Original Research Article

Journal of College of Medical Sciences-Nepal, Vol-18, No 4, Oct-Dec 2022
ISSN: 2091-0657 (Print); 2091-0673 (Online) Open Access
DOI: 10.3126/jcmsn.v18i4.49041

Universal Screening for Hypothyroidism in 1st Trimester of Pregnancy: Where are We for Subclinical Hypothyroidism?

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ABSTRACT

Introduction

Subclinical hypothyroidism is missed to diagnose until fetal/maternal complications supervene and yet treatable if diagnose in 1st trimester. High disease prevalence and adverse pregnancy outcome concerns its timely identification & treatment to prevent, decrease or reverse the forthcoming complications. The objective of this research is to find prevalence of Subclinical hypothyroidism estimating TSH as 1st line test.

Methods

It was a descriptive cross sectional study. Sample size consisted of 153 pregnant women attending antenatal clinic & wards. TSH assessment was done at 1st visit along with antenatal testing. If TSH is ≥4mIu/ml (ATA) and ≥2.5mIU/ml (Iodine deficit area), freeT4 and thyroid perioxidase antibody test (anti-TPO) was further analyzed. Data was analyzed by using SPSS-20.

Results

A study was conducted among 153 pregnant women during their 1st trimester in the department of Obstetrics and Gynecology, College of Medical Sciences, Bharatpur, Nepal. The mean ±SD age was 26.1 ±4.38 years, mean ±SD gestational age was 7.6±1.35 weeks and mean ±SD body mass index (BMI) was 23.1±2.46. Thirteen percent subjects had TSH ≥4 mIU/L & 35% had TSH≥2.5mIU/ml above the cutoff used for definition of hypothyroidism. Anti Thyroid perioxidase (Anti-TPO) test positive were 47.6% (TSH≥4mIU/ml)

Conclusions

Subclinical hypothyroidism is highly prevalent in population visiting our hospital, so a universal screening with TSH estimation will be cost worthy in our area to intervene early before feto/maternal complications supervene.

Keywords: 1st trimester; feto-maternal complication; pregnancy; screening; subclinical hypothyroidism; thyroid stimulating hormone; universal.

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INTRODUCTION

Thyroid disease is the 2nd common cause of endocrine dysfunction in women of child bearing age with higher incidence of hypothyroidism.[1, 2] In Subclinical hypothyroidism (SCH), thyroid stimulating hormone (TSH) value is elevated with normal range of circulating thyroid hormone.[3,4] Its prevalence ranges from 19.5-31% in Nepal which is high compared to developed countries.[5-7] Thyroid hormone is important for fetal brain development in 1st trimester when fetus cannot synthesize its own thyroid hormone till 12 weeks of gestation and solely depend on maternal supply.[8]

The untreated gestational SCH has adverse impact on pregnancy outcomes i.e. association with gestational diabetes[9], hypertension & pre-eclampsia[10]; higher rate of abortion[12], abruption[11], preterm delivery[12,14] and adverse fetal effects[11,] i.e. intrauterine growth restriction, small for gestational age, low birth weight and low APGAR score, increased incidence of neuro-cognitive deficits in off springs, lower intelligence & motor scores.[15,16]

The adverse maternal & neonatal outcomes associated with SCH can be improved, reverse or decrease with thyroid screening in pregnant women and early treatment (Levo- thyroxine supplement) during 1st trimester when fetal thyroid is incapable of producing thyroid hormone and resulted prevention of progeny.[16] So, a universal screening with TSH as 1st step test might be rationale to screen for thyroid disease in pregnancy considering high risk for adverse feto-maternal consequences if untreated/missed.[1-4,17, 18] The reference was TSH 4mIU/ml as upper limit in 1st trimester if the trimester reference range was lacking.[18]

The level of TSH 2.5-10mIU/ml was criteria proposed for SCH screening in 1st trimester.[19]

