Impact of Clinical Pharmacist mediated discharge counseling and SMS reminders service on Medication Adherence in Chronic Disorders

ABSTRACT

Aims: This study aimed to assess the effect of discharge counseling with SMS reminders on medication adherence in chronic disorders.
Study design: Prospective randomized open-label trial
Place and Duration of Study: The study was conducted at the dispensing department of a secondary care referral charity hospital located in a small village called Bathalapalli, Anantapur district, Andhra Pradesh, India. The study was conducted for a period of six months from October 2018 to April 2019.
Methodology: Upon consent, a total of 364 patients were enrolled in this study and randomized into two groups viz., intervention group (n=182) and control group (n=182) respectively, with and without discharge counseling and SMS reminder on medication usage by the clinical pharmacist. The level of medication adherence was measured using a pill count and visual analog scale (VAS) methods at baseline and follow-up visits (gap of two months). A two-sample Wilcoxon rank-sum (Mann–Whitney) was used to compare the statistical mean difference of medication adherence levels between two groups at each follow-up visit.
Results: The mean age of intervention and control groups were 57.1±8.55 and 58.5±8.53; most of the subjects were >60 years of age and were typically suffering from hypertension (30.2%) and diabetes (34.8%). Initially, at baseline, the values of medication adherence level (pill-count method) were closer in both intervention (82.4±7.3) and control group (81.35±6.4), whereas at follow up visits, the levels of the intervention group (93.2±6.0, 95.6±2.25) were significantly increased ($p<0.0001$) as compared to the control group (81.2±8.5, 80.6±8.1).
Conclusion: Thus, the statistical significance infers that the clinical pharmacist-mediated discharge counseling with SMS reminders would increase medication adherence levels in chronic disorders.

Keywords: Medication Adherence, Text Message, Chronic Disorders, Pill Count, Visual Analog Scale

1. INTRODUCTION

According to World Health Organization (WHO), 'Medication adherence" is defined as the degree to which the person's behavior resembles the agreed recommendations from a health care provider [1]. Generically, adherence involves integrating the physician's medical advice and the patient's lifestyle, values, and preferences for care to achieve a better patient's health [2, 3]. Focus on chronic disorders; many factors contributed to the increased morbidity and mortality. Among them, poor medication adherence is one of the critical factors that is associated not only with mortality, but also it causes re-hospitalization and economic burden. [4] There are reports on various documented causes responsible for medication non-adherence, especially the most common is forgetfulness. [5] Subsequently, several techniques have been introduced to solve this problem including, improvements to pillboxes and bottles, including manual and electronic reminder systems. But most of these techniques are costly and limit their use. [6]

Today mobile phone usage was drastically raised, irrespective of region or country, urban area or rural area, literacy or illiteracy. Evidence suggests that SMS reminders can serve as a simple and cost-effective option in improving medication adherence. [7]. Nevertheless, the reported studies were conducted in a specific group of the population. Thus, those studies lack related evidence in connection to patients with chronic disorders in rural settings of south India. [8].

Evidence suggests that the clinical pharmacist plays a critical role in providing counseling services to improve outcomes in chronic disorder patients. Therefore, the present study is designed to evaluate the clinical pharmacist mediated discharge counseling with SMS reminders as a tool for improving desired medication adherence among patients with chronic disorders, especially in rural areas of south India.

2. MATERIAL AND METHODS

2.1 Study design and settings

This prospective, randomized, open-label trial was conducted in a dispensing pharmacy department of the secondary care referral hospital, located in rural settings of Anantapur District, Andhra Pradesh, India. The pharmacy department is a service arm of the hospital, which delivers pharmaceutical services to the outpatient department, inpatient department, Intensive Care Unit (ICU), neonatal ICU, pediatric ICU, and Care & Supportive Centre (CSC) of the hospital. This study was carried out for a period of six months, from October 2018 to April 2019. Due permission was sought from the medical director and chief pharmacist of the hospital.

2.2 Study criteria

Patients aged 18 years or more, irrespective of gender, suffering from chronic disorders, suitable for discharge from the hospital, and use of any model mobile phone (personal) access to SMS services were included in the study. Patients who are not interested in receiving text message reminders about medication intake daily and unable to read Telugu/English text were excluded from this study. Patients were clearly explained about the purpose of the study and enrolled after getting oral and written informed consent.

