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Original research article

Utility of pre-operative serum TSH levels for predicting malignancy in nodular thyroid diseases

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Abstract

Background and Objectives: Thyroid disorders are one of the most common endocrine disorders affecting 4-5% of the general population. The objective of study is to evaluate the predictive value of preoperative serum TSH levels in predicting malignancy in nodular thyroid diseases.

Methods: It is a longitudinal study of 28 patients with thyroid swelling admitted to surgery department in a tertiary care referral hospital, during the period of January 2011 to December 2011. Thyroid function tests were done by standard electro chemiluminescent assay and serum TSH levels, age, sex were compared with malignancy. Logistic regression analysis was used to determine which factors were predictive of malignancy.

Results: 28 cases were analysed. Mean TSH levels were higher in the malignant group and in the age group of 50-65 yrs. Prevalence of malignancy was studied in the all TSH groups and it was found that the higher quartiles of serum TSH levels were found to be associated with increased risk of malignancy. Logistic regression analysis revealed that TSH levels was the only significant risk factor for malignancy.

Conclusion: the serum TSH level may be useful in predicting the probability of cancer and optimizing the extent of thyroidectomy in patients with NTD.

Keywords: Nodular thyroid swelling, serum TSH levels, T3, T4, USG guided FNAC, histopathology

Introduction

Thyroid cancer is the most common (95%) endocrine malignancy and accounts for approximately 1.5% of all human malignancies [1]. In India, the nationwide relative frequency of thyroid carcinoma among all carcinoma cases was 0.1-0.2% [2]. The incidence and mortality of thyroid cancer vary by the geographic location and socio-economic status [3].

Thyroid cancer is considered to be an indolent disease with heterogeneous group of tumours with variable rates of growth, biological aggressiveness, histological responses and response to therapy [4].

The prevalence of thyroid nodules increases linearly with age, with spontaneous nodules occurring at a rate of 0.08% per year beginning early in life and extending into the eighth decade [4]. Clinically apparent nodules are present in 4% to 7% of the adult population and occur more commonly in women [4]. Most nodules are not malignant. Reported malignancy rates are 5% to 12% in patients with solitary nodules and 3% in patients with multiple nodules [4].

In general, there is a 5-10% chance of malignancy in all thyroid nodules in a total population [5]. 4% of the general population has detectable enlargement of thyroid [6]. Although nodules are common, clinically detectable thyroid cancer is rare.

Serum TSH is a well-established growth factor for thyroid nodules and suppression of TSH concentrations by administering exogenous thyroxine may interfere with growth of established nodules as well as formation of new nodules [7]. There is clear evidence of improved survival with aggressive thyroid hormone suppression in high risk cancer patients and improved survival with modest thyroid hormone suppression in thyroid cancer patients [8]. Our study aims to evaluate the association of Serum TSH concentration with thyroid carcinoma, and its significance in management of Thyroid carcinoma.

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Aims and Objectives

1. To measure the preoperative serum TSH level in nodular thyroid diseases.
2. To compare the TSH levels with histological diagnosis of nodular thyroid disease.

Materials and Methods

The predictive study of preoperative serum thyroid stimulating hormone level with definite histological diagnosis of thyroid swellings was done in a tertiary care referral hospital. Twenty-eight consecutive patients with thyroid swelling, admitted to the surgery department, were examined in detail with necessary investigations. Thyroid function test was done by immunochemiluminometric assays (ICMAs) in all cases. Patients which are excluded from study are:-

1. Patients with a final pathological diagnosis of medullary thyroid carcinoma.
2. Patients in whom serum TSH levels were obtained while on thyroid hormone therapy.
3. All cases of neck swelling other than thyroid.

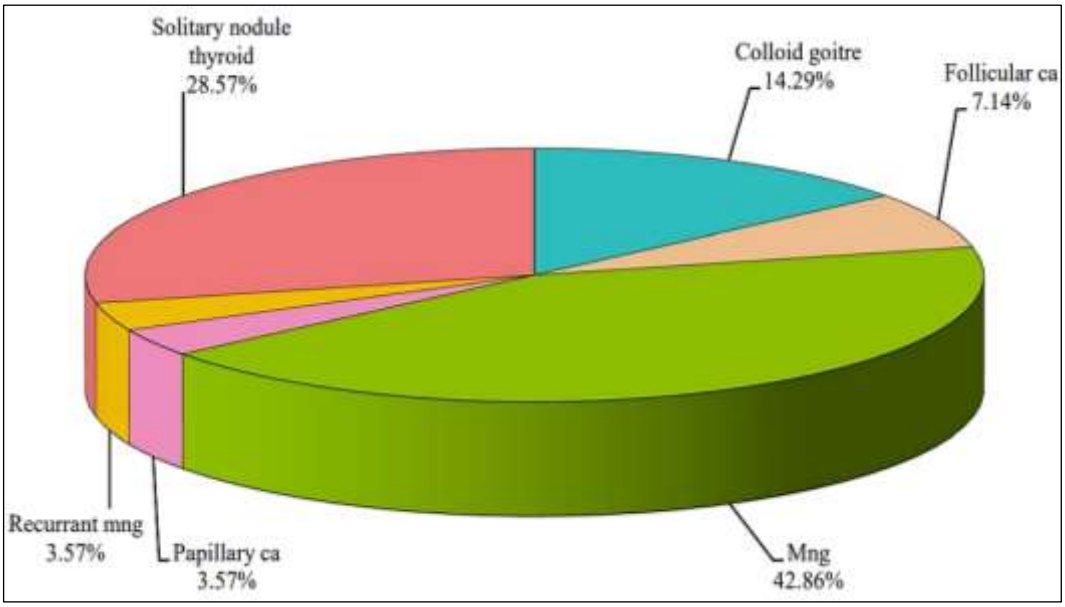
The hospital institutional ethical committee clearance was obtained before undertaking the study. Thyroid function tests were done by immunochemiluminometric assays. Patients were taken up for surgery and operative specimen was sent for histopathological examination. All the data were collected by purposive sampling method and recorded as per the proforma. The data was analysed by using descriptive statistics and results were compared by using inferential statistics.

Results

The predictive study of preoperative TSH levels with definite Histological diagnosis of thyroid swelling was done on twenty-eight patients.

Table 1: The clinical diagnosis in the study group

Clinical diagnosis	No of cases	% of cases
Colloid goitre	4	14.29
Follicular ca	2	7.14
Multinodular goitre	12	42.86
Papillary ca	1	3.57
Recurrant multinodular goitre	1	3.57
Solitary nodule thyroid	8	28.57
Total	28	100.00



Graph 1: Distribution of cases by clinical diagnosis

Multinodular goitre was the predominant diagnosis (42.86%) clinically followed by solitary nodule thyroid (28.57%) however follicular cancer was diagnosed in 2 cases and papillary cancer in in 1 patient.

