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DIGITAL HEALTH SUPPORTED ADVERSE DRUG REACTION REPORTING AMONG ELDERLY PATIENTS RECEIVING CARDIOVASCULAR

Medications Haripravin P. K.*, Suhail Ahmed J.

Department of Pharmacy Practice, J.K.K. Nattraja College of Pharmacy, Kumarapalayam – 638 183.

***Corresponding Author: Medications Haripravin P. K.**

Department of Pharmacy Practice, J.K.K. Nattraja College of Pharmacy, Kumarapalayam - 638 183.

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ABSTRACT

Background: Elderly patients receiving cardiovascular medications are vulnerable to adverse drug reactions (ADRs) because of ageing-related physiological changes, multimorbidity, polypharmacy, and long-term medication exposure. Conventional ADR reporting may miss mild, delayed, or nonspecific medication-related symptoms, particularly in outpatient settings. **Objective:** This study assessed whether pharmacist-supported digital follow-up could improve ADR reporting yield and medication adherence among elderly patients receiving cardiovascular medications. **Methods:** A prospective controlled quasi-experimental study was conducted among 500 elderly outpatients receiving cardiovascular medications at a tertiary care hospital in Erode, Tamil Nadu, India. Participants were allocated into a control group receiving routine care and traditional ADR reporting (n=250) and a digital intervention group receiving pharmacist-supported telephone/WhatsApp-based follow-up (n=250). ADR reporting yield, medication-class-wise ADR reporting, organ-system distribution, Naranjo causality classification, and medication adherence using MARS-10 scores were evaluated. **Results:** Baseline demographic characteristics, cardiovascular diagnoses, medication utilization pattern, and baseline MARS-10 scores were comparable between groups. The digital intervention group documented 243 ADR reports compared with 180 reports in the control group, representing 63 additional reports and a 35.0% higher ADR reporting yield. The aggregate rate ratio was 1.35 (95% CI: 1.11–1.64; p=0.002). Gastrointestinal and cardiovascular reactions were the most frequently reported ADR categories in both groups. Most ADRs were classified as probable using the Naranjo causality assessment scale. Medication adherence improved in both groups, with a greater increase in the digital intervention group. End-of-study MARS-10 scores were significantly higher in the digital intervention group than in the control group (8.4 ± 1.1 vs 7.2 ± 1.4; p<0.001). **Conclusion:** Pharmacist-supported telephone/WhatsApp-based digital follow-up improved ADR reporting yield and medication adherence among elderly patients receiving cardiovascular medications. This simple, low-cost approach may support pharmacovigilance and medication-use behaviour in routine outpatient care.

KEYWORDS: Adverse Drug Reaction Reporting; Pharmacovigilance; Medication Adherence; Cardiovascular Agents; Aged; Telemedicine.

INTRODUCTION

Adverse drug reactions (ADRs) remain a major public health concern and are an important contributor to preventable morbidity, hospital admission, prolonged healthcare utilization, and medication-related harm among older adults.[1] Elderly patients are particularly vulnerable to ADRs because ageing is associated with altered pharmacokinetics and pharmacodynamics, reduced renal and hepatic reserve, frailty, multimorbidity, and frequent exposure to multiple long-term medications.[1,2] A recent systematic review and meta-analysis among hospitalized older adults reported that almost one-quarter of older inpatients experienced at least one ADR during hospitalization, highlighting the magnitude of medication-related harm in this population.[2] In frail older adults with heart failure, ADRs and adverse drug events related to cardiovascular medications remain clinically important because these patients often receive complex multidrug regimens and have reduced physiological reserve.[3]

Cardiovascular disease continues to be one of the leading causes of global morbidity and mortality, accounting for nearly one-third of deaths worldwide.[4] Long-term cardiovascular pharmacotherapy is essential for reducing mortality, preventing disease progression, and improving clinical outcomes; however, the safety and effectiveness of treatment depend on timely identification of ADRs and sustained medication adherence.[4,5] Common medication-related problems among older adults receiving cardiovascular drugs may include hypotension, bradycardia, electrolyte imbalance, renal dysfunction, gastrointestinal bleeding, hepatic enzyme abnormalities, dizziness, and other nonspecific symptoms that may be mistaken for ageing or disease progression.[1,3] This makes active monitoring particularly important in elderly patients receiving cardiovascular therapy.

