International Journal of Pharmaceuticals and Health care Research (IJPHR)
IJPHR |Vol.12 | Issue 4 | Oct - Dec -2024
www.ijphr.com
DOI : https://doi.org/10.61096/ijphr.v12.iss4.2024.339-351
ISSN: 2306-6091

Research

Impact Of Patient Information Leaflet And Management Of Levothyroxine Among Pregnant Women With Hypothyroidism

N. Sahithi*[1], B. Sandeep[1], L. Harikiran[1]

[1]*Department Of Pharmacy Practice, Princeton College Of Pharmacy, Narapally, Ghatkesar, Telangana, India.*

*Author for Correspondence: N. Sahithi
Email: pcopaac2007@gmail.com

Published on: 12 Nov 2024

Published by:
DrSriram Publications

Abstract

Hypothyroidism an endocrine disorderis an underactive thyroid gland, which does not make enough thyroid hormone. Hypothyroidism during pregnancy can have irreversible effects on the fetus. Treatment of hypothyroidism during pregnancy is given with levothyroxine based on the assessment of thyroid functioning. The present study was aimed to counsel patients using patient information leaflet and management of levothyroxine in a tertiary care hospital. The main objectives are to develop a PIL, identify the application and its usefulness, and to understand the drug utilization evaluation in hypothyroid pregnant patients. A prospective observational study was carried out including 98 pregnant women with hypothyroidism during august 2019 to January 2020. A total of 98 patients were enrolled in the study, the percentage distribution of subjects age showed that the age group of 18-25 were predominant. Among them, 48 were in the first trimester. All the patients were counseled using PIL and appropriate feedback was collected. Management of levothyroxine was carried out from the level of TSH and dose of levothyroxine collected during follow up. Hence it can be concluded that patient information leaflets can show a great impact on patients by improving their condition and thus, a reduction in dose can be achieved.

Keywords: Hypothyroidism, levothyroxine, patient information leaflet (PIL), TSH.

INTRODUCTION

Gynaecology

It is the branch of medicine or it is a medical practice which deals with the health and the diseases linked to the female reproductive systems(vagina, uterus, and ovaries) and the breasts.

Pregnancy: Also known as gestation,is the time during which one or more offspring develops inside a woman.

Hypothyroidism: It is also called underactive thyroid, it is a disorder of the endocrine system in which the thyroid hormone doesn't produce enough thyroid hormone.

Hypothyroidism during pregnancy harms both mother and child. Children born to untreated or undertreated mothers have a profound effect on future intellectual development.[15]

If pregnancy has a set of endocrine disorders such as Hypothyroidism then the consequences for the adverse outcomes in the mother and the fetus can be very large. As Hypothyroidism is easily treated with the timely detection and the treatment outcome, it could reduce the adverse effects in the mother as well as in the fetus, which is commonly unplanned. Hypothyroidism is widely prevalent in pregnant women, especially in developing countries like India.

Pregnancy is a period that places great physiological stress on both the mother and the fetus in the best of times. If pregnancy is compounded by endocrine disorders such as hypothyroidism, the maternal and fetal adverse outcomes can be immense. Hypothyroidism is widely prevalent in pregnant women and the rate of detection, especially in a developing country like India, has not kept pace with the magnitude of the problem. Since hypothyroidism can be easily treated, timely detection and treatment of the disorder could reduce the burden of adverse fetal and maternal outcomes.[1]

Thyroid

The thyroid is a 2-inch long, butterfly-shaped endocrine gland weighing less than 1 ounce. Located in the front of the neck below the larynx, it has two lobes, one on each side of the windpipe. The thyroid gland makes two thyroid hormones, tri-iodothyronine (T3) and thyroxine (T4), these hormones act throughout the body, influencing metabolism, growth, and development, and body temperature. The production of thyroid hormones is regulated by thyroid-stimulating hormone (TSH), which is made by the pituitary gland in the brain.

Hypothyroidism

It is also called underactive thyroid, it is a disorder of the endocrine system in which the thyroid hormone doesn't produce enough thyroid hormone

Hypothyroidism

Hypothyroidism (Underactive thyroid or low thyroid) is a disorder of the endocrine system where the thyroid gland doesn't produce enough thyroid hormones.[24] It can cause several symptoms such as the poor ability to live with cold, tiredness, leading to weight gain, depression, and constipation. In the mother, hypothyroidism during pregnancy is associated with spontaneous abortion, placental abruption, preterm delivery, and hypertensive disorders. Therefore, screening and therapeutic intervention are justified to prevent fetal as well as maternal co-morbidities.[3]

Overt hypothyroidism: It occurs when TSH is increased and T4 levels are low. Overt hypothyroidism is defined as having a low free thyroxine level and an elevated thyroid-stimulating hormone (TSH) level

Subclinical hypothyroidism: A primary hypothyroidism in which there is an elevated TSH concentration in the presence of normal T4 and T3. Subclinical hypothyroidism is common in older people and its contribution to health and disease needs to be elucidated further.

