include thyroidectomy, radioiodine therapy and drugs such as amiodarone, lithium, thionamide, iodine, interferon, sunitinib, rifampicin and thalidomide. Transient hypothyroidism may occur in subacute (de Quervain's) and postpartum thyroiditis. In both these conditions, 75–85% of patients regain normal thyroid function.[8,9] Congenital hypothyroidism, due to thyroid gland agenesis or dyshormonogenesis, affects about 4000 newborns and is the most common congenital endocrinopathy.[8,10]

Almost one-third of the world's population lives in areas of iodine deficiency.[11,12] In areas, where the daily iodine intake is <50 μg, goitre is usually endemic and when the daily intake falls <25 μg, congenital hypothyroidism is seen. The prevalence of goitre in areas of severe iodine deficiency can be as high as 80%.[11] Worldwide, approximately 2 billion people are estimated to be hypothyroid.[7]

The classic picture of the slow, dry-haired, thick-skinned, deep-voiced patient with weight gain, cold intolerance, bradycardia and constipation makes the diagnosis easy. Other symptoms include tiredness, poor memory, menorrhagia or oligomenorrhea in women, loss of eyebrows, oedema, arthralgia, poor libido and deafness.[3]

Conventionally, most people with hypothyroidism symptoms and confirmed thyroxine deficiency are treated with a synthetic long-acting form of thyroid hormone (levothyroxine).[8] Patients with symptoms of hypothyroidism but normal biochemistry showed no benefit from levothyroxine in improving well-being and cognitive function.[8,11] Moreover, risks of overtreatment with levothyroxine are reported in 14–21% of patients.[13-15] Therefore, we can surmise that complementary and alternative medicine, including homoeopathy, has some benefits to offer. Some clinical trials[16,17] and case reports[18,19] have demonstrated positive outcomes with homoeopathic treatment of hypothyroidism. Homoeopathic Materia Medica and therapeutics indicate numerous remedies for thyroid conditions. We, therefore, conducted this study to determine the efficacy of homoeopathic remedies in the treatment of hypothyroidism.

MATERIALS AND METHODS

Setting and design

A prospective, interventional study was conducted from November 2020 to November 2021 on 30 individuals who had hypothyroidism in the Outpatient and Inpatient Departments of Mahesh Bhattacharyya Homoeopathic Medical College and Hospital, Howrah. The proposed plan of work was approved by the Ethical Committee of the Institution (Ref. F. No. 906/MBHMCH/CH/PRIN/ADM/20; dated 6 October 2020). The trial was registered in CTRI (Reg. No.- CTRI/2020/12/029637). Each patient was provided with a patient information sheet in English and Bengali (the local language) detailing the objectives, methods, risks and benefits of participating and confidentiality issues. Before enrolment, written informed consent was taken from the patient and/or legal guardian.

Inclusion and exclusion criteria

Inclusion criteria

The following criteria were included in the study:
1. Presenting with clinical symptoms of hypothyroidism
2. Fulfilling the diagnostic criteria for hypothyroidism
3. Aged between 13 and 50 years
4. Not already taking levothyroxine, newly diagnosed
5. Already diagnosed with primary hypothyroidism
6. Any sex, religion or socioeconomic status
7. Willing to undergo the laboratory investigations required
8. Willing to participate in the study and provide informed consent.

Exclusion criteria

The following criteria were excluded from the study:
1. Pregnant or lactating women
2. Those with malignant diseases or any other systemic diseases that require emergency aids
3. Undergoing homoeopathic treatment for chronic diseases within the past 6 months
4. Substance abuse and/or dependence
5. Unwilling to participate in the study and unwilling to provide informed consent.

Outcome assessment

- **Primary outcome:** Assessed based on TSH level at baseline and 6 months[20,21]
- **Secondary outcome:** Assessed based on Zulewski's clinical score at baseline and 6 months.

Intervention and follow-up

All patients were administered appropriate individualised homoeopathic medicines strictly based on homoeopathic principles. Patients were advised to take care of their lifestyle and diet i.e., avoiding cruciferous vegetables such as cabbages, cauliflowers and turnips and to take at least 7 hours of sleep and to exercise regularly to prevent weight gain. Cases were repertorised as required. Remedies were repeated depending on individual requirements. Each patient was followed up

every 3 weeks for 6 consecutive months, with the data noted at baseline and the 6th month. The TSH, T3 and T4 levels were checked once every month.

