Published in final edited form as:
Eur J Cardiovasc Nurs. 2011 March ; 10(1): 50–55. doi:10.1016/j.ejcnurse.2010.04.002.

Clinician-Patient Discord: Exploring Differences in Perspectives for Discontinuing Clopidogrel

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Abstract

Background—Premature stopping of anti-platelet therapy has potentially fatal consequences for myocardial infarction (MI) patients who have received a drug eluting stent (DES). Exploring multiple perspectives to identify contributing factors to the problem is essential.

Aim—We gained patient and clinician perspectives as to why MI patients prematurely stop anti-platelet therapy (clopidogrel) after DES implantation.

Methods—This qualitative, descriptive study of DES-treated MI patients (n=22) and of clinicians (physicians and nurse practitioners; n=17) from multiple U.S. cities used content analysis of interview data. Findings across patients and clinicians were then compared to examine congruent and contrasting reasons for premature clopidogrel discontinuance.

Findings—Patients frequently identified communication and education (e.g. unaware they should be taking clopidogrel, unaware of intended duration of therapy) as the primary reasons for

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Disclosures: Drs. C. Decker, L. Garavalia, and B. Garavalia disclose that they received research grant support from Sanofi-Aventis. Dr. Foody is a consultant for Sanofi-Aventis.

having stopped. Patients rarely cited cost, while clinicians most commonly cited cost as a reason for premature stopping.

Conclusions—The discrepancy in perceptions of patients and clinicians as to the primary reason for early discontinuance suggests an important opportunity for improving persistence. Rather than focusing on the high costs of medications, something outside of their control, physicians should consider communicating more effectively the importance and intended duration of clopidogrel to their patients.

Keywords

myocardial infarction; medication discontinuance; patient-provider communication; qualitative research

1. Introduction

Patients' and clinicians' perspectives of medication regimens may not be aligned, leading to suboptimal compliance with evidence-based guidelines for therapy. Anti-platelets were initially prescribed following percutaneous coronary intervention with drug-eluting stents (DES) for 3 to 6 months, depending on the specific stent used [1]. Concerns of a potential increased risk of stent thrombosis with DES as compared with bare-metal stents contributed to an increase in recommended therapy to 12 months by the American College of Cardiology, the American Heart Association, and the European Society of Cardiology [2-6]. Despite efforts to insure compliance with recommended duration for anti-platelet therapies, such as clopidogrel, we previously reported that ~14% of patients discontinued anti-platelets within 1 month after DES placement following acute myocardial infarction (MI) [7]. These patients had a significantly increased risk of cardiac re-hospitalization and mortality in the subsequent year.

Discontinuance or non-adherence to medications is common for chronic conditions such as hypertension or hyperlipidemia [8]. Prior studies have identified some patient-level factors associated with medication discontinuance (education, adverse effects, number of medications, etc.) [7,9-11] and noted that clinician- and system-level factors can be equally influential [10]. Early discontinuance of clopidogrel therapy can have immediate adverse consequences, such as stent thrombosis and death [12].

In an earlier study, we explored patients' perspectives regarding clopidogrel persistence with a small sample of MI patients treated with a DES [13]. In depth interviews revealed that, most frequently, discontinuance resulted from a failure to understand the intended duration of treatment. Duration awareness is obviously a two-sided problem between the patient and the clinician, so we next sought to understand clinicians' perspectives regarding clopidogrel discontinuance. In other studies with heart patients, researchers have found discord between patients' and clinicians' perspectives. For example, Devereaux and colleagues reported that atrial fibrillation patients were more stroke-averse while clinicians were more bleeding-averse regarding warfarin treatment [14].

Realizing the existence of discord between the patients and clinicians in the warfarin study, we were concerned a similar situation may be occurring with clopidogrel prescriptions for MI patients treated with DES. The purpose of the present study was to examine the congruence between patients and clinicians perceived reasons for patient clopidogrel discontinuance.

2. Methods

2.1 Sample and setting

A purposive sampling technique was used to identify patients with relevant experience from a large U.S. prospective cohort study, the Translational Research Investigating Underlying disparities in acute Myocardial infarction Patients' Health status (TRIUMPH) study (funded by the National Heart, Lung and Blood Institute). MI patients from the TRIUMPH registry who had received a DES were recruited from those patients who were enrolled between June 2005 and March 2006. For patients who prematurely discontinued clopidogrel, we interviewed the first 11 patients in the registry who were prescribed clopidogrel at hospital discharge and who did *not* report continuing clopidogrel at 1-month follow-up. In addition, 11 patients of similar demographics and who continued clopidogrel at 1-month follow-up were interviewed.

