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Original Research Article

A study of foetomaternal outcome among pregnant hypothyroid women

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ABSTRACT

Background: During pregnancy one of the most common endocrinological disorder which are very often overlooked during pregnancy because of their nonspecific symptoms and the hypermetabloic state of pregnancy is Thyroid disorder. Optimal maternal thyroid function during pregnancy is important for both the mother and fetus.

Objectives: The study was planned to determine the prevalence of hypothyroidism using the classical reference range of normal serum TSH as 0.4-6.2μIU/L. It also aimed to study the foetomaternal outcome among pregnant hypothyroid women, using the classical reference range and a lower cut off (<3μIU/L) of TSH for diagnosing hypothyroidism in pregnancy.

Materials and Methods: This was a longitudinal prospective study conducted in the Department of Obstetrics & Gynaecology, Suryanagari Hospital, in collaboration with the Departments of Endocrinology, Laboratory Medicine & Paediatrics. Before starting the study, clearance was taken from ethical committee of the hospital. A total of 522 pregnant women attending the antenatal OPD were recruited to determine the prevalence of hypothyroidism on the basis of TSH evaluation.

Conclusions: With our study we concluded that these very high prevalence of hypothyroidism in India and routine maternal thyroid function testing must be done as soon as pregnancy is confirmed thus saving lives of many infants who could lead rest of their lives happily and prosperously.

1. Introduction

During pregnancy one of the most common endocrinological disorder is Thyroid which is mostly overlooked because of it's hypermetabloic state and nonspecific symptoms of pregnancy. The condition of hypothyroidism affects both maternal and fetal outcome.[1] The overall prevalence of hypothyroidism varies from 0.3-11.1 percent with subclinical hypothyroidism (SCH) being more commoner than overt hypothyroidism (OH). Women with overt hypothyroidism are at increased risk for pregnancy complications such as early pregnancy failure, preeclampsia, placental abruption, low birth weight and still birth.[2–4]

The profound physiological changes of pregnancy significantly affect interpretation of thyroid function. Consequently thyroid function test results of healthy pregnant women differ from those of healthy non pregnant women. As such, the definition of what comprises a normal TSH during pregnancy has been changing. Although serum TSH values of 4.0-6.0 micro IU/ml were considered normal in the past, recent opinions suggest that first trimester values >2.5 micro IU/ml and second and third trimester values >3 micro IU /ml are outside the normal range. There is increasing evidence that by using the classical non pregnant reference range, one might misdiagnose as "normal" for

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those women, who already have a slight TSH elevation. This is reflected in the latest American Thyroid Association Guidelines (ATA Guidelines), which recommend that TSH upper cut off value for pregnant women & for women on L-thyroxine therapy should be <2.5 micro U/ml in first trimester and <3.0 micro IU/ml in second and third trimester.

2. Materials and Methods

A longitudinal prospective study was conducted in the Department of Obstetrics and Gynecology at Suryanagri hospital in collaboration with Department of Endocrinology, Laboratory Medicine & Pediatrics. Ethical approval was taken from the committee before commencing of this study.

2.1. Case selection

A total of 522 pregnant women were selected for the study who attended the antenatal OPD.

2.2. Inclusion criteria

All healthy pregnant women with singleton pregnancy willing to participate in the study.

2.3. Exclusion criteria

Women with known chronic medical disorder, hypothyroidism, bad obstetric history and with multiple pregnancy were excluded for the study.

2.4. Statistical methods

2.4.1. For estimation of prevalence (Objective 1)

Estimation of prevalence of hypothyroidism was based on serum TSH levels >6.2 micro IU/L or evidence of pre-existing hypothyroidism.

2.4.2. For study of foetomaternal outcomes (Objective 2 & 3)

Out of 522 women, all those who fulfilled the inclusion and exclusion criteria and we're planning to deliver at SAIM Hospital were enrolled for evaluation of foetomaternal outcome.

2.5. Evaluation criteria

On the basis of serum TSH level the women were categorized as follows:

Group A: Serum TSH level >6.2ulU/ml (labeled as hypothyroid according to classical reference range for normal TSH).

Group B: Serum TSH level between 3 – 6.2μIU/ml

Group C: Serum TSH level between 0.4-3μIU/ml (labeled as euthyroid)

Women from groups A, B and C were further subdivided into study and control group.

1. **Study group:** Women in group A and B constituted the study group
2. **Control group:** Equal number of age & parity matched women for group A and B constituted the control groups, these were labeled as C1 and C2 respectively.

Serum FT4 was done in all the women with serum TSH>3 micro IU /L. On the basis of FT4 levels women in group A were categorized as subclinically and overt hypothyroidism.

