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Original Article

Major stress as a predictive value in the setting of thyroid nodule development: A prospective study

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Abstract

Background: Thyroid nodule (TN) is defined as the abnormal growth of thyroid cells, with an increasing trend worldwide. In this case-control study, we intended to evaluate demographic and environmental factors involved in TNs to determine the values predicting the risk of TN incidence.

Methods: 103 patients with confirmed TN through ultrasound imaging were assigned to the nodular group, and 101 patients with negative results of TN were considered control counterparts. Data collection was performed using a checklist from February 2021 to August 2022. Uni- and multivariable logistic analyses were applied to ascertain prognostic risk factors.

Results: The results showed that the prevalence of TNs was significantly higher in females (90.3%, p<0.001). We also found that a history of exposure to ionizing radiation with a diagnostic dose (83.5%, p<0.001), hypothyroidism (37.9%, P=0.005), hyperthyroidism (7.8%, P= 0.005), family history of thyroid disease (58.3%, p<0.001), unusual stress (68.9 %, p<0.001), and taking medications inferring thyroid function (10.7%, P=0.01) in the nodular group, which were consistent with the results of logistic regression analysis can be considered the potential prognostic values to predict the risk of incident TN.

Conclusion: The role of unusual stress on TN development is highlighted in this study. diagnosis and proper management of determinants such as unusual stress involved Early in TN pathogenesis through lifestyle modification, community awareness, and screening of the family with TN history would be more appreciable in order to decline TN incidence and prevalence, particularly in the predisposed population.

Keywords: Thyroid nodules; Predictive risk factors; Prognostic value.

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Based on the American Thyroid Association (ATA) criteria, a thyroid nodule (TN), as one of the most common thyroid disorders, is termed an unusual growth of cells in the thyroid gland, which are almost always benign (more than 90%), however, rare reports represent cancerous form (4.0-6.5%) (1). With an incidence of 19–68% in the general population, TN represents a common finding in clinical practice. Based on ultrasound imaging classification, there are four types of TN consisting of solitary, multiple, cystic, and solid forms (2, 3). Some reasons to describe a recent high prevalence of TN are related to the increasing trend of TNs as a clinically concerning issue and a substantial progression in the field of diagnostic measures. In the last decade, the large number of diagnosed TNs has exponentially increased during the extensive use of ultrasound imaging. Of note, the high frequency of incident TN cannot be merely justified by risk factors such as gender, age, iodine deficiency, and radiation exposure (4). Other demographic features, including modified lifestyle, smoking or alcohol consumption, and economic or social status are also taken into account as involved factors in TN promotion (4).

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Gender is defined as the prominent risk factor affecting TN, which is more often observed in females (four times higher than in males), followed by low-income conditions, particularly due to iodine deficiency (4). Some thyroid diseases (e.g., hypothyroidism, hyperthyroidism, Hashimoto's thyroiditis, and Graves' disease), family history of TN or thyroid cancer, aging, iron-deficiency anemia, smoking, obesity, metabolic syndrome components, alcohol consumption, high levels of insulin-like growth factor-1 (IGF-1 hormone), and uterine fibroids are also considered other risk factors involved in TN progression (5-8). Although TN is usually represented as asymptomatic, cervical mass diagnosed through ultrasound and fine needle aspiration biopsy (FNAB), Globus sensation, chronic cough, tracheal disorder, hyperthyroidism, and cervicalgia can be also noted as TN symptoms. Regarding diagnostic tools, 5–7% of TNs can be detected by a physical examination in the adult population. Whilst, the majority of them (20-76%) are detected incidentally through ultrasound assessment, 15% by computed tomography (CT)/ magnetic resonance imaging (MRI), and 1.2% by fluorodeoxyglucose positron emission tomography (PET) (9). Palpable nodules are also reported in approximately 5% of the population, which are randomly observed during an ultrasound examination in 30% of people (10). Although a great body of research was designed to determine risk factors involved in TNs, there are limited case-control studies to precisely evaluate further determinants with a potential prognostic value in this context. Herein, we sought to evaluate various potential predictive factors involved in TN development in subjects who were consecutively admitted to our endocrinology clinic and compared them to patients without TN, as a control group.