Gestational hypothyroidism is more common than generally acknowledged. Testing is not common, and test selection is variable. There is a low rate of postpartum follow-up.[13]

Primary maternal hypothyroidism is defined as the presence of elevated Thyroid Stimulating Hormone (TSH) levels during pregnancy.[4] Proper maternal thyroid function during pregnancy is vital for the health of the mother as well as the developing child. It also plays a critical role in the neonatal and child neuro-development[10]

Overt Hypothyroidism: Overt (OH) or Subclinical (SCH). In overt hypothyroidism, S.TSH levels are elevated and S.T4/Free T4 (FT4) levels are low. S.TSH≥10mIU/l is taken as OH irrespective of FT4 levels. In SCH, the TSH level is elevated (≤ 10mIU/l) with normal Serum T4/FT4. Positive thyroid antibody titers suggest autoimmune thyroid disease. Euthyroid patients with positive Thyroid Peroxidase Antibody (TPO) titershave high chances of developing hypothyroidism.

Functions of thyroid gland

The thyroid gland is one of the main regulators of metabolism. T3 and T4 typically act via nuclear receptors in target tissues and initiate a variety of metabolic pathways. Metabolic processes increased by thyroid hormones include:

- Basal metabolic rate
- Gluconeogenesis
- Glycogenolysis
- Protein synthesis
- Lipogenesis
- Thermogenesis

Risk factors

Pregnancy is seen as a risk factor in the occurrence of thyroid dysfunction

- Labor – dyskinetic, longer due to the existence of the hypotonia and the simultaneous cardio-breathing problems; hypokinesis[28]
- Anomalies of fetus cardiac rhythm (FCR) – fetal suffering: alterations in the basic cardiac rhythm (tachycardia, bradycardia), of FCR variability (diminution until their loss or periodical variations of FCR in relation with the uterus contractions, a type of belated slow-ups)
- APGAR mark – frequently lower at pregnant women who continued to be hypothyroid until the due term
- Vitiated pelvis (limit pelvis) which can be the reason of various cephalic-pelvis disproportions
- Presentations that are close to dystocia – pelvic presentation
- Post-partum hemorrhages occur through uterus hypotony and coagulation disorders (the problem of the plaque adhesiveness)
- Post-partum depression, post-partum thyroiditis, hypokalaemia
- Residing in an area of known moderate to severe iodine insufficiency.(under area mapping)[28,6]
- Obesity[pre-pregnancy/first trimester Body Mass Index(BMI)≥30kg/m²] [BMI=Weight in kg/height in m²]
- History of prior thyroid dysfunction or prior thyroid surgery.
- Having a history diagnosed with mental retardation within the family.
- History of miscarriages abrupted placenta, preeclampsia or eclampsia, and history of pre-term delivery.
- Known case of autoimmune disorders like Type 1 Diabetes, Rheumatoid Arthritis, and Systemic lupus erythematosus (SLE), etc...
- Inability to conceive (history of infertility).
- Use of drugs like amiodarone or lithium or recent administration of iodinating radiologic contrast.

Physiology

The thyroid physiology can be modified during normal pregnancy. The changes can take place throughout the gestational period, which helps the maternal thyroid gland to manage the physiological metabolic demands through the pregnancy.

The most notifiable change is the rise of Thyroxine-Binding Globulin(TBG). This initiates early during the First Trimester, maintains stable during Mid-gestation, and remains until shortly after delivery. This takes place due to the activation of TBG synthesis by increased maternal estrogen levels and also due to reduced hepatic clearance of TBG. The increased TBG synthesis in turn leads to a rise in T3 and T4 levels due to the elevation of maternal hormone thyroid synthesis.

