Assessment of newly developed medication adherence tool in community pharmacy settings. - A Pilot Study.

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Abstract:

Introduction

Ensuring medication adherence is a major issue for patients with chronic illnesses who are on multiple medications. Tools designed to enhance medication adherence, like the MEDSTIK need to be implemented in community pharmacies through the healthcare system to support patients.

Aims

To assess the impact of the newly developed medication adherence tool in improving medication adherence.

Methods

A pilot study was conducted for a month to evaluate the feasibility of the medication adherence tool, which uses colour and shape codes to enhance medication adherence. Patients with chronic conditions were selected from a community pharmacy. Baseline adherence was assessed using a validated questionnaire, followed by administering the tool and reassessment of adherence after one month. Descriptive and inferential statistical tools were used.

Results

A cohort of 30 patients was enrolled from the community pharmacies. The demographic details indicated that the majority of patients were male (n=17, 56.7%), primarily aged 40 to 60 years (n=12, 40%). Hypertension was the most common chronic condition (n=16, 53.3%), majority of them diagnosed within the last five years (n=17, 56.7%). Baseline adherence before MEDSTIK tool was 13.3% of patients adhering to their prescribed regimen. Post-implementation results were significantly better showing an increase in adherence to 73.3%. The non-adherent average score is 5.87 (SD ±1.3) and the adherence average score improved to 3.10 (SD ±1.7). The paired t-test was found to be a p-value <0.0001

Conclusion

The newly developed MEDSTIK tool significantly improved medication adherence in patients with chronic conditions with polypharmacy.

Keywords: Medication adherence, Community Pharmacy, Feasibility study, Chronic diseases, Community pharmacists, Medication non-adherence

Introduction:

Medication non adherence or failure to take medications as prescribed are one of the important factors limiting the effectiveness of medication in practice [1] Around 50 % of patients taking medications for their chronic diseases are non-adherent which leads to increased morbidity, mortality and hospitalization stay. [2] In India there is a growing concern on prevalence of non-communicable diseases (NCDs). [3] The cardiovascular diseases, respiratory diseases, Diabetes mellitus kills around. 4.7million People annually and 226.8 million disability-adjusted life year. [4] Recent evidences from developing countries shows only 50 % of patients are adherent to anti-hypertensive medications, 43.4% are adherent to oral hypoglycemia agents & 48.1% to chronic obstructive pulmonary disease (COPD) medications. [5] Non-adherence is estimated to cost US $289 billion in USA. Over $ 100 billion dollars is spent on preventable hospitalizations as a result of medication non adherence. [6] World Health Organization (WHO) has identified causes of medication non adherence such as

1) Values, attitudes, social backgrounds, culture & age
2) Factors associated with diseases such as medication taking behavior's, treatment duration, treatment complexity, side effect of medication & frequency of expected intake.
3) Patient related such as lack of understanding due to low literacy rates,
4) Health care related factors including limited accessibility to the health care professionals, support from the family, relationship between the patient and the physician or nurse, health care professionals, friends and health education
5) Medication related factors such as complications and socioeconomic factors, which include both socioeconomic status and the stigma surrounding certain chronic conditions
6) Financial factors [7]

To address these causes, there is no particular method to minimize non adherence.

Discussing medication adherence strategy with MEDSTIK Tool.

Addressing the complex and ever-changing nature of non-adherence is an ideal adherence intervention. [8] It should be having the capacity to improve patient education, accessibility, convenience and continuous reminder. [9] Additionally, it should facilitate reciprocal problem solving and assist the patients track their own progress. [10] MEDSTIK Tool was developed to address the medication non-adherence. This method contains colour and shape coding followed by Do you know Leaflets. This method mainly focuses on patients with chronic diseases to

minimize medication non adherence. [11] Community pharmacists will identify the patients who are at risk of non-adherence and provide them with the necessary support and resources to ensure that they take their medication as prescribed.[12] At present community pharmacist is providing newer services to improving medication adherence through the use of various methods such as patient counselling, medication therapy management, Medication Synchronization Programs.[13] Hence this study was carried out to assess the impact of the newly developed MEDSTIK tool in improving medication adherence.

Methodology

Study design: A Pilot study.

Study Period: Study conducted for a period of one month from October 2023 to November 2023.

Study site: This study was conducted in six community pharmacies of mysuru city.

Sample size: Convenience sampling was adopted to this study.

Ethical committee approval: The study protocol was reviewed and approved by Institutional Ethics committee of JSS Medical College, Mysore vide IEC Registration ECR/387/Inst/KA/2013/RR-19 dated on 01.09.2023.

Source of data: The Patients demographic details such as age, gender, disease and year of diagnosis was collected using data collection form. Medication adherence was assessed using developed and validated Medication adherence questionnaire (MAQ).

Study criteria:

Inclusion criteria: Patients with chronic diseases like hypertension, diabetes mellitus, asthma and COPD have consented to participate in the study

Exclusion criteria: Chronic disease patients not willing to participate in study.

Development of MEDSTIK Tool.

13a Method-1 Colour and shape coding.