Table 2: Distribution of cases by age groups

Age group	No. of cases	% of cases
<30 years	10	35.71

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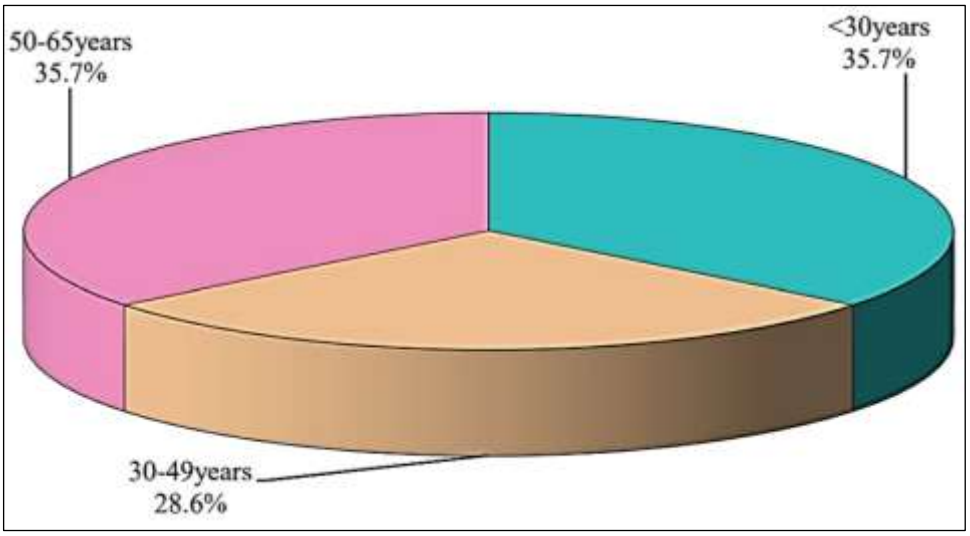
30-49 years	8	28.57
50-65 years	10	35.71
Total	28	100.00

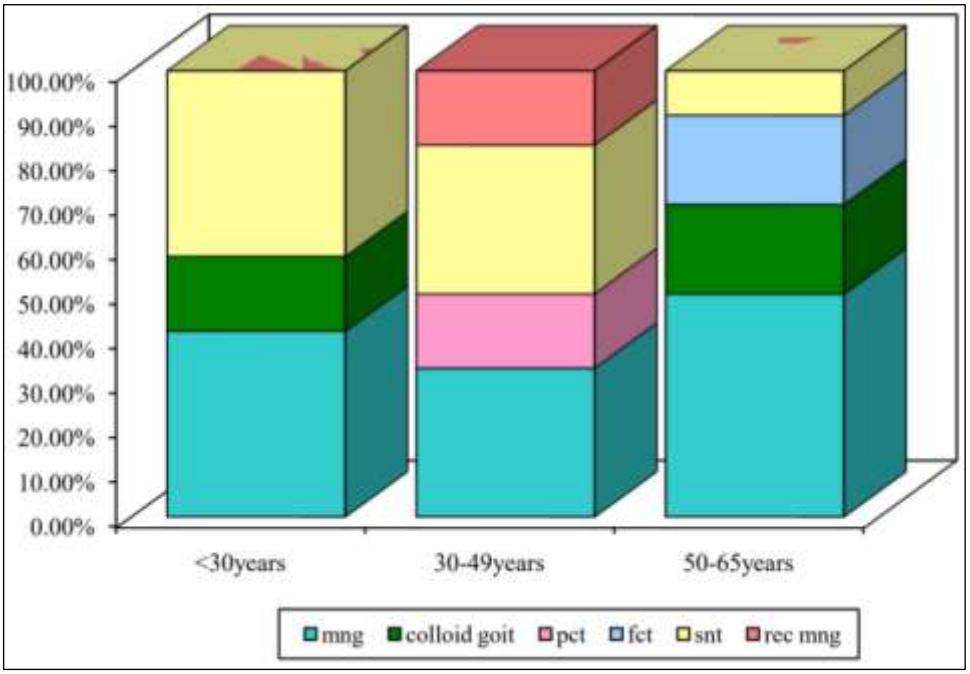


Graph 2: Distribution of cases by age groups

The peak incidence was noted in extremes of age group, 36% of patients were in age group < 30 yrs and 50 to 65 yrs. 28% of patients were in age group of 30-49 yrs.

Table 3: Distribution of cases by clinical diagnosis vs age groups

Clinical diagn	<30years	%	30-49years	%	50-65years	%	Total	%
MNG	5	17.86	2	7.14	5	17.86	12	42.86
Colloid goitre	2	7.14	0	0.00	2	7.14	4	14.29
PCT	0	0.00	1	3.5	0	0.00	1	3.5
FCT	0	0.00	0	0.00	2	7.14	2	7.14
SNT	5	17.8	2	7.14	1	3.5	8	28.57
Recc. MNG	0	0.00	1	3.5	0	0.00	1	3.57



Graph 3: Distribution of clinical cases vs age

In the age group of < 30 yrs the total Multinodular goitre and solitary nodule thyroid cases were 5 in each constituting 17.8%. in the age group of 30-49 yrs cases of MNG and SNT were 2 in each constituting 7.14% and 1 case of papillary carcinoma thyroid (3.5%). In the age group of 50-65 yrs MNG cases were 5

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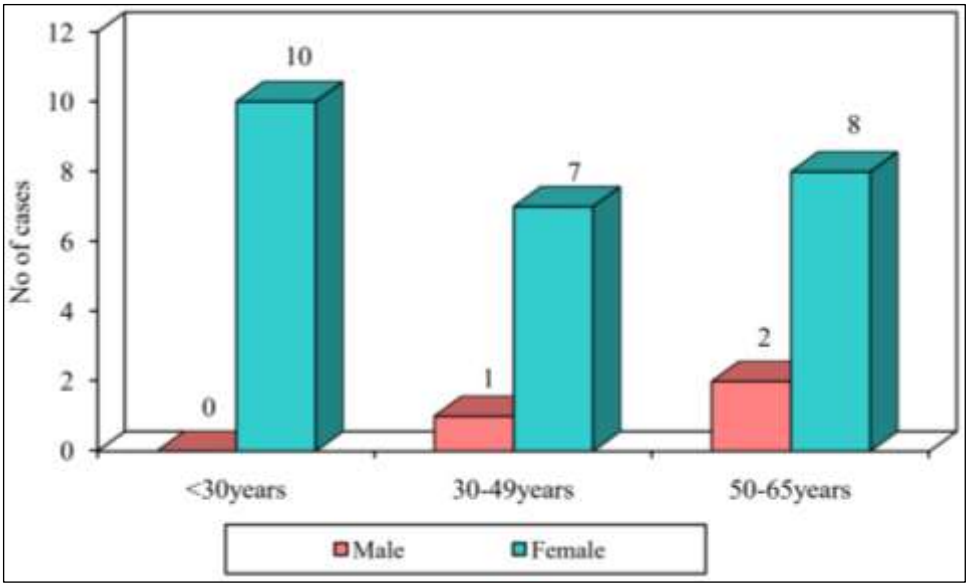
(17.8%) and 2 cases of follicular carcinoma thyroid (7.14).