2.3 Ethical considerations

The study was conducted after getting approval from the Institutional Review Board (IRB) with a number of RIPER/IRB/2016/050 in accordance with Good Clinical Practice (GCP) guidelines.

2.4 Sample size

The sample size was calculated by epi-info, by considering 80% power, 5% margin of error, 95% confidence level, 5% of un-exposed with the outcome, and 15% of exposed with the outcome. After accounting 10% dropout rate, 182 patients were needed in each group.

2.5 Study procedure

A total of 980 patients were approached to participate in the study, in those 364 patients who met study criteria were enrolled and randomized into intervention (n=182) and control (n=182) groups by simple randomization technique. In intervention group 10 and in the control group, eight participants were failed for follow-up visits. A total of 172 in intervention and 174 in the control group were subjected for data analysis.

Patient demographic and clinical profiles including age, gender, educational status, socioeconomic status, current diagnosis, co-morbidities, duration of disease, different categories of drugs used, and a total number of drugs used are collected from all study participants using a suitable predefined and validated data collection form.

2.5.1 Intervention group:

In the intervention group, the clinical pharmacist provided discharge counseling about the dose, frequency, duration, and use of each drug recommended in the prescription. The clinical pharmacist advised about medication intake in relation to meals (before or after) and foods that need to be avoided. After discharge, an SMS reminder about medication intake was sent just before 30 minutes of due dosage time. The SMS were sent every day from the start date to the end date of the study period. The study team bared all costs for sending SMS reminders. All subjects in the intervention group were advised for two follow-up visits with a gap of two months for each visit.

2.5.2 Control group:

In the control group, there were no any sending of SMS reminders regarding medication intake and discharge counseling by the clinical pharmacist. After enrollment, all subjects in control group were advised for two follow-up visits with a gap of two months for each visit. The subjects in the control group receive routine advice from the clinicians in their regular follow-up visits.

2.5.3 Medication adherence measurement:

Baseline medication adherence for the previous 1 month was measured using a pill count and Visual Analog Scale (VAS) methods in both intervention and control groups. In the pill-count method, the number of pills consumed was calculated by the number of remaining pills with the patient, the percentage of medication adherence was calculated as the number of pills consumed in relation to the number of pills prescribed. In the VAS method, patients were asked to mark their medication adherence rate on the scale for the past 1 month. The scale comprises of grading from zero to 10. In this, zero indicates no adherence, and 10 indicates 100% adherence to the medications.[9]

Two follow-up visits were conducted after baseline visit with a gap of two months for each visit. In follow-up visits, again medication adherence levels were measured using pill count and VAS method and compared between two groups to assess the effect of mobile phone text message reminder on medication adherence in chronic disorders compared to without sending SMS.

2.6 Data analysis

GraphPad Prism version 6.04 software (La Jolla, California, USA), was used to analyze the collected data from the participants. Descriptive statistics such as mean, standard deviation, frequency, and proportion were used to represent the patients' baseline demographic, clinical and medication adherence profile. Z-test was used to match the mobile phone use profile between test and control groups. A two-sample Wilcoxon rank-sum (Mann–Whitney) was used to compare the mean difference of medication adherence (measured by pill count and VAS method) levels between two groups at each follow-up visit. $P< 0.05$ was considered statistically significant.

3. RESULTS AND DISCUSSION

A total of 364 patients were enrolled and randomized into the intervention group (n=182) to receive counseling and SMS reminders by the clinical pharmacist, and the control group (n=182) no SMS reminders and counseling about medications by the clinical pharmacist. The mean age of intervention and control groups is 57.1 ± 8.55 and 58.5 ± 8.53; most subjects were > 60 years of age. All patients were equally distributed in intervention and control groups in relation to gender, educational status, marital status, diagnosis, category of drugs used, number of drugs and baseline medication adherence levels with a P - value of > 0.05 as shown in Table 1.