Despite the importance of pharmacovigilance, ADR reporting remains substantially limited in routine care. Underreporting is a major weakness of spontaneous reporting systems and is influenced by knowledge gaps, workload, uncertainty about causality, lack of time, and limited reporting access.[6] Incomplete reporting delays the recognition of safety signals and weakens real-world medication safety surveillance.[6,7] Digital health tools, including mobile applications, electronic reporting platforms, telephone-based follow-up, and messaging services, have been proposed as practical approaches to reduce reporting barriers and improve patient, caregiver, and healthcare professional participation in pharmacovigilance.[7,8] Recent reviews suggest that mobile ADR-reporting tools may improve reporting convenience, timeliness, and communication, although further clinical studies are needed to evaluate their usefulness in routine practice.[7,8]

Medication adherence is another critical issue in cardiovascular care. A large meta-analysis reported that global nonadherence to antihypertensive therapy ranges from 27% to 40%, with higher burden in low- and middle-income settings.[9] Poor adherence to cardiovascular medications contributes to avoidable cardiovascular events, treatment failure, and increased healthcare costs.[4,9] Mobile health and digital interventions have shown promise in improving adherence among patients with cardiovascular disease, particularly when they include reminders, patient education, follow-up support, and healthcare professional involvement.[4,5,10] Self-reported adherence tools such as the Medication Adherence Report Scale remain practical for assessing medication-taking behaviour in clinical research and chronic disease follow-up.[11]

Although digital pharmacovigilance and mHealth adherence interventions are increasingly studied, evidence remains limited in elderly outpatient populations receiving cardiovascular medications, especially in settings where simple and feasible tools such as telephone and WhatsApp-based pharmacist follow-up can be implemented. Therefore, this study assessed whether pharmacist-supported digital follow-up could improve ADR reporting yield and medication adherence among elderly patients receiving cardiovascular medications.

MATERIALS AND METHODS

Study design and setting

This prospective controlled quasi-experimental study was conducted among elderly outpatients receiving cardiovascular medications at a tertiary care hospital in Erode, Tamil Nadu, India. The study was designed to compare traditional adverse drug reaction (ADR) reporting with a digital health-supported ADR reporting approach. Digital methods are increasingly used in pharmacovigilance because mobile and electronic reporting systems can reduce reporting barriers, improve communication, and support faster documentation of suspected ADRs.[7,8]

The study included two groups: a control group receiving routine care and traditional ADR reporting, and a digital intervention group receiving pharmacist-supported telephone/ WhatsApp-based follow-up for ADR reporting and medication adherence reinforcement.

Study participants

A total of 500 elderly patients were included in the study, with 250 participants in the control group and 250 participants in the digital intervention group. Patients were recruited from the outpatient cardiology setting after screening for eligibility.

Patients were eligible if they were ≥65 years old, had a diagnosis of a cardiovascular condition (hypertension, coronary artery disease, heart failure or arrhythmias) and were currently taking one or more cardiovascular medications. Elderly patients receiving cardiovascular medications were selected because older adults are at increased risk of ADRs due to age-related physiological changes, polypharmacy, altered pharmacokinetics, and reduced physiological reserve.[1]

Participants were required to be able to report medication-related symptoms either independently or with assistance from a caregiver or family member. For the digital intervention group, participants or caregivers were required to have access to a mobile phone and the ability to communicate through telephone or WhatsApp-based follow-up.

Patients were excluded if they had severe cognitive impairment, psychiatric illness, severe communication difficulty, or serious medical conditions that could interfere with reliable reporting, follow-up, or interpretation of ADR-related information. Patients receiving palliative care or those unable to participate in follow-up were also excluded.

Group allocation and study procedures
Eligible participants were assigned to either the control group or the digital intervention group according to the study protocol. Since digital reporting required participant or caregiver access to a mobile phone and ability to use digital communication, the study was treated as a quasi-experimental study rather than a randomized controlled trial.

Participants in the control group continued to receive routine care. ADRs in this group were identified and documented mainly during regular outpatient visits, prescription refill visits, or patient-initiated reporting. No proactive digital follow-up was provided to the control group.

Participants in the digital intervention group received pharmacist-supported follow-up through telephone and WhatsApp-based communication. At enrolment, participants or caregivers were oriented regarding the identification and reporting of suspected ADRs. They were instructed to report new symptoms, medication-related problems, or suspected adverse reactions through the assigned digital communication channel. Digital health and mobile-based approaches have been reported to facilitate ADR reporting and may improve patient and healthcare professional participation in pharmacovigilance.[7,8]

During the study period, regular telephonic follow-up was provided to the digital intervention group. The follow-up focused on medication-use reinforcement, identification of suspected ADRs, clarification of patient-reported symptoms, and timely referral for clinical evaluation when required. Pharmacist-led telehealth and mHealth-based interventions have shown potential to improve medication-related communication and adherence outcomes, particularly in chronic cardiovascular conditions.[4,5]

Data collection
Baseline data were collected using a structured data collection form. Variables collected age, gender, education status, cardiovascular diagnosis, current medication profile and baseline medication adherence score. Cardiovascular diagnoses were recorded as hypertension, coronary artery disease, heart failure, arrhythmias or other relevant cardiovascular diseases.