Table 4: Distribution of study cases by age groups compared to sex

Age group	Male	%	Female	%	Total
<30years	0	0.00	10	100.00	10
30-49years	1	12.50	7	87.50	8
50-65years	2	20.00	8	80.00	10
Total	3	10.71	25	89.29	28



Graph 4: Age and sex distribution

In the study group of 28 cases there were 3 male patients (10.71%) and 25 females (89.29%).

Table 5: The Symptoms of the Study Group

Symptoms	Number of patients	Percentage
Neck Swelling	28	100
Pain	2	7.1
Dysphagia	1	3.57
Neck swelling + pain	2	7.14
Neck swelling + dysphagia	1	3.57

In the study it was observed that the chief presenting complaint of all the patients was Neck swelling. Out of which 2 patients had associated pain. 1 patient presented with dysphagia along with neck swelling.

Table 6: Distribution of study cases by TSH levels

TSH groups	No of cases	% of cases
<0.40	2	7.14
0.40-0.90	6	21.43
1.0-1.70	6	21.43
1.8-4.25	13	46.43
>4.25	1	3.57
Total	28	100.00

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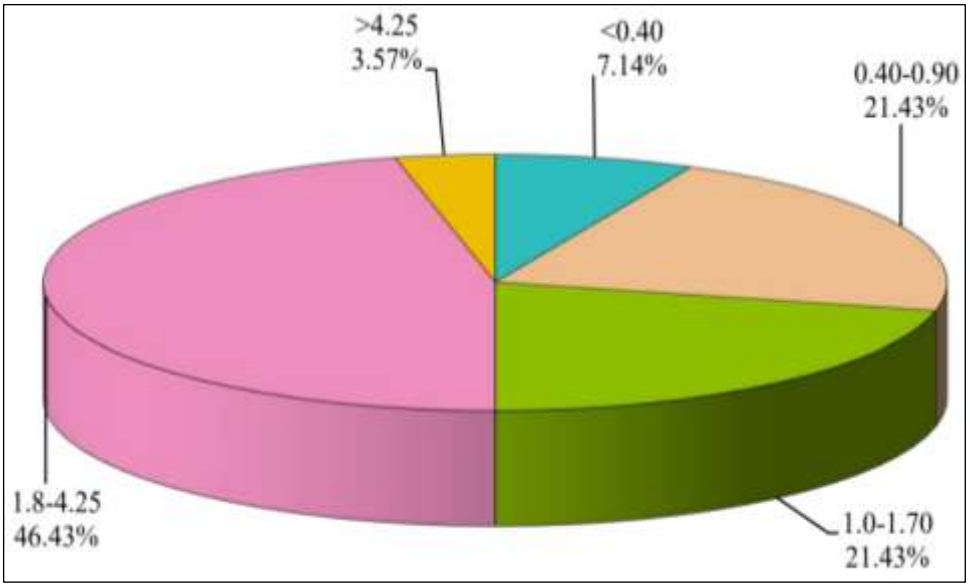
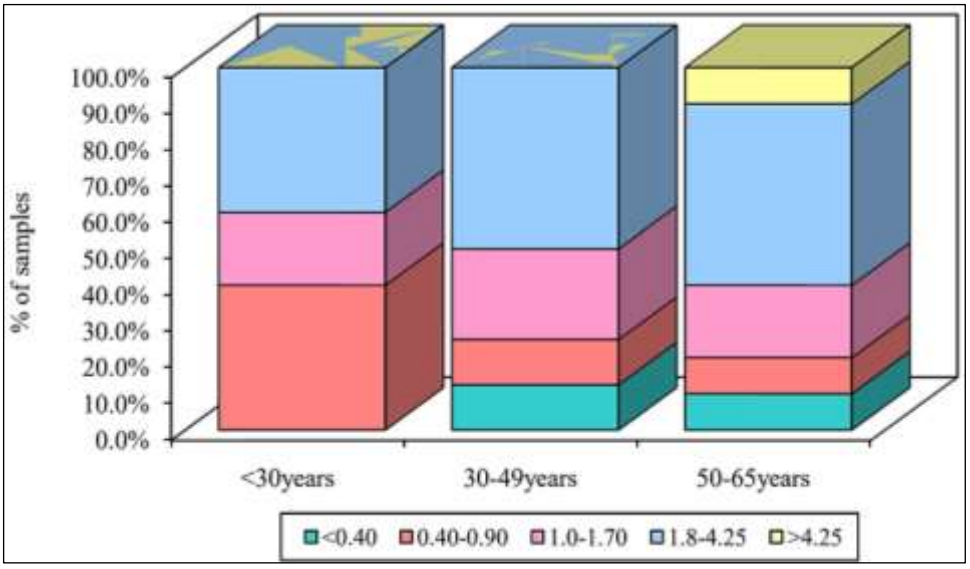


Graph 5: Distribution by TSH levels

TSH levels were divided into 5 quartiles. Out of 28 cases 13 cases (46.43%) had serum TSH levels between 1.8-4.25mcIU/ml and 6 patients had TSH levels between 0.4-0.9 and 1.0- 1.7mcIU/ml which constitute 21.43%.

Table 7: Distribution cases by TSH levels and age groups

TSH groups	<30years	%	30-49years	%	50-65years	%	Total	%
<0.40	0	0.00	1	50.00	1	50.00	2	7.14
0.40-0.90	4	66.67	1	16.67	1	16.67	6	21.43
1.0-1.70	2	33.33	2	33.33	2	33.33	6	21.43
1.8-4.25	4	30.77	4	30.77	5	38.46	13	46.43
>4.25	0	0.00	0	0.00	1	100.00	1	3.57
Total	10	35.71	8	28.57	10	35.71	28	100.00



Graph 6: Distribution of TSH levels and age

In the study group of 28 cases 5 patients of age group 50-65 yrs had TSH levels between 1.8- 4.25mcIU/ml (38.46%) and 2 patients in all the age groups had TSH levels between 1- 1.7mcIU/ml which constitute 33.33%.