Statistical analysis

Frequency distribution of the collected data was done following standard statistical methods and analysed; data are presented in the appropriate format. Analysis was done for a variety of clinical presentations and the effect of homoeopathic prescription. Apart from the basic statistical methods of tabulation, graphical representations are also done. Student's paired *t*-test was used to analyse the changes in TSH levels and Zulewski's clinical score in each patient as a result of the intervention. Data were analysed from the descriptive point of view.

RESULTS

Study flow

A total of 46 patients were preliminarily screened based on the abovementioned inclusion criteria. The final outcome of the study flow is described in Figure 1.

Baseline features

- Data are presented as mean ± standard deviation
- The maximum number of patients were aged 31–40 years (n = 18; 60%), followed by 41–50 years (n = 9; 30%), 21–30 years (n = 2; 6.67%) and 11–20 years (n = 1; 3.33%)
- A majority of the patients were female (n = 22; 73.33%)
- A majority of the patients were from the middle class (n = 20; 66.67%)
- The mean TSH level was 18.18 ± 16.58 and Zulewski's clinical score was 7.30 ± 1.39.

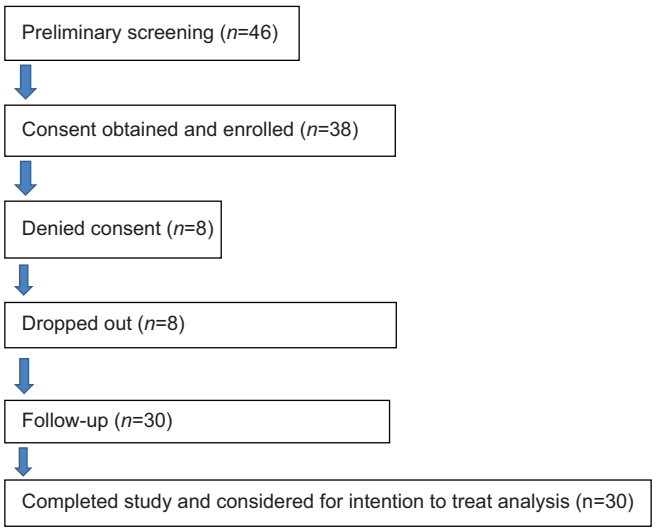

Figure 1: Study flow diagram.

Comparison after treatment for 6 months

- Among 38 patients, three showed increased TSH levels and two showed increased Zulewski's clinical score. The score remained unchanged in one patient.
- The mean TSH level dropped from 18.18 ± 16.58 to 7.68 ± 8.51. Mean reduction 10.5; t = 4.0184, at degrees of freedom (df) 29 and 95% confidence interval, the table value is 2.045, $P < 0.05$ (0.0004) (Student's paired *t*-test).
- The mean Zulewski's clinical score dropped from 7.30 ± 1.39 to 3.60 ± 1.87. Mean reduction 3.7; t = 8.729, at dfs 29 and 95% confidence interval, the table value is 2.045 $P < 0.05$ (0.0001) (Student's paired *t*-test).

Homoeopathic medicines used

Per the totality of symptoms, at baseline, *Calcarea Carbonica* was prescribed in 9 patients (30%); *Natrum Muriaticum* was prescribed in 4 patients (13.33%); *Pulsatilla Nigricans* was prescribed in 3 patients (10%); *Thuja Occidentalis*, *Medorrhinum*, *Sulphur*, *Tuberculinum Bovinum, Natrum Sulphuricum and Lycopodium* were prescribed in 2 patients each (6.67%); and *Sepia Officinalis*, *Lachesis muta* were prescribed in 1 patient each (3.33%).

The indicated medicine was prescribed in different potencies as per each patient's susceptibility, according to the guidelines in the Organon of Medicine. The remedy was changed if there was no marked improvement or the symptom totality changed. Placebo was prescribed as long as improvement continued. Among the 30 patients, no change of medicine was required for 25 patients; however, repetition or prescription of higher potencies was required in several cases. The list of prescribed medicines and the indications of the most frequently used remedies are given below.

