Section: Physiology

Original Research Article

COMPARATIVE STUDY OF PULMONARY FUNCTION BY SPIROMETRIC PARAMETERS BETWEEN CLINICAL AND SUBCLINICAL HYPOTHYROIDISM PATIENTS IN A TERTIARY HEALTH CARE INSTITUTE CATERING VILLAGE POPULATION

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Received : 18/12/2022
Received in revised form : 22/01/2023
Accepted : 07/02/2023

Keywords:
Pulmonary function, Subclinical hypothyroidism, Spirometry.

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DOI: 10.47009/jamp.2023.5.2.70

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2023; 5 (2); 340-345

Abstract

Background: Hypothyroidism is defined as a clinical state resulting from insufficient secretion of thyroid hormone. Clinical hypothyroidism is biochemically defined as an elevated TSH level (> 6.16 μIU/ml) with a decreased serum fT4 levels (< 0.8 ng/dl) along with florid symptoms of hypothyroidism, whereas subclinical hypothyroidism is denoted as a condition where the patients' serum ft4 is within normal limit, but serum TSH level is raised. These patients have no apparent or few clinical features of hypothyroidism. There are several studies regarding the effects of clinical hypothyroidism on respiratory system, but there are very few studies comparing the effects of pulmonary function between clinical and subclinical hypothyroidism. The objective of the study is to assess the presence, if any, and degree of alteration of respiratory function (FVC, FVC %, FEV1, FEV1 %, FEV1/FVC, FEF25-75, FEF25-75%, PEFR, PEFR %) in clinical hypothyroid patients along with subclinical hypothyroid patients. Also to compare the pulmonary function between clinical and subclinical hypothyroid patients with the spirometric parameters (FVC, FVC %, FEV1, FEV1 %, FEV1/FVC, FEF25-75, FEF25-75%, PEFR, PEFR %) **Materials and Methods:** It was a comparative cross-sectional, case-control and non-interventional study done at Burdwan Medical College & Hospital (BMC&H) at Barddhaman, dist – Purba Bardhhaman. The present study was conducted for a period of 12 months commencing from February-2010 & continuing till January-2011 from the patients attending the 'Medicine out-patient clinic' of BMC & H. As many as 43 clinical hypothyroid patients and 41 subclinical hypothyroid patients along with 50 healthy control subjects were chosen for the study based on the laboratory values of TSH and fT4. **Results:** The mean ages of the clinical hypothyroidism, the subclinical hypothyroidism and the control group of subjects are 38.60 ± 5.05 yrs, 37.22 ± 4.43 yrs, 36.78 ± 4.62 yrs respectively. So, there is no significant difference between groups regarding age. It demonstrates that all the spirometric parameters are higher in the control group than the clinical hypothyroidism group and subclinical hypothyroidism group. Also it is evident that spirometric parameters are higher in the subclinical group in comparison with clinical hypothyroidism group. The differences of the FVC, FVC %, FEV1, FEV1 %, FEV1/FVC, FEF25-75, PEFR are also statistically highly significant. **Conclusion:** Our study shows that clinical as well as subclinical hypothyroidism both may cause disorders of respiratory function and ventilation, though in different degree. Since subclinical hypothyroidism is common in general population, the patients, even with mild or no clinical signs & symptoms may be screened with simple spirometry. And this, in turn, would help in management of these patients in time.

INTRODUCTION

Hypothyroidism is common among the various metabolic and endocrine disorders, in the world. It is due to insufficient secretion of thyroid hormone from thyroid gland due to some structural and/or functional impairment of thyroid hormone production.[1] All organ systems are affected by hypothyroidism and the clinical findings include weakness, fatigue, daytime somnolence, cold intolerance, hair loss, lack of concentration & memory, serous fluid collection in pleural & peritoneal cavity etc.[2] The earliest stage of thyroid dysfunction with subjects having normal free thyroid hormones T3 , T4 with elevated thyroid-stimulating hormone (TSH) values is Subclinical hypothyroidism (SCH). It indicates minor thyroidal decompensation with a compensatory increase in TSH secretion.[1] Even though SCH is considered as an asymptomatic condition nearly 30% of patients have symptoms of thyroid hormone deficiency.[3] Studies have shown that the prevalence of SCH was higher in elderly populations. SCH poses an enormous burden in India as the prevalence rates of SCH in India exceed those in the developed nations. The prevalence of SCH in United States is 4–8.5%.[4] while different prevalence rates from Indian studies have been reported as 11.3% with 1: 3.7 male: Female ratio (1) , 8.02% (11) and 4.3–9% . The prevalence showed a rising trend with age and was more in females (6–8%) than in males (3%).[5-7] SCH can be reversible or it can progress to overt hypothyroidism. The annual risk of progression of SCH to overt hypothyroidism is 2–5 %.[8]

The present study that we have designed here may enable us to assess and compare the respiratory function in patients of clinical and subclinical hypothyroidism.