Table 8: Comparison of different age groups with TSH values by one-way ANOVA

Age group	Mean TSH	Std. Dev. TSH
<30years	1.43	0.76
30-49years	1.76	1.20

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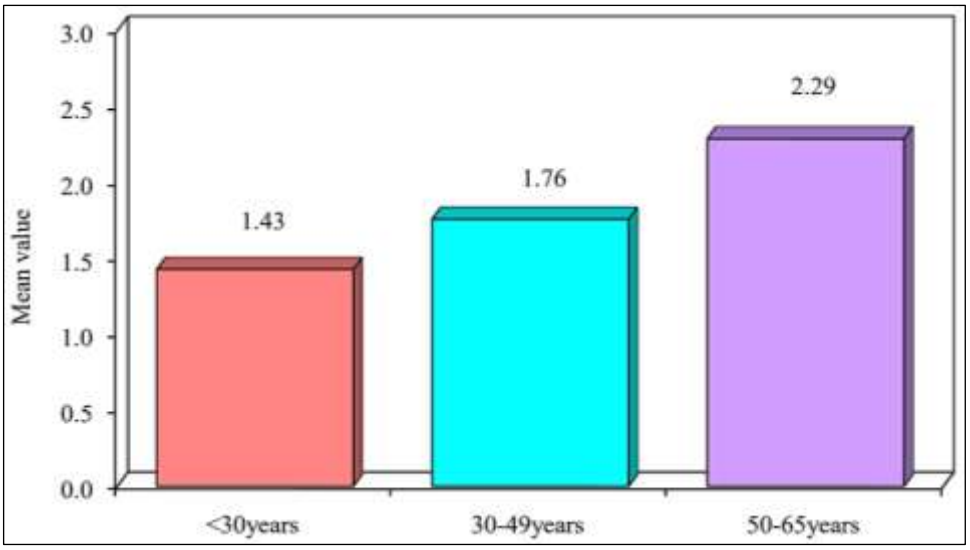
50-65years	2.29	1.95
Total	1.83	1.40
F-value	0.9579	
P-value	0.3973	

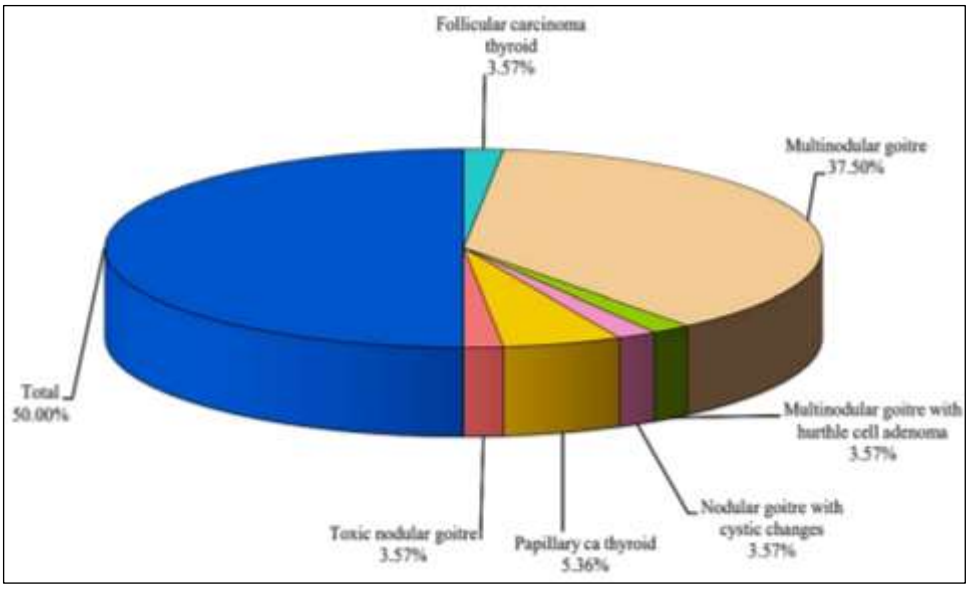


Graph 7: Mean TSH levels in different age groups

The mean TSH levels in the age group of < 30 yrs was 1.43mcIU/ml and in age groups of 30- 49 yrs was 1.76mcIU/ml and in the age group of 50-65 yrs mean TSH was 2.29mcIU/ml.

Table 9: Distribution of study cases by HPR

HPR	No of cases	% of cases
Follicular carcinoma thyroid	1	3.57
Multinodular goitre	21	75.00
Multinodular goitre with hurthle cell adenoma	1	3.57
Nodular goitre with cystic changes	1	3.57
Papillary ca thyroid	3	10.71
Toxic nodular goitre	1	3.57
Total	28	100.00



Graph 8: Distribution of cases by histology

In the Study it was observed that the majority (75%) patients were diagnosed as Nodular Goitre and 10.71% were Papillary Carcinoma and 1 case showed follicular carcinoma (3.57%).

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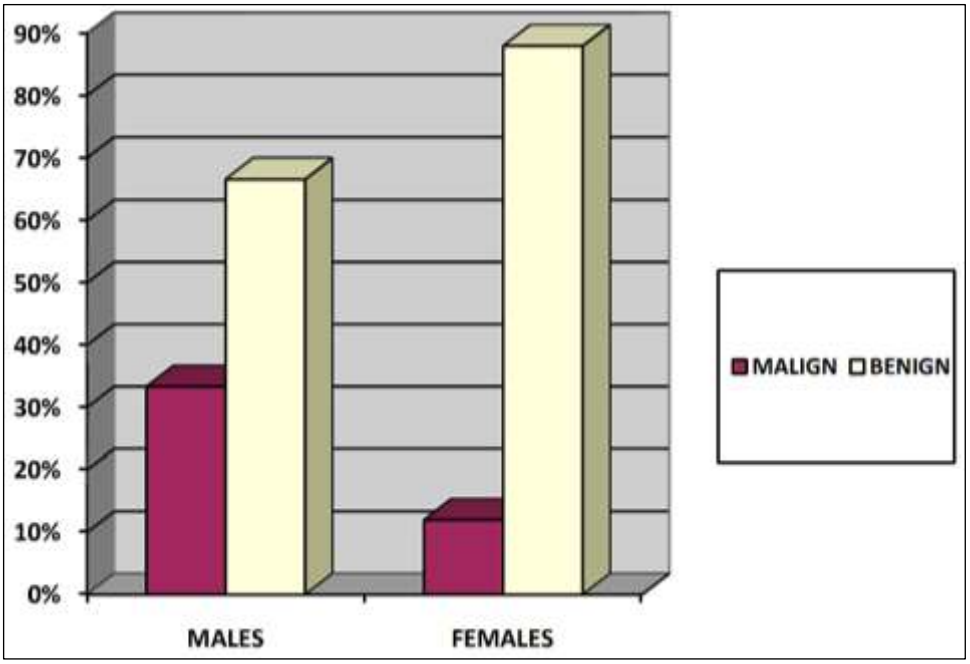
Outcome of Patients

The rate of malignancy was analyzed based on patient age, sex and serum TSH levels.