In the fetus, the pituitary–thyroid axis is controlled in a very similar way, with iodine supplied transplacentally. Before 12 weeks' gestation, maternal thyroxine (but not fT3) crosses the placenta. Following binding to receptors in fetal brain cells, thyroxine is converted intracellularly to fT3, a process thought to be important for normal fetal brain development. From 12 weeks onwards, placental changes prevent the significant passage of maternal thyroxine and fetal thyroid function is controlled independently of the mother, provided that her iodine intake is adequate.[8]

The thyroid function tests can change during the period of pregnancy due to the influence of two hormones: hCG and Estrogen. hCG can rapidly turn on the thyroid and high circulating levels of hCG in the first trimester which may result in low TSH(thyroid-stimulating hormone).When this takes place, TSH will be marginally decreased in the 1st trimester and then it returns to normal throughout the pregnancy.

Thyroid physiology is recognizably modified during normal pregnancy. These alterations take place during the gestation period which helps to prepare the maternal thyroid gland that copes up with the metabolic demands of pregnancy. Are reversibly post Partum and these changes can pose a challenge to the treating physician[1]

This usually begins at the early stage of the first trimester, plateaus during mid-gestation, and persists until shortly after delivery. This is mainly caused due to stimulation of TBG synthesis due to elevated maternal estrogen levels, and most importantly, due to reduced hepatic clearance of TBG due to estrogen-induced sialylation. An increased concentration of TBG leads to an expansion of the extra-thyroidal pool and which canresults in elevation of total T3 and T4 levels because of an increase in maternal thyroid hormone synthesis. Maternal thyroid hormone synthesis can also increase due to accelerated renal clearance of iodide resulting from the increased maternal glomerular filtration rate.

Physiology of fetal thyroid

Fetal thyroid gland develops as an outpouching in the midline of the anterior pharyngeal floor, migrates caudally, to reach its final position by 7 weeks of gestation. Fetal thyroid can trap iodine by 12 weeks and it can synthesize thyroxine by 14 weeks of gestation. Anyhow the hormone secretion is not seen till 18-20 weeks of gestation. Later onwardsfetal TSH, T4, and TBG gradually rise to adult levels by 36 weeks gestation. But T3 and

free T3 levels do not rise to adult levels, as placental type III deiodinase converts most fetal T4 to reverse T3; the fetal brain that has elevated levels of type II deiodinase is an exception. The TSH transfer across the placenta is not significant, but T3 and T4 transport are considerable. This is of special relevance in congenital hypothyroidism, where studies have shown that umbilical cord T4 levels in neonates with congenital hypothyroidism can be up to 50% of the normal. This transferred T4 plays a crucial role in near-normal fetal cognitive development in congenital hypothyroidism. Transplacental transfer of TRH, iodine, anti-thyroid drugs and thyroid stimulatory immunoglobulin (TSI) also occurs.

Features of maternal hypothyroidism

Women having Hypothyroidism have decreased fertility, even if there are chances to conceive it will lead to an abortion. Thyroid disorders are the commonest endocrine disorders affecting women of reproductive age group. The most frequent thyroid disorder in pregnancy is maternal hypothyroidism. During early pregnancy, the fetus is dependent on maternal thyroid hormone supply. Thyroid hormone is critical for fetal brain and intellectual development and some preventable conditions like abruption, pre-eclampsia, etc. which produce morbidity and pose a special risk for pregnancy and the developing fetus.[9]

Mechanism of Thyroid hormone

• Action mediated by

– TSH = cAMP (secondary messenger)mediated

– Thyroxine = intracellular receptor- T3 and T4 penetrate cells by active transport and produce the majority of their actions by combining with a nuclear thyroid hormone receptor (TR) which belongs to the steroid and retinoid superfamily of intracellular receptors. Two TR isoform families (TRα and TRβ) have been identified. Both bind T3 and function similarly, but their tissue distribution differs, which may account for quantitative differences in the sensitivity of different tissues to T3.In contrast to the steroid receptor, the TR resides in the nucleus even in the unliganded inactive state. It is bound to the 'thyroid hormone response element' (TRE) in the enhancer region of the target genes along with corepressors (Fig.3). This keeps gene transcription suppressed. When T3 binds to the ligand-binding domain of TR, it heterodimerizes with retinoid X receptor (RXR) and undergoes a conformation change releasing the corepressor and binding the coactivator. This induces gene transcription → production of specific mRNA and a specific pattern of protein synthesis → various metabolic and anatomic effects. The expression of certain genes is repressed by T3. In their case, the unliganded TR allows gene transcription, while binding of T3 to TR halts the process. Many of the effects, e.g. tachycardia, arrhythmias, raised BP, tremor, hyperglycemiais mediated, at least partly, by sensitization of adrenergic receptors to catecholamines. Induction of adenylyl cyclase, a proliferation of β adrenoceptors, and a better coupling between these two has been demonstrated.