MATERIALS AND METHODS

It was a comparative case-control, cross-sectional and non-interventional study done at Burdwan Medical College & Hospital (BMC&H), Barddhaman, dist – Purba Barddhaman. The present study was conducted for a period of 12 months commencing from February-2010 & continuing till January-2011 from the patients attending the 'Medicine out-patient clinic' of BMC & H.

Sample Size Estimation

The formula used for calculation of sample size (n) was:

n= z2 pq/L2

where z (at 95% confidence level) = 1.96~2;

p is prevalence i.e.,6.2% (1)

q = 100-p= 93.8

L = absolute error of 5%

So, sample size (n)= 93.6~94

So based on sample size formula, 43 clinical hypothyroid patients and 41 subclinical hypothyroid patients along with 50 healthy control subjects were chosen for the study depending on the laboratory values of TSH and fT4. Subclinical hypothyroidism is defined as an elevated TSH level (> 6.16 µIU/ml) together with normal serum fT4 levels (0.8 -2.0 ng/dl). Clinical hypothyroidism is defined as an elevated TSH level (> 6.16 µIU/ml) with a decreased serum fT4 levels (< 0.8 ng/dl). Whereas the persons with both normal TSH level (0.39- 6.16 µIU/ml) and normal serum fT4 levels (0.8 -2.0 ng/dl) were considered as control group of subjects. Serum TSH & serum fT4 were measured by 'Quantitative EIA method' using RFCL- manufactured commercial "ELISCAN – TSH"- kit and "ELISCAN -fT4"-kit. And the Pulmonary Function Test was performed by RMS Helios 401 Spirometer. Statistical analysis was done by SPSS-17 & Microsoft Excel Software of MS-office 2007. Pearson's two tailed correlation study and Student independent t-test were done for analysis. P value < 0.001 was considered as statistically significant The study was approved by Institutional Ethics Committee having a memo no. BMC/PG/167(56) dated 14/01/2010.

Inclusion Criteria for Selecting the Patients

a) Subjects with Body Mass Index under 30 kg/m^2

b) Age between 20 to 50 yrs

Exclusion Criteria for Selecting the Patients

a) Smoking history

b) Any other respiratory illness

c) Any other systemic pathology affecting the respiratory system

d) Persons engaged in a occupation that may affect the respiratory system

Methodology

At first, the details of history, clinical examination and relevant investigation-reports were noted from each subject of the three groups i.e. clinical hypothyroidism, subclinical hypothyroidism and control group following confirmation of thyroid stimulating hormone (TSH) and serum free thyroxin (fT4) values by estimation in our hospital biochemistry laboratory according to respective recommended principles. Then spirometric analysis was performed with Computerised RMS Helios 401 Spirometer and the spirometric parameters i.e. FVC, FVC%, FEV1, FEV1%, FEV1/FVC, FEF25-75, FEF25-75%, PEFR, PEFR% were assessed in all the groups.

Specimen Collection and Preparation

Collection of fasting blood samples (5ml) from each individuals of different age groups who were included in the study, was done by venepuncture with the help of disposable needles and syringes following strict aseptic method. The blood was collected in a plain red top venepuncture tube and allowed to clot at room temperature. Then the samples were centrifuged at 3000rpm and serum was collected in pre-numbered capped tube and stored at -20 0 C temperature for measurement of hormones. Hormonal assay by ELISA of the stored samples was done within one week.

Data Analysis

After the collection of data from 43 clinical hypothyroid patients, 41 subclinical hypothyroid

ISSN (O): 2687-5365; ISSN (P): 2753-6556

patients along with 50 healthy control subjects, master chart for each group were prepared and were analyzed using SPSS software version 17 and Microsoft Excel software of MS-office 2007 software package in computer. Pearson's two tailed correlation study and Student independent t - test were done for analysis. The "p" values were calculated to deduce the significance level.

RESULTS

Table 1: Demographic Features of Participants

		Clinical hypothyroidism (n= 43)	Subclinical hypothyroidism (n= 41)	Control group (n= 50)
Age (years)		38.60 ± 5.05	37.22 ± 4.43	36.78 ± 4.62
Gender	Female	34	30	31
	Male	9	11	19
Presence of Symptoms	Yes	35	24	0
	No	8	17	50

From the table 1, we see that the mean ages of the clinical hypothyroidism, the subclinical hypothyroidism and the control group of subjects are 38.60 ± 5.05 yrs, 37.22 ± 4.43 yrs , 36.78 ± 4.62 yrs respectively . So, there is no significant difference between groups regarding age. The table 2 above shows the mean TSH and4 fT4 values of the participants in clinical, subclinical and control groups.