This method involves assigning a unique colour and shape to each medication that must be taken at specific times throughout the day. [14] The colour and shapes are chosen based on the time of day that the medicines should be taken, making it easier for the patient to identify which medication should be taken at which time & increases medication adherence among chronic diseases. [15]

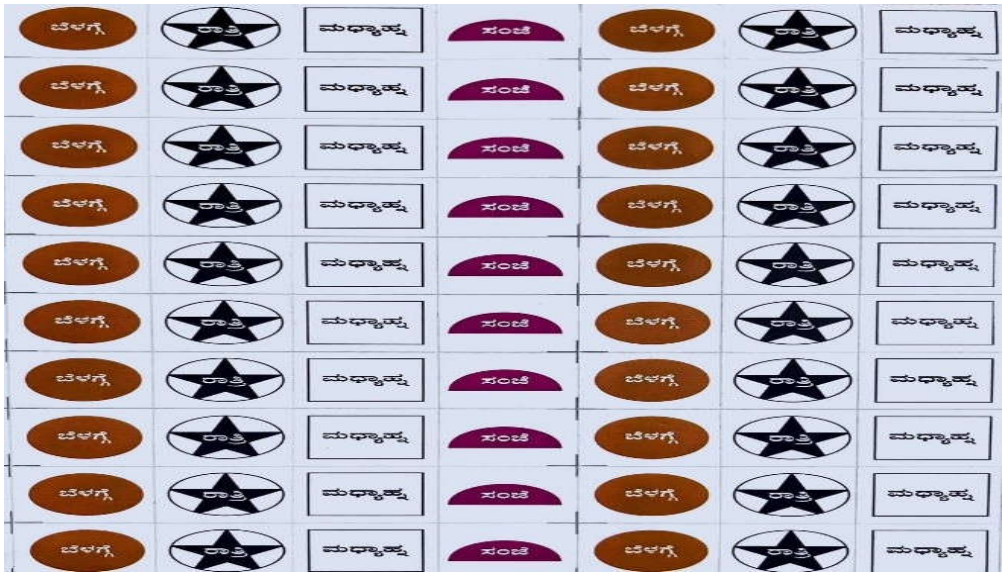


Figure 1 Colour and Shape coding method.

Method-2 Do you know Leaflets.

In this method a leaflet is created for the patients with chronic diseases, which they can take home and refer whenever they have any doubts about their health. These leaflets will be customized to the specific conditions being studied and will be based on extensive research to ensure that the information provided is accurate and helpful. [16]

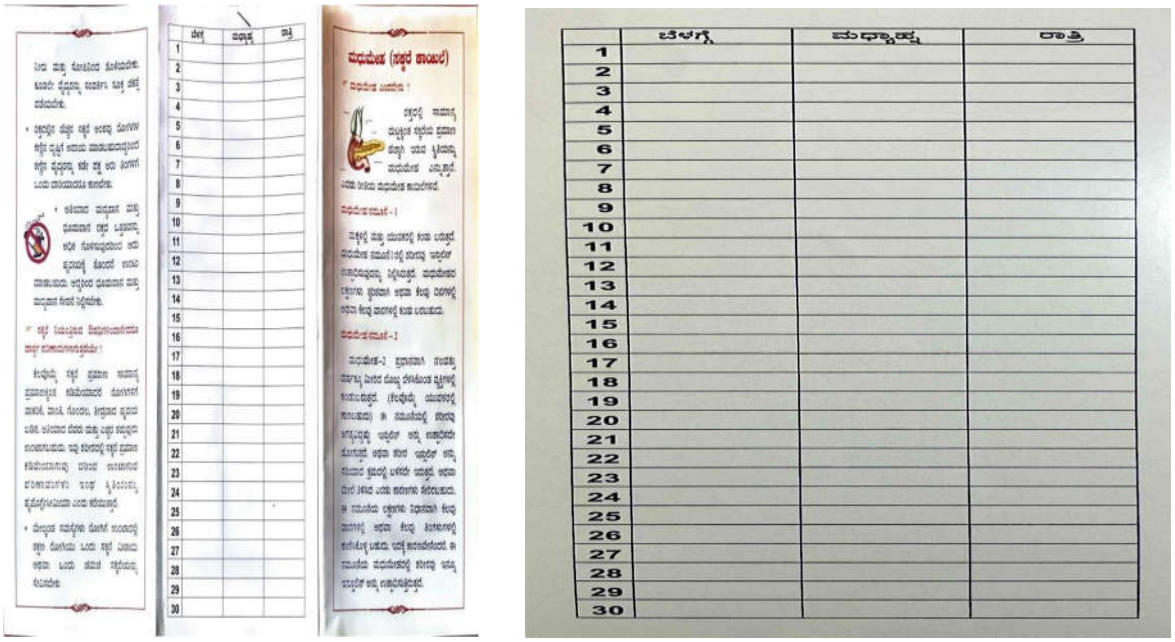


Figure 2: Do you know leaflets

Development of Medication adherence questionnaire (MAQ)

An extensive literature review was carried out to design the MAQ which helps in analyzing if the patient is adherent to their medications.[17] The questionnaire contains demographic details of the patients like their name, age, disease, and medication name. The questions are designed in such a way that they aid in identifying different barriers to adherence in case the patient is not adherent to the prescribed regimen. These are 8-component questions, a patient is considered adherent if the score falls between 0 - 4 and non-adherent if it is > 4. Patients suffering from chronic diseases who frequently visited the pharmacy were presented with the following set of questions.