METHODS

A descriptive cross sectional study was conducted in antenatal department of College of Medical Sciences, Bharatpur of Nepal; after ethical clearance from the Institutional Research Committee (COMSTH-IRC/2022-009). It was a prospective study carried out over the period of four months from April to July 2022. Pregnant women visiting ANC clinic and inpatient ward of COMS in 1st trimester (within 10 weeks of pregnancy) were included in the study after taking informed consent. A detail history, clinical examination was conducted; routine ANC investigations reports were collected. SCH was diagnosed with Anti-thyroid association criteria[18] and Spanish association criteria [19]. Anemia in 1st trimester was labeled below 11 gram percent hemoglobin proposed by world health organization.[20] Ladies with high pre-pregnancy BMI were advised to limit the weight gain throughout the pregnancy (6-9kgs).[21]

Pregnant woman with history of thyroid disorder, high risk women for thyroid disorder i.e. family history of thyroid disorder, pregnant women with pre-existing medical disorders (like diabetes, heart disease, collagen disease, etc), women taking drugs known to alter thyroid level (e.g. amphetamines, dopamine agonist, amiodarone, steroids), if the value of TSH is below 0.35 mIU/ml and ≥ 10mIU/ml, and abnormal fT4 level were excluded from study. One Hundred and fifty three singleton pregnant women in 1st trimester below 10 weeks were included in our study with informed consent.

The sample size was calculated using Fisher's formula. $n=Z^2 P (1-P) /E2$ Where: n= sample size, P (prevalence) = 9.6% compared with study of Alexander EK and colleagues.[18] Z = (1.96) 95% confidence interval was used. E

(error margin) = 5%. Therefore n = $(1.96)^2$ x .096 (1 – 0.096/ $(0.05)^2$= 133. We sampled an extra 5% to account for possible non-response (5% of 133=6.6). So, the sample size in this study will be ≥140. Data was plotted from the written proforma sheet to SPSS sheet. Age, gestational age, body mass index, hemoglobin and TSH value variables were expressed as mean ± standard deviation (SD). The frequencies were calculated in percentages. The outcome variables were correlated with cross tabulation with defined Subclinical hypothyroidism reference.

Paired-samples T test was used to estimate p- value and test of statistical significance would be two-sided and differences taken as significant when *p*-value was less than 0.05. The plotted data were analyzed with SPSS20 software.

RESULTS

Total 153 pregnant women of 1st trimester were included in the study. Out of them, 3 cases were diagnosed with hyperthyroidism [2(1.3%) sub-clinical Hyperthyroidism & one (0.6%) overt hyperthyroidism], 7(4.5%) overt hypothyroidism and 21(13.7%) SCH (TSH≥4mIU/ml) & 55(35.9%) SCH (TSH ≥2.5 mIU/ml). So, cases with hyperthyroidism and overt hypothyroidism were excluded from the study.

In our study population, mean age was 26.1 years (SD: 4.38), mean gestational age at the time of screening was 7.6 weeks (SD: 1.35), mean body mass index (BMI) was 23.1(SD: 2.46) and mean hemoglobin was 11.6gm% (SD: 1.13). The mean serum TSH for our sample population in this study was 2.5mIU/ml (SD: 1.53). The lower and upper values of TSH were 0.50 and 8.7 mIU/ml. Maximum pregnant ladies were Multigravida (50.7%) and from age group 26-35 years (66%ATA, 70% SEGO). Twenty five percentages of women were anemic in 1st trimester of pregnancy during routine 1st ANC investigation (5.5% ATA, 22% SEGO). There was positive co-relation between SCH and anemia (p-value: 0.039ATA, 0.021SEGO), high BMI (p-value: 0.021ATA/0.001SEGO).

