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Using Technology to Create a Medication Safety Net for Cardiac Surgery Patients: A Nurse-Led Randomized Control Trial

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Abstract

Interactive voice response (IVR) technology was used to increase medication compliance and reduce adverse events (hospitalization and emergency visits) in post cardiac surgery patients. Patients randomized to intervention received 11 automated IVR calls in the 6 months after discharge. A total of 331 patients (164 IVR, 167 usual care) participated. Results showed significant differences in the IVR group for the primary composite outcome of compliance and adverse events (Relative risk (RR) and 95% confidence interval (CI): 0.60 (0.37, 0.96), p=0.041) and the secondary outcome of medication compliance (RR: 0.34 (0.20, 0.56), p<0.0001). However, there was no significant impact on emergency room visits (RR: 1.04 (0.63, 1.73)) and hospitalization (RR: 0.77(0.41, 1.45)). Most patients (93%) preferred IVR follow-up to no follow-up.

Using Technology to Create a Medication Safety Net

The transition from discharge to home is a high risk period for patients because current safety research confirms this is a time when patients experience complications and adverse drug effects often many weeks before they can access their primary care provider (Forster, Murff, Peterson, Gandhi, 2003).

Background and Literature Review

Studies have shown that rates of adherence to cardiac medications decline sharply over the first 6 months post discharge and that length of stay and costs of hospitalization for adverse drug events are substantial (Chapman et al., 2005; Eagle et al., 2004). An adverse drug event is associated with a significantly prolonged length of stay, increased economic burden and an almost 2-fold increased risk of death. Medication noncompliance has been linked to poor health outcomes and increased adverse events (Chapman et al., 2005; Eagle et al., 2004).

All patients at the University of Ottawa Heart Institute (UOHI) are randomly selected for participation in a survey to determine satisfaction with their acute care hospital experience. Survey results reveal a high level of satisfaction with their experience in all dimensions; however, survey scores in the area of continuity and transition to home indicate that patients do not feel fully prepared to care for themselves at home regarding their medications (The National Research Corporation, 2001). To better understand the educational needs of patients regarding medications, 3 focus groups were conducted in 2005. Seven to 10 patients were randomly selected from a larger pool of cardiology and surgical patients to form each group. The following themes emerged (a) patients were not ready to learn about their care while in hospital because of poor memory, poor recall, and poor concentration; (b) patients frequently had questions about symptoms or side-effects once they were home; (c) patients did not know what

to do or who to call when side effects did occur at home; (d) the information given was often inconsistent, depending on the health care provider's perspective; (e) the interchangeable use of medication class, generic and trade names of medications such as "statins" or "ACE" were very confusing for patients; (f) all patients wanted additional information on the actions and side-effects of medications and what action to take; and (g) patients were unsure about who would be following them post discharge, and at times expressed that general practitioners were also unsure.

In the Canadian Adverse Events Study, Baker et al. (2004) found the three most common adverse events (AE) in Canadian acute care hospitals were associated with surgery, infection, and medication. They estimated that 1 in 9 patients will potentially be given the wrong medication or medication dosage and 24% of preventable adverse events are related to medication error.

Care transfers or transition from hospital to community are high in risk, providing ample opportunity for error (Forster et al., 2003). This period is associated with a lack of continuity among providers, location of care and in many cases an inadequate communication between hospital and community physicians. Few studies have focused on patients in the ambulatory or community setting but Forster et al. (2004) found that 23% of patients discharged from a general medicine service had an AE after discharge. The most common AEs (72%) were adverse drug events. Half of these AEs were preventable or ameliorable. The study revealed that system modifications could improve patient safety during this period. The system changes should focus on four areas (a) evaluating patients at the time of discharge, (b) teaching patients about drug therapies, (c) identifying side effects and what to do if specific problems develop, and (d) improving monitoring of therapies and monitoring of patients' overall condition.

