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MEDICATION ADHERENCE AND EFFECT OF PATIENT COUNSELLING IN HYPOTHYROIDISM PATIENTS: A RANDOMIZED CONTROL STUDY

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Abstract:

Introduction: Hypothyroidism is a common clinical problem worldwide requiring life-long thyroid hormone replacement therapy for most patients. For more than four decades, numerous researches on how to properly measure and quantify medication adherence have been conducted but none of them can be counted as the gold standard. Different tools have been designed and validated for different conditions, in different circumstances. Generally, measurements of medication adherence are categorized by the WHO as subjective and objective measurements.

Objectives: the aim of this study is to assess patient compliance and to find out the impact of patient counseling to improve compliance among hypothyroidism patients.

Methods: This randomized control research, which involved 88 hypothyroidism patients over the course of three visits, compared the levels of patient compliance in Group A, which received standard counseling, and Group B, which received advanced counseling.

Results Total 88 patients were included in the study 67 female and 21 were males among them 36 female and 8 males in group A and 31 female and 13 males in group B. Mean of age was 45 in total, 44.44 in group A and 45.44 in group B. Mean of duration of disease was 5.53 in total, 5.55 in group A and 5.44 in group B. Mean of No. of drugs prescribed is 2.32 in total, 1.88 in group A and 2.69 in group B respectively. The variables show that high adherence, medium adherence, and low adherence in Group A visit 1 shows 0(0%), 0(0%) and 44(100%), visit 2 shows 0(0%), 2(4.54%) and 42(95.45%), visit 3 has 0(0%), 10(22.72%) and 32(72.72%) respectively. Group B visit 1 has 0(0%), 0(0%) and 44(100%), visit 2 shows 0(0%),3(6.81%) and 41(93.1%) and visit 3 has 7(15.9%), 28(63.63%) and 9(20.45%) respectively. Above variables show that mean of medication adherence in group A 5.97, 4.27 and 3.25 in visit 1, 2 and 3 respectively, and Group B 5.83, 3.74 and 1.72. Reduction shows the improvement but Group B has more significant improvement then Group A.
Medication Adherence improvement in follow-up visits of group A and B has proven with the help of one-way ANOVA on the basis of p value as per Table and Group B in Table. Mean difference shows

Group B has more significant difference comparatively Group A, which reveals that Advance Counselling has significant role in improvement of Adherence.

Conclusion: This study demonstrates the necessity of patient counseling for patients in the healthcare system on the gravity of the illness, medication understanding, and dosing schedules. This study also emphasizes the importance of clinical pharmacists for adequate patient counseling in every healthcare setting to enhance therapeutic results in the case of chronic illnesses.

Keywords: Medication adherence, Patient Compliance, assessment of medication compliance.

1. INTRODUCTION:

Hypothyroidism is a common clinical problem worldwide requiring life-long thyroid hormone replacement therapy for most patients. Studies in Northern Europe, Japan, and the USA have found that its prevalence ranges between 0.6 and 12 per 1,000 women and between 1.3 and 4.0 per 1,000 men. [1-4] In addition, the prevalence of hypothyroidism, mainly due to autoimmune thyroiditis, increases with increasing age. [5]

Thyroid diseases are, arguably, among the commonest endocrine disorders worldwide. India too, is no exception. According to a projection from various studies on thyroid disease, it has been estimated that about 42 million people in India suffer from thyroid disease.[6] The prevalence of hypothyroidism in the developed world is about 4-5%. The prevalence of subclinical hypothyroidism in the developed world is about 4-15%. In a developing and densely populated country like India, communicable diseases are priority health concerns due to their large contribution to the national disease burden.[7] A correct etiological, anatomical, and functional diagnosis of the thyroid problem is absolutely essential for the proper treatment and well-being of the patient.[8] For more than four decades, numerous researches on how to properly measure and quantify medication adherence have been conducted but none of them can be counted as the gold standard. Different tools have been designed and validated for different conditions, in different circumstances. Generally, measurements of medication adherence are categorized by the WHO as subjective and objective measurements.

Subjective measurements involve those requiring the provider's or patient's evaluation of their medication-taking behavior. Self-report and healthcare professional assessments are the most common tools used to rate adherence to medication. The most common drawback is that patients tend to underreport nonadherence to avoid disapproval from their healthcare providers.[9]

2. MATERIALS AND METHODS:

The study was conducted at Parul Sevashram Hospital, Vadodara, after the clearance of the institutional ethics committee. A total of 88 Hypothyroidism patients were included in the study after the consent of the patients. The patients were randomly categorized in two groups (44 in each group) and follow-up was taken over the period of 6 months. One group is named Group A (normal counseling) and another one is Group B (Advanced counseling). Detailed criterion of normal and advanced counselling is mentioned in the study procedure.