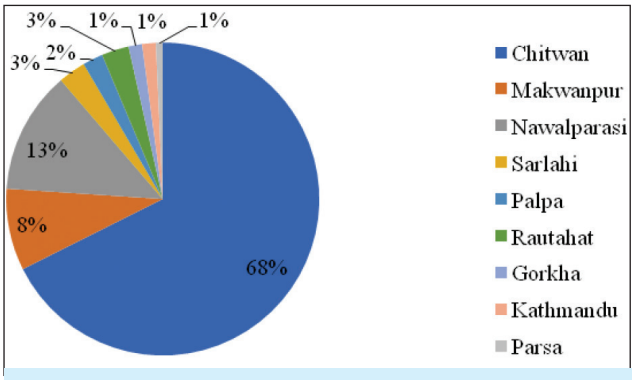

Figure 1. Distribution of population according to districts of Nepal.

Ethnicity of Nepal	Frequency (%)
Chhetri & Brahmins	49(34)
Newars	16(11.1)
Janajatis	53(36.7)
Dalits	14(9.7)
Madhesis	4(2.8)
Muslims	4(2.8)
Others	3(2.1)

The higher numbers of study population were from Chitwan district (province no 3) (Fig.1) and Janajati (36.8%) ethnical group of Nepal (Table.1). Subclinical hypothyroidism with TSH ≥4 mIU/ml) in 1st trimester of pregnancy was higher among Janajati(47.6%) and Chhetris& Brahmins (33.3%) ethnic group; residing in Chitwan district of Province 3 (66.6%) and with higher BMI ≥24(71.4%). SCH in 1st trimester with TSH ≥2.5mIU/ml was commonly observed in Chhetri& Brahmins (41%), Janajati (37.5%); residence of Chitwan (67.8%) and with higher BMI ≥24 (59%).

Table 2. Types of Abortion in past pregnancy in euthyroid and subclinical hypothyroidism group according to SEGO.

Type of Abortion in past pregnancy	SCH (SEGO) (n = 56)	Euthyroid (n = 87)	SCH (ATA) (n = 21)	Euthyroid (n = 122)
Spontaneous	5(8.9%)	5(5.74%)	2(9.5%)	8(6.5%)
Missed	8(14.2%)	4(4.59%)	3(14.2%)	9(7.3%)
Threatened	4(7.14%)	2(2.29%)	2(9.5%)	4(3.2%)
Total	17(30.2%)	11(12.6%)	7(33.2%)	21(17%)

Thirty three percentages of women had abortion in past.(Table 2) with SCH (TSH≥4 mIU/ml) and 17% euthyroid group. Thirty percent of SCH (TSH≥2.5mIU/ml) had past history of abortion which is higher compared to euthyroid group i.e.12.6% (Table 2). Women with SCH with TSH≥4 mIU/ml had statistical significant (p-value <0.005) past history of abortion.

Table 3. Frequency of Anti -TPO status in SCH (ATA & SEGO)

Anti-TPO test	SCH(ATA,n=21)	SCH(SEGO,n=56)
Positive	10(47.6%)	24(42.8%)
Negative	11(52.38%)	32(57.1%)

Among the women with SCH, anti TPO test was positive in 47.6% with TSH ≥4mIU/ml and 42.8% with TSH ≥2.5mIU/ml.(Table 3)

SCH group with TSH ≥4 mIU/ml. Higher BMI, in 1st trimester of pregnancy had statistically significant adverse pregnancy outcome (p- value <0.05) in terms of abortion

DISCUSSION

Early detection of subclinical hypothyroidism and offering levothyroxine treatment can prevent adverse feto-maternal outcome. It is only possible in early 1st trimester or in women planning pregnancy by performing screening test due to lack of symptoms.[22] Universal screening is likely a necessity in Nepal where SCH prevalence is high[23], iodine deficiency is proven [5] and adverse outcome is common if not treated timely in early time of 1st trimester. Universal screening was found to be greatly cost-effective compared with selective screening in a recent cost analysis

Table 4. Distribution of frequency of ATA and SEGO TSH values in 1st trimester complications