Clinicians, including physicians and nurse practitioners, were recruited from 3 geographically different U.S. sites using network sampling. Clinicians (n=17; 15 physicians and 2 nurse practitioners) were from internal medicine and cardiology specialties. The clinicians were not the care providers of the patients in our study.

2.2 Ethical issues

The Saint Luke's Hospital Institutional Review Board approved this extension of the TRIUMPH study for the patient interviews and the Institutional Review Board at each of the 3 U.S. sites approved the clinician interviews.

2.3 Data collection

Semi-structured interviews were conducted with patients and clinicians. The patient interview guide was developed from the existing theoretical and research literature in the fields of medicine and health psychology [7,12,15-23]. Questions elicited patients' cardiac experience, health beliefs, and reasons for continuing or discontinuing clopidogrel. An example of the questions is, "We are particularly interested in why people might stop taking Plavix. Will you tell me about stopping that medication?" A single-experienced interviewer conducted telephone interviews between April 2006 and August 2006. Recorded interviews were transcribed verbatim and coded within 10 days, allowing the researchers to assess the added value of each interview until saturation occurred, meaning no new information was being reported [24].

Clinician interviews probed clinicians' experience with patient cessation of medication(s), strategies that they used to support adherence. The interviews were conducted in-person (either LG or BG) at the clinician's workplace, transcribed, coded, and conducted until saturation occurred [24].

The interviewer reviewed each transcription while listening to the recorded interview to check transcription accuracy. Interviews were 26 minutes on average.

2.4 Data analysis

The transcriptions were coded by 3 senior (CD, LG, BG) researchers. Content analysis was used to search for patterns and themes that occurred frequently in a single interview or across interviews and resulted in categorical codes [25]. Text and codes were input into the electronic data analysis program (NVivo 2, QSR International, Victoria Australia) for organization, summarization and report generation.

2.5 Methodological rigor

Study soundness was established in several ways. First, any conclusions drawn from the qualitative data were reviewed in the context of the entire data set with the goal of finding discrepant information. Conclusions were modified if discrepancies were found. Second, the use of multiple coders from diverse disciplines (nursing, psychology, and anthropology) was important in establishing the credibility of the coding scheme. After separately summarizing and interpreting the findings from patients and clinicians, the 3 researchers thoroughly discussed similarities and differences in individual and group perceptions to reach consensus. In addition, the investigators worked closely with several clinicians (member checking) to obtain feedback and reduce the possibility of researcher bias or faulty clinical logic (i.e. to reflect the trustworthiness of the data). Lastly, in-depth interviews were conducted until data saturation (no new information is gained) occurred.

3. Results

3.1 Sample: Patients

Patients who discontinued clopidogrel were not different from those who continued in clinical (common co-morbidities, prior MI, discharge disposition, PCP follow-up) or demographic characteristics. Both groups were approximately 53 years old and ranged from 45 to 77 years of age, more likely male (55% Continuers vs. 64% Discontinuers), the majority were Caucasian (82% for both), and all patients reported being given medication instructions at discharge. Most patients had a high school education or greater (82% of those discontinuing meds vs. 64% of those continuing meds). All of the patients who continued medications had health insurance compared to 73% of the patients who discontinued.

3.2 Sample: Clinicians

Of the clinicians interviewed, 33% of the physicians specialized in internal medicine, 53% in cardiology, and 13% in interventional cardiology. Most physicians were male (80%), Caucasian (80%), and had been in practice on average for 13.8 years. Two cardiovascular nurse practitioners were also interviewed. Both were Caucasian females, in practice for an average of 17 years, and were employed by hospitals. The sites represented diverse care settings: 1) geographic region (East, Midwest, West), 2) type of practice (academic settings, private practice, and the Veterans Health Administration system), 3) localized versus regional heart centers, and 4) patient socio-demographic diversity.

3.3 Key themes for premature clopidogrel discontinuance

Four themes consistently emerged in our qualitative analyses. From the patient perspective, 1) lack of knowledge about duration and purpose of clopidogrel treatment and 2) poor communication between clinicians and between clinicians and patients were cited as barriers. From the clinician perspective, 3) cost of clopidogrel and 4) poor transitions of care especially from the inpatient setting to outpatient care were acknowledged as problems.

3.3.1 Lack of knowledge (patients)—The most common reason for discontinuance was that patients were unaware they should still be taking clopidogrel. Frequently, these patients were unable to recall receiving education about the medicine or clopidogrel's specific purpose. One patient said "…you know they gave me the medication but I wasn't quite that clear of it. I was just taking it because they were telling me to." He had not refilled his prescription after his initial 30-day supply.

Conversely, patients who continued clopidogrel were more likely to explain coherently the purpose and benefit of taking clopidogrel. Patients could relate it to everyday actions:

“keeps the pipes open” or “so things won’t stick”. Several patients could describe the purpose of clopidogrel in relation to the stent used in their revascularization. One patient described the purpose as “Well, the way he explained it to me…it would keep that plaque from building up around it and keep it open.”

