International Journal of Allied Medical Sciences and Clinical Research (IJAMSCR)

IJAMSCR |Vol.13 | Issue 4| Oct - Dec -2025

www.ijamscr.com

ISSN: 2347-6567

DOI : https://doi.org/10.61096/ijamscr.v13.iss4.2025.924-938

Review

Impact of Patient Information Leaflet and Management of Levothyroxine a mong Pregnant Women with Hypothyroidism

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Published on: 26.12.25

Published by:
Futuristic Publications

Abstract

Hypothyroidism an endocrine disorder is an underactive thyroid gland, which does not make enough thyroid hormone. Hypothyroidism during pregnancy can have irreversible effects on the foetus. 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 subject's age showed that the age group of 18-25 were predominant. Among them, 48 were in the first trimester. All the patients were counselled 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 fatal 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 fatal and maternal outcomes. [1]

2.2 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

2.5 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) – fatal 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 haemorrhages 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)

- 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.

METHODOLOGY

Study site: Rohini Super Speciality Hospital**,** Hanamkonda**,** 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 counselling study.

Exclusion criteria: Patients who are not interested in the counselling 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 Rohini Super Speciality Hospital**,** Hanamkonda**,** and Telangana**.**

Phase I:

A prospective observational study was carried out in the department of gynaecology 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 counselling 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 counselling among pregnant women with hypothyroidism.

Obtaining consent from the Hospital authority:

The 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 gynaecology 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:

We have collected 98 cases of pregnancy with hypothyroidism and follow-up of cases was collected.

We have counselled patients using our patient information leaflet and KAP questionnaire. The feedback of counselling 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

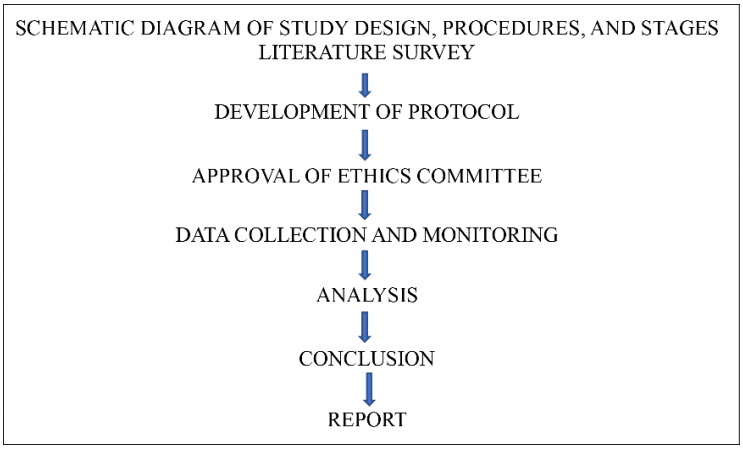
The data of selected patients were collected from the outpatient department of gynaecology from august 2019-February 2020 paying due attention to inclusion and exclusion criteria and were evaluated prospectively for the presence and fulfilment of the following variables:

- 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.

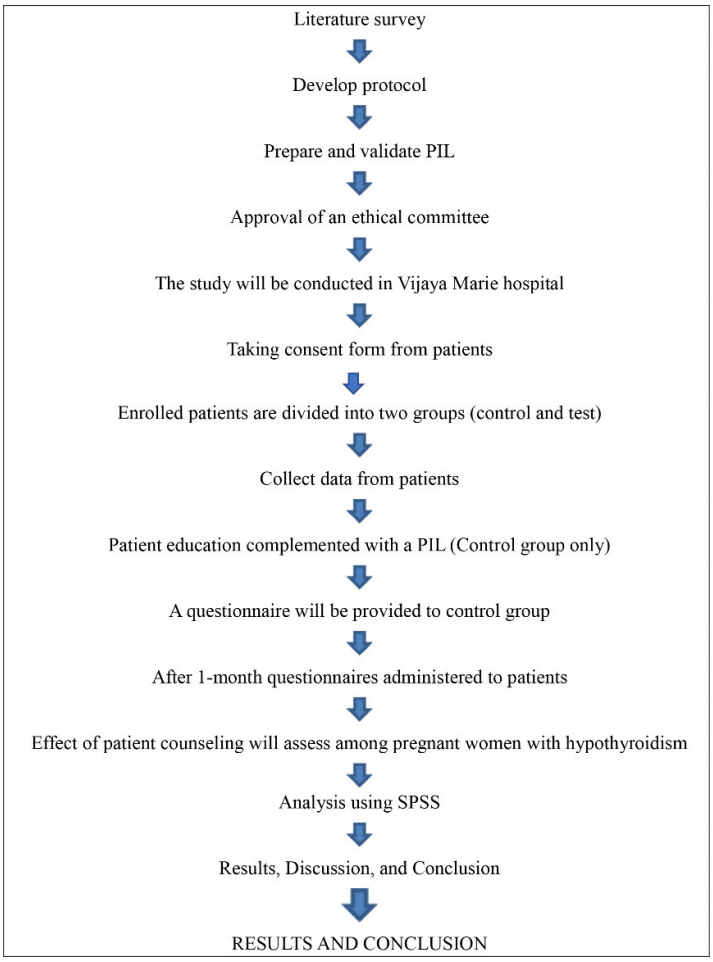
Data evaluation:

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.

Plan of Work



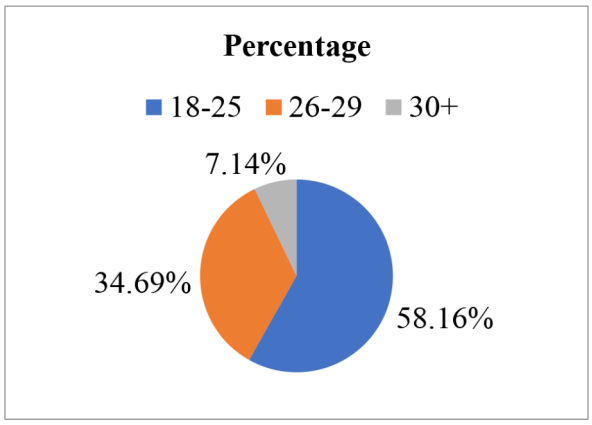
Study Design



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%

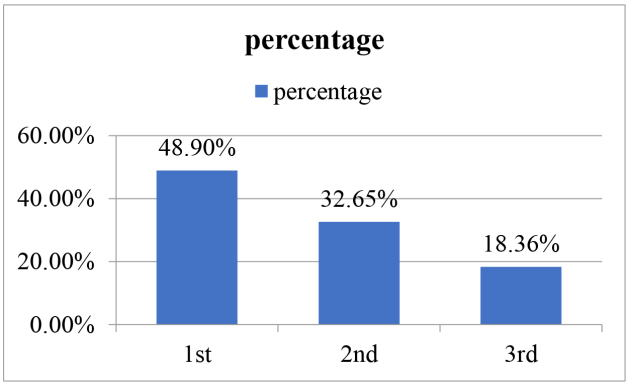


Graph 1: Percentage distribution of patient age

DISCUSSION: 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%



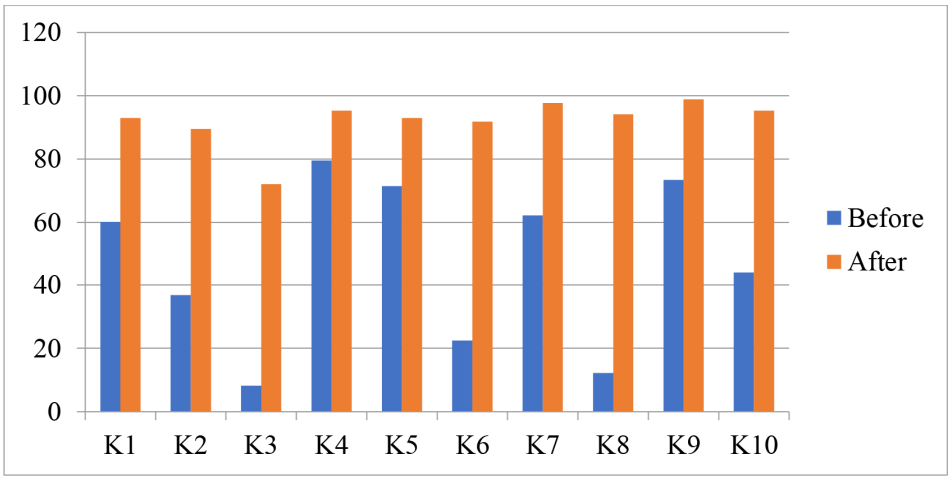
Graph 2: Percentage of patients in trimesters

DISCUSSION: 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



Graph 3: Graphical representation of scores recorded according to pre and post counselling (knowledge)