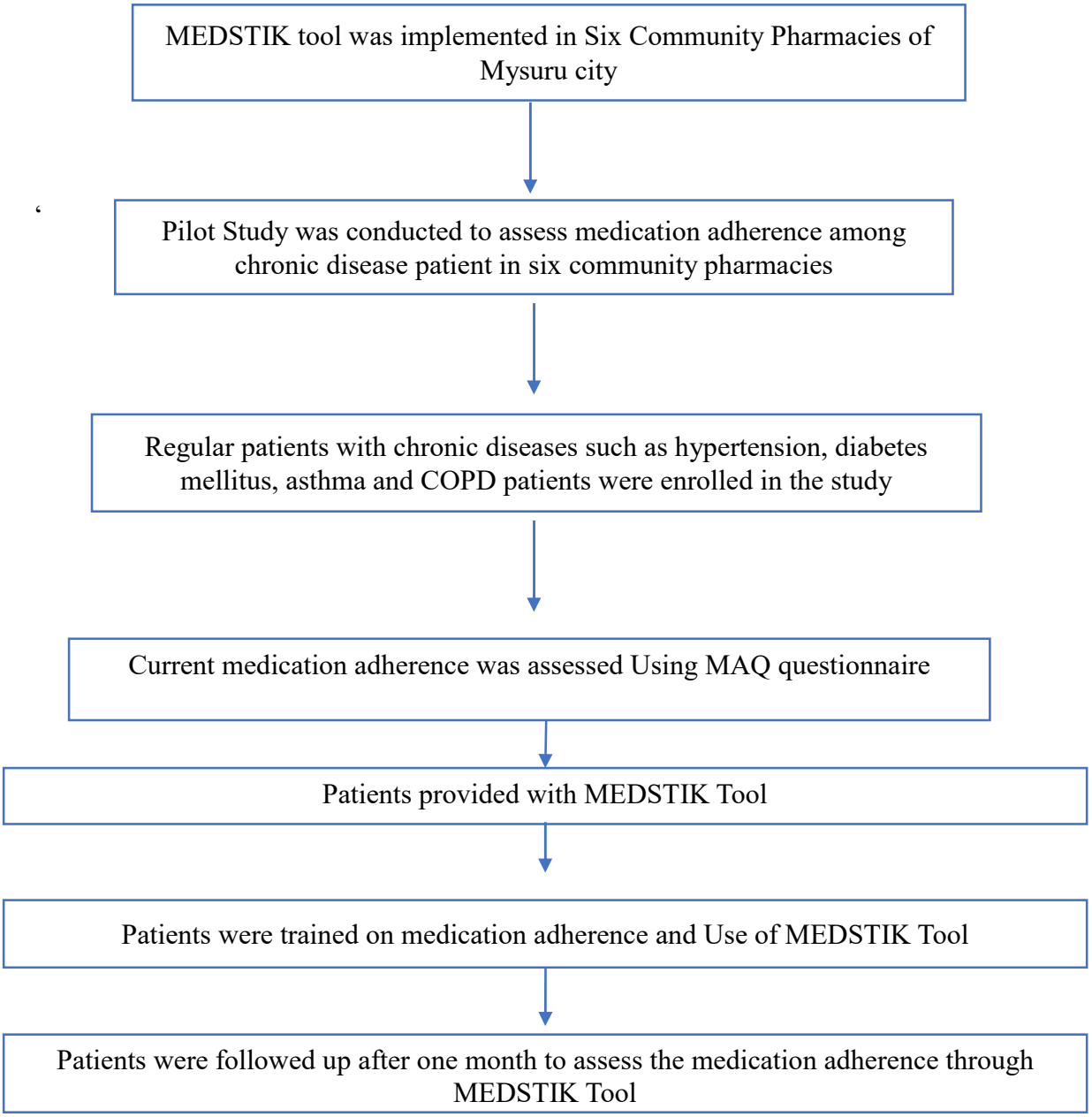
Validation of Medication adherence questionnaire (MAQ)

Individualized questions averages are assessed using the CVI (I-CVI) scores and scale level CVI (S –CVI) is used to evaluate the average in each category. The questionnaire was subject to validated for its content by a group of 20 experts in their fields. They are professor, associate professor, assistant professor, lecturers, postgraduate students, and clinical pharmacists from department of pharmacy practice. The experts are asked to evaluate the questions based on ambiguity, simplicity, clarity and relevance on a scale of one to four, with four being the highest score. Most of the items with CVI scores >0.75 are accepted and items with CVI < 0.75 are modified based on the expert's opinion. Following the completion of the validation process, the results are analyzed and the final questionnaire is developed.[18]

Scoring of Medication Adherence Questionnaire: (MAQ)

