Original Article

Early treatment will prevent feto-maternal complications in thyroid disorders during pregnancy: A prospective study

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Abstract

Context: Associations between adverse maternal complications and fetal outcomes are known entity in thyroid disorders during pregnancy. Thus, prompt identification of thyroid disorders and timely initiation of treatment is essential. Universal screening and early treatment of pregnant women for thyroid disorder should be considered especially in a resource-limited country like India with a high prevalence of undiagnosed thyroid disorders and adverse feto-maternal outcomes. **Aims:** Early treatment will prevent feto-maternal complications in thyroid disorders in pregnant females visiting outpatient department in tertiary care hospital in rural settings. **Settings and Design:** This study was conducted in a tertiary care rural-based medical college with participation from departments of Obstetrics and Gynaecology, Medicine, and ENT. **Methods and Material:** Expectant mothers in first trimester who had urine pregnancy test positive in outpatient clinic were included after a written informed consent. Detailed history and examination was done. TSH was done if abnormal—FT3 and FT4 were done. All thyroid disorders were treated according to American Thyroid Association (ATA) 2017 guideline. All pregnancies were followed up for maternal complications and fetal outcomes. **Statistical Analysis Used:** Data from the performa were entered in Office Excel and analysis was performed using STATA (14.2). Descriptive statistics (mean [standard deviation], Frequency [%], etc.) were used to depict profile of study participants, prevalence of thyroid dysfunction, and outcome measures. Chi-square test was employed to assess the association between thyroid dysfunction and various maternal and fetal outcomes. A *P* value less than. 05 was considered statistically significant. **Results:** Of 350 pregnant females, 83 (23.5%) pregnant females had thyroid disorder. Of which, 33 (9.4%) had subclinical hypothyroidism, 37 (10.5%) had overt hypothyroidism, 11 (3.1%) had subclinical hyperthyroidism, and two (0.5%) had hyperthyroidism. The prevalence of hypothyroidism in pregnancy increases with increasing age (*P* value. 001) and not associated with parity, abortion, and consumption of iodized salt. Total patients with feto-maternal outcome follow-up were 241. Pre-eclampsia (*P* value. 004) was a significant complication in hypothyroid mothers. There was no significant difference in the rate of cesarean section and preterm delivery in hypothyroid and euthyroid mothers. Neonatal outcomes showed more trends of abortion, fetal demise, and IUFD in the hypothyroid group, although not statistically significant. (*P* value. 07). **Conclusions:** Due to the high prevalence of thyroid disorders during pregnancy, universal screening of thyroid disorders should be done in early pregnancy instead of high-risk screening. Early detection and early treatment in the first 10 weeks of pregnancy help to prevent maternal and fetal complications of thyroid disorders in pregnancy. Pre-eclampsia is to be monitored in treated pregnant females with hypothyroidism.

Keywords: Early treatment of thyroid disorders in pregnancy, fetal and maternal outcomes, thyroid disorders in pregnancy

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Introduction

Evaluation of thyroid disease in pregnancy is important for gestational maternal health, obstetric outcome, and subsequent development of the child. Pregnancy has a profound impact on the thyroid gland and its function. During pregnancy, the thyroid gland increases in size by 10% in iodine replete countries but by 20% to 40% in areas of iodine deficiency.[1] There is a wide geographic variation in the prevalence of thyroid disorders during pregnancy. Thyroid dysfunction affects up to 5%-7% of all pregnancies. Hypothyroidism in pregnant women is common with a prevalence of about 2%-3%, and the prevalence of undiagnosed subclinical hypothyroidism in pregnancy is 3%-15%. Hyperthyroidism during pregnancy occurs in 0.4%-1.7% of pregnant women.[2] Overt hypothyroidism varies from 2.5% in the West to 11%-31.6% from India.[3-8] In India, many studies have identified a high undetected prevalence of thyroid disorders in pregnancy and various adverse feto-maternal outcomes.[3,4,6,7]In most studies, identification and treatment of thyroid disorders are usually done in the second trimester of pregnancy. The present study was carried out to study the prevalence of undetected thyroid dysfunction during the first trimester of pregnancy and to start early treatment within 10 weeks of gestation and follow-up for feto-maternal outcomes, whether with early timely treatment has any effect on outcomes.