All the women with serum TSH > 6.2 micro IU / ml were referred to endocrinologist for simultaneous treatment and follow up. Foetomaternal outcomes were compared between groups A & CI between B and C2.

3. Observation & Results

A total of 522 cases were studied and observed.

Out of 522 cases, a total of 52 women had TSH >6.2 micro IU/L, giving a prevalence of hypothyroidism as 10.08 percent on the basis of FT4 estimation in these 52 women, 19 were overtly hypothyroid while 33 were subclinically hypothyroid. Thus, the prevalence of overtly hypothyroidism was 1.92 percent while subclinical hypothyroid it was 3.32 percent. It was observed that 17 hypothyroid women, who were already on the treatment with 2 thyroxine therapy were excluded from the study. The remaining 35 women with TSH > 6.2 micro IU /L were placed in study group A.

In group B, there were 33 women with serum TSH ranges between 3-6.2 micro IU /L available for study. Equal number of age and parity matched controls were taken for group A and B treated as Group C1 consist of 35 women and Group C2 consists of 33 women respectively.

TPO positivity was detected in 10 (28.6%) women of group A while 3 (8.6%). Women of group C1 and that were confirmed statistically significant ($p<0.03$) reflected that thyroid peroxidase antibody positivity may be influenced upto some extent the type of samples whether study subject or control. In the group A, 11.4% of overtly hypothyroid and 17.1% of subclinical hypothyroid women were identified positive for thyroid peroxidase antibody.

3.1. The observations of studies are as followed respectively

The prevalence of hypothyroidism amongst antenatal population was 10.08% (52 out of 522), using the classical reference range for normal TSH as 0.4-6.2μIU/L.; however, if a lower threshold of TSH (3.0 IU/L) was used, an additional 6.3% (33 out of 522) women would have been classified as hypothyroid. Overt hypothyroidism was found in 1.92% (10 out of 522) women and sub-clinical

Table 1: The demographic profile of Group A and C1

Age (Years)	Group A (N=35)		Group CI (N=35)	
	N	%	N	%
<20	3	8.6	3	8.6
21-25	14	40.06	13	37.1
26-30	13	37.1	13	37.1
>30	5	14.3	6	17.1
Parity				
Primigravida	12	34.3	12	34.3
Multigravida	23	65.7	23	65.7
Education				
Illiterate	20	57.1	21	60.0
Primary	7	20.0	7	20.0
Middle	7	20.0	6	17.1
Graduate	1	2.9	1	2.9
Socioeconomic status				
Lower	3	8.6	3	8.6
Upper lower	19	54.3	21	60.0
Lower middle	8	22.9	7	20.0
Upper middle	3	8.6	2	5.7
Upper	2	5.7	2	5.7
Occupation				
House wife	28	80.0	29	82.9
Self employed	3	8.6	2	5.7
Professional	4	11.4	4	11.4

Table 2: The demographic profile of Group B and C2

Age (Years)	Group B (N=35)		Group CI (N=35)	
	N	%	N	%
<20	2	6.1	2	6.1
21-25	23	69.7	23	69.7
26-30	6	18.2	6	18 2
>30	2	6.1	2	6.1
Parity				
Primigravida	17	51.5	17	51.5
Multigravida	16	48.5	16	48.5
Education				
Illiterate	17	51.5	15	45.5
Primary	7	21.2	9	27.3
Middle	7	21.2	6	18.2
Graduate	2	6.1	3	9.1
Socioeconomic status				
Lower	2	6.1	4	12.1
Upper lower	15	45.5	17	51.5
Lower middle	8	24.2	8	24.2
Upper middle	6	18.2	2	6.1
Upper	2	6.1	2	6.1
Occupation				
House wife	28	84.8	29	87.9
Self employed	3	3.0	1	3.0
Professional	4	12.1	3	9.1

Table 3: Distribution of women according to BMI in group A and C1

BMI (Kg/M.sq)	Group A (N=35)		Group CI (N=35)	
	N	%	N	%
<18.5	0	0.0	0	**0 .**0
18.5-24.9	20	57.1	17	48.6
25.0-29.9	10	28.6	11	31.4
>30	5	14.3	7	20.0

Table 4: Distribution of women according to BMI in group B and C2

BMI (Kg/M.sq)	Group A (N=35)		Group CI (N=35)	
	N	%	N	%
<18.5	0	0.0	0	**0 .**0
18.5-24.9	21	63.6	19	57.6
25.0-29.9	6	18.2	7	21.2
>30	6	18.2	7	21.2