The relation between T4 and T3

- Thyroid secretes more T4 than T3, but in the iodine-deficient state, this difference is reduced.
- T4 is the major circulating hormone because it is 15 times more tightly bound to plasma proteins.
- T3 is 5 times more potent than T4 and acts faster. The Peak effect of T3 comes in 1–2 days while that of T4 takes 6–8 days.
- T3 is more avidly bound to the nuclear receptor than T4 and the T4-receptor complex is unable to activate/derepress gene transcription.

MATERIALS

Study site: SunshineHospitals**,** Secunderabad**,** Telangana**.**
Study duration: 6 months.
Type of the study: Prospective Observational Study
Inclusion criteria: 1. Pregnant women with hypothyroidism
2. Patients who interested in the counseling study.
Exclusion criteria: Patients who are not interested in the counseling study.

Study procedure
Study Tools

- Data collection form
- Patient information leaflet.
- Questionnaires to assess the usefulness of PIL.
- Inform the consent form.

Data collection

Patient's case sheets were selected based upon inclusion and exclusion criteria from the Medical Record Department after attaining the permission from Medical Record Officer, in Sunshine Hospitals, Secunderabad, Telangana.

Phase I

A prospective observational study was carried out in the department of gynecology for 6 months to find the scope of the study. All the prescription on pregnant women suffering from hypothyroidism containing drug levothyroxine were monitored and potent of dose awareness use of knowledge have been studied. Also, the attitude of patients towards the leaflets and counseling and their response to the questionnaire. Works of literature that support the study were collected and reviewed for the study on the management of levothyroxine and the effect of patient counseling among pregnant women with hypothyroidism.

Obtaining consent from the Hospital authority

study was carried out in the hospital by the department of pharmacy practice. So it has to be approved by Medical Superintendent (MS) and the same should be informed to the complete gynecology department of the hospital. For obtaining the consent, a study protocol has been prepared which includes the proposed title, study site, Inclusion and Exclusion criteria, objectives, and methodology about the works to be carried out. Then the protocol of the study was submitted to Medical Superintendent. MS permitted to perform the study in the outpatient department and utilize the hospital facilities through a letter (Annexure No.1). Data Entry Format/Proforma: A separate data entry format for incorporating outpatient details was designed (Annexure No.2). It includes Demographic data of the subject, the drug is given, the dose of the drug, route of administration of the drug, laboratory investigations, and review date and trimester of the patient.

Phase II

Collection of Data

have collected 98 cases of pregnancy with hypothyroidism and follow-up of cases was collected. We have counseled patients using our patient information leaflet and KAP questionnaire. The feedback of counseling and the use of PIL was assessed during follow-up. The dose of levothyroxine prescribed was evaluated in each trimester.

Assessing the prescription

Prospective data of patients were obtained concerning includes Demographic data of the subject, the drug is given, the dose of the drug, route of administration of the drug, laboratory investigations, and review date and trimester of the patient. A total number of 98 patients were observed and recorded.

PHASE III

Analysis of Data

The data of selected patients were collected from the outpatient department of gynecology from august 2019-February 2020 paying due attention to inclusion and exclusion criteria and were evaluated prospectively for the presence and fulfillment of the following variables:

- To develop a PIL for pregnant women with hypothyroidism.
- To identify the application of PIL in pregnant women.
- To know about the usefulness of PIL.
- To understand the drug utilization evaluation in hypothyroid pregnant patients.

Data evaluation

The data collected from all the subjects were evaluated by using SPSS-STATISTICAL PACKAGE OF SOCIAL SCIENCE SOFTWARE. The significance of the data was summarized.

RESULTS AND DISCUSSION

Table 1: Age Of The Patients Enrolled In The study

Age	Frequency	Percentage
18-25	57	58.16%
26-29	34	34.69%

30 and above	07	7.14%
Total	98	100%

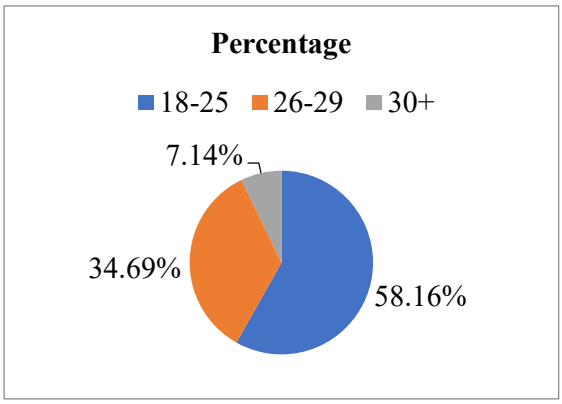

Fig 1: Percentage distribution of patient age

A total of 98 patients were enrolled in the study, the percentage distribution of patient's age showed that the age group of 18-25 were predominant.