In an observational study conducted by R. L. Howard, Avery, P. D. Howard and Partridge (2003) medication problems were also examined as the reason for admission to hospital. Drugs and types of medication management problems most frequently associated with preventable drug related admissions to an acute medical admissions unit were described. Of the 4,093 admissions deemed preventable by a pharmacist, 7% were drug related and 67% of these were preventable. The drug related admissions were mainly due to prescribing related problems (35%), monitoring problems such as in the case of Warfarin (26%) and patient adherence problems (30%). The drugs most commonly implicated were non-steroidal anti-inflammatory drugs, anti-platelets, anti-epileptics, hypoglycemics, diuretics, inhaled corticosteroids, cardiac glycosides and beta-blockers. These results challenge us to find improved methods of monitoring patients after discharge.

One such method is an interactive voice response (IVR) system. IVR is an automated telephone call system that is programmed to call patients at predetermined intervals to deliver a pre-set list of questions or health care information. Patients answer questions and report clinical problems using voice response technology through their telephone. The answers to the questions are then captured in a database. Depending on the response, a colored flag appears in the database next to the question indicating no action is needed, the call was not answered, or alerting the nurse to intervene by calling the patient to provide education and counseling.

The reliability and validity of IVR has been tested most frequently in the mental health sector. Alemi et al. (1994) compared the information received from patients about drug and alcohol abuse using both an IVR system and mailed surveys. They found the IVR results consistent with mailed survey responses. Kobak et al. (1997) used IVR to compare diagnoses obtained using an IVR algorithm versus those obtained by a trained psychiatrist over the telephone. In a population

of 200 adult volunteers from primary care and mental health clinics and community controls, the rates for psychiatric disorders were similar between diagnoses made by an automated IVR call and a clinician using the telephone. Patients followed by IVR reported more alcohol abuse to the system than when speaking with clinicians on the telephone which indicated that for some situations there was a higher reporting of symptoms during IVR assessments. Mundt et al. (1998) found IVR assessments correlated with face to face assessments in a cross sectional comparison of an IVR version of the Hamilton Rating Scale for depression. In a subsequent study Mundt, Clarke, Burroughs, Brenneman, and Griest (2001) used IVR as a tool to disseminate public education regarding Alzheimer disease and other dementias, as well as access to dementia resources. Populations using the service were those who were not typically computer and Internet users such as the elderly, lower socioeconomic status and those living in rural areas.

There are few peer-reviewed studies on the impact IVR interventions may have on patient outcomes. Of the few that have been done, there are some indications that outcomes may be improved. Friedman et al. (1996) found that patients randomized to weekly IVR monitoring and feedback of assessment data to physicians had improvements to antihypertensive medication adherence compared to the control group. Meneghini, Albisser, Goldberg and Mintz (1998) used a pretest-posttest study design to test IVR effectiveness with diabetic patients in terms of health information, changes in glycemic control and access to decision support for making insulin dose adjustments. They found a three fold decrease in diabetic crises and a 0.8% average decrease in HgA1c levels. Piette (2000) also demonstrated improvements in self care and glycemic control for patients receiving an IVR intervention.

Purpose

The purpose of this study was to determine if IVR can improve medication compliance and reduce adverse events as patients transition from hospital to home. An adverse event is defined as a problem requiring an emergency visit with or without hospitalization.

Method

Design

This study was a randomized control trial with two arms: (a) IVR follow-up and (b) usual care (UC). Endpoints included medication compliance, medication information delivery, ER visits, hospitalization and patient satisfaction with the IVR system.

Sample

All patients over the age of 18 who were discharged from the UOHI were considered for inclusion if they underwent coronary artery bypass grafts &/or valvular surgery, had telephone service to their home, and spoke either English or French. Patients were excluded if they underwent other surgeries such as cardiac transplantation and/or they were discharged to a care facility or other institution. Allocation to the treatment group was blinded by using a sealed envelope identified by study number and containing the random allocation. Randomization occurred once consent to participate was obtained.