Table 5: Distribution of women according to pretreatment TSH level

Pretreatment serum TSH	Group A (N=35)	
	N	%
6-10	33	94.3
>10	2	5.7

Table 6: -Comparison of maternal variables in Group A and C1

Maternal Variables	Group A	(N=35)	Group (N=35)	C1	LOS
	Present	%	Present	%	
Anemia	26	74.3	25	71.4	p>0.05
Spontaneous abortion	1	2.9	1	2.9	p>0.05
Hypertensive	Disorder				
GHTN	2	5.7	1	2.9	p>0.05
PE	6	17.1	1	2.9	P<0.05
GDM	7	20.0	1	2.9	P<0.03
Placental abortion	0	0	0	0	-

Table 7: Distribution of women according to mode of delivery in Group A and C1

Mode of delivery	Group A	(N=35)	Group C1		LOS
	Present	%	Present	%	
Vaginal Delivery	27	77.1	29	82.9	P>0.05
LSCS FOR FD	5	14.3	2	5.7	p >0.5
LSCS for other causes	3	8.6	4	11.4	P>0.05

Table 8: Comparison of variables in Group A and C1

Mode of delivery	Group A	(N=35)	Group C1		LOS
	Present	%	Present	%	
Prematurity	3	8.6	2	5.7	P>0.05
IUGR	5	14.3	3	8.6	p >0.5
IUFD	2	5.7	1	2.9	P>0.05
Fetal Distress	10	28.6	3	8.6	P<0.3
Low APGAR at 5 minutes	3	8.6	2	5.7	P>0.05
NICU Admission	6	17.1	2	5.7	P>0.05
Neonatal Hypothyroidism	-	-	-	-	-

hypothyroidism was observed in 3.32% (17 out of 522) women.

3.2. Foetomaternal outcomes in group A and C1

The mean age of the women in groups A was 26.43-4.45 years while for control C1, was 26.60±4.51 years. More than one third (34.3%) of the women in both the groups were primigravida while approximately two third (65.7%) were multigravida It was seen that major part of selected population of pregnant women in group A (57.1%) and in group C1 (60.0%) were illiterate. Most of the women in group A (54.3%) and C1 (60.0%) belonged to upper lower class while 28 (80.0%) and 29 (82.9%) were housewives respectively. The mean body mass index (BMI) of the women in group A and CI was observed to be 25.90±4.14 and 26.50+4.38 kg/m^2 respectively. In group A and Cl the mean gestational age at presentation to the hospital was 23.02±7.38 and 22.01±6.69 weeks respectively.

The pretreatment serum TSH level was between 6-10 IU/L in 33 (94.3%) women, and >10uIU/L in 2 (5.7%) women, measured for group A. Preeclampsia developed in 6 (17.1%) and 1 (2.9%) women in group A and C1 respectively and the difference was confirmed statistically significant (p<0.05). Gestation Diabetes Mellitus was found associated with subjects whether study subject or control and the association was significant (p<0.03) concreted statistically which was present in 7 (20,0%) and 1 (2.9%) women in group A and C1 respectively. Amongst the other maternal variables assessed, the difference between the two groups was not statistically significant. Major part of the women (77.1%) in group A and 82.9% women in group CI delivered vaginally. LSCS for foetal distress was done in 5 (14.3%) women in group A and 2 (5.7%) women in group C1 and the difference was confirmed statistically insignificant (p>0.05). Foetal distress was observed in 10 (28.6%) women in group A; this was significantly higher as compared to group C1, i.e. 8.6%. The difference between prevalence was observed statistically significant (p <0.03). None of the other foetal variables were significantly different in both the groups.

3.3. Foetomaternal outcome in subclinically hypothyroid and overtly hypothyroid women in comparison to controls

PE and GDM was developed in significantly higher number of OH women as compared to controls with p 0.009 and p-0.002 respectively. Amongst all the maternal variables assessed in SCH group none was significantly different. Intrauterine foetal demise occurred in none of the women in OH group, (8.0%) in SCH group and 1 (2.9%) in euthyroid group; the difference between OH and euthymid control group was statistically insignificant. While foetal distress between OH and control group was poorly significant (p<0.05) but between SCH and control group it was significant. Amongst all the other foetal variables assessed between SCH, OH and control groups, none was statistically significant. None of the neonates in either of the groups had neonatal hypothyroidism. Majority of women in OH (9,900), SCH (18, 72.0%) and euthyroid (29, 82.9%), group delivered vaginally with insignificant associations (p>0.05) respectively.

No significant difference was found between OH SCH and Euthyroid controls for the rate of LSCS performed. The pre-delivery serum TSH level was adequately controlled in 10(28.6%) women who had < 3 U/L, while 25 (71.4%) women were inadequately controlled had serum TSH level>3 ut/L. Amongst all the maternal variables assessed, LSCS for fetal distress was done in a significantly higher number of women with serum TSH >3μIU/L, as compared to women with serum TSH >3μIU/L, (p=0.026). None of the other variables were significantly different in the two groups. None of the fetal variable was found significant between the group of women with serum TSH <3μIU/L and serum TSH>3μU/L (p>0.05).