Methods

Study population: In this case-control, single-center, and prospective study with ethics committee code: IR.UMSU.REC.1400.008) All patients with thyroid problems from February 2021 to August 2022, who were admitted to our endocrinology clinic were enrolled. As inclusion criteria, patients with diagnosed TN through ultrasound examination were assigned as the case group, while those without TN were defined as the control group.

Sampling: The sample size was calculated based on a previous study conducted by Jiang et al., (11), with a 1% error level and 80% power using the below formula:

$$n = \frac{(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2 [P_1(1-P_1) + P_2(1-P_2)]}{(P_1 - P_2)^2}$$

α=0.01, β=0.8, P1= 0.639, P2= 0.361

The thyroid gland's nodularity was assessed through physical examination and ultrasound imaging performed by an expert sonographer in the Imam Khomeini Hospital (the gold standard diagnostic method, device name: SuperSonic Ultimate Ultrasound System). Any abnormal mass detected in the thyroid tissue was defined as a thyroid nodule.(12) Moreover, thyroid abnormality was defined according to the ATA definition and using Chemiluminescent immunoassay (CLIA) as below (10):

- Hypothyroidism defined as TSH> 4.2 mIU/L,
- Euthyroidism defined as 0.4< TSH < 4.2 mIU/L,
- Hyperthyroidism defined as TSH <0.4 mIU/L

Finally, based on statistical analysis and following ethical approval, the sample sizes for case and control groups were considered 103 and 101, respectively. In this study, the ethical standards of the Declaration of Helsinki were followed.

Data collection method: Data were collected through a designed checklist in which the predictive risk factors, including age, gender, body mass index [BMI, calculated according to weight (kg)/ height (m^2)], smoking, alcohol consumption, taking the iodized salt, a history of ionizing radiation exposure with a diagnostic dose (very low dose), a history of thyroid/non-thyroid autoimmune disorders, a history of drug consumption modifying the thyroid function (i.e., Amiodarone, Methimazole, and Propylthiouracil), a history of unusual stress (defined as all socioeconomically issues such as an experience of severe disease or serious car accident for patient and/or relatives, experience of any financial bankruptcy, and emotional problems), weekly seafood consumption (the participants were categorized based on the rate of sea food consumption 0-1 time per week, 1-2 times per week, and more than 2 times per week), a family history of TNs, location, economic status (divided into three categories, including low income: ≤ 4.5 million tomans /month, moderate income: 4.5 -10 million tomans/ month, and good income > 10 million tomans/ month), and the total number of pregnancies was listed.

Statistical analysis: Mean±SD and frequency (percent) were used for descriptive data. Relative frequencies were presented for each variable. Fisher's test, chi-square, and logistic regression analysis were also used for analytical data. The relationship between variables and incident TN was calculated using odds ratio (OR) and 95% confidence interval (CI) through the uni- and multivariate regression models. Upon filling out the questionnaires, the gathered data were analyzed by the SPSS software Version 17 packages (SPSS Inc., Chicago, IL, USA). A p-value level lower than 0.05 was considered statistically significant.

Results

Demographic characteristics: Of the total of 204 participants, 103 (50.5%) patients were included in the nodule group. A large portion of the patients was 45 years and over (53.4%). The high-frequency distribution of BMI and pregnancy is related to the range of 25-30 kg/m2 (45.1%) and > 3 pregnancies (28.2%), respectively. Most of the patients (90.7%) were also familiar with iodized salt and used it daily. Regarding the history of thyroid disease, 64.7% of patients were euthyroid, with a median income level (53.4%). A complete report of demographic features is detailed in table 1.

Comparison of frequency of studied variables among patients with and without TNs: The comparison of the studied variables between the two groups revealed that the frequency of gender, history of head and neck exposure to ionizing radiation with a diagnostic dose, status of thyroid diseases, literacy level, family history of nodules, stress condition, and receiving the medications that interfere with thyroid function significantly differed between the two groups ($p<0.05$, table 2). Among the patients with and without nodules, the highest frequency is related to women; this difference is statistically significant ($p<0.001$). In patients with nodules, the frequency of history of head and neck exposure to ionizing radiation with a diagnostic dose was also higher compared to the control group ($p<0.001$). Despite significant differences in the case of occupation (housekeeping) and education (diploma) between the two groups, they were lack of specific orientation and importance.