Subjects and Methods

The prospective observational study was conducted at a rural-based tertiary care center and medical college from November 2017 to August 2018. Approval from the institutional ethics committee was obtained. Expectant mothers in first trimester who had a Urine Pregnancy Test Positive were included after written informed consent. Those females with a past history of thyroid disorders were excluded. Detailed history and examination were taken with special regard to age, parity, history of abortion, consumption of iodized salt, and clinical features of thyroid disorders. For participants with frank goitre or thyroid nodules, an ENT opinion was taken. A screening TSH was done if abnormal—FT3 and FT4 were done. All thyroid disorders were treated according to ATA 2017 guidelines within first 10 weeks of pregnancy.[1]

All pregnancies were followed up for maternal complications like anemia (hemoglobin level less than 10 g/dL), pre-eclampsia (blood pressure more than 140/90 with proteinuria after 20 weeks gestation), gestational hypertension (blood pressure more than 140/90 without proteinuria after 20 weeks gestation), oligohydramnios (amniotic fluid index ≤5), preterm delivery (delivery before completion of 37 weeks of gestation), abortion (delivery before 20 weeks of pregnancy), postpartum hemorrhage, and increased rate of cesarean section. Fetal outcomes include Low Birth Weight (LBW) (weight at birth less than 2.5 kg), Intrauterine fetal demise (IUFD), increased Neonatal Intensive Care Unit (NICU) admission, and any fetal anomaly.

S. TSH assay was performed with Flash Chemiluminescence Immunoassay method done by Centaur XP machine by Siemens and the reference value for TSH was 0.35-5.5 mIU/L and cut-off used for pregnant females was 4.0 mIU/L. The laboratory reference value for Free T3 was 3.542 to 6.468 pmol/L and for Free T4 was 11.5 to 22.7 pmol/L. Accordingly, they were further classified into Subclinical Hypothyroidism: Raised TSH with Normal Free T3, T4, Overt Hypothyroidism: Raised TSH with Low free T3, T4 values, Subclinical Hyperthyroidism: Suppressed TSH with Normal Free T3, T4 Values, and Hyperthyroidism: Suppressed TSH with Raised Free T3, T4 Values.

Data from the performa were entered in Office Excel and analysis was done using STATA (14.2). Descriptive statistics [mean (standard deviation, SD), frequency (%)] were used to display the profile of study participants and the prevalence of thyroid dysfunction. Chi-square test/Fisher's exact test was done to assess the association between thyroid dysfunction and various factors.

Observation and Results

The study was conducted at a tertiary care institute in the rural area of Anand district, central Gujarat. It is representative of the mix of the urban plus rural population.

A total of 392 expectant mothers visited the outpatient department in the first trimester. Of them, 37 never came back with blood work and other reports, whereas five denied any test and insisted on consultation only. Thus, basic test reports were available for 350 expectant mothers. The mean (SD) [median (Q1, Q3)] age of the participants was 26.86 (4.80) [27 (23, 30)] years. The mean (SD) [median (Q1, Q3)] weight of the participants was 60.66 (8.67) [59 (55, 66)] kilograms. Most participants conceived for the first time [243 (69.4%)] [Table 1]. Only 15 (4.3%) participants presented with signs of hypothyroidism, whereas only one participant showed signs of hyperthyroidism. No one reported a family history of hypothyroidism/hyperthyroidism. Almost all participants [342 (97.7%)] reported using iodized salt. Only two participants had mild hypertension.

Most of the participants had normal thyroid function 267 (76.3%), whereas overall prevalence of thyroid disorder during first trimester of pregnancy was found to be 22.7% (83 females). Of these 83 females, 33 (9.4%) had subclinical hypothyroidism, 37 (10.6%) had overt hypothyroidism, 11 (3.1%) had subclinical hyperthyroidism, and two (0.5%) females were found to have overt hyperthyroidism [Table 2].

Hypothyroidism was significantly greater in older age as compared to younger age ($P < .001$), but parity, history of abortion, or anemia status of mother were not significantly different in the hypothyroid and euthyroid group [Table 3].

Only 13 (4.4%) participants had hyperthyroidism (subclinical + overt) and they were excluded from the analysis of the association of thyroid dysfunction with maternal and fetal outcomes due to small numbers. As per tradition, many participants went to

their parent's place for delivery. Some outcome measures could be assessed in 241 participants. These 241 participants were included in further analysis.