Medication utilization was recorded according to drug class. The major cardiovascular medication classes included ACE inhibitors, beta-blockers, calcium channel blockers, diuretics, statins, aspirin, aldosterone antagonists, and antiarrhythmics. Supportive and non-cardiovascular medications, including proton pump inhibitors, multivitamins/supplements, and other drugs, were also documented.

Medication adherence was assessed at baseline and at the end of the study using the MARS-10 score. Higher MARS-10 scores were interpreted as better medication adherence. Self-report adherence tools remain useful in clinical research because they are practical, patient-centered, and feasible for repeated follow-up assessment; recent evidence supports MARS-based tools as acceptable self-report measures across chronic disease settings.[12]

ADR reporting and documentation
All suspected ADRs reported during the study period were documented using a standardized ADR reporting format. The recorded information included suspected medication, nature of reaction, organ-system category, time of onset, clinical description, action taken, and outcome where available.

In the control group, ADR details were collected during routine outpatient visits, prescription refill visits, or patient-initiated reporting. In the digital intervention group, ADR details were collected through telephone/WhatsApp communication and regular pharmacist follow-up. If a reported ADR was deemed to need further clinical assessment, the participant was advised to attend the hospital for confirmation and appropriate management..

The primary analysis focused on ADR reporting yield, defined as the total number of ADR reports documented during the study period. This outcome was selected because the study evaluated the effect of a digital reporting approach on ADR capture and documentation, rather than measuring true biological ADR incidence.

Causality assessment and ADR classification
All documented suspected ADRs were reviewed and classified according to suspected medication class and organ-system category. The organ-system categories included cardiovascular, gastrointestinal, renal, hepatic, respiratory, musculoskeletal, neurological, haematological, allergic reactions, and other relevant categories.

Causality assessment was performed using the Naranjo Adverse Drug Reaction Probability Scale. ADRs were classified as definite, probable, possible, or doubtful based on the Naranjo score. The Naranjo scale is commonly used in pharmacovigilance and clinical ADR assessment because it provides a structured approach to causality evaluation, although recent comparative studies have highlighted that causality assessment retains some degree of subjectivity.[13,14]

Outcome measures
The primary outcome was ADR reporting yield, defined as the total number of ADR reports documented in the control and digital intervention groups during the study period.

Secondary outcomes included medication-class-wise ADR reporting, organ-system distribution of reported

ADRs, Naranjo causality classification, specific ADR manifestation pattern, suspected drug–ADR pattern, and change in medication adherence score from baseline to the end of the study.

Statistical analysis

Categorical variables were summarized as frequencies and percentages. Continuous variables were expressed as mean ± standard deviation. Baseline categorical variables, including age group, gender, educational status, cardiovascular diagnosis, and medication utilization pattern, were compared using Pearson's chi-square test or row-wise chi-square analysis where appropriate. Continuous variables such as medication adherence score were compared using Welch's t-test.

ADR reporting yield between the control and digital intervention groups was compared using an aggregate rate-ratio approach. Medication-class-wise ADR reporting was analyzed using the number of exposed participants in each medication class as the denominator. Rate ratios with 95% confidence intervals were calculated for medication-class-specific ADR reporting comparisons. A p-value of less than 0.05 was considered statistically significant.

Ethical considerations

The study was conducted after obtaining approval from the Institutional Ethics Committee of J.K.K. Nattraja College of Pharmacy, Kumarapalayam, Tamil Nadu, India. The study was approved with certificate number JKKNCP/IEC-CER/0172124/MP. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki.[15] Eligible participants were informed about the purpose of the study, voluntary nature of participation, confidentiality of collected information, and their right to withdraw from the study at any stage without affecting their routine medical care. Informed consent was obtained from all participants before enrolment. Patient-related data and ADR information were maintained confidentially and used only for research purposes.

RESULTS

Study population and baseline comparability

A total of 500 elderly patients receiving cardiovascular medications were included in the study analysis, with equal distribution between the control group and the digital intervention group. The two groups were comparable across baseline demographic and clinical variables. Age distribution, gender, educational status, cardiovascular diagnoses, and baseline medication adherence did not show statistically significant differences between groups. The baseline comparison showed p-values above 0.05 for age, gender, education, cardiovascular diagnoses, and baseline adherence, supporting adequate comparability between the two groups before outcome assessment. The complete baseline profile is presented in

Table **1**.