Table 1. Comparison of studied variables among patients with and without thyroid nodules

Variables		With nodules	Without nodules	P-value
		N number (%)		
Age (year)	<20 yr	1 (1)	5 (5)	F=0.085
	20-45 yr	51 (49.5)	38 (37.6)	
	45 yr<	51 (49.5)	58 (57.4)	
Gender	Man	10 (9.7)	38 (37.6)	Ch<0.001
	Woman	93 (90.3)	63 (62.4)	
BMI (kg/m^2)	<25	24 (23.3)	19 (18.8)	Ch= 0.13
	25-30	51 (49.5)	41 (40.6)	
	30<	28 (27.2)	41 (40.6)	
Smoking	Yes	11 (10.7)	14 (13.9)	Ch= 0.49
	No	92 (89.3)	87 (86.1)	
Consumption of iodized salt	Yes	97 (94.2)	88 (87.1)	Ch= 0.083
	No	6 (5.8)	13 (12.9)	
Alcohol consumption	Yes	7 (6.8)	2 (2)	F= 0.17
	No	96 (93.2)	99 (98)	
Exposure to ionizing radiation	Yes	86 (83.5)	48 (47.5)	Ch= 0.001
	No	17 (16.5)	53 (52.5)	
Occupation	Unemployed	2 (1.9)	5 (5)	Ch< 0.001
	Self-employment	5 (4.9)	25 (24.8)	
	Employee	16 (15.5)	18 (17.8)	
	Housewife	75 (72.8)	46 (45.5)	
	Farmer	5 (4.9)	7 (6.9)	
Thyroid Diseases	Euthyroid	56 (54.4)	76 (75.2)	Ch= 0.005
	Hypothyroid	39 (37.9)	23 (22.8)	
	Hyperthyroid	8 (7.8)	2 (2)	
Other autoimmune Disorders	Yes	3 (2.9)	0	F= 0.25
	No	100 (97.1)	101 (100)	

Variables		With nodules N number (%)	Without nodules N number (%)	P-value
The number of Pregnancy	0	7 (7.5)	13 (20.6)	Ch= 0.099
	1	12 (12.9)	8 (12.8)	
	2	29 (31.2)	11 (17.5)	
	3	19 (20.4)	13 (20.6)	
	More than 3	26 (28)	18 (28.6)	
Location	Urban	68 (66)	70 (69.3)	Ch= 0.17
	Rural	15 (14.6)	19 (18.8)	
	Other	20 (19.4)	12 (11.9)	
Income Level	Low	30 (29.1)	30 (29.7)	Ch= 0.88
	Medium	54 (52.4)	55 (54.5)	
	High	19 (18.4)	16 (15.8)	
Literacy Level	High school	42 (40.8)	60 (59.4)	Ch=0.005
	Diploma	37 (35.9)	17 (16.8)	
	Academic	24 (23.3)	24 (23.8)	
Family History	Yes	60 (58.3)	3 (3)	Ch<0.001
	No	43 (41.7)	98 (97)	
Seafood Consumption	Yes	38 (36.9)	35 (34.7)	Ch=0.74
	No	65 (63.1)	66 (65.3)	
Unusual Stress	Yes	71 (68.9)	21 (20.8)	Ch<0.001
	No	32 (31.1)	80 (79.2)	
Medications	Yes	11 (10.7)	2 (2)	Ch=0.011
	No	92 (89.3)	99 (98)	

F= Fisher's exact test, Ch= Chi-square

We also found that the highest frequency of occupation in both groups was referred to housewives; however, it was significantly higher in the group with nodules (p<0.001). As shown in table 2, the frequency of hypothyroidism and hyperthyroidism in patients with nodules was higher than in those with the non-nodular thyroid, while the frequency of euthyroidism was higher in patients without nodules (P=0.005, table 2). Regarding the levels of literacy, the order of education level included sub-diploma, diploma, and academic education in the case group, while the order of education level was sub-diploma, academic, and diploma in the control group (P=0.005, table 2). Compared to the control group, most of the patients with TN have a positive family history, as well as unusual stress experiences (p<0.001, table 2). A small fraction of patients with and without nodules used drugs interfering with thyroid function, and notably, this difference was statistically significant between the two groups (P=0.0011, table 2). Together, beyond the well-known determinants, unusual stress can be considered a novel predictive and independent risk factor in the case of TN development.