The maturity (P = .59) and mode of delivery (P = .75) were similar between participants with hypothyroidism as compared to euthyroid participants. The admission to neonatal intensive care unit [7 (3.61%) vs. 2 (5.13%), P = .65] was similar across groups. Fetal demise/abortion or IUFD [20 (10.31%) vs. 8 (20.51%), P = .10] trend was higher in the hypothyroid group, although not significant. Only one participant from the euthyroid group had a fetal anomaly. Incidence of low birth weight was similar [44 (25.58%) vs. 9 (26.47%), P = .91] across groups. Although the maternal and fetal outcome indicators at a broader level were similar across groups, pre-eclampsia [5 (12.82%) vs. 5 (2.58%), P = .01] was significantly greater in participants with hypothyroidism [Table 4]. Mean (SD) birth weight of the babies was also similar across these groups [2.54 (0.65) vs. 2.71 (0.57) Kg, P = .13].

Table 1: Profile of study participants (*n*=350)

Characteristic	Frequency (%)
Religion	
Hindu	313 (89.43)
Muslim	15 (4.29)
Christian	22 (6.29)
Gravida	
1	243 (69.43)
2	60 (17.14)
3	32 (9.14)
4 or more	15 (4.29)
	Mean (SD) [Median (Q1, Q3)]
Age	26.86 (4.80) [27 (23, 30)]
Weight	60.66 (8.67) [59 (55, 66)]

Table 2: Thyroid dysfunction in the first trimester (*n*=350)

Type	Frequency (%)
Euthyroid	267 (76.3)
Subclinical Hypothyroidism	33 (9.4)
Overt Hypothyroidism	37 (10.6)
Subclinical Hyperthyroidism	11 (3.1)
Hyperthyroidism	2 (0.5)

Table 3: Association between thyroid dysfunction and maternal variables

	Thyroid dysfunction, *n* (%)		*P*
	No	Yes	
Age Groups			
15-25	124 (46.44)	28 (33.73)	<0.001
26-34	133 (49.81)	42 (50.60)	
35 and more	10 (3.75)	13 (15.66)	
Parity			
Primigravida	189 (70.79)	54 (65.06)	0.32
Multigravida	78 (29.21)	29 (34.94)	
History of Abortion			
No	234 (87.64)	69 (83.13)	0.29
Yes	33 (12.36)	14 (16.87)	
Anemia			
No/Mild	185 (69.29)	51 (61.45)	0.18
Moderate/Severe	82 (30.71)	32 (38.55)	

Discussion

Thyroid disorders are one of the most common endocrine disorders in women during pregnancy and are associated with adverse maternal and perinatal outcomes. Universal screening at the first antenatal visit helps in detecting thyroid dysfunction in pregnancy. Preferably preconceptional screening for thyroid dysfunction is ideal as any abnormal thyroid state can be corrected before attempting pregnancy. This clinical study to know the prevalence of thyroid dysfunction in pregnancy was conducted in the rural-based medical college of Anand, Gujarat during the time period from November 2017 to August 2018. During this period, 350 consecutive antenatal women attending OPD in the first trimester were evaluated for thyroid status and subjects with abnormal TSH were studied further with Free T3 and Free T4 levels. Fetal and maternal outcomes were studied in 241 pregnant mothers.

The overall prevalence of thyroid disorder during first trimester of pregnancy in this study was found to be 22.7% (83 females), which is significant. Of 83 patients suffering from a thyroid disorder, 33 (9.5%) were found to have subclinical hypothyroidism, 37 (10.6%) were found to have overt hypothyroidism, 11 (3.9%) were found to have subclinical hyperthyroidism, and two (0.5%) females were found to have hyperthyroidism. Being a tertiary care rural center, more high-risk patients may have come or were referred from the peripheral center, and micronutrient deficiencies may be an added factor for our study showing high prevalence of thyroid disorder (22.6%).

The prevalence of thyroid disorders in pregnancy varies in different regions and different studies. The overall prevalence of thyroid disorder in pregnancy in our study is 22.7% which is comparable to the study conducted by Rajput *et al.*[8] at PGIMS Rohtak, who studied the thyroid function of 461 pregnant females, which also showed a high prevalence of thyroid disorders 26.5% with anti-TPO was elevated in 30.4% and 4.7% subclinical/overt hypothyroidism women. A similar study was conducted in Ahmedabad, Gujarat by Dr. Kalpesh Kubavat *et al.*[6] in which 16.57% of females had a thyroid disorder, which supported the fact of the higher prevalence of thyroid disorders among the population of Gujarat and neighbouring states. In the same study, 56.5% patients with thyroid disorders were found anti-TPO antibody positive, which suggests emerging autoimmunity in this region. However, other side of Gujarat in the north prevalence seemed to be on the lower side total of 13%, but the study was on a low number of pts.[9]

