



## Impact of pharmacist directed counseling on knowledge, attitude, practices and medication adherence among hypothyroidism patients: a quasi-experimental design

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### Article History:

Received on: 04.03.2019

Revised on: 07.06.2019

Accepted on: 11.06.2019

### Keywords:

Hypothyroidism,  
KAP,  
Medication adherence,  
Patient counselling

### ABSTRACT

The pharmacist plays an important role in providing counseling services to patients suffering with various chronic disorders and to improve health outcomes. The study aims to evaluate the effect of pharmacist mediated counseling on Knowledge, Attitude, and Practice (KAP) and medication adherence (MA) among hypothyroidism patients attending outpatient department of a secondary care referral hospital. This is a Quasi-Experimental design without control. A total of 403 patients were enrolled and subjected for KAP assessment by pre-validated questionnaire, and medication adherence levels by pill count and visual analogue scale methods. All patients were counselled by the pharmacist regarding hypothyroidism and its management. After three months, post-KAP and medication adherence levels were measured. Chi-square test was used to compare the adequacy of KAP levels. The paired t-test was used to compare mean medication adherence and mean KAP percentage levels. The mean KAP percentage levels were significantly improved after counselling ( $80.5 \pm 16.4$ ;  $86.2 \pm 15.7$ ;  $67.5 \pm 13.8$ ) compared to before ( $34.1 \pm 21.7$ ;  $33.8 \pm 22.9$ ;  $24.5 \pm 20.9$ ) with a *P* value less than  $<0.0001$ . There was a significant improvement in mean medication adherence levels measured by visual analogue scale method and pill count method after counselling ( $92.4 \pm 4.8$ ,  $97.4 \pm 3.2$ ) compared to before counselling ( $76.8 \pm 6.8$ ,  $80.3 \pm 6.4$ ). Improving KAP and medication adherence levels will promote positive clinical outcomes and prevents complications associated with hypothyroidism.



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ISSN: 0975-7538

DOI: <https://doi.org/10.26452/ijrps.v10i3.1388>

Production and Hosted by

IJRPS | <https://ijrps.com>

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### INTRODUCTION

Hypothyroidism is a chronic endocrine disorder in which thyroid gland unable to produce an adequate amount of thyroid hormones to fulfil body requirements (Surana *et al.*, 2017). The global prevalence of hypothyroidism was ranging between 1% and 10% (Sethi *et al.*, 2018). The wide variation in the prevalence was majorly due to changes in the socio-demographic, geographical, and environmental characteristics (Unnikrishnan and Menon, 2011). In India, one in ten adults suffers with

hypothyroidism with a prevalence between 3.9% and 10.95% (Unnikrishnan *et al.*, 2012). Most of them were unaware of their condition. Women are at higher risk to develop hypothyroidism than men, especially during menopause, puberty, first menstruation, pregnancy, and within six months after birth (Kalra *et al.*, 2015).

Hypothyroidism symptoms are gradual and non-specific in nature, so most of the cases were undiagnosed (Canaris *et al.*, 2000). Untreated hypothyroidism cases can cause a significant effect over the physical and mental health of the patients (Canaris *et al.*, 2013). The standard treatment for hypothyroidism is levothyroxine replacement therapy. Levothyroxine replacement therapy is the most effective, convenient and economical strategy to manage hypothyroidism and to prevent complications (Chakera and Pearce, 2012). The most common problem that exists in the treatment of hypothyroidism is sub-optimal or over treatment, which causes profound effects on organs of the cardiovascular, nervous and endocrine system (Glivic *et al.*, 2015).

Evidences show that, most of the patients in Meerut and central India are having poor knowledge, attitude and practices (KAP) towards hypothyroidism and its management (Rai *et al.*, 2016; Mithal *et al.*, 2014). The lack in KAP among patients was majorly due to, deprived knowledge about trustworthy sources of information, inadequate education, wrong beliefs, and very less amount of time spent by the doctor in counselling of the patients (Maheshwari *et al.*, 2017).