Another issue was the *intended duration* of clopidogrel. One patient reported “Now when I first got out, the doctor, I think it was Plavix [clopidogrel], he said I would have to be on it for the rest of my life. And when I went to the [Primary Care Physician/PCP] doctor, you know, on my return visit, he just said it would be 30 days, and at the end of 30 days that was it.” She had stopped her clopidogrel after her visit with her PCP. In contrast, patients continuing clopidogrel knew the intended duration of clopidogrel. Several patients reported that they would be taking the drug for a year, while one patient said “…I ask them, and they said I may be taking it for the rest of my life.”

3.3.2 Poor communication (patients)—One of the most frequently reported barriers was a breakdown in communication, which in turn lead to poor transitions of care (e.g., hospital to outpatient or specialist to PCP). Poor communication beyond the transition of care was also a barrier for some patients. Several patients who discontinued reported feeling limited by the time available for seeking information from caregivers during hospital discharge and later during follow-up visits. One patient, for example, commented on his hospital discharge experience, “… she rushed through [discharge] so she could get to dinner…I don’t really have much recollection of what the hell she said … I didn’t get anything out of it to be honest about it.”

Likewise, some patients who continued reported similar experiences, but then identified other sources that they used for acquiring more information. Patients who continued could easily recall having heard about their clopidogrel medication, including the purpose and specifically the duration. In addition, several described communications between their hospital physicians or cardiologists and their regular primary care physician. Describing that communication, one patient stated, “… you know he’s just a general practitioner, but he has helped me out with pills and medicines you know. He would call [cardiologist] and set the appointment for me--be sure I could see someone as quick as I could. …” Both groups of patients reported receiving conflicting information from caregivers, but those who discontinued did not usually seek clarification or additional answers to their questions.

3.3.3 Cost (clinicians)—Clinicians mentioned cost of clopidogrel as the greatest perceived barrier to clopidogrel continuation, regardless of patients’ insurance status. As one cardiologist explained, “…a patient said to me, ‘It’s either food or medicines.’” For uninsured patients, an assumption was often made that social services would provide adequate assistance to help pay for treatment and prescriptions; however, patients frequently reported that it took time to initiate these services. Unfortunately, patients receiving DES treatment need anti-platelet therapy immediately upon hospital discharge; a time lag could prove fatal.

3.3.4 Gaps in the transitions of care (clinicians)—The transition of care, particularly from the inpatient setting to outpatient care, was described by clinicians. Problems ranged from loss of information in transitioning the patient, poor communication between patients and caregivers on necessary follow-up, insufficient patient education, problems with medication reconciliation, and patient failure to follow-up or refill prescriptions.

Clinicians reported that information was frequently conveyed poorly to the patient, or not at all, during the discharge process. A cardiologist described a recent patient who stopped clopidogrel at five months instead of six months. Other clinicians agreed that miscommunication is a problem and that physicians sometimes do a poor job of explaining prescriptions to patients. Another cardiologist said, “We basically don’t have time ourselves as the attending…to sit down with every patient, and maybe get the pill bottle out and say, ‘This is for this…” I think people need extra help.” Unfortunately, the extra help provided in standard patient education is typically a large amount of reading material, which may not be effective, especially for low-literacy and/or non-English speaking patients.

Each transition of care was described as a possibility for medication reconciliation errors. An internist said, “The most medication errors I have ever seen, by far and away, are patients who have been hospitalized…And we see everything from patients doubling their medication, to taking nothing, to taking every combination in between. And so those handoffs of care are huge sources of problems.”

4. Discussion and Implications for Practice

The objective of this study was to understand patients’ and clinicians’ perspectives on premature clopidogrel discontinuance. Four distinct themes emerged in patient and clinician interviews. Patients reported lack of knowledge and poor communication as the most common reasons for early clopidogrel cessation. In contrast, clinicians identified cost and poor transitions of care as more common causes for premature cessation. Although both groups report problems in transitions of care, patients focused on direct communication breakdowns whereas clinicians saw system-level factors as being more problematic, such as medication cost or delays in faxing reports to primary care physicians or confusion over medication reconciliation.

With regard to the patients’ perspective, our findings are consistent with those of a prior study in which less than half of patients at hospital discharge were able to list their diagnoses, names of medications or their purpose [26]. Several studies have found that when patients were given instructions on medication use, important information was often omitted, such as the name of the drug, duration of treatment or purpose of the medication [27,28]. Further, medication discrepancies occurring shortly after hospital discharge have been associated with increased risk of re-hospitalization within 30 days of hospital discharge [11]. Our findings complement prior reports describing the transition period as a potential high risk period for medication errors. Additional studies are urgently needed to identify more effective methods of transitioning patients from the inpatient setting to outpatient care and ensuring that patients understand their medication regimens.