Determining a correlation between the studied factors with the risk of TNs using logistic analysis: Univariate logistic regression analysis was used to determine the relationship between variables with statistically significant differences between the two groups. In this respect, the results showed that in the patients with TN, the OR of female gender and exposure to ionizing radiation with a diagnostic dose was significantly higher (OR=5.61, 95% CI: [2.61-12.07], p<0.001; OR=5.59, 95% CI: [2.91-10.71], p<0.001, respectively). In addition, hypothyroidism (OR=2.3, 95% CI: [1.24-4.28], P=0.008) and hyperthyroidism (OR=5.43, 95% CI: [1.11- 26.55], P=0.037) also showed a remarkable difference when compared to Euthyroid subjects. Furthermore, the OR of a family history of thyroid disease (OR=45.58, 95% CI: [13.54-153.42], p<0.001), a history of unusual stress (OR=8.45, 95% CI: [4.47-15.97], p<0.001), and drug consumption (OR=5.92, 95% CI: [1.28-27.42], P=0.023) were significant in patients with TN when compared to non-nodular group (table 3). Besides, the results of multivariate logistic regression analysis also showed that in patients with

a TN, a history of head and neck exposure to ionizing radiation (OR=2.47, 95% CI: [0.99-6.17], P=0.05), hyperthyroidism (OR=16.8, 95% CI: [1.07- 26.56], P=0.045), a family history (OR=22.3, 95% CI: [5.15-96.64], p<0.001), and history of unusual stress (OR=3.34, 95% CI: [1.39-7.99], P=0.007) can be considered independent risk factors with predictive potential (table 3).

Table 2. The correlation between the studied variables with incident thyroid nodules in Univariate Logistic Regression

Variables		Odd Ratio (OR)	Confidence Interval (CI, 95%)	P-value
Gender	Man	ref =1	-	-
	Woman	5.61	(2.61-12.07)	<0.001
History of exposure to ionizing radiation	Yes	5.59	(2.91-10.71)	<0.001
	No	1	-	-
Thyroid diseases	Euthyroid	1	-	-
	Hypothyroid	2.3	(1.24-4.28)	0.008
	Hyperthyroid	5.43	(1.11- 26.55)	0.037
Family history	Yes	45.58	(13.54-153.42)	<0.001
	No	1	-	-
Unusual stress	Yes	8.45	(4.47-15.97)	<0.001
	No	1	-	-
Medications	Yes	5.92	(1.28-27.42)	0.023
	No	1	-	-

Table 3. The correlation between the studied variables with incident thyroid nodules in Multivariable Logistic Regression

Variables		Odd Ratio (OR)	Confidence Interval (CI, 95%)	P-value
Gender	Man	ref =1	-	-
	Woman	2.61	(0.57-11.88)	0.21
History of exposure to ionizing radiation	Yes	2.47	(0.99-6.17)	0.05
	No	1	-	-
Thyroid diseases	Euthyroid	1	-	-
	Hypothyroid	1.73	(0.69-4.36)	0.24
	Hyperthyroid	16.8	(1.07- 26.56)	0.045
Family history	Yes	22.3	(5.15-96.64)	<0.001
	No	1	-	-
Unusual stress	Yes	3.34	(1.39-7.99)	0.007
	No	1	-	-
Medications	Yes	2.38	(0.21-27.1)	0.48
	No	1	-	-

Discussion

To the best of our knowledge, TN is most likely to be a benign thyroid abnormality with increasing trends worldwide (13). Considering the importance and prevalence of TNs on one hand, and the existing limited case-control study to determine the prognostic values of the involved risk factors on the other hand, we intended to explore a variety of variables in patients who were admitted to a tertiary hospital. Notably, we found that the unusual stress, ionizing radiation with a diagnostic dose, and not therapeutic dose, as well as the medication i.e., Amiodarone beyond the anti-thyroid drugs (Methimazole and Propylthiouracil) can be

considered the strong prognostic values increasing the risk of TNs incidence along with other studied factors. According to our results, the frequency of TNs was higher amongst the women ($p<0.001$), indicating that female gender can be considered a factor in predicting the risk of TNs, which is consistent with the results of the studies conducted by Dauksiene and Jiang (11, 14).