The similarity in baseline cardiovascular diagnosis distribution was important for interpreting ADR outcomes. Hypertension remained the most frequent cardiovascular diagnosis in both groups, followed by coronary artery disease, heart failure, and arrhythmias. Since the diagnosis pattern did not differ significantly between groups, the subsequent difference in ADR reporting was less likely to be explained by baseline clinical imbalance.

Table 1: Baseline demographic and clinical characteristics of the study participants.

Characteristic	Control group (n=250)	Digital intervention group (n=250)	p-value
Age group, years			
65-74	117 (46.8)	124 (49.6)	0.591
75-84	133 (53.2)	126 (50.4)	
Gender			
Male	131 (52.4)	141 (56.4)	0.419
Female	119 (47.6)	109 (43.6)	
Educational status			
Primary education	42 (16.8)	45 (18.0)	0.949
Secondary education	83 (33.2)	80 (32.0)	
Higher secondary	60 (24.0)	64 (25.6)	
Graduate and above	65 (26.0)	71 (28.4)	
Cardiovascular diagnosis*			
Hypertension	128 (51.2)	120 (48.0)	0.531
Coronary artery disease	67 (26.8)	78 (31.2)	0.324
Heart failure	48 (19.2)	38 (15.2)	0.286
Arrhythmias	14 (5.6)	14 (5.6)	1.000
Baseline MARS-10 score, mean +/- SD	6.3 +/- 1.5	6.4 +/- 1.6	0.471

Note: Values are n (%) unless otherwise indicated. Age, sex, and education were compared using Pearson chi-square tests. Cardiovascular diagnoses were tested row-wise because categories may not be mutually exclusive. MARS-10 baseline score was compared using Welch's t-test.

Medication utilization pattern

The baseline medication utilization pattern was comparable between the groups. Cardiovascular medication exposure was mainly represented by beta-blockers, diuretics, ACE inhibitors, aspirin, statins, calcium channel blockers, aldosterone antagonists, and antiarrhythmics. Supportive medications, including proton pump inhibitors and multivitamins/supplements, were also similarly distributed.

No medication class showed a statistically significant baseline difference between the control and digital intervention groups, with all medication-utilization comparisons showing p-values greater than 0.05. This indicates that the two groups had broadly similar drug exposure before ADR reporting outcomes were analyzed. Therefore, the higher ADR reporting observed later in the digital intervention group should be interpreted in the context of comparable baseline prescribing patterns. The detailed medication utilization profile is shown in

Table **2**.

Table 2: Baseline medication utilization pattern in the control and digital intervention groups.

Medication category	Medication class	Control group n (%)	Digital intervention group n (%)	p-value
Cardiovascular	ACE inhibitors	83 (33.2)	86 (34.4)	0.850
	Beta-blockers	109 (43.6)	107 (42.8)	0.928
	Calcium channel blockers	58 (23.2)	60 (24.0)	0.916
	Diuretics	92 (36.8)	94 (37.6)	0.926
	Statins	73 (29.2)	69 (27.6)	0.766
	Aspirin	77 (30.8)	74 (29.6)	0.846
	Aldosterone antagonists	47 (18.8)	49 (19.6)	0.910
	Antiarrhythmics	34 (13.6)	36 (14.4)	0.897
Supportive/non-cardiovascular	Proton pump inhibitors	38 (15.2)	39 (15.6)	1.000
	Multivitamins/supplements	29 (11.6)	27 (10.8)	0.887
	Others	22 (8.8)	24 (9.6)	0.877

Note: Medication classes were compared row-wise using chi-square tests with continuity correction. Percentages are based on 250 participants in each group.

ADR reporting yield and suspected medication pattern

Based on the study analysis, ADR reporting yield was higher in the digital intervention group than in the control group. The digital intervention group documented 243 ADR reports compared with 180 ADR reports in the control group, corresponding to 63 additional reports and a 35.0% higher reporting yield. Aggregate comparison showed significantly higher ADR reporting in the digital intervention group, with a rate ratio of 1.35 (95% CI: 1.11–1.64; p=0.002). The overall ADR reporting yield is shown in