3.4. Foetomaternal outcome in groups B and C2

The mean age of the women in group B was 24.39±4.47 years while for control C2, was 24.27+4.54 years. In group B and C2, 17 (51.5%) of the women were primigravida while rest of the 16 (48.5%) were multigravida. Major part of selected population of pregnant women in group B (51.5%) and in group C2 (45.5%) were illiterate. Most of the women in group B (45.5%) and C2 (51.5%) belonged to upper lower class while 28 (84.8%) and 29 (87.9%) were housewives respectively.

Majority (63.6%) of the women in group B and most (57.6%) of the women in group C2 had normal BMI. Mean gestational age at presentation to the hospital was 22.16+8, 46 years and 22.949. 3 years in group B and C2 respectively. Among all the maternal variables assessed, none was significantly different between group B and control group (CI). Majority of women in both the groups delivered vaginally. Equal number of women in both the groups had LSCS for fetal distress. Among all the foetal variables assessed in women in group B & C2, none was significantly different.

4. Discussion

Thyroid disorders are the second most common disorder found in pregnancy. The present study was aimed to determine the prevalence of hypothyroidism in 522 pregnant women attending the antenatal OPD using the classical reference range for normal serum TSH (0.4 – 6.2 micro IU/L).

It also aimed to evaluate Foetomaternal outcome among pregnant hypothyroidism women using the classical

reference range for TSH and in women with TSH level of 3-6.2 micro IU /L.

The overall prevalence of hypothyroidism observed in the present study was 10.08% with SCH and OH being present in 3.32% & 1.92% women respectively, Our observations are similar to those of an Indian study by Sahu et al who reported a prevalence of SCH and OH as 6.47% & 4.38% respectively. Both these studies were conducted in tertiary care hospitals, which are important referral centres; hence they get a large number of referral cases even from neighbouring states. The observed prevalence is relatively higher than that reported from United States Of America (USA), United Kingdom (UK), Netherland and Finland Studies from USA have reported the overall incidence of hypothyroidism between 2.2% 2.5% with an incidence of SCH and OH ranging from 2.2% -2.3% and 0.2% -0.3% respectively. The observed overall incidence of hypothyroidism from UK was also lower at 2.6%, with SCH and OH being 1.6% and 1% respectively. Studies from Finland and Netherland have also yielded lower rates of hypothyroidism.[5] All these studies vary in their definition of hypothyroidism and sample size. Besides, there are differences in the iodine intake of the population screened. Prevalence of both SCH & OH is likely to be higher in iodine deficiency regions. The USA, UK and Finland are a relatively iodine sufficient countries; there is adequate iodine supplementation and even pregnant population has sufficient iodine intake. On the other hand, the situation of Indian pregnant women is different. Although Marwaha et al. have reported that India has become iodine sufficient after two decades of salt iodinisation, there is no normative data for thyroid 11 function for healthy pregnant women of this country. In a recent review of nine studies on the assessment of iodine nutrition of pregnant women in India, Yadav et al identified significant iodine deficiency among pregnant Indian women. According to the review, the household level of adequately iodised salt consumption in pregnant women ranged from 59.5% to 95%. However, even a 95% household level coverage of adequately iodised salt may not lead to iodine sufficiency in pregnant women. This is because the current salt lodisation Guidelines (15ppm of iodine at consumer level) is designed to deliver only 150μg/L of iodine per day, whereas the dietary requirements of pregnant women are much greater (250μg/day). The current available data in India shows that pregnant women in India are iodine deficient as per the World Health Organization/United Nations International Children's Emergency Fund criterion. This is probably the reason for the high prevalence of 35 hypothyroidism observed by Sahu et al. and the present study.[6]

Pregnancy is a period which afflicts great physiological stress on both the mother and the fetus but if pregnancy is compounded by endocrine disorders such as hypothyroidism, the potential for maternal and fetal adverse outcomes can be immense.[7] Uncorrected thyroid dysfunction in pregnancy increases the incidences of miscarriages, low birth weight, fetal death and still birth.[8] Early diagnosis and prompt treatment of hypothyroidism is very essential for both mother and fetus.

5. Conclusions

We concluded that our longitudinal prospective study shows there is significant association between hypothyroidism and Foetomaternal outcomes. With very high prevalence of hypothyroidism in India, we would like to state the fact that routine maternal thyroid function testing must be conducted as soon as pregnancy is confirmed thus saving lives of many infants who could lead their lives happily and prosperously forever.

6. Source of Funding

None.

7. Conflict of Interest

None.

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