A total of eight questions was developed and validated. Questions help to determine whether the patient is adherent to the medications or not. Scoring for the questions was done by allotting one point to answers which indicates non-adherence and zero points to answers which indicates adherence. In questions 1, 2, 6, 5c, 5d and 8, "yes" receives one point and "no" receives zero points. In questions 3, 4, 7, 5a and 5b, "yes" receives 0 points and "no" receives 1 point. If the score falls above 4 points the patient is considered to be non-adherent to their medications. [19]

Assessment of medication adherence using MEDSTIK Tool in community pharmacies



The MEDSTIK Tool was implemented in six community pharmacies of mysuru city. To assess the medication adherence on chronic disease patients a pilot study was conducted in community pharmacies. Patients visiting regular with chronic diseases like hypertension, diabetes mellitus, asthma and COPD were enrolled in the study after taking inform consent form. Baseline medication adherence was evaluated using developed and validated Medication adherence questionnaire (MAQ). The patients were provided with MEDSTIK Tool and they were trained on medication adherence, use of MEDSTIK Tool. After one month of follow up chronic disease patient's medication adherence was assessed using Medication adherence questionnaire (MAQ). The above flow chart describes the process of assessment of medication adherence using MEDSTIK Tool in community pharmacies.

Statistical analysis:

Data collected were analyzed with software -Statistical Package for Social Sciences (SPSS) version 26. Descriptive statistics such as number, percentage, mean ± standard deviation, median, was used to collect the demographics of chronic disease patients & response of medication adherence questionnaire. Inferential statistics such as student paired t- test was applied to assess medication adherence before and after MEDSTIK Tool.

Results:

Medication Adherence Questionnaire (MAQ):

Following a thorough review of the literature on medication adherence assessment a total of eight questions were include in medication adherence questionnaire. (MAQ). On a scale of one to four, with four being the greatest score, the team experts were asked to score the questions according to relevance, clarity, simplicity, and ambiguity. If the I-CVI and S-CVI percentage for a newly prepared questionnaire are greater than 82% the they are considered as minimum acceptable rate. The developed questionnaire items all receives score above 80% and can be used for the proposed medication adherence assessment in this study. All of the questions received a CVI greater than 0.75, thus no questions were eliminated. According to the Cronbach's alpha, the questionnaire internal consistency was 0.90. The details are presented in Table 1:

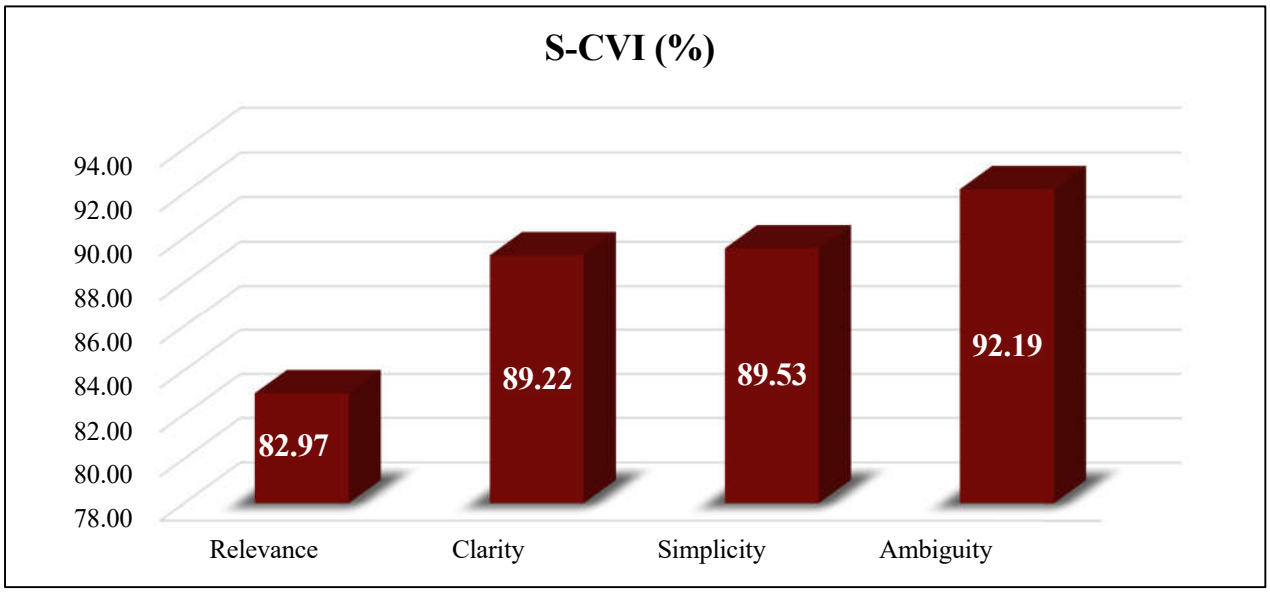
Table 1: Medication Adherence Questionnaire (MAQ) Content Validity Index score.