Inclusion criteria:

- Hypothyroidism patients of age 18-70 years.
- Both male and female patients.

Exclusion criteria:

- Patients other than hypothyroidism.
- Patients who are not willing to come for follow-up.
- Pregnant women.

Study procedure

Patients were selected from the Endocrine Disease Department of Parul Sevashram Hospital, Vadodara. Patients were selected on the bases of inclusion and exclusion criteria. Once the patient was found suitable for the study, their voluntary consent was taken by Principle Investigator. Further patients were randomized by simple randomization method in Group A and Group B. Medication adherence assessment was done by Morisky Medication Adherence Assessment (MMAS8).

Further Group A was given normal counseling related to drug administration, drug timings, and route of drug administration, and Group B was given advanced counseling like the seriousness of the disease, the effect of the drug, and administration procedures with the help of printed leaflets. They were also instructed to come for the next follow-up on the date mentioned in the prescription by the physician.

3.RESULTS:

In total, there were 88 participants in the study. among them study 67 were female and 21 were male among them 36 were female and 8 males in Group A and 31 were female and 13 males in Group B. Age, income, educational qualification, and number of prescribed drugs, were further categorized as follows and patient compliance was also assessed accordingly (Table no. 1 & 3). The Mean of age was 45 in total, 44.44 in group A and 45.44 in group B. The mean duration of disease was 5.53 in total, 5.55 in group A and 5.44 in group B. Mean of No. of drugs prescribed is 2.32 in total, 1.88 in group A, and 2.69 in group B respectively. (Table 2) Hypothyroidism patients were randomized into groups as per previously mentioned, Group A and Group B. MMAS8 was applied in both groups to assess patient compliance. On the first visit The results show Group A has high adherence of 0(0%), medium adherence of 17(38.63%), and low adherence of 27(61.36%), and Group B high adherence of 0(0%), medium adherence 26 (59.09%) and low adherence 18(40.90%) has distribution in hypothyroidism group,(Table 4), which shows that in group A and group B, there is a difference in medium adhered patients and high adhered patients at visit 1 but a mean of both groups are almost same and the same has proven by the Student T-test (p-value- non-significant) in table 5. Compliance shows significant improvement in follow-up visits. The mean of medication adherence in Group A 5.97, 4.27, and 3.25 in visits 1, 2, and 3 respectively, and in Group B 5.83, 3.74, and 1.72. Reduction shows the improvement but Group B has a more significant improvement than Group A. (Table. 6) Both the groups showed improvement in of p-value but the mean difference represents more significance in Group B. (Table no, 7-9).

Table: Demographic Data of participants

Parameters	Total	Percentage	Group A	Male	Female	Group B	Male	Female
	88		44	9	35	44	12	32
Gender Ratio								
Male	21	23.86						
Female	67	76.14						
Age Group (Years)								
18-30	20	22.73	13	3	10	7	2	5
31-40	14	15.91	5	0	5	9	0	9
41-50	25	28.41	13	4	9	12	4	8
51-60	17	19.32	6	1	5	11	5	6
>60	12	13.64	7	2	5	5	1	4
Income (INR/Month)								
<200000	45	51.14	20	3	17	25	8	17
>200000	43	48.86	24	6	18	19	4	15
Educational Qualification								
<10	20	22.73	13	2	11	7	1	6
10th	21	23.86	8	1	7	13	5	8
12th	13	14.77	5	1	4	8	1	7
>12	34	38.64	18	5	13	16	5	11
Duration of Disease(years)								

<1	15	17.05	8	1	7	7	2	5
1-5	30	34.09	16	6	10	14	4	10
6-10	32	36.36	14	1	13	18	5	13
>10	11	12.50	6	1	5	5	1	4
No. of Prescribed Drugs								
1-2	55	62.50	34	7	26	21	5	16
3-5	33	37.50	10	2	8	23	7	16
6-8	0	0.00	0	0	0	0	0	0
>8	0	0.00	0	0	0	0	0	0

Table 2: Demographic data of participants- Mean and Standard error (SEM)

	Total	Group A	Group B
Female	67	36	31
Male	21	8	13
Age in years (mean ± SEM)	45±1.42	44.44±2.10	45.44±1.95
Duration of disease in years (mean ± SEM)	5.53±0.43	5.55±0.68	5.44±0.0.55
No. of prescribed drugs (mean ± SEM)	2.32±.10	1.88±0.15	2.69±0.12

Table 3: Demography and Medication Adherence Assessment by Moriski's Medication Adherence Assessment Scale (MMAS8)