Procedure

Based on early successes with IVR, a multidisciplinary team developed an algorithm of eleven questions addressing medication compliance, reporting of adverse events, providing information on common medications and offering general medication safety tips. The intent of the IVR algorithm was to provide early identification of issues permitting timely intervention, provide a mechanism for tracking medication compliance, and provide medication information at

the time deemed most valuable by the patient at their request and to provide longer term follow-up as the patient transitions from hospital to home.

Patients in the IVR follow-up group received automated telephone calls at a predetermined time for six months, with calls made at 1, 2, 3, 4, 6, 8, 10, 12, 16, 20 and 24 weeks after discharge. The IVR system recorded patients' voiced responses (yes or no) into a central database. Patients were asked questions about medication compliance such as "Did you fill the prescriptions given to you at discharge?" and were offered additional information on eight common medications prescribed to cardiac surgical patients on discharge. All data were stored in the IVR system using a study identifier. The data was password protected and the drive was backed up daily for protection against data loss. Patients in the UC group received the usual standard of care provided to all patients discharged post cardiac surgery which included receiving an IVR call on day 3 and day 10 after discharge to screen common symptoms. This current surgical follow-up algorithm does not contain questions or information on medications. Both groups of patients were then contacted at six months to answer questions on medication compliance, adverse events and satisfaction with the IVR system delivery. This study was approved by the UOHI Human Research and Ethics Board.

Analysis

Statistical analysis was conducted on an intention-to-treat basis. For baseline characteristics comparisons, Wilcoxon rank sum-tests were used for continuous variables and Fisher's exact tests for discrete variables. The Fisher's exact test was used to evaluate the primary outcome (a composite based on compliance and adverse events with the outcome occurring if there was both an increase in compliance and a decrease in adverse events at six months) and discrete secondary outcomes. By consensus a rate of 40% for the primary outcome in the UC group was determined

and a 16% absolute improvement was deemed clinically important to detect. A sample size of 166 patients per group was sufficient to detect the important difference of 16% in the primary outcome with an alpha-value of 0.05 and power of 80% using the Fisher exact tests. A drop-out rate of 10% was anticipated over the 6 months follow-up period and therefore a sample size of 368 patients (184 per group) was needed to assess the important difference of 16% in the primary outcome. Statistical analyses were performed using the Statistical Analysis System (SAS) and the statistical significance was defined as $p<0.05$.

Results

Sample

A total of 858 patients were approached during the recruitment period of June 19, 2006 to May 1, 2007. Of these, the final sample was 331. Reasons for not participating include refusals, no consent for chart review, speech or hearing disability and language other than English or French.

Three-hundred and thirty one patients were enrolled (UC n = 167; IVR n = 164). As shown in Table 1, there were no statistical differences in baseline characteristics between the 2 groups.

IVR follow-up

The IVR system generated 1658 calls into 3 response categories in the database: (a) complete (15%), meaning full compliance and no follow-up is required; (b) callbacks (31%), a nurse called the patient for further assessment, education or possible intervention; (c) unreached (54%), the system could not reach the patient after 3 attempts because of a busy signal, an answering machine, no one answered the call or the call was discontinued. Two attempts were made by the

nurse to call the patient to review the algorithm questions. Loss to follow up during the study accounted for the cancellation of 135 calls in the IVR system during the 6 months.

When a call was flagged as "callback", the nurse would telephone the patient to discuss the question that indicated the patient required further assessment. The nurse would then assess if there was a need to provide further education or intervention. Of the 516 calls flagged as "callback" in the system, 63 calls required an intervention by the nurse. Examples of interventions included offering the patient tips on how to remember to take medications, facilitating prescription renewal if the patient had run out of medication and providing information about adverse reactions that could be experienced when taking certain medications. On one occasion, a doctor discontinued a medication prescribed by the cardiac surgeon who wanted the patient to remain on the medication for 6 months to prevent a possible surgery-related adverse event. The doctor was informed of the rationale for continuing the medication and the physician subsequently re-issued a prescription. Table 2 illustrates the number of issues identified by the IVR system as patients responded to the calls.