Indication of most frequently prescribed medicines

Calcarea Carbonica

In simple goitre in those of strumous diathesis, this remedy has been used successfully. Dr. Zopfy of Germany who has much experience in the treatment of hypothyroidism, claims that the remedy will cure most simple cases of Hypothyroidism within a few weeks. Swelling is hard; worst toward the new moon.

Natrium Muriaticum

The general state of gloominess and mental depression characterises the natrum group. They almost delight in making themselves and others miserable by looking at the dark side; have a strong aversion to consolation and sometimes alternate gaiety and gloom. Particularly, emaciates about the neck even when eating ravenously. Tears are a keynote of Nat Mur.

Pulsatilla

Hypochondriacal moroseness takes everything in the bad part. Patients of Pulsatilla have characteristics of sullenness, breaking out into weeping when interrupted in their work. They are also highly emotional and love to get sympathy and are thirstless.

Table 1: Sociodemographic profile of the patients (*n*=30).

Characteristics	Estimates *n* (%)
Age (years)	
11–20	1 (3.33)
21–30	2 (6.67)
31–40	18 (60)
41–50	9 (30)
Sex	
Male	8 (26.67)
Female	22 (73.33)
Religion	
Hinduism	18 (60)
Islam	12 (40)
Level of education	
Illiterate	2 (6.67)
Below secondary	6 (20)
Up to secondary	7 (23.33)
Up to higher secondary	7 (23.33)
Up to graduation and above	8 (26.67)
Marital status	
Married	21 (70)
Unmarried	6 (20)
Widow/widower	3 (10)
Socioeconomic status	
Upper class	6 (20)
Middle class	20 (66.67)
Lower class	4 (13.33)
Body mass index (kg/m^2)	
Underweight (<18.5)	0
Healthy (18.5–24.9)	7 (23.33)
Overweight (25–29.9)	10 (33.33)
Obese (30 and above)	13 (43.33)

Categorial data presented as absolute values (%)

Thuja

Hahnemann's sycotic dyscrasia. patients of hydrogenoid constitution. Patients are chilly and have fixed ideas and symptoms are predominantly left sided. There is roughness and scrapping in throat, pressure and pain in throat and palate as from excoriation especially during deglutition. Clinically used in exophthalmic goitre.

Medorrhinum

A powerful and deep-acting medicine often indicated for chronic ailments due to suppressed gonorrhoea. Patients have weak memory, time passes too slowly with predominant sycotic miasm. Patients are melancholic with suicidal thoughts. There is oedema of limbs and dropsy of serous sacs.

Lycopodium

For persons intellectually keen, but physically weak; the upper part of the body is emaciated, lower part semi dropsical. There is 4–8 p.m. aggravation with sensation of constriction in the throat along with obstructed deglutition and dryness of throat.

DISCUSSION

Compared to the baseline, the participants' TSH levels and Zulewski's clinical scores reduced significantly over 6 months. As per the totality of symptoms, 11 different homoeopathic medicines were used, *Calcarea Carbonica* being the most common. All the medicines were prescribed in centesimal potency. Each case was followed up for a minimum of 6 months. The interval between every 2 follow-ups was 14–21 days depending on the case.

Table 2: Medicines prescribed during the study (in centesimal potency).

At baseline	At 1st month	At 2nd month	At 3rd month	At 4th month	At 5th month	At 6th month
Calc carb (*n*=9)	*Calc carb* (*n*=2)	*Calc carb* (*n*=5)	*Calc carb* (*n*=3)	*Calc carb* (*n*=2)	*Calc carb* (*n*=2)	*Calc carb* (*n*=2)
Nat m (*n*=4)	*Nat m* (*n*=1)	*Nat m* (*n*=3)	*Nat s* (*n*=1)	*Pulsatilla* (*n*=2)	*Nat m* (*n*=2)	*Pulsatilla* (*n*=1)
Pulsatilla (*n*=3)	*Thuja* (*n*=1)	*Pulsatilla* (*n*=1)	*Sepia* (*n*=1)	*Thuja* (*n*=1)	*Tuber* (*n*=1)	*Sulphur* (*n*=1)
Thuja (*n*=2)	*Sepia* (*n*=1)	*Thuja* (*n*=1)	*Lach* (*n*=1)	*Medo*. (*n*=2)	*Lach* (*n*=1)	*Lyco* (*n*=1)
Medo (*n*=2)	*Placebo* (*n*=25)	*Medo* (*n*=1)	*Placebo* (*n*=24)	*Nat s* (*n*=1)	*Placebo* (*n*=25)	*Sepia* (*n*=1)
Sulphur (*n*=2)		*Sulphur* (*n*=1)		*Placebo* (*n*=22)		*Placebo* (*n*=24)
Tuber (*n*=2)		*Tuber* (*n*=1)				
Nat s (*n*=2)		*Lyco* (*n*=1)				
Lyco (*n*=2)		*Placebo* (*n*=16)				
Sepia (*n*=1)						
Lach (*n*=1)						