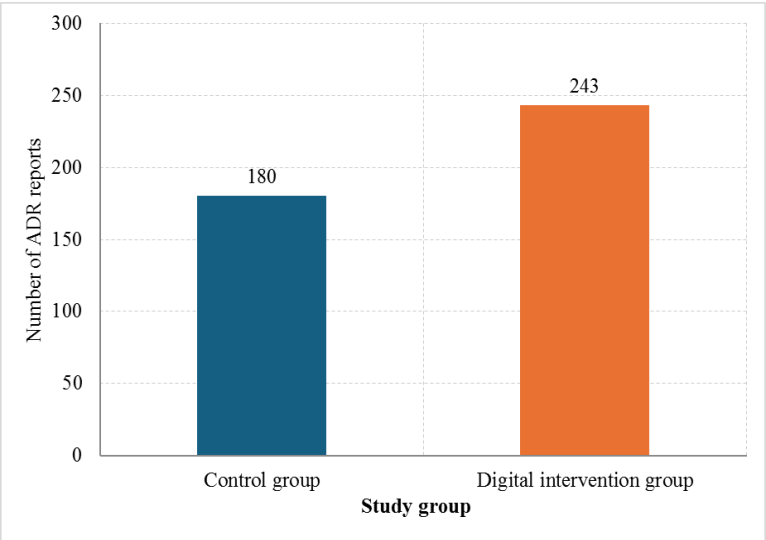

Figure 1.

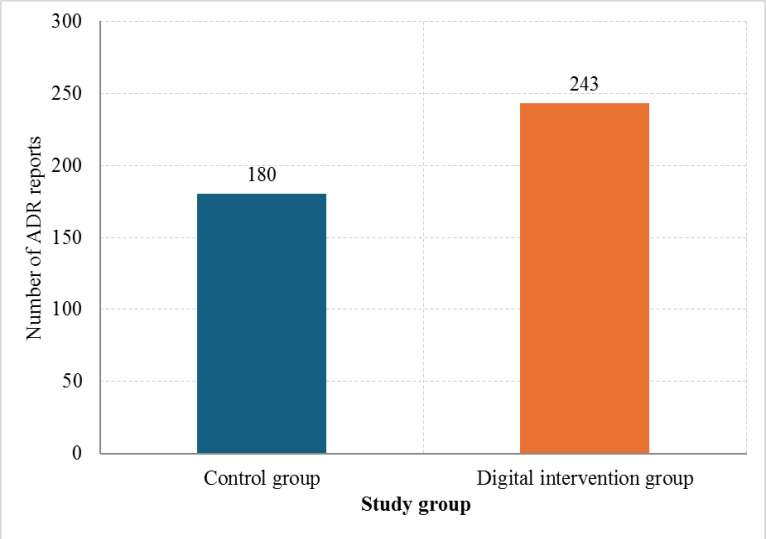

Figure 1: Adverse drug reaction reporting yield in the control and digital intervention groups.

The digital intervention group documented a higher number of ADR reports than the control group during the study period. A total of 243 ADR reports were recorded in the digital intervention group compared with 180 ADR reports in the control group. These values represent ADR reporting yield rather than ADR incidence.

Medication-class-wise analysis showed a consistent numerical increase in ADR reports across most cardiovascular and supportive medication classes in the digital intervention group. However, after recalculation using medication exposure as the denominator, individual medication-class comparisons were not statistically significant. The class-specific rate ratios ranged from 1.23 to 1.79, with p-values ranging from 0.180 to 0.618. This indicates that digital follow-up improved overall reporting sensitivity rather than selectively increasing ADR detection for a single medication class. The medication-class-wise ADR reporting pattern is presented in

Table **3**.

Table 3: Medication-class-wise adverse drug reaction reporting in the control and digital intervention groups.

Medication class	Control users	Control ADR reports	Control reports per 100 exposed	Intervention users	Intervention ADR reports	Intervention reports per 100 exposed	Rate ratio (95% CI)	p-value
ACE inhibitors	83	13	15.7	86	20	23.3	1.48 (0.74-2.98)	0.267
Beta-blockers	109	18	16.5	107	26	24.3	1.47 (0.81-2.68)	0.208
Calcium channel blockers	58	18	31.0	60	25	41.7	1.34 (0.73-2.46)	0.341
Diuretics	92	25	27.2	94	33	35.1	1.29 (0.77-2.17)	0.334
Statins	73	20	27.4	69	28	40.6	1.48 (0.83-2.63)	0.180
Aspirin	77	38	49.4	74	46	62.2	1.26 (0.82-1.94)	0.292
Aldosterone antagonists	47	10	21.3	49	16	32.7	1.53 (0.70-3.38)	0.288
Antiarrhythmics	34	15	44.1	36	21	58.3	1.32 (0.68-2.56)	0.409
Proton pump inhibitors	38	30	78.9	39	38	97.4	1.23 (0.76-1.99)	0.389
Multivitamins/supplements	29	3	10.3	27	5	18.5	1.79 (0.43-7.49)	0.425
Others	22	8	36.4	24	11	45.8	1.26	0.618