Table: 2 Trimester's Of The Patients Enrolled In The Study

Trimester	Frequency	Percentage
First trimester	48	48.9%
Second trimester	32	32.65%
Third trimester	18	18.36%
Total	98	100%

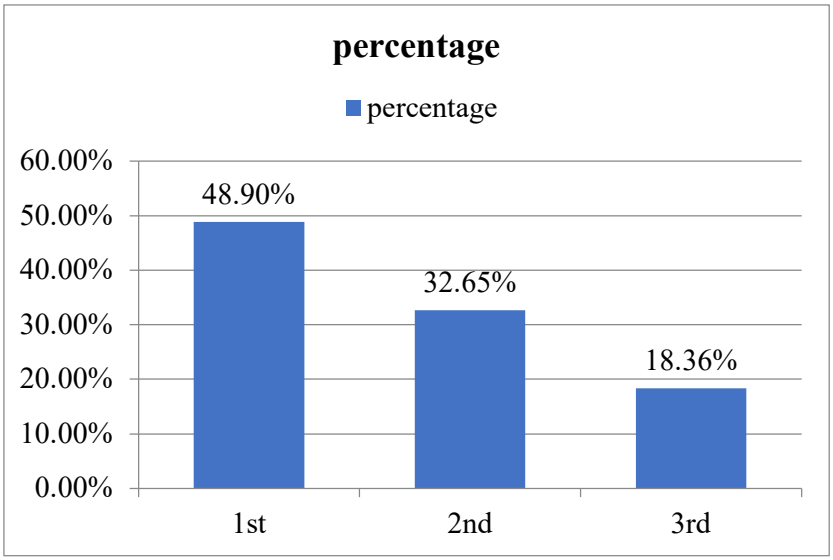

Fig 2: Percentage of patients in trimesters

The majority of the patients were under the first trimester i.e.,48.9% which is graphically represented.

Table 3: Pre and post counselling responses of knowledge based questions

Questions on the knowledge domain.	Pre-counselling n=98		Post-counselling n=86	
	YES	NO	YES	NO
1.The thyroid is a butterfly-shaped gland, located in the neck.	59	39	80	6
2. Hypothyroidism is due to low hormone levels.	36	62	77	9
3. Hypothyroidism may cause dry skin.	8	90	62	24
4. Hypothyroidism may cause weight gain.	78	20	82	4
5. Hypothyroidism may cause fatigue.	70	28	80	6
6. Can hypothyroidism cause birth defects?	22	76	79	7
7. Can hypothyroidism cause a miscarriage?	61	37	84	2
8. Iodine deficiency in the diet may lead to hypothyroidism.	12	86	81	5
9. Alternative forms of medicine, such as Ayurveda and homeopathy, may be useful to treat hypothyroidism	72	26	85	1
10. Will the TSH level affect pregnancy?	42	56	82	4

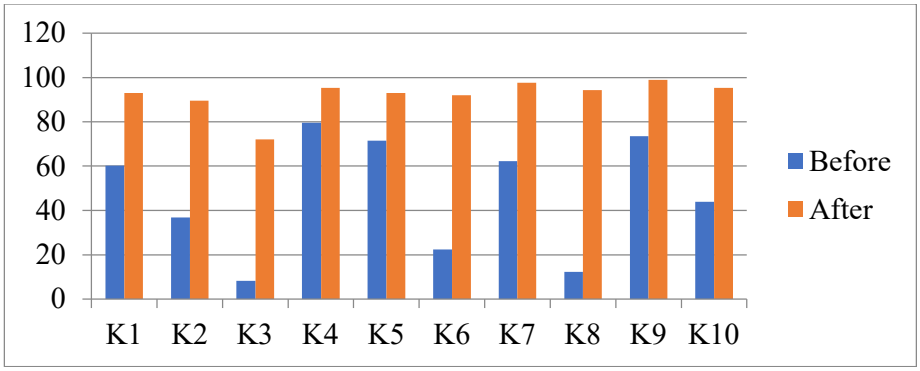

Fig 3: Graphical representation of scores recorded according to pre and post counseling (knowledge)

The above graph represents the responses of a patient to each question. Here, the scores were given as follows for each question:

- YES- (1)
- NO- (2)

It shows that the knowledge of the patient was improved after counseling from the above comparison. Therefore, from the above responses, the knowledge of the patient was assessed.