Medication information

The IVR system was designed to offer patients information on their medications. During each call made by the system, patients were asked if they were continuing to take each medication they were prescribed on discharge. After being asked if they were continuing on a certain medication, the system would offer the patient the option of hearing more information on that medication. If they responded "yes", a short description of the medication including trade and generic names, desired effects and possible adverse effects was provided by the system. According to the IVR database a total of 409 requests for information were made by individual patients representing 56% of the group. Sixty-two patients listened to information on more than

one medication. The majority (90%) responded that they were satisfied with the medication information provided by the system. When asked if they had any further questions about their medications, 97% indicated that they had no further questions.

Six month surveys

The survey response rates were 84% and 86% for the IVR and UC group respectively. Both groups were contacted at 6 months by telephone for an interview that consisted of questions on whether they were seen in the emergency department or admitted in the last 6 months. In addition the UC group was asked whether they were still taking all the medications prescribed on discharge from the UOHI. Patients followed by IVR were surveyed on their satisfaction with the medication information delivery. As shown in Table 3, 90% of patients were satisfied with the medication information provided by IVR and 93% responded that they preferred an IVR follow-up as opposed to no telephone follow-up which reflects the usual practice.

Outcomes

An analysis of the composite primary outcome of increased compliance with medications and decreased AE's (emergency room visits and hospitalization) at 6 months revealed that patients in the IVR group were significantly different from the patients in the UC group (RR and 95% CI: 0.60 (0.37,0.96), p=0.041) as shown in Table 4. In the IVR group, 51.1% remained compliant with their medications and did not have an AE, compared to 38.5% in the UC group. Analysis of the discreet secondary outcomes determined a significant difference for medication compliance (RR: 0.34 (0.20, 0.56), $p < 0.0001$) whereas, there was no impact on the emergency room visits (RR: 1.04 (0.63, 1.73), $p = 0.897$) and hospitalization (RR: 0.77 (0.41, 1.45), $p = 0.519$).

Discussion

Interactive voice response technology is a low cost innovative service that provides ongoing follow-up for patients. It can successfully reach patients and they can interact with the system effectively. It provides a system of early identification of issues to assist in preventing adverse events. The patients found it to be a satisfactory mode for follow-up.

A nurse was able to provide counseling on medication safety when patients indicated that they had missed a dose or had taken more medication than prescribed. Timely nursing interventions prevented adverse events when patients had run out of medications or had difficulty having their prescriptions refilled. A concerning number of responses early in the study regarding patients running out of medications, prompted the research team to examine the discharge prescriptions. The usual practice was to provide patients with a 30 day supply of medication with no refills. Patients were instructed to see their PCP and surgeon within 2 to 4 weeks after discharge when prescriptions could be renewed if necessary. In actual practice follow-up appointments frequently fell outside of the 2-4 week timeframe for several reasons including not having a PCP to call, unable to reach physicians, and holidays. For safety reasons a change in prescribing practices was instituted allowing patients more time to contact physicians to make follow-up appointments before running out of medications.

Patients in focus groups have told us that they want more information on their medications other than at discharge when they are anxious about going home and still on pain medications. The IVR telephone calls gave patients the option of listening to information on common discharge medications such as calcium channel blockers, beta blockers, angiotensin receptor blockers, anti-platelets, amiodorone, ACE inhibitors and cholesterol-lowering medicines in the comfort of their own home.

IVR is a low cost high-yield method of contacting a large number of patients that allows for information capture and delivery when they would not ordinarily be contacted. It also allows for longer term follow-up using minimal resources. The patients feel a continued link to the UOHI which offers them peace of mind as demonstrated in the following comments made during the 6 month telephone interview survey: "It is comforting to know the Heart Institute is there to catch you if you stumble." "I am very happy with the calls, it seems like the Heart Institute is very interested in what happens to its patients."