In a study done by Rajput *et al.*,[8] attributable reasons for the higher prevalence of thyroid disorders, for both overt as well

Table 4: Association of hypothyroidism with maternal and neonatal outcomes

Outcome/Complications	Euthyroid	Subclinical Hypothyroidism	Overt Hypothyroidism	Subclinical Hyperthyroidism	*P**
Mode of delivery (*n*=206) [*n* (%)]					
Normal	78 (48.45)	12 (70.59)	8 (36.36)	2 (33.33)	0.75
LSCS	83 (51.55)	5 (29.41)	14 (63.64)	4 (66.67)	
Maturity (*n*=220) [*n* (%)]					
Full-term	130 (82.28)	9 (75)	16 (84.21)	6 (85.71)	0.59**
Pre-term	28 (17.72)	3 (25)	3 (15.79)	1 (14.29)	
Abortion	19 (10.7%)	2 (14.3%)	2 (9.5%)	1 (12.5%)	
Fetal demise/abortion or IUFD (*n*=241) [*n* (%)]					
Yes	20 (10.31)	3 (17.65)	5 (22.73)	1 (12.5)	0.10**
No	174 (89.69)	14 (82.35)	17 (77.27)	7 (87.5)	
Admission to NICU (*n*=241) [*n* (%)]					
Yes	7 (3.61)	1 (5.88)	1 (4.55)	0 (0)	0.65**
No	187 (96.39)	16 (94.12)	21 (95.45)	8 (100)	
Pre-eclampsia (*n*=241) [*n* (%)]					
Yes	5 (2.58)	3 (17.65)	2 (9.09)	1 (12.5)	0.01**
No	189 (97.42)	14 (82.35)	20 (90.91)	7 (87.5)	
Birth Weight (*n*=212) [*n* (%)]					
Normal	128 (74.42)	11 (78.57)	14 (70)	6 (100)	0.91
Low Birth Weight	44 (25.58)	3 (21.43)	6 (30)	0 (0)	

**P* value refers to a comparison between euthyroid vs. hypothyroid (overt + subclinical). **Fisher's exact test

as subclinical, possibly are increased intake of iodine-fortified salt leads to increased chances of autoimmunity, presence of goitrogens in diet, and micronutrient deficiency such as selenium or iron deficiency and being a tertiary center, more possibility of patients being referred belonging to the high-risk group. Trimester-specific cut-off values for S. TSH used was 0.1–2.5 mIU/L in the first trimester of pregnancy to diagnose hypothyroidism. Prevalence of thyroid disorder in pregnancy in our study is more despite the first trimester cut-off of TSH being 4 as per ATA 2017 guideline.[1]

As compared to other regions in India in which prevalence ranges from 11.6%-14.3%, it is more in northeast and sub Himalayan regions maximum being in Assam (R Saraladevi *et al.* 11.6%,[10] Ajmani, *et al.*[11] 13.25%, Sahu *et al.* 12.7%,[4] Dhanwal *et al.* 14.3%[12] and Saikia 30.79).[13] In neighboring countries like Nepal, the total prevalence of thyroid disorders is 24.62% with subclinical hypothyroidism at 19.75% and overt thypothyroidism 2.43%.[14] Present study was comparable for the prevalence of SCH to the studies conducted by Ajmani, *et al.*[11]

In India, the prevalence of hypothyroidism in pregnancy is much higher compared to Western countries. Overall, pooled prevalence of overt hypothyroidism in recent metanalysis by Vikas Yadav *et al.*[5] is 11% which is similar to our study, but varies widely among various states in India, as we still face iodine deficiency in many parts of the country but with iodine supplementation, the prevalence of thyroid disorders due to autoimmune etiology is increasing. The prevalence of overt hypothyroidism in pregnancy according to the studies conducted by Dr. Kalpesh Kubavat *et al.*[6] (7.43%) and Rao S *et al.*[15] (6.2%) which show similar results as seen in this study.

Although hyperthyroidism in pregnancy is uncommon, its effects on both the mother and child are critical. Pregnancy complicated by poorly controlled overt hyperthyroidism can be associated with increased rates of spontaneous abortion, premature labor, low birth weight, stillbirth, pre-eclampsia, and heart failure. In our study, the prevalence of hyperthyroid disorders is 4.55%. Study done by Dr. Kalpesh Kubavat *et al.*[6] in Ahmedabad, Gujarat showed hyperthyroidism in 3.43% patients, of which 1.43% patients had overt hyperthyroidism and 2.0% patients had subclinical hyperthyroidism which supports similar prevalence of hyperthyroid disorders as seen in this study.