The KAP and medication adherence (MA) plays a vital role in achieving good clinical outcomes, preventing complications, reducing morbidity and mortality associated with hypothyroidism. Evidence shows that, pharmacist plays a important role in providing counseling services to patients suffering with various chronic disorders (hypertension and diabetes) and to achieve positive economical, clinical and humanistic (ECHO) outcomes (Palo and Kish, 2018; Shareef and Fernandes, 2016). There was a lack of evidence in relation to the effect of counselling or educational services on KAP and MA levels in hypothyroidism patients. Most of the study findings are limited to an assessment of the gap present in KAP and MA levels of patients treated for hypothyroidism. The present study aims to evaluate the impact of pharmacist delivered counseling services on KAP, and MA levels in patients with hypothyroidism.

## MATERIALS AND METHODS

This prospective interventional study (Quasi-Experimental design without control) was conducted in the Outpatient Department of General Medicine of secondary care referral hospital located in rural settings of Anantapur district, Andhra Pradesh, India, over a period of six months from April 2018 to September 2018. The study was approved by the Institutional Review Board (IRB) with a number of RIPER/IRB/2018/031.

All primary hypothyroidism patients, irrespective of gender, aged more than 18 years, who are under Levo-thyroxine therapy for more than six months were included in the study. Patients who had a history of neck irradiation, undergone thyroid surgery, not willing to participate, and suffering with secondary causes of hypothyroidism were excluded from the study. To estimate the number of patients to be recruited into the study, the single population proportion formula was used with an assumption of 50% of patients have optimum knowledge, with 95% confidence interval and 5% precision, it was determined as 384. The final sample size was calculated as 403 by assuming 5% non-response rate. All subjects who met study criteria are included and interviewed by using pre-validated KAP questionnaire about hypothyroidism and its management (Polit and Beck, 2006).

### Validation of KAP questionnaire

The KAP questionnaire was subjected for content validation by a panel of experts comprising of an endocrinologist (2), pharmacist (2), and dietician (1). Knowledge domain contains 18 questions, attitude domain 10 questions, and practice domain 10 questions. Expert opinion towards each item was placed on a five-point Likert scale ranging from strongly agree 4, agree 3, disagree 2, and strongly disagree 1. Content Validity Index (CVI) indicators like Item-level Content Validity Index (I-CVIs), and Scale level Content Validity Index (S-CVI) were calculated for each domain. The knowledge, attitude, and practice domains S-CVI/Average number (Average of all I-CVIs) was estimated as 0.9, 0.84, and 0.9 ( $\geq 0.8$  acceptable). S-CVI/Utility agreement (proportion of items on a scale that achieves a relevance rating of 3 or 4 by all the experts) was calculated as 1 ( $\geq 0.8$  acceptable) for all the domains.

The questionnaire encompasses four parts to collect data regarding the socio-demographic profile of study subjects, knowledge, attitude and practices towards hypothyroidism and its management. The socio-demographic characteristics comprised of age, gender, residence, educational status, occu-

pation, and family income.

### **Assessment of knowledge towards hypothyroidism and its management**

The knowledge of hypothyroidism, and its management was assessed by using a 16-point scale. There were 18 knowledge related closed-ended, open-ended, and multiple-choice questions that carried 16 correct responses. Each correct response was given a point of 1 and a wrong response of 0. The maximum points estimated to be 16 and a minimum of 0. Points to, aware about thyroid gland location (1 point), definition of hypothyroidism (1 point), symptoms of hypothyroidism (1 point for any four correct responses among symptoms like Hair fall, Neck pain, neck swelling, sore throat, constipation, weight gain, menstrual irregularities, infertility, and lethargy), major causes of hypothyroidism (1 point for any four correct responses among causes like lack of iodine in diet, damage or disorders of pituitary gland, thyroid surgery, radiation therapy, genetic dysfunction, auto-immunity against thyroid gland, treatment of hyperthyroidism, and certain medications), population at risk (1 point for any four correct responses among female, elderly people, pregnant women, family history of hypothyroidism, and obese person), curability of hypothyroidism (1 point), hypothyroidism affects their children (1 point), to consult endocrinologist (1 point), thyroid profile tests and their interpretation with hypothyroidism (1 point), foods need to avoid in hypothyroidism (1 point), treatment option in hypothyroidism (1 point), dose titration requirement in pregnant women (1 point) different brands of thyroid tablets does not show similar effect (1 point), lifelong usage of thyroid tablets (1 point), drugs not to be taken with thyroid tablet (1 point), and complications of under or no treatment of hypothyroidism (1 point). After determination of knowledge points, original Blooms Cut Off Points were used to categorize knowledge levels, where 80-100% correct responses contain a score of (13-16) meant a good knowledge, 60-79% correct responses comprise a score of (10-12) meant a moderate knowledge and <60% correct responses comprise a score of (9 or less than 9) meant a poor knowledge (Narayana et al., 2017).