Parameters	Relevance score	Clarity score	Simplicity score	Ambiguity score	Average score	I-CVI (%)
q1	3.8	3.5	3.6	3.7	3.6	90.63
q2	3.5	3.7	3.7	4.0	3.7	92.19
q3	3.2	3.5	3.5	3.9	3.5	87.50
q4	3.2	3.5	3.7	3.6	3.5	86.88
q5	3.2	3.5	3.6	3.6	3.5	86.56
q6	3.3	3.7	3.6	3.4	3.5	86.88
q7	3.2	3.6	3.7	3.7	3.5	88.13
q8	3.3	3.8	3.5	3.8	3.6	89.06

AVG	**3.3**	**3.6**	**3.6**	**3.7**		
S-CVI (%)	**82.97**	**89.22**	**89.53**	**92.19**		

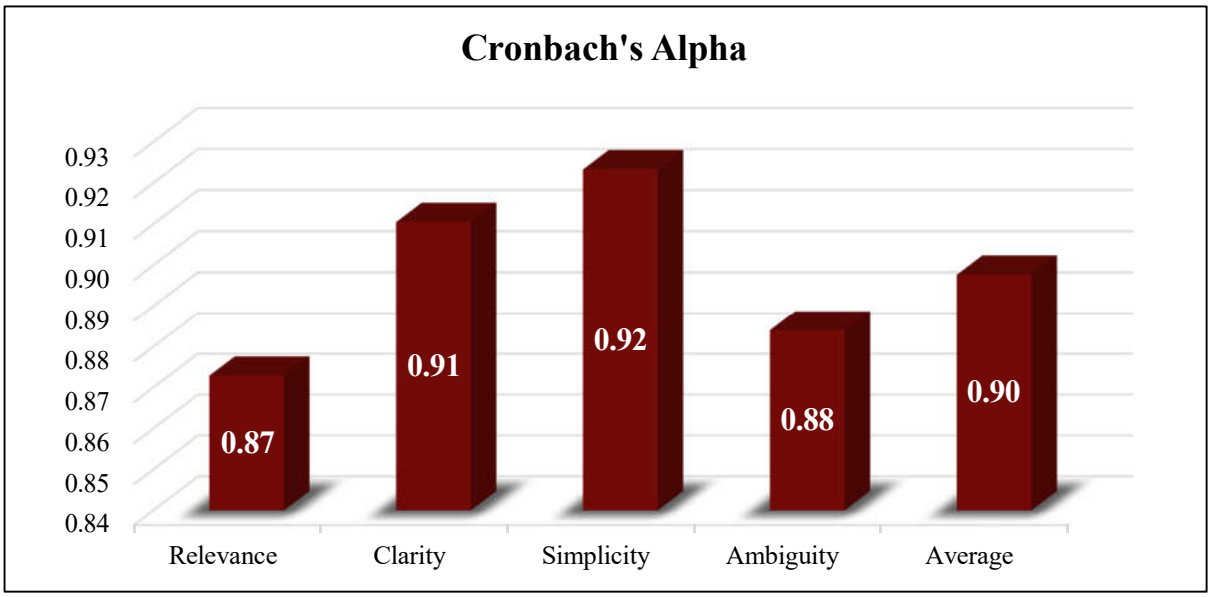
Ambiguity (92.19%) and simplicity (89.53%) were high among all parameters followed by clarity and relevance as shown in Figure 3

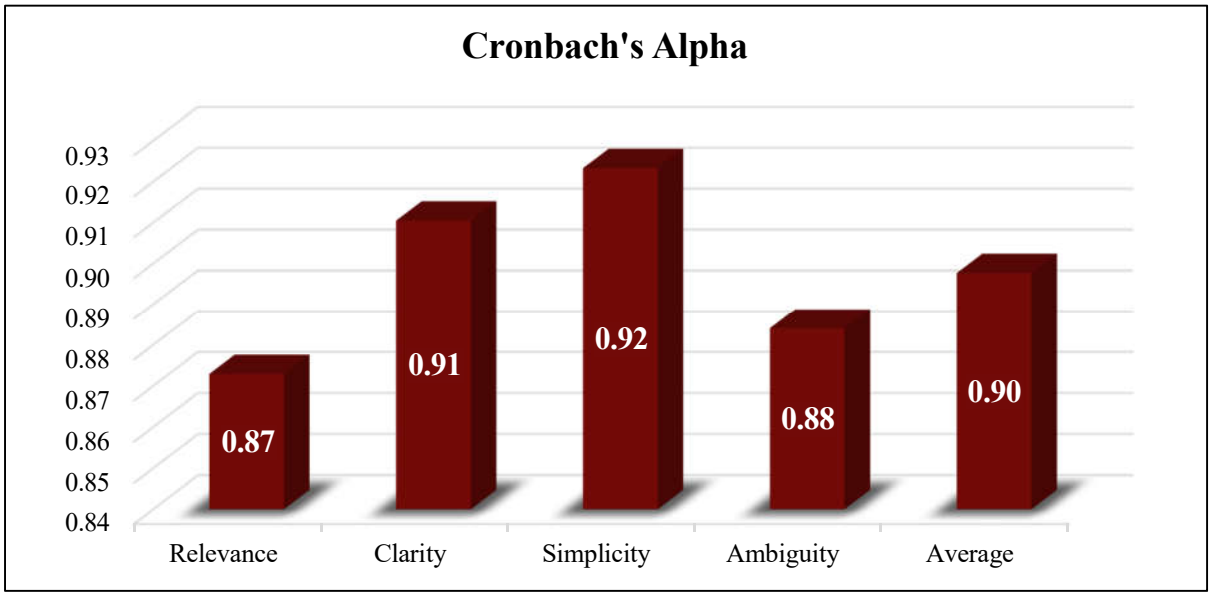
Figure 3: S-CVI Scores of Medication adherence questionnaire