In our study, there is no significant association between parity and prevalence of thyroid disorder during pregnancy which is comparable to other studies.[16]

Now it is fairly established that overt hypothyroidism leads to various maternal complications including pre-eclampsia, placental abruption, anemia, postpartum haemorrhage, pre-term births, and abortions. Fetal complications included low birth weight, pre-term birth, and higher chances of intensive care admission. Likewise adverse neurocognitive effect on the offsprings—the detrimental effects of maternal hypothyroidism, data from a large case-control study demonstrated a seven-point reduction in IQ among children born to untreated overtly hypothyroid women compared to euthyroid controls.[17] Findings also supported a delay in motor skill development, language development, and attention at 7-9 years of age. Separately, three small studies analyzing only TPOAb positivity appear to similarly show an effect on neurocognitive outcomes in the offsprings. The evidence for the treatment of subclinical hypothyroidism for the prevention of complications is less. Recent two metanalysis suggested PROM, placental abruption, IUGR, and neonatal

deaths were more common in subclinical hypothyroidism. Some risk of intellectual impairment was also associated with subclinical hypothyroidism and more with isolated hypothyroxemia.[18]

Maternal and fetal outcomes are studied in many Indian and international studies. The main maternal adverse outcomes are pre-eclampsia, pregnancy induced hypertension, and placental abruption and main fetal adverse outcomes were fetal demise, spontaneous abortions, low birth weight, NICU admissions, and IUGR.[3,5-7] All studies included pregnant females in the second trimester. In our study, main adverse outcome was pre-eclampsia, but surprisingly there were no significant preterm deliveries, or abortion or neonatal complications noted. The possible reason would be starting early detection and treatment in mothers with thyroid disorders within the first 10 weeks of pregnancy. Ours is a tertiary care referral center for complicated deliveries, thus overall maternal and fetal complication rate is higher even in euthyroid mothers.

Treatment of overt and subclinical hypothyroidism seems to be a prudent course of action. While a treated woman with subclinical hypothyroidism had less pregnancy loss[19] and a thyroid supplement started as early as 8 weeks had is shown to be safe and improves gestation progression.[20] But on the other side, there is mounting evidence of early treatment leading to complications like gestational diabetes and pre-eclampsia.[19] An Indian study found possible beneficial effects of thyroxine therapy started at 8 weeks of gestation in subclinical hypothyroidism but with increased risk of GDM.[21] Subclinical hypothyroidism in pregnancy is associated with an increased risk of developing hypertensive disease during pregnancy, and this association exists regardless of the gestational period, which may not improve with thyroxine supplement.[22]

Our study not only found a high prevalence of thyroids disorders especially hypothyroidism and subclinical hypothyroidism, but also had more frequent pre-eclampsia despite of early treatment. Thus, treated patients may have to be watched for the development of pregnancy-induced hypertension.

Also, in India despite the Indian Thyroid Society's recommendation of universal screening in for thyroid disorders by S.TSH in all pregnant women, government policy still remains high-risk screening.[23] Most notable impact of a universal screening mandate for thyroid dysfunction would be the identification of the large proportion of patients with subclinical hypothyroidism. Although hyperthyroidism in pregnancy is uncommon, its effects on both the mother and fetus are critical. Thus, universal screening of pregnant women for thyroid disorder should be considered especially in a country like India and especially the state of Gujarat. Universal screening of S.TSH should be considered to be a part of different Government schemes as well as routine screening of mothers coming for antenatal check-up at primary health centers. With mounting evidences, early levothyroxine treatment may be beneficial in hypothyroidism with careful follow-up for the development of hypertensive disorder of pregnancy.

Limitations

We did not screen expectant mothers for anti-TPO antibody levels. Larger number of participants should be studied to establish early treatment of hypothyroidism in pregnancy.

Conclusion

Due to high prevalence of maternal thyroid disorders during pregnancy, universal screening of thyroid disorders should be done in early within 10 weeks of pregnancy. Early treatment of hypothyroid expectant mothers will prevent most maternal and neonatal complications. Pre-eclampsia to be monitored in pregnancy with hypothyroidism even if treated early.

Ethical policy and Institutional Review board statement

This study is approved by Institutional Ethics Committee wide letter IEC/HMPCMCE/77/faculty/16/201/17.

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Conflicts of interest

There are no conflicts of interest.

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