One issue that clinicians and patients agreed upon was the lack of time for thorough medication education and instructions during hospital discharge. Both groups reported that hospital discharge is often a hurried process and may not be the ideal time for education and information retention. As such, future interventions to improve persistence to clopidogrel and other medications might include an educational component at one-month follow up. In addition, educational interventions should target both providers and patients, perhaps creating a multi-modal intervention. Lehane and colleagues report that physical aids or ‘reminder packaging’ strategies along with the development and maintenance of medication taking routines are effective [29].

Implications for practice

As a final question, clinicians were asked to suggest possible interventions to improve persistence to clopidogrel and/or medications in general. A few of the more concrete suggestions included 1) packaging/combining 6 to 12-months of clopidogrel medication with the stent for delivery at the time of DES implantation; 2) adding a duration column to all medication lists (at discharge in materials accompanying the patient, in dictated letters/

materials being sent to the PCP's); 3) creating prescription pads that have a space for "Intended Duration"; and 4) making follow-up phone calls to patients to inquire about medication persistence. Many clinicians recommended more time for patient education (with reimbursement) during visits so that the importance of clopidogrel as an adjunctive treatment following DES implantation can be emphasized. Engaging other health care providers throughout the continuum of care for the MI patient (e.g. pharmacists, primary care clinicians and office staff) may also be an effective strategy that warrants further research.

Opportunities during the index hospitalization should also be explored. These might include daily medication education during medication administration by nursing staff. Another opportunity for medication reinforcement is available during in-patient cardiac rehabilitation visits.

Several limitations to the present study should be considered in the interpretation of the findings. When compared to large quantitative studies, qualitative studies have relatively small sample sizes and are exploratory in nature. The present study is no exception, but the more relevant factor to consider is whether the sample size is adequate to address the research question. The richness of the data and the attainment of saturation in the present study indicate a sufficient number of patients and clinicians were interviewed to make the results credible, trustworthy, and meaningful. However, the findings should not be generalized to patients or clinicians outside the scope of the sample in the present study. A further issue is the difference in national health systems that may make these findings unique to the U.S. where healthcare is provided on a fee for service basis without universal coverage for all citizens. This limitation may influence continuation of therapy. It would be interesting to examine medication discontinuance in other countries.

An important factor to consider is the timing of this study; only AMI patients who discontinued therapy at 1-month post-DES were included. Investigating discontinuance at other time points (e.g. 6 months, 9 months) may reveal different barriers to medication continuance as the patient copes with adhering to a possibly complex and expensive medical regimen over time. Future research should identify patients discontinuing medications at later time points to understand discontinuance beyond early recovery. In addition, the patients in this study were not under the care of the clinicians we interviewed. Examining the alignment between patients' perspectives and their care providers to gain further insight into the discord between the two perspectives should be the goal of future study.

In summary, we found four distinct themes among the patient and clinician interviews including lack of knowledge, poor communication, cost of the medication, and poor care transitions. Thus, the discord between patients' and clinicians' perspectives could be alleviated by 1) enhancing communication between clinicians and patients, 2) enhancing communication among clinicians, and 3) providing more effective patient education. In turn, increased alignment between patients' and clinicians' could lead to improved compliance with evidence-based guidelines for therapy.

Acknowledgments

Funding Source: Funding was received from Sanofi-Aventis and NIH SCCOR (P50 HL077113) grants. The sponsors were not involved in the conduct of the study, analysis of the data, or preparation of the manuscript.

Appendix A

The coding procedure was divided into three main phases [25]: preparing, organizing, reporting.

Phase 1: Preparation

Transcribed interviews were read independently by 3 experienced qualitative researchers from different disciplines (nursing, psychology, anthropology).

A holistic discussion of interview content among the researchers informed the selection of themes as our unit of analysis that reflected Health Belief Model (HBM)[21,22] barriers to health promoting behaviors.

Consensus was reached among the researchers regarding relevant themes.

Phase 2: Organization

Narrative passages were classified into much smaller content units (open coding). A coding schema was developed by constant comparison of content units within and across interviews.

Phase 3: Reporting

Four categories emerged and reflected barriers to health promoting behavior (HBM): 1) lack of knowledge about duration and purpose of clopidogrel treatment and 2) poor communication between clinicians and between clinicians and patients were cited as barriers. From the clinician perspective, 3) cost of clopidogrel and 4) poor transitions of care especially from the inpatient setting to outpatient care were acknowledged as problems.

An affinity diagram was created to visually display content units/quotes within the themes.

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