Medication class	Control users	Control ADR reports	Control reports per 100 exposed	Intervention users	Intervention ADR reports	Intervention reports per 100 exposed	Rate ratio (95% CI)	p-value
							(0.51-3.13)	

Note: ADR report categories by suspected medication class are not mutually exclusive; a single ADR report may involve more than one suspected medication class. Class-specific p-values were recalculated using an aggregate Poisson rate-ratio approach with number exposed as the denominator.

Additional drug-level analysis showed that several commonly used cardiovascular medications had higher ADR reporting in the digital intervention group. Lisinopril-related ADR reports increased numerically from 7 to 10. Furosemide-related ADR reports increased from 12 to 16, and aspirin-related reports increased from 19 to 23. Atenolol-related bradycardia reports increased from 5 ADR reports in the control group to 7 ADR reports in the digital intervention group. These findings suggest that digital follow-up may have helped patients recognize and report clinically expected medication-related symptoms more effectively.

Clinical characteristics, specific ADR manifestations, and causality assessment

The clinical distribution of reported ADRs was broadly similar between groups, although the absolute number of reports was higher in the digital intervention group. Gastrointestinal reactions were the leading ADR category, followed by cardiovascular, renal, and hepatic reactions. Respiratory, musculoskeletal, neurological, hematological, and allergic reactions were less frequently reported. The proportional distribution across organ-system categories did not show a statistically significant difference between groups, indicating that digital follow-up increased the overall volume of ADR reporting without substantially changing the clinical pattern of reported ADRs. The organ-system distribution is provided in

Table 4.

Table 4: Clinical pattern and Naranjo causality classification of reported adverse drug reactions.

ADR characteristic	Control group (180 ADR reports)	Digital intervention group (243 ADR reports)
Cardiovascular	46 (25.6)	62 (25.5)
Gastrointestinal	70 (38.9)	92 (37.9)
Renal	25 (13.9)	35 (14.4)
Hepatic	22 (12.2)	30 (12.3)
Respiratory	8 (4.4)	12 (4.9)
Musculoskeletal	5 (2.8)	7 (2.9)
Neurological	2 (1.1)	3 (1.2)
Hematological	1 (0.6)	1 (0.4)
Allergic reactions	1 (0.6)	1 (0.4)
Total ADR reports	180 (100.0)	243 (100.0)
Naranjo: Definite	0 (0.0)	0 (0.0)
Naranjo: Probable	172 (95.6)	233 (95.9)
Naranjo: Possible	8 (4.4)	10 (4.1)
Naranjo: Doubtful	0 (0.0)	0 (0.0)
Naranjo total	180 (100.0)	243 (100.0)

Note: Values are n (%) of reported ADRs. Distribution across listed organ-system classes: p=1.000. Naranjo probable/possible distribution: p=1.000.

Based on the detailed ADR manifestation analysis, cardiovascular ADRs commonly included hypotension, bradycardia, palpitations, and peripheral edema. Hypotension reports increased from 10 in the control group to 14 in the digital intervention group. Similar increases were observed for bradycardia, palpitations, and peripheral edema, suggesting improved capture of cardiovascular symptoms that may otherwise be underreported during routine follow-up.

Gastrointestinal ADRs included gastritis, gastrointestinal bleeding, peptic ulcer-related events, and constipation. Renal and hepatic ADRs included electrolyte imbalance, proteinuria, elevated liver enzymes, hepatotoxicity, jaundice, and cholestasis. Respiratory ADRs included dyspnea, bronchospasm, and cough; cough reports increased from 1 in the control group to 2 in the digital intervention group. Musculoskeletal and neurological ADRs included myalgia, arthralgia, muscle cramps, rhabdomyolysis, headache, dizziness, and syncope. No fatal ADRs were documented during the study period.

Naranjo causality assessment showed that most reported ADRs were classified as probable, while a smaller proportion was classified as possible. No ADRs were classified as definite or doubtful in either group. The Naranjo probable/possible distribution did not differ significantly between groups. This supports the reliability of the reported ADRs and indicates that the higher reporting yield in the digital intervention group was not due to an increase in doubtful or poorly attributable reports. The causality classification is included in

Table 4.