### **Assessment of attitude towards hypothyroidism and its management**

Attitude towards hypothyroidism and its management was assessed by putting 10 statements regarding the causes, dietary restrictions, complications, levothyroxine therapy, medication adherence, and herbal medicine on Likert's scale. The statement on Likert's scale has positive and negative replies that

ranged from agree 3, neither agree or nor disagree 2, and disagree 1. The maximum score expected from all statements is 30 and a minimum of 10. If the persons scored above or equal to 15, will be considered as a positive attitude and less than 15 considered as a negative attitude towards hypothyroidism and its treatment (Susheela et al., 2018).

### **Assessment of practices towards hypothyroidism and its management**

Practices toward hypothyroidism and its management was assessed by using 10 closed, and multiple-choice questions that carried 10 correct responses. Each correct response will be given "1" point and wrong answer of "0". The maximum estimated points were "10" and a minimum of "0". The patient scores above or equal to "8" will be considered as good practice and patient who scores less than "8" will be considered as a poor practise towards hypothyroidism and its management.

### **Assessment of medication adherence**

Adherence towards Thyroxine therapy was assessed by Visual Analogue Scale method and Pill count method. In the VAS method, the respondents were asked to mark their medication adherence rate for past 1 month on the scale. The scale comprises grading from zero to 10. In this, zero indicates no adherence and 10 indicates 100% adherence to the thyroxine therapy. In the pill-count method, the number of thyroxine tablets consumed were calculated based on the number of remaining thyroxine tablets with the patient, the percentage of medication adherence was calculated as the number of thyroxine tablets consumed in relation to the number of thyroxine tablets prescribed (Goruntla et al., 2018).

### **Pharmacist delivered patient counselling**

After assessment of baseline KAP and MA levels, patients are subjected for counselling session given by pharmacist for 15-20 minutes. The pharmacist delivered a counselling session comprises of education regarding hypothyroidism symptoms, causes, risky population, dietary restrictions, type of doctor to be consulted, frequency of physician visit, and frequency of taking thyroid function tests and its interpretation in hypothyroidism. The pharmacist also counseled regarding the time of administration and duration of thyroxine therapy, the importance of medication adherence, administration of the skipped dose, thyroxine therapy in pregnancy, drugs interfere with thyroxine therapy, and complications associated with non-adherence. The counselling session was aided by providing patient information leaflet (PIL) on hypothyroidism and its management in a local/English language versions.

**Table 1: Socio-demographic profile of study participants (n=403)**

Characteristic	Categories	Frequency (%)
Age in years	Mean ( $\pm$ SD)	44.2 $\pm$ 7.30
	<30	12 (2.9)
	30-39	62 (15.4)
	40-49	234 (58.1)
	>50	95 (23.6)
Gender	Male	64 (15.9)
	Female	339 (84.1)
Residence	Rural	297 (73.7)
	Semi Urban	64 (15.9)
	Urban	42 (10.4)
Educational status	Illiterate	184 (45.6)
	Primary School	128 (31.7)
	Secondary School	48 (11.9)
	College/University Level	43 (10.6)
Occupation	Farmer	156 (38.7)
	House Wife	167 (41.4)
	Student	49 (12.1)
	Trader	12 (2.9)
	Teacher	5 (1.2)
	Health Care Professional	10 (2.5)
	Others	4 (1.0)
	Monthly Household Income (INR)	<10,000 INR
10,000 – 20,000 INR		135 (33.5)
20,000 - 30,000 INR		56 (13.9)
30,000 – 40,000 INR		43 (10.6)
>40,000 INR		12 (2.9)

SD=Standard deviation; INR=Indian rupee

### Follow-up visit

At the end of the counselling, all patients are instructed to come for a follow-up visit after three months. In a follow-up visit, the KAP scores and medication adherence levels were measured by using an interview-based questionnaire method.

Knowledge, attitude, and practice scores were changed to the percentage by dividing the total score obtained for an individual patient for each domain with a maximum score of the same domain and then multiplied with 100. The mean percentage of KAP levels and medication adherence levels were compared between pre and post pharmacist intervention (counselling).