Therefore, it can be concluded that the TNs development is more likely sex hormone-dependent, whereby sexual hormones may play a key role in disease pathogenesis. In this regard, a cross-sectional SPECT-China study displayed that in patients with TNs, serum levels of testosterone and sex hormone-binding globulin (SHBG) remarkably reduced. At the same time, higher levels of estradiol were observed (15). Also, it can be implicated that among the women with metabolic syndromes and related components, the risk of TNs would be higher (16). Although aging was not regarded as a leading cause of TN in the current study, Kwong et al. indicated that the prevalence of TN disease, but not the risk of malignancies, enhances positively with advancing age (with a 1.6% annual increased risk) (17). In previous literature, it has also been well-established that radiation-induced thyroid diseases could occur upon long-term exposure to ionizing radiation with a therapeutic dose (low and high dose) (18-21), while we elegantly reported TN development is associated with the frequency and odds of receiving ionizing radiation in the head and neck area with a diagnostic dose (very low dose), which was significantly higher than the non-nodular thyroid group ($p<0.001$). In the study conducted by Ramos et al., it has also been demonstrated that a history of radiation and obesity would be considered two risk factors (22).

In parallel with our findings, both Ramos and Karger's research teams indicated that the history of the family has been taken into account as a strong risk factor due to a higher rate of frequency and OR (23). In the current study, some factors, comprising age, BMI, smoking, iodized salt consumption, alcohol consumption, occupation, non-thyroid autoimmune disorders, number of previous pregnancies, location (urban or rural), economic status, literacy levels, and seafood consumption did not show significant differences between two groups. Similarly, Dauksiene et al. investigated the association of BMI, smoking, thyroid hormone levels, and different metabolic parameters with the prevalence of TN and goiter in the middle-aged (45-49 years old) euthyroid population. They surprisingly found that female gender, thyroid volume, and higher TSH levels but not BMI and smoking were independent predictors for TN incidence (14). However, a previous study indicated that smoking was partially involved in TN pathogenesis, and found an association between thyroid multi-nodularity and smoking but not with the incremental prevalence of solitary TN (24).

In line with our findings, in a community-based cross-sectional study in China, the results also showed that BMI was not a strong risk factor, while sufficient iodine intake, as well as waist circumference, and were superior to BMI to predict the risk of TN (25). Based on our results, a relationship between pregnancy and the incident TNs was not found. While Karger et al. showed that the prevalence of TN disease and goiter among pregnant women (up to 45%), especially among those living in regions with borderline sufficient iodine supply is remarkably higher accompanied by a positive correlation with BMI and family history (23). A variety of medications, such as Amiodarone, Methimazole, and Propylthiouracil, has been proven to affect thyroid function, therefore, we examined whether or not these drugs have an impact on TN development. The results showed that in patients with TN, a history of drug consumption was significantly greater than in those without TN. However, they are not considered strong predictive factors to develop TNs. Except for gender, timely detection and proper management of these risk factors through modification of lifestyle, community awareness, and screening of the family with TN history would be more appreciable in the prevention and early diagnosis of TNs, particularly in a vulnerable population. It is also worth noting that our findings claimed that the unusual stress, ionizing radiation with a diagnostic dose, and the medication beyond the anti-thyroid drugs i.e., Amiodarone can be regarded as the risk stratification of patients with TN.

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Conflict of interests: The authors declared that they have no conflict of interest.

Authors' contribution: Ebrahim Mohammadi: Supervision, Conceptualization & Investigation; Reza Hatami Novi: Methodology & Formal analysis, Neda Valizadeh: Writing – original draft, – review & editing.

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