During this study, we discovered several symptoms that did not belong to Zulewski's clinical score but were symptoms of hypothyroidism, including brittle nails, irregular uterine bleeding, dyspareunia or vaginal dryness and arthralgia. This study elicited the potential effect of individualised homoeopathic medicines in not only reducing the TSH level but also improving in activity and well-being of patients with hypothyroidism, without any substantial adverse effects.

Comparison with other studies

A clinical study on the management of hypothyroidism in women using LM potency

This was a clinical trial including 30 female patients using only LM potency.[22] No centesimal potency was used in this study; hence, we cannot determine the effectiveness of the centesimal potency. No clinical scoring was used and the outcome of the study was assessed using only pre- and post-treatment TSH levels.

The study showed a positive correlation between TSH level and the body mass index. Our study had similar findings.

Homoeopathic thyroidinum 3x – an adjuvant in the treatment of hypothyroidism

This study included 30 individuals with thyroidinum as an adjuvant with levothyroxine 100 mg.[17] While this was a randomised controlled study, the small sample size makes randomisation impossible. Moreover, only thyroidinum 3X was used as an adjuvant and synthetic drugs were used by the subjects regularly. No effectiveness of homoeopathic treatment can be found in this study.

Efficacy of homoeopathic intervention in subclinical hypothyroidism with or without autoimmune thyroiditis in children: An exploratory randomised control study

This study included 5059 children, screened for thyroid disorders, 537 children had subclinical hypothyroidism/ autoimmune thyroiditis and 194 consented to participate. Based on primary outcome measures (TSH and/or antiTPOab) three major groups were formed: (50 millesimal potency).[16]

Statistically significant differences were not found in the post-treatment reduction of serum TSH levels and no clinical scoring was used which concludes the requirement of further clinical studies. No harm or serious adverse effects were noted.

In our study, all the acute symptoms of hypothyroidism were found to be resolved within 15 days. Among the used medicines, *calc carb*, *nat mur*, *pulsatilla nigricans*, *T. occidentalis*, *medorrhinum*, *sulphur*, *tuberculinum*, *nat sulph* and *lycopodium* were common. Our findings are preliminary and further studies are warranted. In comparison to other studies, our study was better in terms of the use of validated questionnaires as secondary outcomes, longer duration of follow-ups and comparatively rigorous statistical analysis. However, hypothyroidism is a chronic, multifactorial disorder that needs multicentric clinical trials, with larger sample sizes and longer durations to show the effectiveness of homoeopathic medicines.

CONCLUSION

Homoeopathic management has adequate potential in not only alleviating Zulewski's clinical score and the TSH level in hypothyroidism but also has a significant role in improving the well-being, activity and quality of life of patients with hypothyroidism, without adverse effects. This open-label interventional clinical trial, though preliminary, revealed a positive treatment effect of individualised homoeopathic medicines in hypothyroidism. The study findings need to be interpreted with caution. Multicentric studies using a randomised placebo-controlled design with enhanced methodological rigour and longer follow-up times are required to further study the topic.

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Ethical approval

The proposed plan of work was approved by the Ethical Committee of the Mahesh Bhattacharyya Homoeopathic Medical College and Hospital, Howrah (Ref. F. No. 906/ MBHMCH/CH/PRIN/ADM/20; dated 6 October 2020). The trial was registered in CTRI (Reg. No.- CTRI/2020/12/029637).