Table 10: Risk of malignancy in males and females

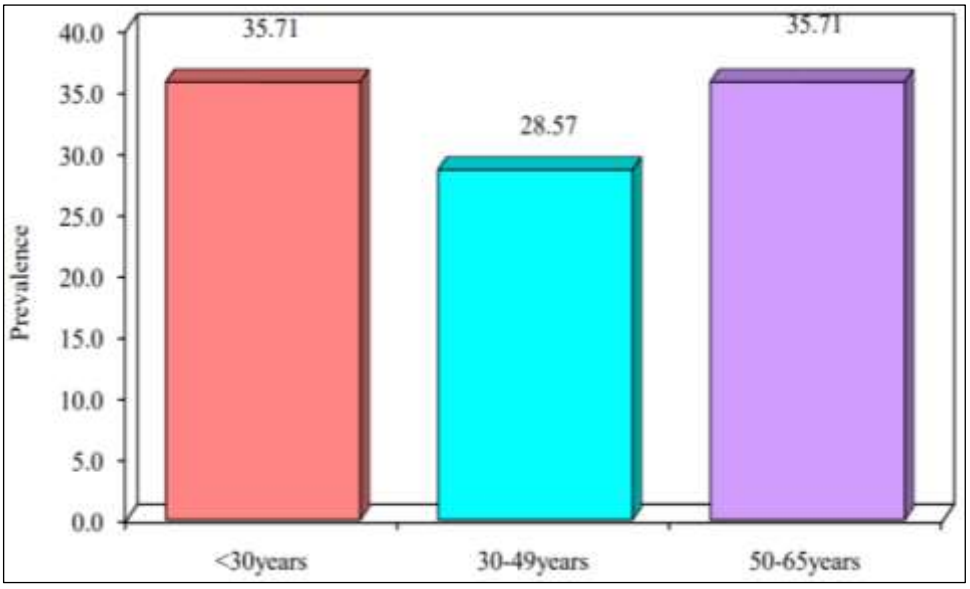
	Gender			
	My study	**Judy Jin *et al*. (2010) [9]**	**Boelaert *et al*. (2006) [10]**	**Haymart *et al*. (2008a) [8]**
Rate of malignancy	M>F, Males 33%, Females 12%	M>F, Males 25%, Females 19%	M>F, Males 31.2%, Females 3.2%	M>F, Males 39%, Females 26%



Graph 9: Risk of malignancy in males and females in my study

Table 11: Prevalence of malignancy by age groups

Age group	No of cases	Prevalence
<30years	10.00	35.71
30-49years	8.00	28.57
50-65years	10.00	35.71



Graph 10: prevalence of malignancy by age groups

The risk of malignancy was more in age group of 50-65 yrs and age group < 30 yrs- 35.71%. The risk of malignancy in age group of 30-49 yrs was 28.57%.

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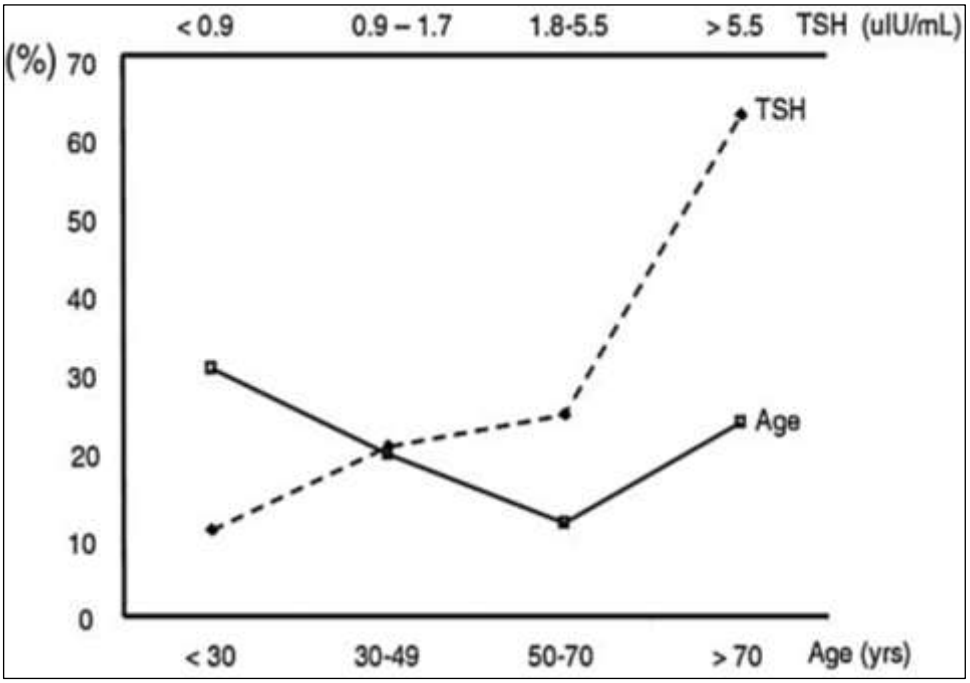
In my study the prevalence of malignancy was more in extremes of age which is similar in study groups of Judy Jin *et al*. [9] and Boeleart *et al*. [10].

Table 12: Parameters showing the risk of malignancy by age

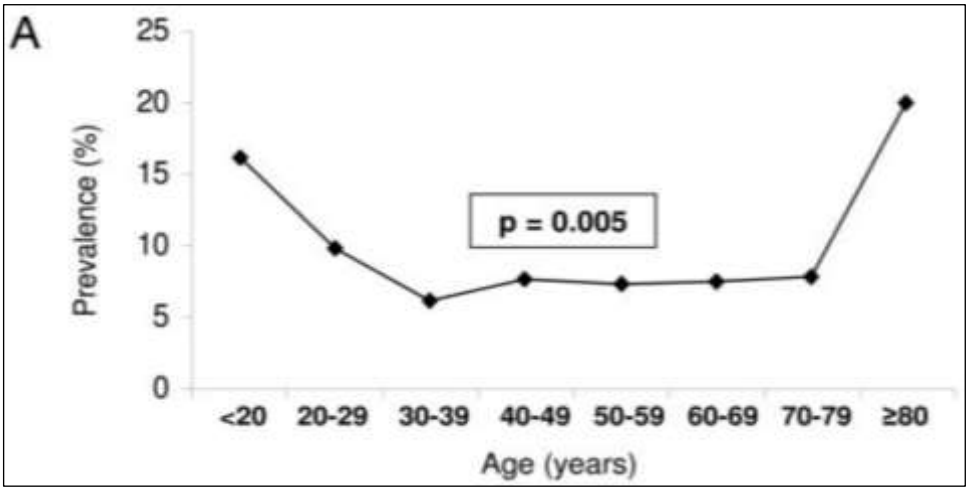
	Rate of malignancy (%)				
Age	**Our study**	**Judy Jin *et al*. (2010) [9]**		**Boelaert *et al*. (2006) [10]**	
< 30 yrs	35.71	<30 yrs	32%	< 20 yrs	15%
30- 49 yrs	28.57	30- 49 yrs	20%	40- 59 yrs	8%
50- 65 yrs	35.71	50- 70 yrs	10%	60- 79 yrs	9%
		>70 yr	25%	>80 yrs	20%

Study conducted by Judy Jin *et al*. [9] shows that the risk of malignancy was more in age group of < 30 yrs (32%) which is comparable to my study in which the risk of malignancy in age group of < 30 yrs was 35.72%.