Table 1: Distribution of Socio-demographic Characteristics and Medication adherence levels of study population

Table 1: Baseline Socio-demographic and Medication adherence levels of study population

Characteristics	Intervention (n=182) Frequency (%)	Control (n=182) Frequency (%)	Total (n=364) Frequency (%)	Z – score	*P* - value
Age (Mean ± SD)	57.1 ± 8.55	58.5 ± 8.53	-	-	0.054
30-39	14 (7.69)	13(7.14)	27 (7.41)	0.200	0.841
40-49	27 (14.83)	16 (8.79)	43 (11.81)	1.786	0.073
50-59	49 (26.92)	44 (24.17)	83 (22.80)	0.601	0.548
≥ 60 years	92 (50.55)	109 (59.89)	201 (55.2)	1.791	0.073
Gender					
Male	112 (61.54)	118 (64.83)	223 (61.2)	0.652	0.51
Female	70 (30.46)	64 (35.16)	141 (38.7)	0.652	0.51
Educational status					
Literate	62 (30.06)	74 (40.66)	136 (37.3)	1.300	0.193
Illiterate	120 (65.93)	108 (59.34)	228 (62.6)	1.300	0.193
Marital status					
Single	23 (12.64)	16 (8.79)	39 (10.7)	1.186	0.234
Married	155 (85.16)	158 (86.8)	313 (85.9)	0.453	0.652

Others	4 (2.19)	8 (4.39)	12 (3.2)	1.174	0.242
Diagnosis					
Hypertension	58 (31.87)	52 (28.57)	110 (30.2)	0.684	0.496
Diabetes Mellitus	64 (35.16)	63 (34.61)	127 (34.8)	0.110	0.912
Arthritis	49 (26.92)	39 (21.43)	88 (24.1)	1.224	0.222
CCF	26 (14.28)	18 (9.89)	44 (12.1)	1.286	0.197
Bronchial Asthma	33 (18.13)	34 (18.68)	67 (18.4)	0.135	0.888
Pulmonary Tuberculosis	12 (6.59)	11 (6.04)	23 (6.3)	0.215	0.826
Epilepsy	23 (12.64)	24 (13.18)	47 (12.9)	0.156	0.873
Category of drugs used					
Antihypertensive	58 (31.87)	52 (28.57)	110 (30.2)	0.685	0.496
Antidiabetics	64 (35.16)	63 (34.61)	127 (34.9)	0.110	0.912
NSAIDS	54 (29.67)	46 (25.27)	100 (27.5)	0.939	0.347
Acid suppressants	45 (24.72)	38 (20.88)	83 (22.8)	0.874	0.384
Antibiotics	16 (8.79)	18 (9.89)	34 (9.3)	0.360	0.718
Antiepileptic	23 (12.64)	24 (13.18)	47 (12.9)	0.156	0.873
Corticosteroids	35 (19.23)	32 (17.58)	67 (18.4)	0.406	0.682
Bronchodilators	38 (20.88)	36 (19.78)	74 (20.3)	0.260	0.795
Nutritional supplements	20 (10.99)	18 (9.89)	38 (10.4)	0.343	0.728
Number of drugs for prescription					
1-2 drugs	112 (61.54)	108 (59.34)	220 (60.4)	0.429	0.667
3-4 drugs	52 (28.57)	50 (27.47)	102 (28.0)	0.233	0.818
≥ 5 drugs	18 (9.89)	24 (13.18)	42 (11.5)	1.577	0.114
Medication Adherence					
Pill Count (Mean ± SD)	82.4 ± 7.3	81.35 ± 6.4	-	-	0.076
VAS (Mean ± SD)	78.8 ± 5.2	79.1 ± 4.9	-	-	0.267

SD: Standard Deviation, VAS: Visual Analogue Scale, CCF: Congestive Cardiac Failure, NSAID: Non-Steroidal Anti Inflammatory Drug, Intervention: Mobile phone text message reminder, Control: No mobile phone text message reminder

The mobile phone use profile of the study participants in intervention and control was similar except that the control group reported more messages received from relatives (P = 0.006) and bank notification (P = 0.009). The intervention group showed more messages from cricket alerts (P = 0.02) as shown in Table 2.