Medication adherence outcome

Medication adherence improved during the study period, with a greater improvement observed in the digital intervention group. Baseline adherence scores were comparable between groups, while the end-of-study adherence score was significantly higher in the digital intervention group than in the control group (8.4 ± 1.1 vs 7.2 ± 1.4; p<0.001). The adherence trend suggests that pharmacist-supported digital communication may have served two roles: improving patients' ability to report ADRs and reinforcing medication-use behaviour through repeated follow-up. The change in medication adherence score is shown in

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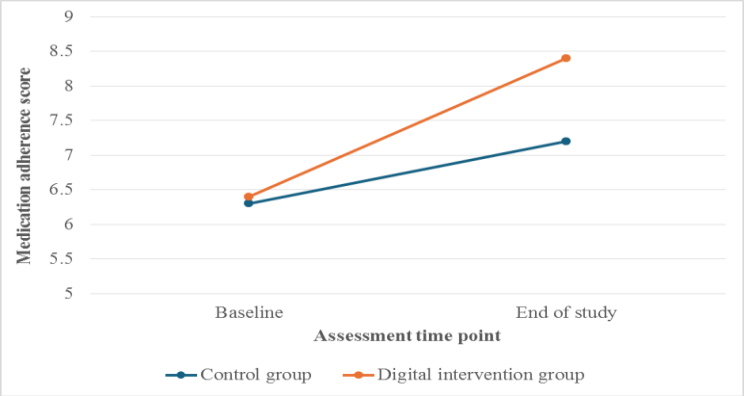

Figure 2: Change in medication adherence scores from baseline to end of study.

Baseline medication adherence scores were comparable between the control and digital intervention groups. During the study period, adherence improved in both groups, with a greater increase observed in the digital intervention group. The mean MARS-10 score increased from 6.3 ± 1.5 to 7.2 ± 1.4 in the control group and from 6.4 ± 1.6 to 8.4 ± 1.1 in the digital intervention group. Error bars, if shown, represent standard deviation.

DISCUSSION

Digital Pharmacovigilance in Elderly Cardiovascular Care

This study supports the practical role of digital pharmacovigilance in elderly patients receiving cardiovascular medications. Older adults are more vulnerable to ADRs because of age-related physiological changes, frailty, multimorbidity, and frequent exposure to long-term medications.[1–3] In the present study, both groups were comparable at baseline in terms of demographic characteristics, cardiovascular diagnoses,

medication utilization, and baseline adherence. Therefore, the higher ADR reporting observed in the digital intervention group is more likely to reflect the effect of pharmacist-supported digital follow-up rather than baseline group differences.

The need for active monitoring in this population is supported by recent evidence showing that ADRs remain common among older adults, particularly in those receiving complex cardiovascular therapy.[1–3] Digital tools have been increasingly proposed as supportive methods to reduce reporting barriers and strengthen pharmacovigilance participation.[7] In this context, the present study shows that simple telephone/WhatsApp-based pharmacist communication can be used as a feasible outpatient strategy for improving ADR capture in elderly cardiovascular care.

Effect of Digital Follow-Up on ADR Reporting Yield

The main finding of this study was the higher ADR reporting yield in the digital intervention group. The digital intervention group documented 243 ADR reports compared with 180 reports in the control group, representing 63 additional reports and a 35.0% higher reporting yield. The aggregate comparison showed significantly higher ADR reporting in the digital intervention group, with a rate ratio of 1.35 (95% CI: 1.11–1.64; p=0.002). This should be interpreted as improved ADR detection and reporting, not as increased true ADR incidence.

This finding is consistent with recent evidence that spontaneous ADR reporting remains affected by underreporting and system-level barriers.[6,7] Digital reporting tools may improve accessibility, timeliness, and ease of reporting.[7,8,16] Parracha et al. highlighted that mobile ADR-reporting tools can serve as complementary approaches to conventional spontaneous reporting systems.[7] The present study extends this idea by showing that even a low-cost pharmacist-supported model using routine communication tools can improve ADR reporting yield in elderly outpatients.

Clinical Pattern and Suspected Medication-Related ADRs

The clinical pattern of ADRs was broadly similar between groups, although the absolute number of reports was higher in the digital intervention group. Gastrointestinal and cardiovascular reactions were the most frequent categories, followed by renal and hepatic events. This pattern is pharmacologically plausible because the study population was receiving commonly used cardiovascular and supportive medications, including aspirin, diuretics, beta-blockers, ACE inhibitors, statins, antiarrhythmics, and proton pump inhibitors.