However, even though the risk of malignancy was more in extremes of ages as shown in above table, the risk of malignancy in age group of 50-65 yrs in my study was 35.71% and in study conducted by Judy Jin *et al*. [9] was 10% which statistically shows large difference.



Graph 11: Thyroid malignancy rate based on serum TSH and age groups [9]



Graph 12: Prevalence of malignancy in relation to patients' age in years, demonstrating increased prevalence in patients at the extremes of age [10]

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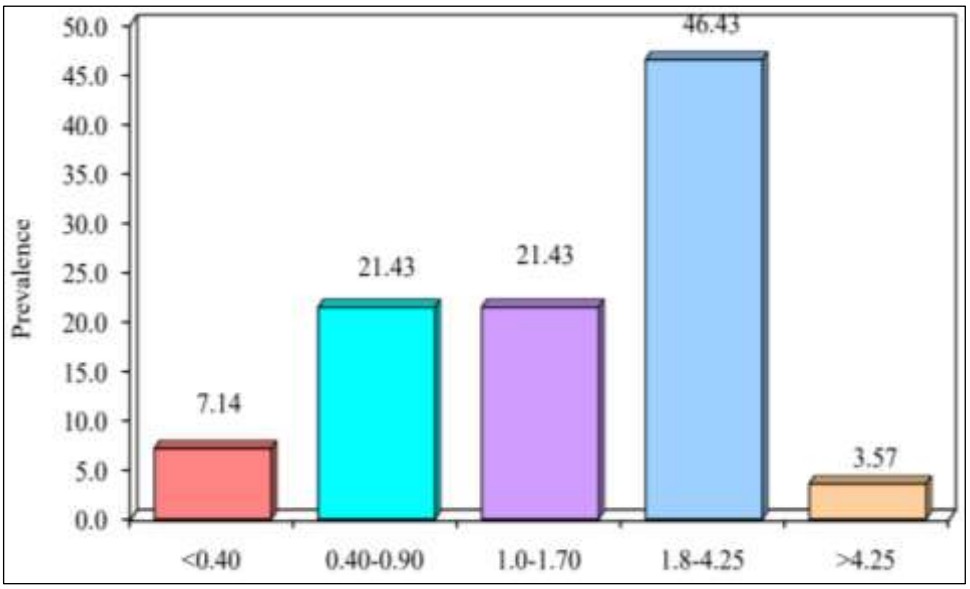
Table 13: Prevalence of malignancy by TSH levels

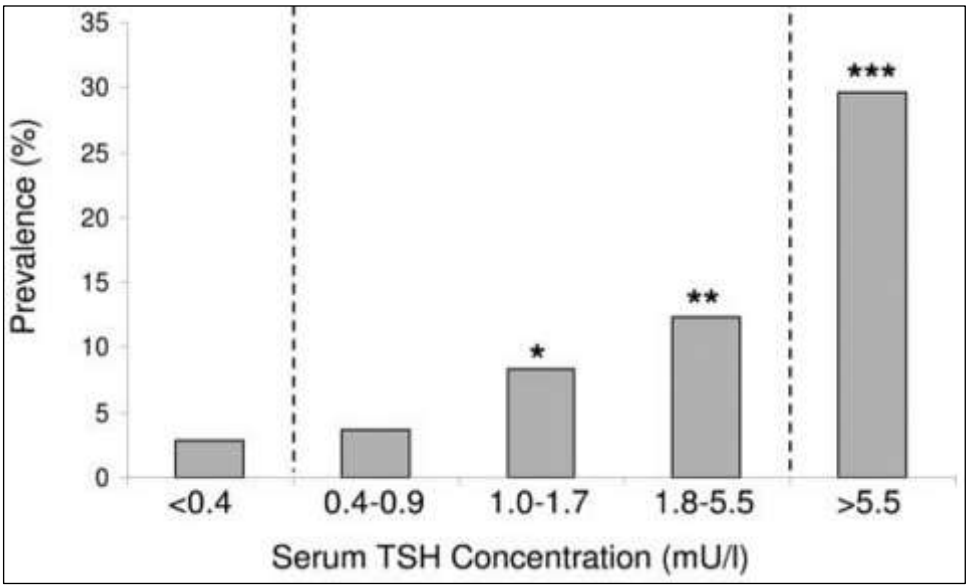
TSH groups	No of cases	Prevalence
<0.40	2.00	7.14
0.40-0.90	6.00	21.43
1.0-1.70	6.00	21.43
1.8-4.25	13.00	46.43
>4.25	1.00	3.57



Graph 13: Risk of malignancy by serum TSH levels

The risk of malignancy was more in higher quartiles of TSH levels. i.e., the risk of malignancy was 46.43% for the TSH levels of 1.8-4.25mcIU/ml. And the risk of malignancy was 21.43% for TSH levels 1.0-1.70mcIU/ml and 0.40-0.90mcIU/ml.

Above findings were comparable to the study done by Boelaert *et al.* [10] which says that increased prevalence in those with higher TSH levels.



Graph 14:

Graph 14: Prevalence of malignancy according to the serum TSH concentration measured at presentation, indicating increased prevalence in those with higher TSH. The dashed vertical lines denote the normal reference range for serum TSH. Subjects with TSH measurements within the normal range were divided into tertiles of similar size. The number of patients in each group is given beneath the graph. *, P _ 0.05; **, P _ 0.01; ***, P _ 0.001, compared with TSH less than 0.4 mU/liter50.