Table 2: Mobile Phone use profile among study population

Characteristic	Intervention (n=182) Frequency (%)	Control (n=182) Frequency (%)	Total (n=364) Frequency (%)	Z-test	*P*-value
Purpose of use					
Personal	45 (24.7)	39 (21.4)	84 (23.1)	0.746	0.453
Professional and Personal	137 (75.3)	143 (78.6)	280 (76.9)	0.746	0.453
Habit of sending SMS					
Yes	72 (39.5)	65 (35.7)	137 (37.6)	0.757	0.447
No	110 (60.4)	117 (64.3)	227 (62.4)	0.757	0.447
Habit of sending SMS with images					
Yes	36 (19.8)	23 (12.6)	59 (16.2)	1.848	0.646
No	146 (80.2)	159(87.4)	305 (83.8)	1.848	0.646
Habit of reading SMS					
Yes	156 (85.7)	145 (79.6)	301 (82.7)	1.524	0.128
No	26 (14.3)	37 (20.3)	63 (17.3)	1.524	0.128

Usually receive SMS from					
Relatives	123 (67.6)	146 (80.2)	269 (73.9)	2.745	0.006
Friends	85 (46.7)	74 (40.6)	159 (43.7)	1.162	0.246
Advertisement	12 (6.6)	11 (6.0)	23 (6.3)	0.215	0.826
News	8 (4.4)	7 (3.8)	15 (4.1)	0.264	0.795
Cricket	11 (6.0)	24 (13.2)	35 (9.6)	2.311	0.020
Bank	54 (29.7)	33 (18.1)	87 (23.9)	2.581	0.009
Others	23 (12.6)	21 (11.5)	44 (12.1)	0.321	0.748
Payment type					
Prepaid	162 (89.0)	155 (85.1)	317 (87.1)	1.094	0.276
Post paid	20 (11.0)	27 (14.8)	47 (12.9)	1.094	0.276

At baseline, medication adherence levels measured by pill count method were nearly similar in both intervention (82.4 ± 7.3) and control group (81.35 ± 6.4), whereas these levels were increased in the intervention group (93.2 ± 6.0, 95.6 ± 2.25) compared to control group (81.2 ± 8.5, 80.6 ± 8.1) in both first and second follow up visits. Medication adherence measured by the VAS method also shown a rise in adherence level in the intervention group compared to the control group in follow-up visits, as depicted in Table 3.

Table 3: Distribution of Medication adherence levels in two groups at each follow-up visit

Groups	Baseline (Mean± SD)	1st Follow up (Mean± SD)	2nd Follow up (Mean± SD)
Mean Medication adherence levels at each visit by Pill count method			
Intervention	82.4 ± 7.3	93.2 ± 6.0	95.6 ± 2.25
Control	81.35 ± 6.4	81.2 ± 8.5	80.6 ± 8.1
Mean Medication adherence levels at each visit by VAS method			
Intervention	78.8 ± 5.2	85.9 ± 3.3	90.7 ± 3.7
Control	79.1 ± 4.9	79.9 ± 3.8	79.5 ± 3.0

SD: Standard Deviation, Intervention: Mobile phone text message reminder, Control: No mobile phone text message reminder

The mean difference of medication adherence levels (measured by pill count method) was higher in the intervention group (10.8 ± 6.1, 13.2 ± 7.1) during baseline to first follow-up and baseline to second follow-up visits, compared to the control group (0.09 ± 5.7, 0.76 ± 10.2) with a P = 0.00001 in both visits. In the VAS method also the mean difference of medication adherence levels in the intervention group (7.1 ± 6.3, 11.9 ± 6.6) was higher from baseline to first follow-up and baseline to second follow-up compared to the control group (0.82 ± 5.77, 0.4 ±5.89) with a P = 0.00001, as represented in Table 4.

Table 4: Comparison of the difference in Medication adherence levels between two groups at each follow-up visit

Visits	Intervention (Mean ± SD)	Control (Mean ± SD)	*P* - value	Z – Value
		Pill count method		
Baseline to 1st follow-up	10.8 ± 6.1	0.09 ± 5.7	<0.00001	10.473
Baseline to 2nd follow-up	13.2 ± 7.1	0.76 ± 10.2	<0.00001	13.036
		VAS method		
Baseline to 1st follow-up	7.1 ± 6.3	0.82 ± 5.77	<0.00001	8.666
Baseline to 2nd follow-up	11.9 ± 6.6	0.4 ± 5.89	<0.00001	13.148

VAS: Visual Analog Scale, SD: Standard Deviation, Intervention: Mobile phone text message reminder, Control: No mobile phone text message reminder