Statistical Analysis Of Knowledge-Based Scores Obtained Pre And Post Counseling Of Each Patient

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	pre-counselling(K1)	19.2326	86	2.88474	.31107
	post counselling	11.1395	86	.94760	.10218

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	pre-counselling(K1) & post counselling	86	.259	.016

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	pre-counselling(K1) - post counselling	8.09302	2.79339	.30122	7.49412	8.69193	26.868	85	.000

Fig 4: Statistical analysis of knowledge based scores obtained by pre or post counselling of each patient

Table 4: Responses of patients to attitude based questions

Questionnaire on attitude	Strongly agree		Agree		Disagree		Strongly disagree	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
1.Pregnant women are at greater of developing hypothyroidism and should be tested at regular intervals of hypothyroidism.	23	26	01	59	15	01	0	0
2.People above the age of 35 years should be tested frequently for hypothyroidism	03	42	23	37	75	04	02	03
3.Pregnant women should be tested for hypothyroidism	41	51	51	33	01	02	05	0
4. People with relatives/family members diagnosed with hypothyroidism should be tested for hypothyroidism	01	21	16	58	69	05	12	02
5.Treatment for hypothyroidism should be initiated after consultation with a physician only.	51	74	43	12	01	0	03	0

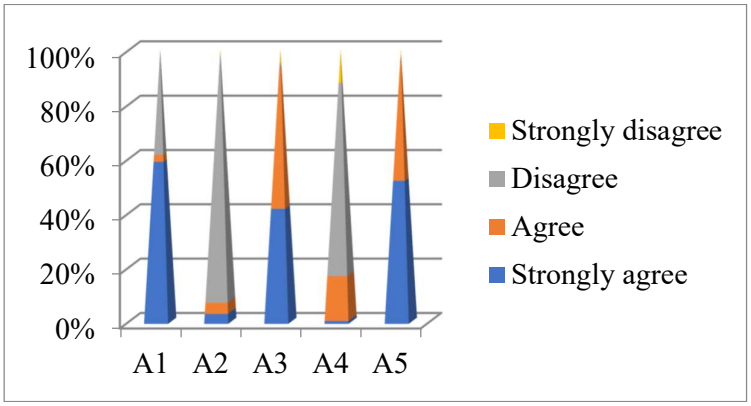

Fig 5: Outcomes of attitude-based questions before counselling

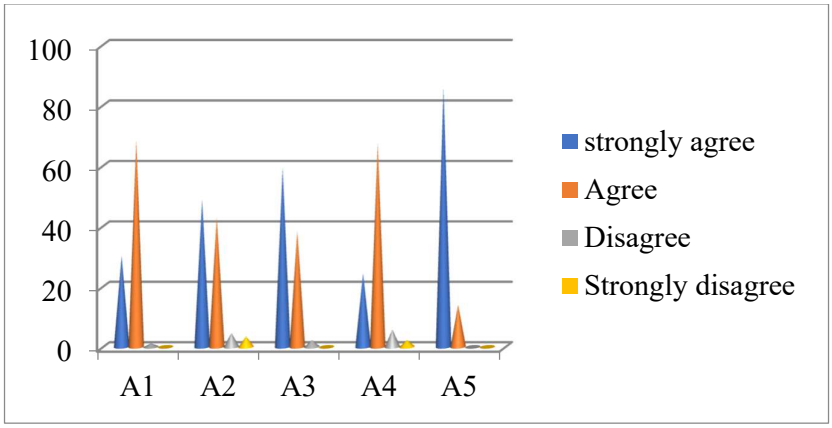

Fig 6: Outcomes of attitude-based questions after counselling

The above graphs represent the responses of patients to each question based on attitude. The scores were recorded as follows:

- STRONGLY AGREE- (1)
- AGREE- (2)
- DISAGREE- (3)
- STRONGLY DISAGREE- (4)

Based on the above scores the patient's attitude was assessed. The comparison of outcomes obtained from pre and post counseling shows that there is a marked difference in patients.