DISCUSSION: 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 counselling 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

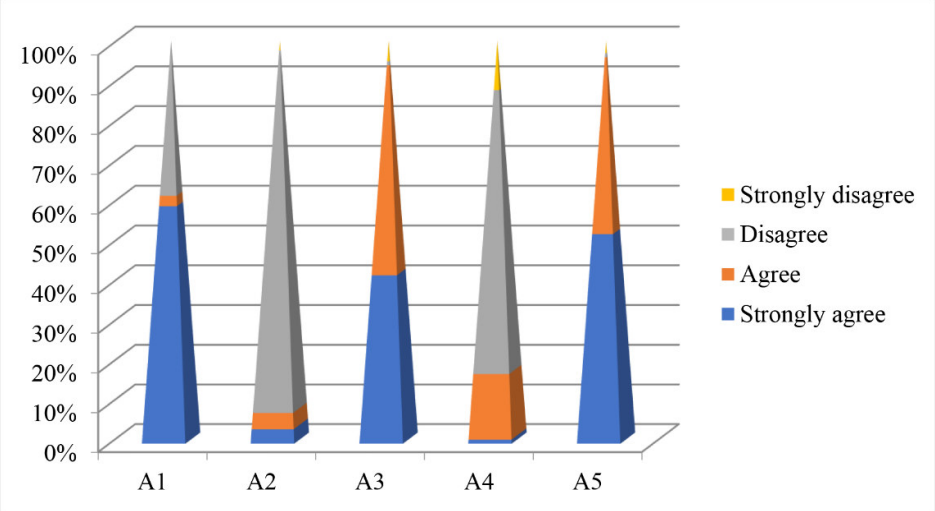
Paired Samples Test

		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

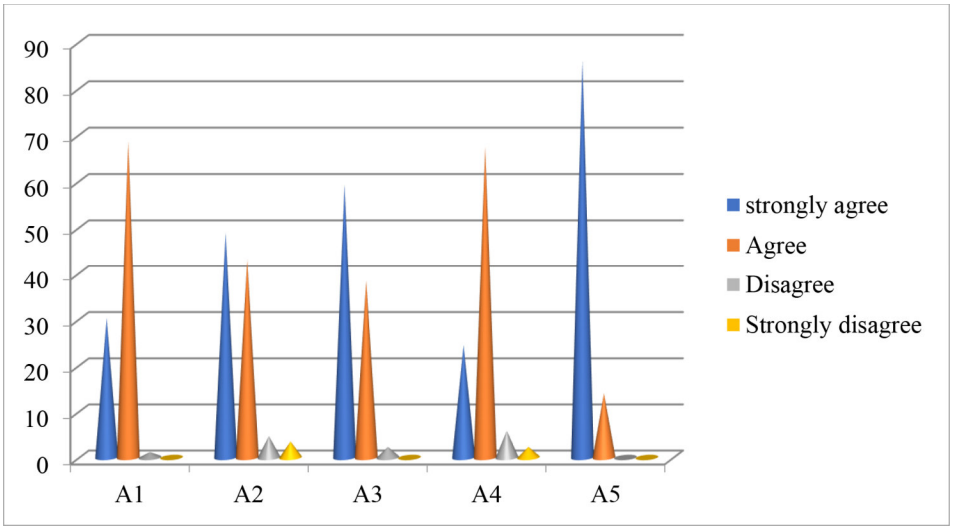
Fig 9: Statistical analysis of knowledge based scores obtained by pre or post counselling of each patient

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



Graph 4: Outcomes of attitude-based questions before counselling:



Graph 4.1: Outcomes of attitude-based questions after counselling:

DISCUSSION: 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 counselling 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(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