Variables	Total	%	High adherence	%	Medium adherence	%	Low adherence	%
	88	(100.00%)						
Gender Ratio								
Male	21	(23.86%)	2	(9.52%)	9	(42.86%)	10	(47.62%)
Female	67	(76.14%)	5	(7.46%)	29	(43.28%)	33	(49.25%)
Age Group (Years)								
18-30	20	(22.73%)	1	(5.00%)	8	(40.00%)	11	(55.00%)
31-40	14	(15.91%)	1	(7.14%)	6	(42.86%)	7	(50.00%)
41-50	25	(28.41%)	3	(12.00%)	9	(36.00%)	13	(52.00%)
51-60	17	(19.32%)	2	(11.76%)	10	(58.82%)	5	(29.41%)
>60	12	(13.64%)	0	(0.00%)	5	(41.67%)	7	(58.33%)
Income (INR/Month)								
<200000	45	(51.14%)	3	(6.67%)	26	(57.78%)	16	(35.56%)
>200000	43	(48.86%)	4	(9.30%)	12	(27.91%)	27	(62.79%)
Educational Qualification								
<10	20	(22.73%)	1	(5.00%)	11	(55.00%)	8	(40.00%)
10th	21	(23.86%)	3	(14.29%)	7	(33.33%)	11	(52.38%)
12th	13	(14.77%)	2	(15.38%)	6	(46.15%)	5	(38.46%)
>12	34	(38.64%)	1	(2.94%)	14	(41.18%)	19	(55.88%)
Duration of Disease(years)								
<1	15	(17.05%)	0	(0.00%)	5	(33.33%)	10	(66.67%)
1-5	31	(35.23%)	0	(0.00%)	13	(41.94%)	18	(58.06%)
6-10	32	(36.36%)	6	(18.75%)	15	(46.88%)	11	(34.38%)
>10	10	(11.36%)	1	(10.00%)	5	(50.00%)	4	(40.00%)
No. of Prescribed Drugs								
1-2	55	(62.50%)	4	(7.27%)	20	(36.36%)	31	(56.36%)
3-5	33	(37.50%)	3	(9.09%)	18	(54.55%)	12	(36.36%)
6-8	0	(0.00%)	0	(0.00%)	0	(0.00%)	0	(0.00%)
>8	0	(0.00%)	0	(0.00%)	0	(0.00%)	0	(0.00%)

Table 4: Medication Adherence Assessment by HJR in first visit (Screening visit)

	Group A	Group B
High Adherence	0	0
Medium Adherence	17(38.63%)	26(59.09%)
Low Adherence	27(61.36%)	18(40.90%)

Table 5: Patient compliance score difference in both groups by MMAS8 in first visit (Screening visit)

	Group A	*Group B*
Mean	5.977	5.841
SD	0.8209	0.9631
Hypothesized Mean Difference	0.5	
P value	0.2986	
F value	1.376	
P(T<=t) two-tail	0.2383	
t Critical two-tail	0.7148	

Non-significant. Student T-test is applied in the medication adherence assessment of both groups.

Table 6: Medication Adherence Score from baseline to follow-ups by MMAS8

	Group A			**Group B**		
	visit 1	visit2	visit3	visit 1	visit2	visit3
Mean±SEM	5.97±0.12	4.27±0.11	3.25±0.12	5.83±0.14	3.74±0.14	1.72±0.14

Mean±SEM of medication adherence by MMAS8 in all three visits of both the group. The reduction in mean shows the improvement in adherence.