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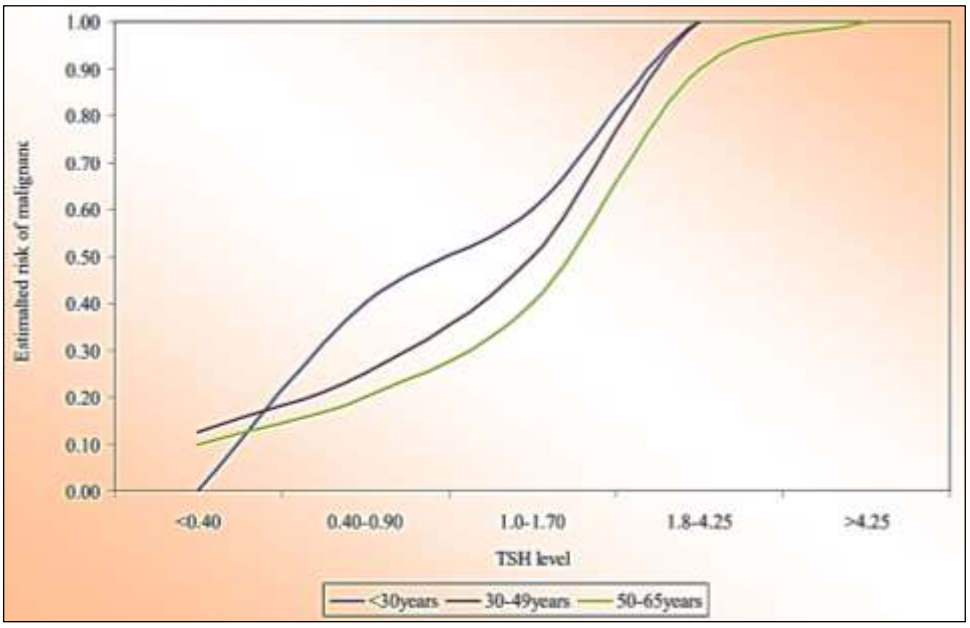
Table 14: Parameters showing the risk of malignancy in different TSH quartiles

	Our study	Judy Jin *et al.*		Boelaert *et al.*		Haymart *et al.*	
TSH groups	Risk of malignancy	TSH groups		TSH groups		TSH groups	
<0.40	7.14%			<0.4	2.8%	0.40-1.39	25%
0.40-0.90	21.43%	< 0.9	11%	0.4-0.9	3.7%		
1.0-1.70	21.43%	0.9-1.7	22%	1.0-1.7	8.3%		
1.8-4.25	46.43%	1.8-5.5	26%	1.8-5.5	12.3%	1.40-4.99	35%
>4.25	3.57%	>5.5	65%	>5.5	29.6%		

Judy Jin *et al*. [9] shows the risk of malignancy of 22% in the TSH levels of 0.9-1.7mcIU/ml which is comparable to my study which shows the risk of malignancy of 21.43% for the TSH levels of 1.0-1.7mcIU/ml. For TSH levels between 1.8-4.25 mcIU/ml, Judy Jin shows the risk of malignancy of 26% and Boeleart *et al*. [10] shows 35% but in my study, it is 46.43%. Though there is a margin of difference here, the risk of malignancy is definitely high for the TSH levels of higher quartiles.

Table 15: Binary logistic regression of status of malignancy status by age, gender and TSH

Variables	Coefficient	Std. Err.	Z-value	P-value	Adjusted Odds	[95% Conf.	Interval]
Age	0.21	0.71	0.30	0.7700	1.24	-1.18	1.61
Sex	-1.25	1.46	-0.85	0.3900	0.29	-4.11	1.62
TSH	0.37	0.57	0.65	0.5100	1.45	-0.74	1.49
Constant	-1.17	3.68	-0.32	0.7500	0.31	-8.39	6.05



Graph 15: Analysis of thyroid malignancy based on TSH levels

Table 16: Estimated risk of malignancy compared to other studies (adjusted odds ratio)

	Our study	Judy jin *et al.* [9]	Boeleart *et al.* [10]	Haymart *et al.* [8]
Odds ratio	1.45	1.4	1-2.91	1-4.56

The estimated risk of malignancy (odd's ratio) shows that there is risk of malignancy of 1.45 times in higher levels of TSH levels compared to lower levels of TSH. Similarly, Judy Jin *et al*. [9] also shows the odd's ratio of 1.4. odd's ratio derived from my study is comparable to study done by Judy Jin *et al*. [9]. Boeleart *et al*. [10] shows the odds ratio of 1-2.91 and Haymart *et al*. shows odd's ratio of 1-4.56. when my study is compared to Boeleart *et al*. [10] and Haymart *et al*. [8] there is a variation in odd's ratio.

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Table 17: Summary Table of Studies Investigating the Relationship Between Serum TSH Concentration and Thyroid Cancer [50]

Authors	journals	No. of patients studied	Country of study	Date of publication	Significant findings
Boelaert *et al*. (2006) [10]	Journal of Clinical Endocrinology and Metabolism	1500	UK	Nov 2006	Serum TSH is independent predictor of malignancy in thyroid nodules Risk of malignancy rises in parallel with serum TSH within normal range.
Haymart *et al*. (2008a) [8]	Journal of Clinical Endocrinology and Metabolism	843	US	Mar 2008	Likelihood of thyroid cancer increases with higher TSH concentration Higher serum TSH associated with advanced stage-differentiated thyroid cancer.
Jonklaas *et al*. (2008) [11]	Thyroid	50	US	Sep 2008	Higher TSH concentrations are associated with diagnosis of thyroid cancer.
Polyzos *et al*. (2008) [12]	Journal of Cancer Research and Clinical Oncology	565	Greece	Sep 2008	Higher rates of thyroid malignancy in patients with TSH in upper tertile of normal range.
Haymart *et al*. (2008b) [8]	Clinical Endocrinology	1361	US	Dec 2008	Thyroid cancer incidence correlates with serum TSH independent of age Higher TSH is associated with extrathyroidal extension of disease.
Fiore *et al*. (2009) [13]	Endocrine-Related Cancer	10178	Italy	Sep 2009	Higher TSH in patients with T3-T4 disease and in those with lymph node metastases Autonomously functioning thyroid nodules are less likely to be malignant.

Discussion

Data show that having a high-normal serum TSH concentration is a risk factor for a subsequent diagnosis of thyroid cancer in individuals with abnormal thyroid examinations. Only patients who were euthyroid were recruited for this study, so all patients had serum TSH levels within the normal range. Thus, the increased risk of thyroid cancer was associated with higher TSH values within the normal range.

The baseline characteristics of the studied patients are described above. The mean age of the group 39 yrs in females and 50 yrs in males., All patients underwent TSH assays. serum TSH levels were broken down into five quartiles. Of the 28 patients in this analysis 13 patients had TSH levels between 1.8-4.25mcIU/ml which constitute 46.43%.

1. Patient had TSH level > 4.25mcIU/ml.
2. Patients had TSH levels < 0.40mcIU/ml.

And there were 6 patients in each group of 0.4-0.9 mIU/ml and 1-1.7mIU/ml.

Mean TSH levels in the age group <30 yrs is 1.43mcIU/ml. And in the age group of 30- 49 yrs. was 1.76mIU/ml and in the age group of 50-65 yrs it was 2.29mIU/ml. Prevalence of malignancy was studied in the all TSH groups and it was found that the higher quartiles of serum TSH levels were found to be associated with increased risk of malignancy showing the risk of malignancy 46.43% in quartiles of TSH levels 1.8-4.25mcIU/ml and the risk of malignancy 21.43% each in the quartiles of TSH levels 0.4-0.9mcIU/ml and 1.0-1.7mcIU/ml which demonstrate the significance of the study however in the quartiles of serum TSH levels of < 0.4mcIU/ml and > 4.25mcIU/ml group had only 2 patients and 1 patients respectively and hence statistical significance could not be assessed. The histopathology reports of all the cases were analysed and out of 28 cases 4 cases were malignant and 24 were benign. Of these 4 malignant cases 3 cases had serum TSH levels between 1.8-4.25mcIU/ml. And hence it can be said that higher quartiles of TSH levels are associated with increased risk of malignancy.