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Nil.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The author(s) confirms that there was no use of artificial intelligence (AI)- assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

REFERENCES

1. Unnikrishnan AG, Menon UV. Thyroid disorders in India: An epidemiological perspective. Indian J Endocrinol Metab 2011;159 Suppl 2:S78-81.
2. Kochupillai N. PDF Currsci ias; 2000. Available from: https://www.ias.ac.in/currsci/oct252000/n%20kochupillai.pdf [Last accessed on 2019 Jun 09].
3. Kumar PJ, Clark ML. Kumar and Clark's clinical medicine. 8th ed. Spain: Saunders Elsevier; 2012. p. 959-63.
4. Khandelwal D, Tandon N. Overt and subclinical hypothyroidism: Who to treat and how. Drugs 2012;72:17-33.
5. Davidson S, Boon N, Colledge N, Walker B, Hunter J. Davidson's principles and practice of medicine. 20th ed. Churchill Livingstone Elsevier; 2006. p. 750.
6. Garber JR, Cobin RH, Gharib H, Hennessey JV, Klein I, Mechanick JI, *et al*. Clinical practice guidelines for hypothyroidism in adults: Cosponsored by the American Association of Clinical Endocrinologists and the American Thyroid Association. Thyroid 2012;22:1200-35.
7. Kasper D, Fauci A, Hauser S, Longo D, Jameson J, Loscalzo J. Harrison's principles of internal medicine. 19th ed. United States of America: The McGraw-Hill Companies; 2015.p. 2283-90.
8. Chakera AJ, Pearce SH, Vaidya B. Treatment for primary hypothyroidism: Current approaches and future possibilities. Drug Des Devel Ther 2012;6:1-11.
9. Roberts CG, Ladenson PW. Hypothyroidism. Lancet 2004;363:793-803.
10. Harris KB, Pass KA. Increase in congenital hypothyroidism in New York State and the United States. Mol Genet Metab 2007;91:268-77.
11. Vanderpump M, Menon U. The epidemiology of thyroid disease. Indian J Endocrinol Metab 2011;99:39-51. DOI: https://doi.org/10.1093/bmb/Idr030
12. Zimmermann MB. Iodine deficiency. Endocr Rev 2009;30:376-408.
13. Javed Z, Sathyapalan T. Levothyroxine treatment of mild subclinical hypothyroidism: A review of potential risks and benefits. Ther Adv Endocrinol Metab 2016;7:12-23.
14. Halfand M, U.S. Preventive Services Task Force. Screening for subclinical thyroid dysfunction in nonpregnant adults: A summary of the evidence for the U.S. Preventive Services Task Force. Ann Intern Med 2004;140:128-41.
15. Flynn RW, Bonellie SR, Jung RT, MacDonald TM, Morris AD, Leese GP. Serum Thyroid Stimulating hormone concentration and morbidity from cardiovascular disease and fractures in patients on long-term thyroxine therapy. J Clin Endocrinol Metab 2010;95:186-93.
16. Chauhan VK, Manchanda RK, Narang A, Marwaha RK, Arora S, Nagpal L, *et al*. Efficacy of homoeopathic intervention in subclinical hypothyroidism with or without autoimmune thyroiditis in children: An exploratory randomized control study. Homeopathy 2014;103:224-31.
17. Kiruthiga S. To assess the role of homoeopathic remedy Thyroidinum 3X as an adjuvant along with synthetic Levothyroxine in the treatment of Hypothyroidism. Int J Complement Alternat Med 2018;11:1-4.
18. Sevar R. Aurum muriaticum natronatum - four case reports. Homeopathy 2007;96:258-69.
19. Master F. Suppressed staphysagria. 1st ed. New Delhi: B. Jain; 1998.
20. Zulewski H, Muller B, Exer P, Miserez AR, Staub JJ. Estimation of tissue hypothyroidism by a new clinical score: Evaluation of patients with various grades of hypothyroidism and controls. J Clin Endocrinol Metab 1997;82:771-6.
21. Billewicz WZ, Chapman RS, Crooks J, Day ME, Gossage J, Wayne E, *et al*. Statistical methods applied to the diagnosis of hypothyroidism. Q J Med 1969;38:255-66.
22. Mohan A. A clinical study on the management of Hypothyroidism in Females using LM potency [dissertation]. Tamil Nadu: The Tamil Nadu Dr. MGR Medical University; 2019.

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