Table 2: Thyroid Function Values of the Participants

	Clinical hypothyroidism (n=43)			Subclinical hypothyroidism (n=41)			Control group (n=50)		
	Mean	**Standard Deviation**	**Standard Error**	**Mean**	**Standard Deviation**	**Standard Error**	**Mean**	**Standard Deviation**	**Standard Error**
fT4 (ng/dL)	0.57	0.12	0.02	1.26	0.24	0.04	1.4	0.26	0.04
TSH (µlU/ml)	50.77	22.84	3.48	12.08	4.11	0.64	2.12	0.62	0.09

Table 3: Spirometric Parameters of the Participants

	Clinical hypothyroidism (n=43)			Subclinical hypothyroidism (n=41)			Control group (n=50)		
	Mean	**Standard Deviation**	**Standard Error**	**Mean**	**Standard Deviation**	**Standard Error**	**Mean**	**Standard Deviation**	**Standard Error**
FVC (L)	2.83	0.29	0.04	3.17	0.24	0.04	3.57	0.35	0.05
FVC %	92.42	1.16	0.18	97.76	2.46	0.38	106.20	2.80	0.40
FEV_1 (L)	2.57	0.24	0.04	2.96	0.21	0.03	3.41	0.35	0.05
FEV_1 %	85.30	2.09	0.32	89.37	2.62	0.41	98.64	2.53	0.36
FEV_1 / FVC (%)	90.70	2.04	0.31	93.63	1.60	0.25	95.53	2.00	0.28
FEF_{25-75} (L)	4.68	0.33	0.05	5.36	0.35	0.05	5.98	0.35	0.05
FEF_{25-75} %	75.63	5.43	0.83	78.29	4.54	0.71	78.78	3.72	0.53
PEFR (L)	4.63	0.32	0.05	5.28	0.34	0.05	5.94	0.39	0.06
PEFR %	74.86	5.33	0.81	77.78	4.35	0.68	79.50	3.56	0.50

Table 3 shows the mean values of different spirometric parameters, i.e FVC, FVC %, FEV1, FEV1 %, FEV1/FVC, FEF25-75, FEF25-75%, PEFR, PEFR % in clinical, subclinical and control groups of subject.

Table 4: Comparison of Spirometric Means Between Clinical Hypothyroidism and Control Group of Subjects

	Clinical hypothyroidism (n=43)			Control group (n=50)			t-stats	p-value	Significance level
	Mean	**Standard Deviation**	**Standard Error**	**Mean**	**Standard Deviation**	**Standard Error**			
FVC (L)	2.83	0.29	0.04	3.57	0.35	0.05	-11.26	<0.001	HS**
FVC %	92.42	1.16	0.18	106.20	2.80	0.40	-31.784	<0.001	HS**

ISSN (O): 2687-5365; ISSN (P): 2753-6556

FEV1 (L)	2.57	0.24	0.04	3.41	0.35	0.05	-13.696	<0.001	HS**
FEV1 %	85.30	2.09	0.32	98.64	2.53	0.36	-27.851	<0.001	HS**
FEV1 / FVC (%)	90.70	2.04	0.31	95.53	2.00	0.28	-11.473	<0.001	HS**
FEF25-75 (L)	4.68	0.33	0.05	5.98	0.35	0.05	-18.380	<0.001	HS**
FEF25-75 %	75.63	5.43	0.83	78.78	3.72	0.53	-3.213	0.002	S*
PEFR (L)	4.63	0.32	0.05	5.94	0.39	0.06	-17.669	<0.001	HS**
PEFR %	74.86	5.33	0.81	79.50	3.56	0.50	-4.856	<0.001	HS**
Note: HS = Highly Significant, S* = Significant, NS = Not Significant**									

Table 4 shows the comparison between spirometric values of the clinical hypothyroidism & control groups of patients. It demonstrates that all the spirometric parameters are higher in the control group than the clinical hypothyroidism group. The differences of the FVC, FVC %, FEV1, FEV1 %, FEV1/FVC, FEF25-75, PEFR, PEFR % are highly significant; and the t values & p-values are (t= -11.226, p <0.001), (t= -31.784,p <0.001), (t= -13.696, p <0.001), (t= -27.851, p <0.001), (t= -11.473,p <0.001), (t= -18.380, p <0.001), (t= -17.669, p <0.001) and (t= -4.856, p <0.001) respectively. The difference of FEF25-75% between these two groups are only significant (t= -3.213, p= 0.002).