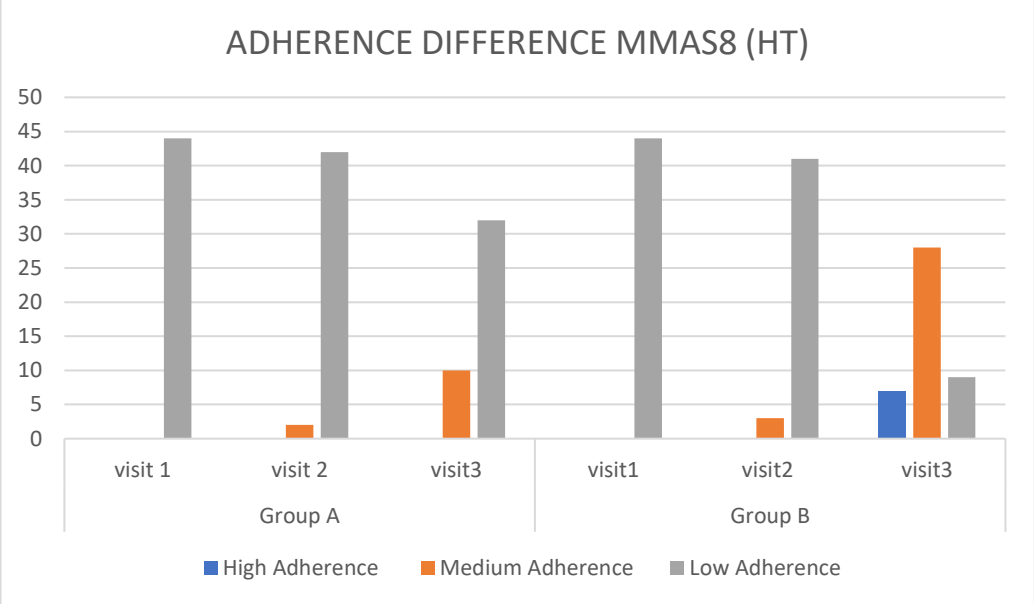

Figure 1: Patient compliance assessment visit-wise

Table 7: Medication Adherence Score from baseline to follow-ups by MMAS8.

	Group A			**Group B**		
	visit 1	visit2	visit3	visit 1	visit2	visit3
High Adherence	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	7(15.9%)
Medium Adherence	0(0%)	2(4.54%)	10(22.72%)	0(0%)	3(6.81%)	28(63.63%)
Low adherence	44(100%)	42(95.45%)	32(72.72%)	44(100%)	41(93.1%)	9(20.45%)

Table 8: Group A Medication Adherence Score from baseline to follow-ups by MMAS8

Bonferroni's multiple comparison test	**Mean Diff.**	**95%CI of diff.**	**Significant**	**Summary**
Visit 1 vs. Visit 2	1.682	1.264 to 2.100	Yes	***
Visit 1 vs. Visit 3	2.727	2.309 to 3.146	Yes	***
Visit 2 vs. Visit 3	1.045	0.627 to 1.464	Yes	***

P value <0.0001=****, <0.001=***, <0.01=**, <0.05=*

One way ANOVA used on medication adherence of all the visits, visit 1 vs. visit 2, visit 1 vs. visit 3 and visit 2 vs. visit 3 showed in the table

Table 9: Group B Medication Adherence Score from baseline to follow-ups by MMAS8

Bonferroni's multiple comparison test	Mean Diff.	95%CI of diff.	Significant	Summary
Visit 1 vs. Visit 2	2.068	1.570 to 2.567	Yes	***
Visit 1 vs. Visit 3	4.091	3.592 to 4.589	Yes	***
Visit 2 vs. Visit 3	2.023	1.524 to 2.521	Yes	***

P value <0.0001=****, <0.001=***, <0.01=**, <0.05=*

One way ANOVA used on medication adherence of all the visits, visit 1 vs. visit 2, visit 1 vs. visit 3 and visit 2 vs. visit 3 showed in the table

4. DISCUSSION:

Results show high compliance in Group B (advanced counseling). Similarly, the study reported an overall medication adherence level in subjects was 34.6% according to Morisky-8- the item questionnaire.[10] This study has shown improvement in compliance with the patients of the mean of medication adherence in group A 6.06, 4.34, and 2.88 in visit 1, 2 and 3 respectively, and Group B 5.67, 3.81 and 1.95. Reduction shows an improvement but Group B has more significant improvement than Group A. Similar A cross-sectional study was conducted in Dhulikhel Hospital, Kathmandu University Hospital. Patients with hypothyroidism on levothyroxine fulfilling the inclusion criteria were enrolled in this study. After obtaining informed consent from the patients, a structured questionnaire was used to interview the patients.

The study concluded that more than half of the patients have adhered to the Levothyroxine therapy.[11] Results also showed 15.09% of patients reported forgetting to take their medication, 23.86% of patients don't take their medication for the reason other than forgetting, 54.54% of patients stopped their medication when they feel worse, 30.68% of patients forgot to carry their medicines during travel, 39.77% of patients cut their medications while they feel their disease was under control, 23.86% patients feel hassled about sticking on their treatment plan, 27.27% patients forget to take all their medications. Various studies have been conducted on MMAS8 and other questionnaires, which showed similar results. According to a study Among the patients who are not taking the medication regularly the major reason for their missing the dose is forgetfulness about the medication. In a few studies, it has been observed that patients don't take their medicines because of hesitation to stick to one medication plan to reduce thyroid.[12] during same study shows It was observed that significant number of non-adherent patients had discontinued medication for some interval of time because of the reduction of symptoms due to medication. The patients have the intensity to discontinue medication when symptoms disappear as suggested by previous report.[12]

5. CONCLUSION:

This study reveals that Hypothyroidism patients have very low compliance which can lead to life-threatening conditions. Compliance significantly improved in both groups but the counseling group (group B) show more significant improvement, which concludes that patients should be given proper counseling about the importance of drugs in their disease. This study also concludes the need for other professionals in the healthcare setups for patient counseling to improve compliance as well as a therapeutic outcome among patients.

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