When the binary logistic regression analysis was applied as done by many authors of different studies, there was no significant P value because of small sample size but the odds ratio was 1.45 and hence conclusion is that higher quartiles of serum TSH levels were associated with 1.45 times the risk of malignancy compared to lower quartiles of TSH levels.

Conclusion

There is increasing evidence that higher serum TSH concentrations are found in patients with thyroid nodules harbouring malignancy [10]. Several studies have indicated that inclusion of serum TSH concentrations may be useful when evaluating the risk of thyroid malignancy in patients with nodular thyroid disease [10]. The mechanisms underlying these observations have not been fully explained, although TSH is a known growth factor for thyroid cells and animal data have demonstrated that TSH suppression in rats exposed to radioiodine prevents the formation of thyroid cancer [10]. Both benign nodules and well-differentiated thyroid cancer express TSH receptors. The role of the TSH receptor has been more extensively evaluated in benign nodules. It is unlikely that TSH suppression reduces benign nodule size;

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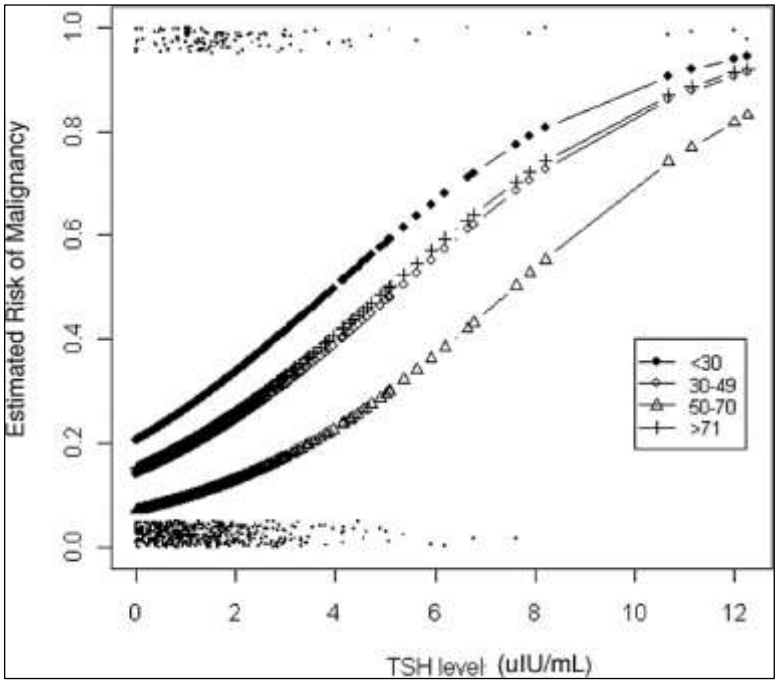
however, it may prevent the development of new nodules and decrease rate of growth [8].
Within normal range TSH, a TSH level above the population mean had an increased risk of malignancy relative to a TSH level below the mean hence TSH may play a central role in the development and progression of thyroid cancer. It is well documented that TSH has a trophic effect on thyroid cancer growth, which is most likely mediated by TSH receptors on tumor cells and furthermore that TSH suppression is an independent predictor of relapse-free survival from differentiated thyroid cancer [10].
And hence that the increased risk associated with serum TSH concentrations in the upper half of the normal range, and even more strikingly in those whose TSH measurements were above normal, may at least in part be mediated by this trophic effect of TSH.
It is conceivable, therefore, that the higher rate of thyroid malignancy observed in patients with higher serum TSH concentration is caused by trophic effect of TSH on thyroid tissue that promotes neoplasia and carcinogenesis. In patients with higher TSH levels, the risk of malignancy increased in a near linear fashion. This pattern was true even for serum TSH increases that occurred within normal range [9].



Graph 16: Logistic regression analysis of thyroid malignancy rate based on TSH level when adjusted for age and sex 69

Despite the limitations of the study, the results have important clinical implications for the management of patients presenting with thyroid nodules and FNAC results consistent with either a follicular or hurthle cell neoplasm have an ~20% incidence of carcinoma. Currently, the most conservative approach is to proceed with thyroid lobectomy and isthmusectomy [14].
Complete thyroidectomy is performed for a patient with a final pathological diagnosis of cancer [14]. It is conceivable that serum TSH levels may be useful to help further stratify the risk of cancer and help clinicians decide who should be treated with definitive total thyroidectomy at initial operation [9].
Patients with follicular or hurthle cell neoplasm and a serum TSH level above normal (> 5.5mcIU/ml) may be counselled to undergo total thyroidectomy knowing the likelihood of malignancy can be as high as 65%. The additional information provided by serum TSH level can further aid in patient education as well as the proper use of resources in avoiding a second surgical procedure [9].
Similar results have been produced by the different authors from various studies.

Summary

In the present study 28 cases were studied and the age group is divided into 3 groups as < 30 yrs, 30-49 yrs, 50-65 yrs. All the patients underwent serum TSH estimation by standard Immunochemiluminiscent assay and the outcome is assessed in age groups, gender and serum TSH levels in comparison to malignancy. In the age groups it is shown that extremes of age has high incidence of malignancy in the age group of < 30 yrs the risk of malignancy was 35.71% and in the age group of 30-45 yrs it is 28.57% and in the age group of 50-65 yrs the risk of malignancy was 35.71%.
Gender wise males have a high incidence of malignancy (33.33%) compared to females (12%). When serum TSH levels were compared with malignancy it was seen that higher levels of serum TSH levels were associated with increased risk of malignancy. Serum TSH levels of 1.8-4.25mcIU/ml has the risk of malignancy of 46.43% and serum TSH levels of 1.0-1.7mcIU/ml has risk of malignancy of 21.43%. So

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from this it can be said that the higher levels of serum TSH levels is associated with increased risk of malignancy.

Ethics approval and consent to participate
Institutional ethics committee approval and consent from all the patients has been obtained.

List of Abbreviations
CVS-Cardiovascular system.
CNS-Central Nervous System.
FNAC-Fine needle aspiration cytology.
HPR-Histopathology report.
Hb%-Hemoglobin percentage.
PA-Per abdomen.
RBS-Random blood sugar.
RS-Respiratory system.
TNM-Tumor node metastasis.
USG-Ultrasonography.
TSH-Thyroid stimulating hormone.
Tg-Throglobulin.
T4-Thyroxine.
T3-Triiodothyronine.

Conflicts of Interest: None.

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