### Statistical analysis

The Epi Info 7 software (Epi-Info 7 for Dos version 3.5.1 software, Centers for Disease Control and Prevention, Clifton Road Atlanta, USA) was used for the analysis of data. Descriptive statistics like mean, standard deviation, frequency, and proportion were used to represent the socio-demographic profile of study subjects. Inferential statistics like Chi-square

test was used to test the adequacy of KAP between the pre and post-intervention. The paired t-test was used to compare mean KAP percentage and medication adherence levels before and after the intervention. A *P* value less than 0.05 was considered statistically significant.

### RESULTS AND DISCUSSION

A total of 403 patients were enrolled into the study. All study subjects given response towards KAP questionnaire, and they were counselled by a pharmacist regarding hypothyroidism and its management. On a follow-up visit (after three months), the majority (386; 95.8%) of the subjects were given a response, and only 17 (4.2%) of the participants are failing to attend follow-up visit due to their personal and professional work. Among 403 respondents, most (234; 58.1%) of them were between 40 and 49 years of age. The mean age of study subjects was (SD = 44.2 $\pm$ 7.30). Majority of enrolled subjects were females (339; 84.1%), residing in rural area (297; 73.7%), illiterate (184; 45.6%), farmer (156;

**Table 2: Knowledge levels before and after pharmacist mediated patient counselling**

Variable	Before Freq. (n=403)	(%)	After Freq. (n=386)	(%)
Knowledge about the location of thyroid gland location	380	(94.3)	381	(98.7)
Knowledge about hypothyroidism means	220	(54.6)	308	(76.4)
Knowledge about common symptoms of hypothyroidism	156	(38.7)	295	(73.2)
Knowledge about common causes of hypothyroidism	168	(41.7)	281	(69.72)
Knowledge about the persons who are more likely to get hypothyroidism	128	(31.7)	325	(80.6)
Knowledge about the curability of the disease	154	(38.2)	381	(94.5)
Knowledge about the familial predisposition of hypothyroidism	123	(30.5)	325	(84.2)
Knowledge about type of doctor to be consulted for hypothyroidism	116	(28.8)	347	(86.2)
Knowledge about thyroid function tests and its interpretation in hypothyroidism	82	(20.3)	215	(53.3)
Knowledge about foods need to be avoided in hypothyroidism	98	(24.3)	228	(56.5)
Knowledge about treatment strategy for hypothyroidism	102	(25.3)	301	(74.6)
Knowledge about necessity of dose titration in pregnant women	86	(21.3)	309	(76.6)
Knowledge about the same brand of thyroxine tablets use	105	(26.0)	230	(59.6)
Knowledge about how long thyroid tablets should be taken	132	(32.7)	339	(84.1)
Knowledge about drugs not to be taken along with thyroid tablets	69	(17.1)	281	(69.7)
Knowledge about complications associated with under or no treatment of hypothyroidism	86	(21.3)	331	(82.1)

38.7%) and housewife (167; 41.4%) as shown in Table 1.

Pharmacist mediated counselling about hypothyroidism definition, location of the gland, symptoms, causes, risk groups, familial predisposition, curability, endocrinologist consultation, thyroid function tests interpretation, avoiding foods, significance of levothyroxine therapy, dose titration during pregnancy, use of similar brand tablets, duration of therapy, contra concomitant drug administration, and complication of under or over treatment parameters shown a good improvement in knowledge, attitude, and practice at individual parameter levels as shown in Tables 2, 3 and 4.

Before counselling, most of the patients had moderate (141; 34.9%) and poor knowledge (168; 41.7%) levels. Patients had shown a wider improvement in attainment of the good knowledge levels after counseling (326; 80.8%) compared to baseline (94; 23.3%) with a  $P < 0.0001$ . Less than half of the patients only had a positive attitude (178; 44.1%)

in the baseline, but after counseling it was drastically raised (372; 92.3%) with a  $P < 0.0001$ . Good practice towards hypothyroidism management was more after counseling (375; 93.1%) compared to baseline (134; 33.2%) with a  $P < 0.0001$  as illustrated in Table 5.

The mean KAP percentage levels were significantly improved after counselling ( $80.5 \pm 16.4$ ;  $86.2 \pm 15.7$ ;  $67.5 \pm 13.8$ ) compared to before ( $34.1 \pm 21.7$ ;  $33.8 \pm 22.9$ ;  $24.5 \pm 20.9$ ) with a  $P$  value less than  $< 0.0001$  as depicted in Table 6.