Table 5: Comparison of Spirometric Means Between Subclinical Hypothyroidism and Control Group of Subjects

	Subclinical hypothyroidism (n=41)			**Control group (n=50)**			**t-stats**	**p-value**	**Significance level**
	Mean	**Standard Deviation**	**Standard Error**	**Mean**	**Standard Deviation**	**Standard Error**			
FVC (L)	3.17	0.24	0.04	3.57	0.35	0.05	-6.529	<0.001	HS**
FVC %	97.76	2.46	0.38	106.20	2.80	0.40	-15.314	<0.001	HS**
FEV1 (L)	2.96	0.21	0.03	3.41	0.35	0.05	-7.501	<0.001	HS**
FEV1 %	89.37	2.62	0.41	98.64	2.53	0.36	-17.047	<0.001	HS**
FEV1 / FVC (%)	93.63	1.60	0.25	95.53	2.00	0.28	-5.018	<0.001	HS**
FEF25-75 (L)	5.36	0.35	0.05	5.98	0.35	0.05	-8.321	<0.001	HS**
FEF25-75 %	78.29	4.54	0.71	78.78	3.72	0.53	-0.552	0.583	S*
PEFR (L)	5.28	0.34	0.05	5.94	0.39	0.06	-8.568	<0.001	HS**
PEFR %	77.78	4.35	0.68	79.50	3.56	0.50	-2.034	<0.001	HS**
Note: HS = Highly Significant, S* = Significant, NS = Not Significant**									

Table 5 compares the spirometric values of the subclinical hypothyroidism with the control group of patients. Here also spirometric parameters are higher in the control group and lower in patients with subclinical hypothyroidism. The differences of the FVC, FVC %, FEV1, FEV1 %, FEV1/FVC, FEF25-75, PEFR are statistically highly significant; the t values and p-values are (t= -6.529, p < 0.001), (t= -15.314, p < 0.001), (t= -7.501, p < 0.001), (t= -17.047, p < 0.001), (t= -5.018, p < 0.001), (t= -8.321, p < 0.001) and (t= -8.568, p < 0.001) respectively. The difference of PEFR % is significant (t= -2.034, p = 0.045) while the difference of FEF25-75% between these two groups does not reach statistical significance (t= -0.552, p = 0.583).

Table 6: Comparison of Spirometric Means Between Clinical Hypothyroidism and Subclinical Hypothyroidism Group of Patients

	Clinical hypothyroidism (n=43)			**Subclinical hypothyroidism (n=41)**			**t-stats**	**p-value**	**Significance level**
	Mean	**Standard Deviation**	**Standard Error**	**Mean**	**Standard Deviation**	**Standard Error**			
FVC (L)	2.83	0.29	0.04	3.17	0.24	0.04	-5.832	<0.001	HS**
FVC %	92.42	1.16	0.18	97.76	2.46	0.38	-12.631	<0.001	HS**

ISSN (O): 2687-5365; ISSN (P): 2753-6556

FEV1 (L)	2.57	0.24	0.04	2.96	0.21	0.03	-7.914	<0.001	HS**
FEV1 %	85.30	2.09	0.32	89.37	2.62	0.41	-7.830	<0.001	HS**
FEV1 / FVC (%)	90.70	2.04	0.31	93.63	1.60	0.25	-7.351	<0.001	HS**
FEF25-75 (L)	4.68	0.33	0.05	5.36	0.35	0.05	-9.261	<0.001	HS**
FEF25-75 %	75.63	5.43	0.83	78.29	4.54	0.71	-2.445	0.017	S*
PEFR (L)	4.63	0.32	0.05	5.28	0.34	0.05	-9.038	<0.001	HS**
PEFR %	74.86	5.33	0.81	77.78	4.35	0.68	-2.758	0.007	S*
Note: HS** = Highly Significant, S* = Significant, NS = Not Significant									

The above table 6 shows the comparison between the spirometric values of the clinical and the subclinical hypothyroidism groups of patients and the values in the subclinical group are higher than the clinical one. It points to the fact that the differences of all the parameters, i.e FVC, FVC %, FEV1, FEV1 %, FEV1/FVC, FEF25-75, FEF25-75%, PEFR, PEFR % are statistically significant ($p < 0.05$). The t values & p values are (t= -5.832, p< 0.001), (t= -12.631, p <0.001), (t= -7.914, p <0.001), (t = -7.830, p <0.001), (t= -7.351, p <0.001), (t= -9.261, p <0.001), (t= -2.445, p= 0.017), (t= -9.038, p <0.001) and (-2.758, p =0.007) respectively.