Cronbach's alpha is used to assess the questionnaire's internal consistency, and its total score is 0.90. The questionnaire is deemed "Good" as its internal consistency is higher than 0.80.

Figure 4: Cronbach's Alpha of Medication Adherence Questionnaire (MAQ)





Demographics of chronic disease patients:

A total of 30 regular patients with chronic diseases were enrolled for the study from the community pharmacies. The majority of the patients were males (n = 17, 56.7%) and from the age range of 41-60 years old (n = 12, 40%). The patients were mostly diagnosed with hypertension (n = 16, 53.3%) and the majority were diagnosed within the last 5 years (n = 17, 56.7%). The detailed demographics of the patients enrolled for the study are mentioned in the below table: 2

Category	Features	Number (N)	Percentage (%)
Age (Mean = 56.4±15.9)	0-20 Years	0	0.0
	21-40 Years	6	20.0
	41-60 years	12	40.0
	61-80 Years	11	36.7
	Above 80 Years	1	3.3
Gender	Male	17	56.7
	Female	13	43.3
Disease	Hypertension	16	53.3
	Diabetes Mellitus	6	20.0
	Asthma/COPD	2	6.7
	Hypertension & Diabetes Mellitus	6	20.0
	Hypertension & Asthma/COPD	0	0.0
	Diabetes Mellitus & Asthma/COPD	0	0.0
Diagnosis	0-5 Years	17	56.7
	5-10 Years	8	26.7
	10-15 Years	4	13.3

Table 2: Demographics of chronic disease patients:

Responses of the patients to medication adherence questionnaire: (MAQ)

The medication adherence questionnaire responses by the 30 patients are shown below in Table 3.

Table 3: Responses of Patients to the Medication Adherence Questionnaire (MAQ)

The responses are recorded before and after providing the medication synchronization program (MEDSTIK). The responses were calculated to percentage to gain an understanding of the usefulness of the technique. In Question 3 (Do you know when to take your medication?), before MEDSTIK a small number of patients said “Yes” (n = 10, 33.3%) and after MEDSTIK

Questions	Yes	Percentage (%)	No	Percentage (%)
Before Medication Synchronization Program (MEDSTIK)				
Do you forget to take your medications ?	23	76.7	7	23.3
Have you ever cut down or stopped taking your medication?	24	80.0	6	20.0
Do you know when to take your medicine?	10	33.3	20	66.7
Do you know your prescribed medicines?	16	53.3	14	46.7
How often do you miss taking a dose?	21	70.0	9	30.0
Do you get confused between your medicines?	22	73.3	8	26.7
Do you take the right medications at the prescribed time?	6	20.0	24	80.0
Do you use any tools to help you remember to take your medication?	5	16.7	25	83.3
After Medication synchronization program (MEDSTIK)				
Do you forget to take your medications ?	18	60.0	12	40.0
Have you ever cut down or stopped taking your medication?	11	36.7	19	63.3
Do you know when to take your medicine?	25	83.3	5	16.7
Do you know your prescribed medicines?	23	76.7	7	23.3
How often do you miss taking a dose?	17	56.7	13	43.3
Do you get confused between your medicines?	14	46.7	16	53.3
Do you take the right medications at the prescribed time?	15	50.0	15	50.0
Do you use any tools to help you remember to take your medication?	27	90.0	3	10.0

the number of patients that said “Yes” increased (n = 25, 83.3%). Similar results are seen with Question 7 (Do you take the medication at the prescribed time?), before MEDSTIK a small number of patients said “Yes” (n = 6, 20%) and after MEDSTIK the number of patients that said “Yes” increased (n = 15, 50%).