There was a significant improvement in mean medication adherence levels measured by visual analogue scale method and pill count method after counseling ( $92.4 \pm 4.8$  and  $97.4 \pm 3.26$ ) compared to before counseling ( $76.8 \pm 6.8$  and  $80.3 \pm 6.4$ ) with a  $P$ -value  $< 0.0001$  as shown in Table 7.

Good knowledge, positive attitude, and rational practice towards hypothyroidism among patients play a vital role in achieving better long-term outcomes. There are very limited studies in relation

**Table 3: Attitude levels before and after pharmacist mediated patient counseling**

Variable	Before Freq. (n=403)	(%)	After Freq. (n=386)	(%)
Attitude toward hypothyroidism causes excessive weight gain and obesity	158	(39.2)	367	(91.1)
Attitude toward goitrogens like soya been, cauliflower, and cabbages should be avoided in hypothyroidism	172	(42.7)	291	(72.2)
Attitude toward normal conceive is difficult in thyroid insufficiency	110	(27.3)	352	(87.3)
Attitude toward dose titration is necessary if pregnancy is confirmed	89	(22.1)	370	(91.8)
Attitude toward hypothyroidism will acquires through genetically	192	(47.6)	331	(82.1)
Attitude towards herbal medicines are not helpful in cure of hypothyroidism	80	(19.8)	281	(69.7)
Attitude towards consultation with endocrinologist will gives an appropriate therapy for hypothyroidism	96	(23.8)	301	(74.7)
Attitude towards thyroxine tablets should not be stopped once thyroid laboratory profile comes normal	136	(33.7)	312	(77.4)
Attitude toward medication adherence plays a vital role in controlling symptoms and normalization of thyroid laboratory profile	148	(36.7)	351	(87.1)
Attitude towards self-adjustment of dose is not recommended in hypothyroidism	184	(45.6)	373	(92.5)

**Table 4: Practice levels before and after pharmacist mediated patient counseling**

Variable	Before Freq. (%) (n=403)	After Freq. (%) (n=386)
Practice of consulting thyroid doctor for every three months	106 (26.3)	329 (81.6)
Practice of taking thyroid functions tests for every three months	98 (24.3)	311 (77.1)
Practice of taking thyroid medications morning time immediately after bed	168 (41.7)	281 (69.7)
Practice of taking thyroid tablets before 60 minutes of food	150 (37.2)	269 (66.7)
Practice of never missing of thyroid tablet intake	82 (20.3)	243 (60.2)
Practice of double dose in the next day morning if the regular dose is missed	42 (10.4)	163 (40.4)
Practice of avoiding intake of calcium, iron, vitamin D, and Antacid tablets along with thyroid tablets	84 (20.8)	295 (73.2)
Following rational practice when switch on to alternative medicine	22 (5.4)	64 (16.6)
Practice of avoiding goitrogenic foods	106 (26.3)	281 (69.7)
Persons strongly agreed that thyroid tablets helps in control of hypothyroidism and its symptoms	128 (31.7)	369 (91.5)

**Table 5: Comparison of Adequacy of Knowledge, Attitude, Practices, and Medication Adherence of patients before and after Counseling**

Variable	Before Freq. (%) (n=403)	After Freq. (%) (n=386)	$\chi^2$ -value	P-value
Knowledge				
Good Knowledge	94 (23.3)	326 (80.8)	93.23	<0.0001
Moderate Knowledge	141 (34.9)	39 (9.7)		
Poor Knowledge	168 (41.7)	21 (5.2)		
Attitude				
Positive Attitude	178 (44.1)	372 (92.3)	46.20	<0.0001
Negative Attitude	225 (55.8)	14 (3.5)		
Practice				
Good Practice	134 (33.2)	375 (93.1)	78.14	<0.0001
Poor Practice	269 (66.7)	11 (2.7)		

**Table 6: Comparison of mean KAP before and after patient counselling**

Variable	Before (n=403) Mean $\pm$ SD	After (n=386) Mean $\pm$ SD	p-value
Knowledge	34.1 $\pm$ 21.7	80.5 $\pm$ 16.4	<0.0001
Attitude	33.8 $\pm$ 22.9	86.2 $\pm$ 15.7	<0.0001
Practice	24.5 $\pm$ 20.9	67.5 $\pm$ 13.8	<0.0001