Statistical Analysis Of Attitude Based Scores From Each Patient Pre And Post Counselling

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	pre-counselling(A1)	10.5465	86	1.41967	.15309
	post-counselling(A2)	6.4419	86	1.10192	.11882

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	pre-counselling(A1) & post-counselling(A2)	86	.130	.234

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	pre-counselling(A1) - post-counselling(A2)	4.10465	1.68054	.18122	3.74434	4.46496	22.650	85	.000

Fig 7: statistical analysis of attitude based scores from each patient pre and post counselling

Table 5: Responses to practise based questions

Questionnaire on practice	Pre-counselling n=98		Post-counselling n=86	
	YES	NO	YES	NO
1. Do you take your medication for hypothyroidism daily?	90	08	86	0
2. Do you miss any doses of your medication for hypothyroidism?	18	81	86	0
3. Do you take your medication 30-60 min before breakfast on empty stomach?	90	08	80	06
4. Do you take your thyroid medicine with any other medicines?	24	74	05	81
5. As advised by your physician, do you get your TSH level tested regularly?	74	24	78	08
6. Do you for information on hypothyroidism on the internet/smartphone?	25	73	52	34
7. Did you ask your doctor for more information/counseling on how to manage hypothyroidism?	48	50	47	39
8. Do you avoid eating cabbage, cauliflower, and soya?	84	14	85	01

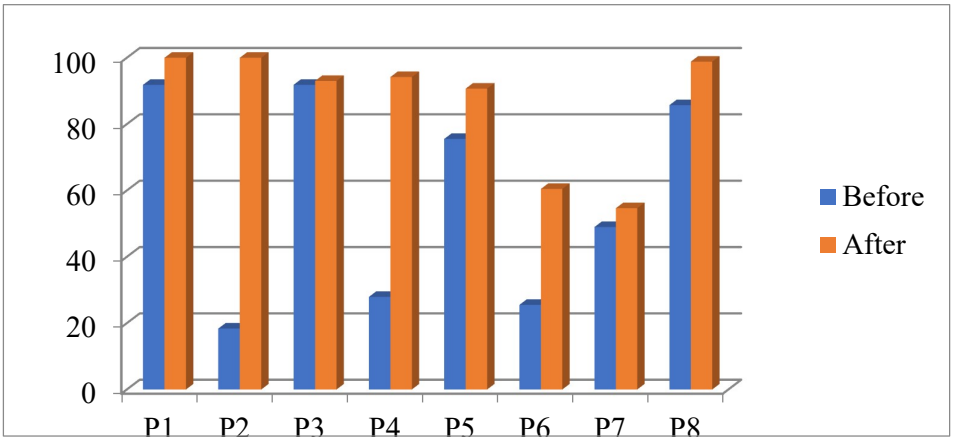

Fig 8: Graphical representation of the effect of practice-based questions

The above graph represents the responses of the patient to each practice based question. The scores were given as follows:

- YES- (1)
- NO- (2)

From the above scores, the patients' practice towards medication adherence and lifestyle were assessed and there was a notable change in patients after counselling.

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	pre-counselling(P1)	11.0000	86	.73565	.07933
	post-counselling(A2)	8.2907	86	.45675	.04925

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	pre-counselling(P1) & post-counselling(A2)	86	.035	.749

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	pre-counselling(P1) - post-counselling(A2)	2.70930	.85221	.09190	2.52659	2.89202	29.482	85	.000

Fig 9: Statistical analysis of Practice based scores from each patient pre and post counselling

Table 6: Management of levothyroxine

Trimester	Follow-up	Change in dose	No change
First trimester	36	34	02
Second trimester	25	16	09
Third trimester	10	07	03

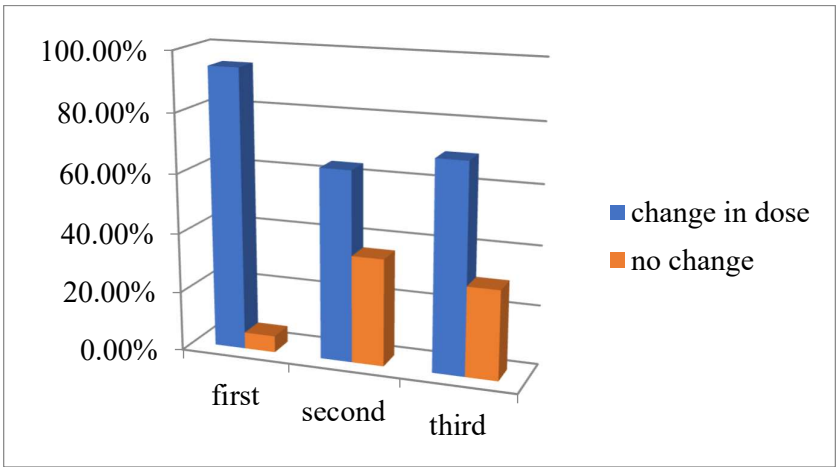

Fig 10: Graphical representation of evaluation of levothyroxine

The above table indicates that out of 98 patients 70 patients follow up was collected. The results of follow up showed that 57 patients had a decrease in dose from each trimester. This indicates the response of patients to counseling, lifestyle modifications, and medication adherence.