One of the innovative processes in improving medication adherence is technology-based health care delivery, including mobile health, E-health, and telehealth. These techniques will offer ease delivery of health care according to patients' needs and improve the Economical, Clinical, and Humanistic outcomes (ECHO). Evidence shows that SMS reminder has a more significant impact over improvement in medication adherence. [10, 11]These text messages have distinct benefits in terms of reducing interferences into the patient's life and their relative easiness and low cost compared to voice communication. [12]However, there is a lack of evidence on how messages can help in the management of chronic

diseases in resource-limited settings of south India. This study provides evidence on the effect of discharge counseling and SMS reminders by the clinical pharmacist on medication adherence in chronic disorders.

In the current study, most of the patients are above 60 years (201; 55.2%) of age, and the majority of them were suffering from hypertension (110; 30.2%) and diabetes (127; 34.8%). A similar type of findings are also observed in the study conducted by Haung et al. [13] At baseline, medication adherence levels, which are measured by pill count and VAS method in the intervention (82.4 ± 7.3, 78.8 ± 5.2) and control (81.35 ± 6.4, 79.1 ± 4.9) group are nearly similar with a P-value of 0.076 and 0.267. Medication adherence measured by the VAS method was slightly lower compared to the pill-count method. These findings are contrast with the findings of a study conducted by Amico KR et al. [14] There is no gold standard method to assess accurate medication adherence levels; every method has its own acceptable error in the measurement of medication adherence. The current study used both pill-count and VAS methods to assess medication adherence, which will increase the reliability of the results.

Most of the participants (156; 85.7%) in this study have the habit of reading a text messages. The habit of sending messages was low (72; 39.5%). More than half of the participants (137; 75.3%) use their mobile phones for personal and professional purposes. All these findings are nearly similar to the study conducted Da Costa TM et al on Brazilian women. [15]

The mean difference of medication adherence levels measured by pill count method, in the intervention group, from baseline to first and second follow-up visits (10.8 ± 6.1, 13.2 ± 7.1) were significantly improved compared to the control group (0.09 ± 5.7, 0.76 ± 10.2) with a P<0.00001. The mean difference of medication adherence levels measured by the VAS method, in the intervention group, from baseline to first and second follow-up visits (7.1 ± 6.3, 11.9 ± 6.6) were significantly improved compared to the control group (0.82 ± 5.77, 0.4 ± 5.89) with a P<0.00001. The study shows that the clinical pharmacist-mediated SMS reminders and discharge counseling positively impact medication adherence in patients suffering from chronic disorders compared to no intervention. These findings are parallel to the findings of a study conducted by Vervloet M et al. [16] Even, counseling and SMS reminders had shown a rise in medication adherence levels in chronic disorders, there is still a gap in the achievement of 100% adherence towards medications. This can be achieved by using a combination of various tools, including patient information leaflet, collaborative health support (Pharmacist, clinician, and nurse-led interventions), use of reminders (beepers, pagers, smartphone apps, and automated telephone calls), one dose packaging, and regular clinic visits. [17]

3.1 Strengths and limitations

This study provides insights for improving medication adherence levels in chronic disorders by adapting an SMS reminder system in medication management policies. The study was conducted for a shorter duration, so a time and effect relationship was not established. After the withdrawal of the intervention, whether the study population constantly maintained the medication adherence levels is unknown. Pill count and VAS methods will not give accurate value about medication adherence levels. Still, there is a need to develop novel techniques to measure and improve medication adherence, which will further improve the outcomes of the diseases.

4. CONCLUSION

The study concludes that clinical pharmacist-mediated discharge counseling with SMS reminders had shown increased medication adherence levels in chronic disorders. This technique is very simple, effective, and has low interference with patients' lives in improving adherence towards prescribed medications. A combination of medication adherence measurement and improvement tools should be used to prevent variations and make accuracy in the study findings. Clinical measures of outcomes are needed to know them a better identity of SMS reminders in the management of chronic disorders.

ABBREVIATIONS

CSC=Care and Supportive Centre; ECHO=Economical Clinical and Humanistic Outcomes; SMS=Short Message Service; GCP=Good Clinical Practice; ICU=Intensive Care Unit; IRB=Institutional Review Board; VAS=Visual Analogue Scale; WHO=World Health Organization.

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