KAP=Knowledge, Attitude, and Practice; SD=Standard Deviation

**Table 7: Comparison of mean medication adherence levels before and after patient counselling**

Method	Before (Mean $\pm$ SD)	After (Mean $\pm$ SD)	Difference (Mean $\pm$ SD)	p-value
Pill count	80.3 $\pm$ 6.4	97.4 $\pm$ 3.26	12.1 $\pm$ 6.4	<0.0001
VAS	76.8 $\pm$ 6.8	92.4 $\pm$ 4.8	10.3 $\pm$ 5.8	<0.0001

VAS=Visual Analogue Scale; SD=Standard Deviation

to KAP towards hypothyroidism in India (Kannan, 2010; Perumal *et al.*, 2015). Most of the studies focused towards the assessment of the KAP towards hypothyroidism, but no study made an attempt to provide intervention to improve the KAP levels among hypothyroidism patients. This is the first study intended to explore the effect of pharmacist delivered counseling on KAP and medication adherence levels in hypothyroidism patients. The study was performed in the rural settings of south India, where people deprived with financial status, formal education, and primary health care. So, there is a huge need of structured counselling sessions to improve their KAP towards hypothyroidism management.

The mean age of the study participants was 44.2 $\pm$ 7.30 years, most of them were age between 40-49 years. The findings were supported by a case-control study conducted at Nepal and the mean age of patients was 42 $\pm$ 13.4 years (Sushma

and Himad, 2015).

The findings of the study shown there was a poor baseline mean KAP levels among patients with hypothyroidism, which are similar with a cross-sectional study conducted in Delhi (Kumar *et al.*, 2017). This is majorly due to the majority of the respondents were illiterate (73.7%) and rural background (45.6%).

The knowledge levels in our study are very low compared to the knowledge results of the multi-centric study conducted in India (Sethi *et al.*, 2018). The major reason for the presence of the knowledge gap between these studies was due to enrollment of only literate patients in there study (Sethi *et al.*, 2018), whereas our study findings, explores the baseline knowledge levels of patients irrespective of their literacy, residing in rural settings in India. After delivery of counselling session about hypothyroidism and its management, most of the patients shown a significant improvement in the answering of knowl-

edge related questions with a  $P < 0.0001$ .

The study findings reveal that, less than half of the respondents had the right attitude towards hypothyroidism and its management. After the pharmacist delivered counselling session there was a significant ( $P < 0.0001$ ) improvement in positive attitudes towards various aspects like a consultation with endocrinologist requires to get a better patient care, self-dose adjustment was not advised, taking thyroid tablets should never stop without consulting endocrinologist, and dose titration is required if pregnancy is confirmed. A similar type of elevated positive attitudes levels are also observed in the pharmacist intervention study conducted among hypothyroidism patients attending endocrine clinic of Nepal (Sushma and Himel, 2015).

The study shown a significant improvement in the medication adherence levels measured by pill count and VAS methods after pharmacist mediated patient counselling. This suggests counselling about the importance of medication intake, and complications associated with non-adherence will have a greater impact over adherence levels in hypothyroidism patients.

#### Strengths and Limitations

This the first study aims to improve the KAP and medication adherence towards hypothyroidism and its management. Most of the hypothyroidism patients benefited by this study by resolving their misbeliefs, negative attitude, and wrong practices after delivery of counselling. Even the study was conducted in a large number of population, Quasi-Experimental design without control may cause interference of confounders (socio-demographic characteristics) with KAP and medication adherence levels of the study participants after the intervention.

Pill count and VAS methods will not give accurate values about medication adherence. Still, there is a need to develop novel techniques to measure and improve the medication adherence, which will further improve the outcomes of the diseases.

#### CONCLUSION

Pharmacist mediated patient counseling shown a positive effect on patient's knowledge toward hypothyroidism and its management. Therefore, there is a wide need of providing counseling and educational program to resolve stigmas, misconceptions, and wrong practices present in the minds of hypothyroidism. This study will give an initiation to promote the implementation of educational programs towards hypothyroidism patients.

#### ACKNOWLEDGEMENT

The authors would like to thank all participants who are involved in this research study. We also thank Dr. Sudheer Kumar, Director, RDT Hospital, Anantapur for his support to conduct the study in the hospital. All the authors are whole heartedly thankful to the people who are directly or indirectly responsible for the completion of the work.

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