There are limitations to this study. The 6 month surveys were conducted by telephone interview by the research nurse coordinator who had intervened with the patients during the study. The lack of anonymity may have caused a favorable response bias. Recall was required for questions on emergency visits and hospitalization. The interview schedule was not pre-tested. Close-ended, forced choice dichotomous questions limited the potential responses of the patients. Qualitative research in the area of using technology in the follow-up of cardiac patients is needed to probe into the complexities of human behaviors and feelings. Furthermore human factor research would provide valuable information on the interaction between patients and technology such as the IVR system.

Conclusion

This study provided an extended outpatient follow-up, offered a novel form of delivering medication information, and improved medication compliance and safety. The results indicate that an IVR system can successfully reach patients and they are willing to use these kinds of systems. In a healthcare environment where both financial and human resources are limited, IVR has confirmed it is an effective way to deliver medication information to patients when they can choose when best to learn the information.

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Table 1

Baseline Characteristics

Variables	IVR (N=164)	Usual Care (N=167)	P value
Age	64.5±10.2	62.4±11.0	0.079
Living Alone	21 (12.8%)	26 (15.6%)	0.530
Have Physician	159 (97.0%)	161 (96.4%)	1.000
Schooling			0.387
No Formal Ed.	1 (0.6%)	2 (1.2%)	
Elementary	29 (17.7%)	18 (10.8%)	
High School	60 (36.6%)	69 (41.3%)	
College	20 (12.2%)	26 (15.6%)	
University	33 (20.1%)	35 (21.0%)	
Post graduate	15 (9.2%)	15 (9.0%)	
Other	6 (3.7%)	2 (1.2%)	
Employment			0.015
Full time	45 (27.4%)	55 (32.9%)	
Part time	18 (11.0%)	10 (6.0%)	
Unemployed	5 (3.1%)	2 (1.2%)	
Retired	91 (55.5%)	84 (50.3%)	
Homemaker	1 (0.6%)	0	

Other	4 (2.4%)	16 (9.6%)	
Language (English)	157 (95.7%)	162 (97.0%)	0.571
Surgery			0.800
CABG+Valve	14 (8.5%)	13 (7.8%)	
CABG	110 (67.1%)	120 (71.9%)	
Valve	37 (22.6%)	31 (18.6%)	
Other	3 (1.8%)	3 (1.8%)	

Table 2

IVR Algorithm Responses "Callbacks"

Responses	(n)
Patients who did not fill the prescriptions given to them at discharge.	9
Patients taking medications other than those prescribed for them at discharge.	163
Patients having symptoms they believe to be related to their medications.	72
Patients who took more medication than prescribed or missed a dose of a medication.	41
Patients who were prescribed a drug to which they are allergic.	11
Patients who ran out of medication before they could get the prescription refilled or who have had difficulty getting a repeat prescription.	28
Patients whose physician added, stopped or changed any of the medications.	176
Patients who contacted a health care provider i.e. a nurse, pharmacist or doctor for any reasons.	223
Patients who were seen in an emergency department or readmitted to a hospital.	69
Patients who have other issues about medications they would like to discuss or would like further medication information.	44

Table 3.

IVR Group Patient Satisfaction

Responses	(%)
Patients who listened to medication information provided by IVR system	56
Patients who were satisfied with the IVR generated medication information	90
Patients who required more medication information after listening to IVR	2.9
Patients who preferred IVR follow-up to no telephone follow-up	93

Table 4

Outcomes

	IVR (N=137)	Usual care (N=143)	P value
Composite primary outcome	70 (51.1%)	55 (38.5%)	0.041
Increased compliance with medication and decreased AE (ER visit and hospitalization)			
Secondary outcomes			
Compliance with medication	102 (74.5%)	71 (49.7%)	<0.0001
Adverse events			
ER visit	41 (29.9%)	44 (30.8%)	0.897
Hospitalization	25 (18.3%)	21 (14.7%)	0.519