Statistical Outcomes Of Management Of Levothyroxine In Each Trimester

- Statistical analysis of outcomes of first-trimester patients pre and post counseling

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	TSHBEFORE	8.0859	34	3.63297	.62305
	DOSEBEFORE	77.9412	34	19.23214	3.29828
Pair 2	TSHAFTER	3.7094	34	1.50531	.25816
	DOSEAFTER	38.2353	34	13.74179	2.35670

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	TSHBEFORE & DOSEBEFORE	34	.591	.000
Pair 2	TSHAFTER & DOSEAFTER	34	.509	.002

Fig 11: Statistical outcomes of management of levothyroxine in each trimester

The above statistical analysis shows that from the first trimester 34 patients are found to have decreased TSH levels after counseling which reduced the dose of levothyroxine prescribed before the counseling.

- STATISTICAL OUTCOMES OF SECOND TRIMESTER

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	TSHBEFORE	8.5575	16	1.99565	.49891
	DOSEBEFORE	81.2500	16	17.07825	4.26956
Pair 2	TSHAFTER	4.2831	16	1.37849	.34462
	DOSEAFTER	43.7500	16	17.07825	4.26956

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	TSHBEFORE & DOSEBEFORE	16	.223	.408
Pair 2	TSHAFTER & DOSEAFTER	16	.116	.670

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	TSHBEFORE - DOSEBEFORE	-72.69250	16.74762	4.18690	-81.61667	-63.76833	-17.362	15	.000
Pair 2	TSHAFTER - DOSEAFTER	-39.46687	16.97425	4.24356	-48.51182	-30.42193	-9.300	15	.000

Fig 12: Statistical analysis of outcomes of second-trimester patients

From the above table the statistical analysis of the second trimester, a total of 16 patients follow up was collected. It shows that a significant difference was seen after counseling and the dose of levothyroxine was found to be reduced.

Statistical outcomes of third trimester:

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	TSHBEFORE	7.4800	7	2.11089	.79784
	DOSEBEFORE	64.2857	7	19.66989	7.43452
Pair 2	TSHAFTER	3.8629	7	1.18458	.44773
	DOSEAFTER	32.1429	7	12.19875	4.61069

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	TSHBEFORE & DOSEBEFORE	7	.892	.007
Pair 2	TSHAFTER & DOSEAFTER	7	.566	.185

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	TSHBEFORE - DOSEBEFORE	-56.80571	17.81228	6.73241	-73.27933	-40.33210	-8.438	6	.000
Pair 2	TSHAFTER - DOSEAFTER	-28.28000	11.56908	4.37270	-38.97962	-17.58038	-6.467	6	.001

Fig 13: Statistical outcomes of third-trimester patients

The above table represent the statistical outcomes of levothyroxine management from the third trimester. This shows a significant difference in dose before and after management.

CONCLUSION

In our study, pregnant women with hypothyroidism both in-patient and out-patient cases were collected from Sunshine Hospitals, Secunderabad, Telangana for the period of 6months. Hence, in the permitted time 98cases were collected which was counseled using patient information leaflet, and management of levothyroxine was analyzed.

- We collected a total no. of 98 cases of pregnancy with hypothyroidism including all three trimesters.
- Among 98 patients 48 were in the first trimester, 32 were in the second trimester and 18 were in the third trimester.
- We collected feedback and assessed the usefulness of PIL from 86 patients, the rest 12 patients did not respond and left the study without any reason.
- The scores of questionnaires were collected from all the patient's pre and post counseling from 86 patients and statistically analyzed using paired sample t-test.
- From the statistical data, the results showed the usefulness of PIL and its impact on patients pre and post counseling.
- Management of levothyroxine was evaluated in each trimester among them 36 were from the first trimester, 25 patients from the second trimester, and 10 were from the third trimester. The follow-up of these cases was collected and the level of TSH, a dose of levothyroxine was evaluated.
- The results showed that there was a change in the dose of levothyroxine, which represents the impact of patient counseling, lifestyle modifications, and medication adherence.

Hence, patient information leaflets are very useful in counseling and a show a great impact on patients which improved their condition and reduced the dose of the drug.

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