Abortion	SCH (≥4mIU/ml) (n=21)	Euthyroid population(n=122)	SCH(TSH≥2.5mIU/ml(n=56)	Euthyroid population(n=87)	Total
Spontaneous	0(0%)	2(1.6%)	1(1.78%)	1(1.14%)	4(4.52%)
Missed	3((14.2%)	1(0.81%)	3(5.35%)	1(1.14%)	8(21.5%)
Threatened	3(14.2%)	7(5.73%)	6(10.7%)	4(7.14%)	20(37.7%)
	(P-value: <0.05)				

The present pregnancy was highly complicated with various type of abortion in both group of SCH in comparison to euthyroid group (Table 4). The complication (various type of abortion) was statistically significant (p value <0.05) among the

and meets most of the general criteria that justify screening for a disease.[22]High prevalence of SCH is documented by various studies of Nepal by Shrestha B[6] et al, Khakurel G[23] *et al* Upadhaya TL [7] *et al,* ie., 25.2% (TSH ≥2.5mIu/

ml), 19%(TSH≥4mIU/ml), 31%(TSH≥2.5mIU/ml) respectively. Iodine deficiency and different cut off value of TSH might be reasons for high prevalence in our country. It is similar to our study SCH(TSH≥4mIU) prevalence is 13.7% and SCH(TSH≥2.5mIU/ml) is 35% in contrast to studies by Dhanwal et al (4.3%)[24], Sannaboraiah S[25] et al(9.5%). Our study population had maximum Multigravida in both SCH group, higher maternal age (26-35 years), high BMI (≥24) similar to study by Sannaboraiah[25] et al and Knudsen et al.[26] A positive association was proven between serum TSH and BMI (p=0.003), proving SCH associated with Obesity and overweight. Increase in prevalence of SCH in older age and high BMI women might be due to late child bearing & multiparity. Anemia in pregnancy (22%) was positively correlated with serum TSH (p=0.020) in our study, and the result was similar to the study by Sannaboriah[25] et al.(31.5%0 and Akter[27] et al(17.2%). Complication in past pregnancy (SCH ≥4mIU/ml, p=0.005) and present pregnancy (miscarriage in 1st trimester) was statistically significant in both group of SCH (p=0.002 for ATA, and p=0.000for SEGO) in our study. Abortion (4.35%) was reported as 1st trimester complication in a study by Thammaiah J.[28] in 400 study population. Maximum SCH group women were found to be anti-TPO Ab positive status (42-47%). There is statistical significance of TPO positive status in SCH with TSH ≥2.5mIU/ml (p=0.000). Higher 1st trimester abortion might be the reason for high anti TPO positive status. The study by Moleti[29] et al observed positive evidence of miscarriage in TPO positive status women, similar to our study. Anti thyroid association has changed its 1st trimester range for thyroid screening of 2011 as upper limit from 2.5mIU/L to 4.0mU/L where trimester specific reference value was lacking. In our study, the mean TSH value was 2.5mIU/ml, prevalence of SCH was also high, high frequency of TPO positive status, significant past and present pregnancy complications and area of low iodine uptake. So, our population might benefit with universal screening of each pregnant women with TSH. The upper limit of TSH might suite 2.5mIU/ml, so that maximum cases were included in further work up and proper diagnosis as well as evaluation of anti-TPO test is must.

CONCLUSIONS

Subclinical hypothyroidism is highly prevalent in population visiting our hospital, so a universal screening with TSH estimation will be cost worthy in our area to intervene early before feto/maternal complications.

ACKNOWLEDGEMENTS

We are thankful to all women enrolled in our study and central laboratory of COMS for timely co-operation

Limitation of the study:

This is a hospital based study and the results may not be generalized to population.

Conflicts of Interests: None.

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Citation: Shrestha S, Shrestha BK, Baniya P, Kayastha B, Lamsal S. Universal Screening for Hypothyroidism in 1st Trimester of Pregnancy: Where are We for Subclinical Hypothyroidism?. JCMS Nepal. 2022; 18(4); 432-439.