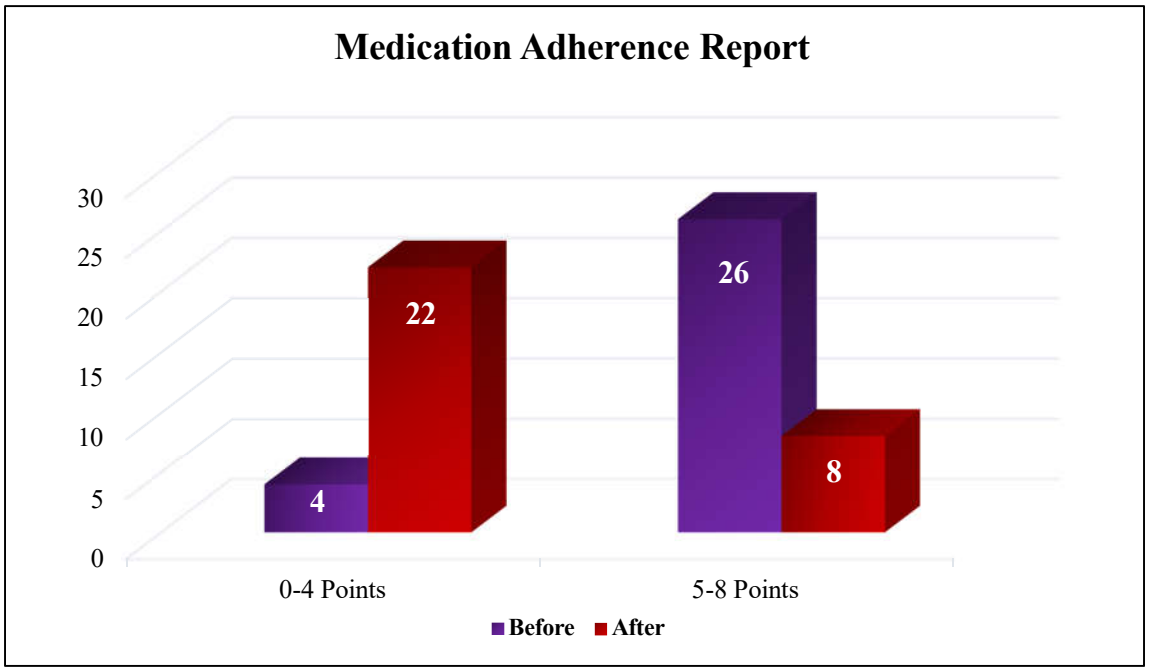
The overall medication adherence scores are shown in Table 4.

Table 4: Medication Adherence Report:

Score	Before MEDSTIK	Percentage (%)	After MEDSTIK	Percentage (%)	Adherence
0-4 Points	4	13.3	22	73.3	Adherent
5-8 Points	26	86.7	8	26.7	Non-adherent

Before administering MEDSTIK only 13% (n=4) of patients were adherent to their prescribed medications. After MEDSTIK the adherence rate increased to 73.3% (n=22) for chronic disease patients.

Figure 5: **Medication adherence report before and after MEDSTIK**



The patient scoring more than 4 points is considered to be adherent to their medications. The improvement in medication adherence is observed after medication synchronization program was given to the chronic disease patients.

Paired T- Test results:

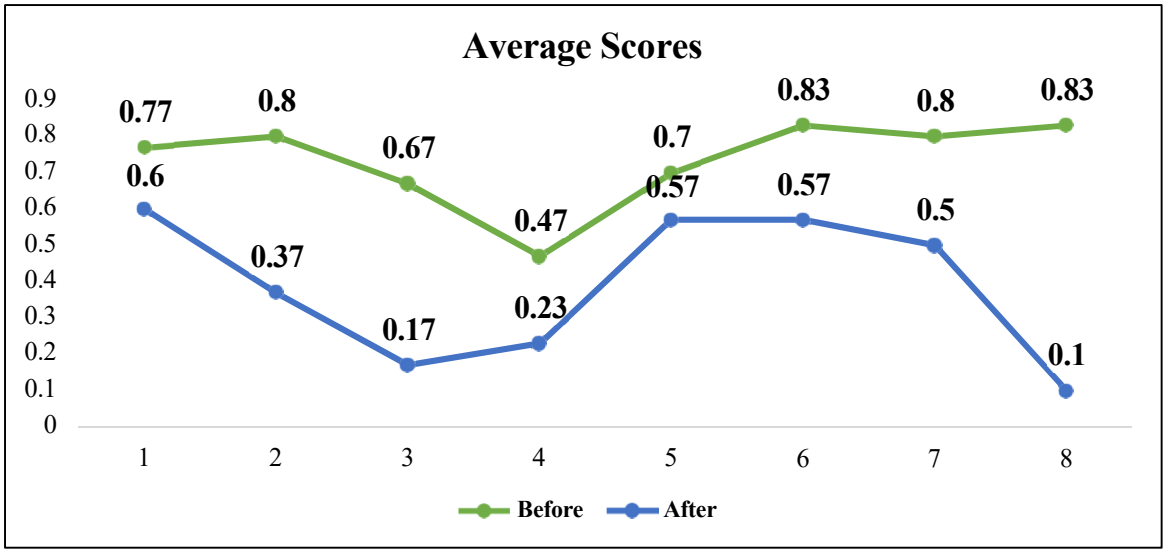
To evaluate the initial medication adherence patient responses to each question were recorded. Follow-up assessments were conducted after administering the "MEDSTIK and patient responses to each question were again taken Paired t-tests were performed using the individual responses for each question before and after the technique to determine its significance. Additionally, the complete medication adherence score for each patient was used to perform paired t-tests to assess the overall medication adherence significance. The average scores for each question are shown in Table 14 along with the corresponding p-values. For questions 2,3,7 and 8 the p-value < 0.05 and is considered to be statistically significant. The average medication adherence score before MEDSTIK is 5.87±1.38 (non-adherent) and after the MEDSTIK the average score is 3.10±1.70 (adherent). The overall p-value for the medication adherence scores is less than 0.05 which is considered to be statistically significant. The MEDSTIK shows improvement in medication adherence in that part of the MAQ which is statistically significant.