The observed reactions, including gastrointestinal bleeding, gastritis, hypotension, bradycardia, electrolyte imbalance, renal events, hepatic enzyme elevation, cough, and muscle-related symptoms, are consistent with known medication-related risks in elderly cardiovascular patients.[1–3,17] The similar proportional distribution of ADR categories between groups suggests that the digital intervention did not alter the type of ADRs being reported. Instead, it improved the capture of expected medication-related events that may otherwise remain underreported during routine visits.

Causality Assessment and Reliability of Reported ADRs

Most ADR reports in both groups were classified as probable using the Naranjo causality assessment scale, with a smaller proportion classified as possible. No ADRs were classified as definite or doubtful. This supports the reliability of the reported ADRs and suggests that the higher reporting yield in the digital intervention group was not due to an increase in doubtful or weakly attributable reports.

Structured causality assessment is important because symptoms in older adults may overlap with underlying disease progression or age-related changes. However, causality tools such as Naranjo and WHO-UMC may show variable agreement, and their interpretation can be influenced by the availability of clinical details, dechallenge information, and assessor judgment.[13,14,18,19] Therefore, while the Naranjo findings strengthen the credibility of the ADR reports, they should still be interpreted with appropriate clinical caution.

Medication Adherence and Pharmacist-Supported Digital Care

Medication adherence improved in both groups, but the improvement was greater in the digital intervention group. The mean MARS-10 score increased from 6.3 ± 1.5 to 7.2 ± 1.4 in the control group and from 6.4 ± 1.6 to 8.4 ± 1.1 in the digital intervention group. The end-of-study adherence score was significantly higher in the digital intervention group than in the control group (8.4 ± 1.1 vs 7.2 ± 1.4; p<0.001).

This finding suggests that pharmacist-supported digital follow-up acted not only as an ADR reporting pathway but also as a medication-use support strategy. Al-Arkee et al. reported that mobile health interventions may improve medication adherence in cardiovascular disease when supported by reminders, patient education, and healthcare professional involvement.[4] Other recent reviews also support the role of mHealth and eHealth interventions in improving adherence among patients with cardiovascular disease.[5,10,20] In the present study, repeated pharmacist contact, medication-use reinforcement, and timely clarification of suspected ADRs may have helped patients continue therapy more confidently and avoid unsupervised discontinuation.

Overall, this study suggests that pharmacist-supported digital follow-up is a feasible and low-cost approach for improving ADR reporting yield and medication

adherence among elderly patients receiving cardiovascular medications. However, the findings should be interpreted considering the quasi-experimental design, single-center setting, possible digital literacy-related selection bias, patient-reported ADRs, and self-reported adherence assessment. Future randomized multicentre studies with longer follow-up and patient-level ADR incidence assessment are needed to confirm the broader clinical value of digital pharmacovigilance in geriatric cardiovascular care.

CONCLUSION

Pharmacist-supported digital follow-up improved adverse drug reaction reporting yield and medication adherence among elderly patients receiving cardiovascular medications. The digital intervention group documented a higher number of ADR reports than the control group, indicating better detection and reporting of suspected medication-related problems rather than an increase in true ADR incidence. The clinical pattern of reported ADRs remained broadly similar between groups, with gastrointestinal and cardiovascular reactions being the most frequently reported categories. Most ADRs were classified as probable based on Naranjo causality assessment, supporting the reliability of the reported events.

The improvement in MARS-10 medication adherence scores further suggests that telephone/WhatsApp-based pharmacist communication may support both pharmacovigilance and medication-taking behavior in elderly cardiovascular outpatients. This low-cost and feasible digital approach may be useful in routine clinical practice, particularly in settings where advanced digital infrastructure is limited. Future multicenter randomized studies with longer follow-up and patient-level ADR incidence assessment are warranted to confirm the broader clinical value of digital pharmacovigilance in geriatric cardiovascular care.

Declarations

Ethics approval and consent to participate

The study was conducted after obtaining approval from the Institutional Ethics Committee of J.K.K. Nattraja College of Pharmacy, Kumarapalayam, Tamil Nadu, India. The study was approved with certificate number JKKNCP/IEC-CER/0172124/MP. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Written informed consent was obtained from all participants before enrolment. Patient-related data and ADR information were maintained confidentially and used only for research purposes.

Availability of data and materials

The datasets generated and analyzed during the present study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Author contributions

Conceptualization: VN; methodology: VN and HPK; data collection: HPK and SAJ; data analysis: VN and HPK; interpretation of results: VN and HPK; manuscript drafting: VN and HPK; reference formatting: VN and HPK; manuscript revision: VN and HPK; supervision: VN. All authors read and approved the final manuscript.

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