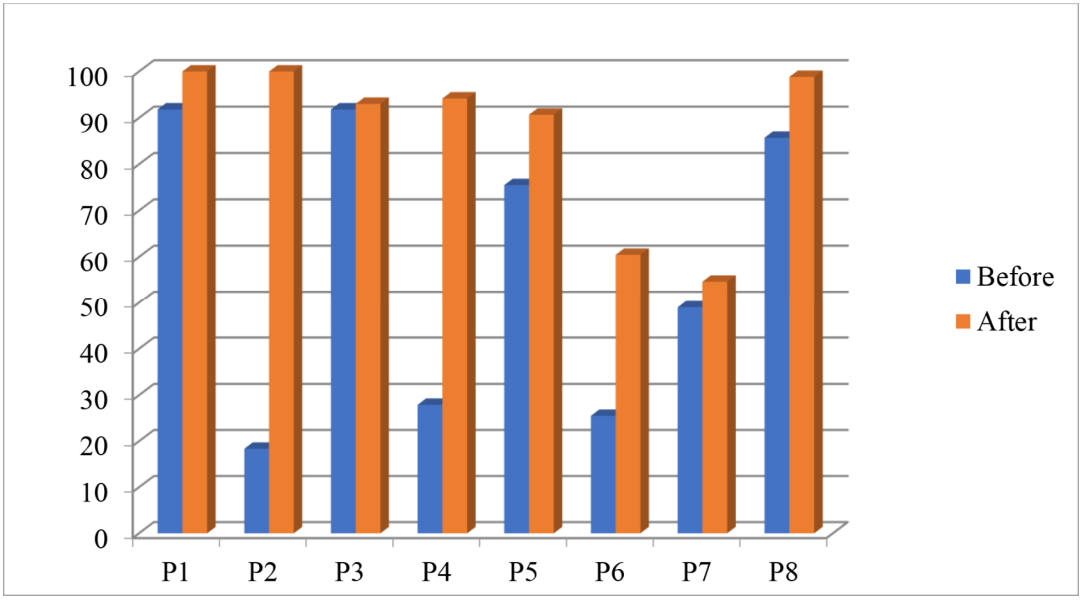
Paired Samples Test

		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 10: 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/counselling on how to manage hypothyroidism?	48	50	47	39
8. Do you avoid eating cabbage, cauliflower, and soya?	84	14	85	01



Graph 5: Graphical representation of the effect of practice-based questions:

DISCUSSION: 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

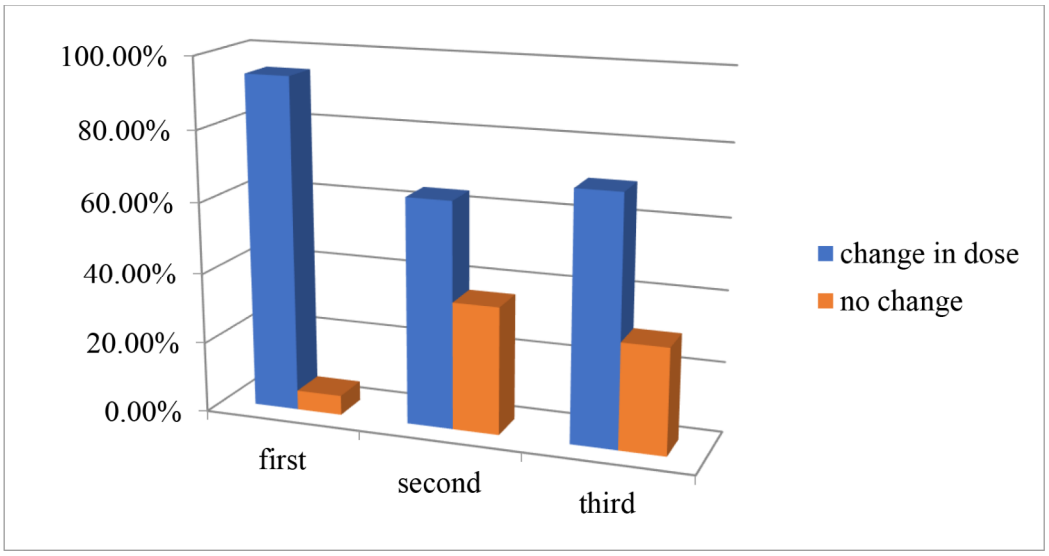
Paired Samples Test

		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 11 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



Graph 6: Graphical representation of evaluation of levothyroxine

DISCUSSION: 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 counselling, 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 counselling:

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

Fig12 Statistical outcomes of management of levothyroxine in each trimester

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

- 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 13: Statistical analysis of outcomes of second-trimester patients

DISCUSSION: 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 counselling 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 14 Statistical outcomes of third-trimester patients

DISCUSSION: 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 Rohini Super Speciality Hospital**,** Hanamkonda**,** Telangana for the period of 6months. Hence, in the permitted time 98cases were collected which was counselled 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 counselling 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 patient's pre and post counselling.
- 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 counselling, lifestyle modifications, and medication adherence.
- Hence, patient information leaflets are very useful in counselling and a show a great impact on patients which improved their condition and reduced the dose of the drug.

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