DISCUSSION

Our results in hypothyroid subjects are consistent with the results of Goswami et al.[11] and Birring S et al.[12] who also confirmed that the hypothyroidism is associated with decreased vital capacity, FEV1, FVC and total lung capacity. In our study, we observed that between the clinical and control groups of patients, the differences of the mean values of FVC, FVC %, FEV1, FEV1 %, FEV1/FVC, FEF25-75, FEF25-75%, PEFR, PEFR % are significant ($p \leq 0.05$). Goswami et al also showed that there is significant decrease in PFT parameters in hypothyroid patients as compared to controls[11] and have confirmed that patients with hypothyroidism develop diaphragmatic dysfunction, which can vary from mild forms associated with reduced tolerance to physical effort to very severe forms of diaphragmatic weakness which even might imitate diaphragmatic paralysis. The authors of the study showed that these changes are reversible with levothyroxin therapy even after only 8 weeks.[11, 12] Birring et al[12] noted that in patients with low levels of thyroid hormone there is an increased sensitivity of the cough reflex, and increased airway hyper responsiveness, and an increased number of inflammatory cells in sputum. Cakmak et al. [5] found that in patients with subclinical hypothyroidism, there is a significant reduction in lung function. The authors evaluated the parameters of lung function in patients with subclinical hypothyroidism and in the healthy control group of subjects and found significantly lower values of FVC (Forced Vital Capacity), FVC% (Forced Vital Capacity percentage of predicted), FEV1 (Forced Expiratory volume in one second), FEF25-75 (Forced Expiratory Flow 25-75). Siafakas et al., found a significant decrease in the strength of inspiratory and expiratory muscles in patients with clinical hypothyroidism. [14] In the aforementioned study, vital capacity (VC), forced vital capacity (FVC), forced vital capacity in one second (FEV1), FEV1/FVC are significantly lower in patients with clinical hypothyroidism compared to healthy controls. Our results in hypothyroid subjects are consistent with the results of Martinez et al[9] and Ladenson et al[10] who also confirmed that the hypothyroidism is associated with decreased vital capacity, FEV1, FVC and total lung capacity. The authors suggested that the inspiratory muscle weakness might be a possible explanation of alveolar hypoventilation. Martinez et al[9] have also showed that hypothyroid patients might develop diaphragmatic dysfunction. The authors of this study pointed that levothyroxine therapy can reverse these changes. Ladenson et al. [10] found better pulmonary functions in treated patients of hypothyroidism as compared to untreated newly diagnosed patients. The study done by Goswami et al. [11] found decreased pulmonary functions in hypothyroid patients who were already on thyroid hormone therapy and on doing pranayama for 6 months these patients showed significant improvement in FEV1, Maximum Voluntary Ventilation and Inspiratory Capacity and suggested that this beneficial effect of yoga could be due to respiratory muscle strength improvement and increased oxygen concentration at tissue level by increased air entry.

CONCLUSION

Depending on the duration, cause and the degree of deficiency of thyroid hormone, the clinical presentation of thyroid hormone deficiency alters from person to person. In patients with subclinical hypothyroidism, the decrease in both inspiratory and expiratory muscle strength, alveolar hypoventilation due to depression of hypoxic and hypercapneic ventilatory drives and decrease in maximal breathing and diffusing capacity are evident. We have found that all of the spirometric parameters, i.e FVC, FVC

ISSN (O): 2687-5365; ISSN (P): 2753-6556

%, FEV1, FEV1 %, FEV1/FVC, FEF25-75, FEF25-75%, PEFR, PEFR % are higher in the control group than the clinical hypothyroidism group. Similarly, spirometric parameters are higher in the control group and lower in patients with subclinical hypothyroidism group. And between clinical and subclinical hypothyroid patients, the spirometric parameters (FVC, FVC %, FEV1, FEV1 %, FEV1/FVC, FEF25-75, FEF25-75%, PEFR, PEFR %) have been compromised or reduced much more in clinical hypothyroidism group than the subclinical one and the differences are clinically significant.

Thus to conclude, our study shows that clinical as well as subclinical hypothyroidism may cause disorders of respiratory function and ventilation. Since subclinical hypothyroidism is much common in general population, the subjects who is suspected to have mild clinical signs & symptoms may be screened with simple spirometry at the earliest and this may help in earlier management of these patients leading to reduction of sick days with curtailing health expenditure in the long run.

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ISSN (O): 2687-5365; ISSN (P): 2753-6556