Table 5: Paired t-test Medication adherence questionnaire scores

Questions	Before	After	Paired t-test
1	0.77±0.42	0.6±0.49	0.1694
2	0.80±0.40	0.37±0.48	0.0015*
3	0.67±0.47	0.17±0.37	<.0001*
4	0.47±0.50	0.23±0.42	0.0698
5	0.70±0.46	0.57±0.50	0.2927
6	0.83±0.37	0.57±0.50	0.0299*
7	0.80±0.40	0.50±0.50	0.0174*
8	0.83±0.37	0.10±0.30	<.0001*
Total	**5.87±1.38**	**3.10±1.70**	**<.0001***

The graph below represents the average scores of the medication adherence questions. The green line represents the scores before the administration of the technique and the blue line represents the scores after the administration of the technique. A lower score represents that the patient is more adherent to that aspect of the questionnaire.

Figure 6: Average Medication Adherence Scores.



Discussion:

The global scenario on medication non adherence remains the leading source of morbidity and mortality. In countries like USA only poor medication adherence estimates 1,25,000 annual deaths, 10% of hospital admission, and an estimated annual cost of $289 billion in 2024. Non adherence leads to frequent hospital visit, increased hospitalization stays & medication related

hospital admission. In order to reduce the consequences of non-adherence like morbidity, mortality rate, increased hospitalization stay and medication related hospital admissions the health care provides can minimize medication non adherence through a medication synchronization program by coordinating all of a patient's chronic medication refills to be picked up on the same day of each month. Numerous studies indicate that when patients enrolled in medication adherence programs their medication adherence rates are increased from 2-6 times higher when they handle their own refilled prescription. Several countries throughout the globe indicates community pharmacists are providing medication adherence programs in their community pharmacies to minimize non adherence. A Pilot study was conducted involving regular patients with chronic diseases visiting the community pharmacies in Mysuru City. The objective of this study was to improve the patient's medication adherence by providing them with MEDSTIK Tool. The study started with developing a unique method after an extensive literature search. The developed method was MEDSTIK, which helps the patients identify easily the frequency and timing of the medications and also helps to track if they have taken the right medications at the right time through "do you know" cards. In our study, 30 regular patients with chronic diseases visiting community pharmacies were enrolled and their initial baseline medication adherence was assessed using a developed and validated questionnaire. The patients were then provided with the medication MEDSTIK Tool and counselled on their medications. The patients were followed up after a month to assess their medication adherence once again to gain an understanding if the technique proved useful for adherence or not. At the baseline assessment of medication adherence, only 13.3% of patients were adherent to the medications and after providing the patients with the technique the adherence improved to 73.4% of the patients and the non-adherence decreased in 26.7% of the patients. The average adherence score before MEDSTIK in patients is 5.87±1.38 which is considered to be non-adherent according to the validated questionnaire. An average score of less than 4 (3.1±1.7) is considered to be adherent in the validated questionnaire and has a p-value less than 0.05 (p-value <0.0001) which is significant. The pilot study showed that the developed medication adherence technique is useful in improving the adherence of patients to their medications. The developed method "MEDSTIK" has proven to help patients in identifying the frequency and timing of the medications. The similar study conducted by **Wilson, D. H et al** [20] aimed to assess the impact of primary medication non-adherence intervention (PMN) across four diseases. In the study, the patients received personalized calls from the pharmacists to identify reasons for PMN and discuss potential solutions. The intervention across the disease states showed a 9% difference in PMN rates but was not

statistically significant. The primary study was carried out at the same community pharmacy with greater zeal to assist more patients in enhancing their general health and medication adherence.

Limitations:

- Patients' lack of interest in gaining information towards medication adherence.
- Lack of cooperation in answering the medication adherence questionnaire.
- During follow-up, researchers were not able to contact the patients for follow-up assessment.
- Only six community pharmacies could able to implement MEDSTIK Tool. Due to busy schedule of patient's community pharmacists could not able to implement in their community pharmacies.

Conclusion:

Being accessible healthcare professionals, community pharmacists play an important role in helping patients with medication adherence. MEDSTIK Tool implemented in the community pharmacies have shown benefits in improving medication adherence in Hypertension, Diabetes Mellitus and Asthma/COPD patients. Six of the community pharmacists agreed to implement the developed tool in their pharmacies. Regular patients with chronic diseases received the MEDSTIK Tool and patients were counselled on their prescribed medications, and followed up after a month. "MEDSTIK" demonstrated an impact on patients to identify the frequency and timing of the medications; these approaches assisted in enhancing the patients' overall adherence. The developed technique improved medication adherence in hypertensive patients by 40%, in diabetic patients by 36% and in Asthma/COPD patients by 57.2%. The medication adherence score before MEDSTIK was 5.47±1.61 and after MEDSTIK was 2.96±1.63 which is considered to be adherent.

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