PSNet
PATIENT SAFETY NETWORK

Dual Therapy Debacle

September 1, 2015
Kayser SR. Dual Therapy Debacle. PSNet [internet]. 2015.
https://psnet.ahrq.gov/web-mm/dual-therapy-debacle

The Case

An elderly man with a history of arthritis, benign prostatic hypertrophy with urinary obstruction, hyperlipidemia, obesity, and a long history of tobacco use presented to a local emergency department for chest pain. An electrocardiogram revealed a new anterior myocardial infarction, and a cardiac catheterization confirmed single-vessel disease isolated to the left anterior descending artery. The resulting percutaneous coronary intervention (PCI) resulted in the placement of two drug-eluting stents. After stent placement, the patient was placed on triple anticoagulation therapy consisting of warfarin, clopidogrel (Plavix), and aspirin (ASA).

One month after placement, he received follow-up from a cardiologist and was informed he should remain on triple therapy for 6 months, at which time the warfarin would be discontinued. The plan was to continue the clopidogrel and aspirin (dual anticoagulation therapy [DAPT]) for an additional 6 months.

The patient saw his primary care provider (PCP) periodically over the next few years. These visits presented opportunities for his PCP to reconcile his medications. However, despite the plan to discontinue the DAPT after 1 year, the patient remained on this regimen 3 years after stent placement. On a preoperative visit for prostate surgery, he saw a cardiologist, who determined the patient had asymptomatic, stable coronary artery disease and affirmed his surgical candidacy. He further recommended discontinuing the clopidogrel, while continuing aspirin indefinitely. The cardiologist noted that an FDA Advisory Panel recommends just 12 months of DAPT after drug-eluting stent implantation, due to an increased risk of bleeding after 24 months of DAPT. The patient's PCP documented a telephone conversation with the patient in which he informed him to stop the clopidogrel and cleared him for prostate surgery. Nonetheless, the patient re-started the medication after the operation.

During yet another preoperative visit (this for removal of a skin cancer), it was discovered that the patient had re-started the clopidogrel. At this point, the clopidogrel was finally discontinued, and the PCP removed the drug from the patient's medication list in the electronic medical record.

The Commentary

by Steven R. Kayser, PharmD

Dual antiplatelet therapy (DAPT) is required following implantation of a drug-eluting stent to reduce the risk for stent thrombosis and major adverse cardiac events. However, some patients, such as the one described in this case, are also candidates for the addition of a vitamin K antagonist (warfarin). The risk for bleeding in patients on triple antithrombotic therapy is 2–5 fold the already increased risk observed in patients on DAPT.(1-4) This fact emphasizes the necessity to balance the risk for sufficient, but not excessive, duration of therapy. The longer the course of therapy, the greater the risk for bleeding; however, inappropriately early discontinuation of therapy increases the risk for stent thrombosis. Despite the availability of national guidelines regarding treatment duration, the risk remains that therapy may continue longer than necessary. While the duration of therapy may be debated (and is beyond the scope of this commentary), the first cardiologist consulted in this case specifically recommended that the warfarin be discontinued after 6 months and the DAPT to be discontinued after 12 months.

The etiology for the breakdown in communication is not clear in the current case. However, despite many occasions when the therapy could have been appropriately discontinued, this unnecessary, potentially unsafe therapy was continued for 3 years.

When the initial cardiologist informed the patient regarding the anticoagulant therapy plan, it is not clear whether these recommendations were documented and communicated to the PCP. In the current case, the PCP had access to an electronic medical record (EMR). If the cardiologist was also a member of the delivery system using the EMR, the recommendation regarding the length of therapy should have been documented (preferably with a templated note embedded in the EMR) and would have been available for review. If the cardiologist was outside the health care system, the recommendations should have been forwarded to the PCP by email, fax, or mail and entered into the medical record. For those patients referred from an acute care setting to a site with no access to the EMR, communication can be difficult. Right or wrong, the patient becomes the constant at all visits and the patient (or his or her advocate) should be educated about, and then empowered to convey, important information.

With the EMR, medication lists are standardized and available to all providers. Reconciliation of medications at every office visit (regardless of provider) should prompt a reminder to discontinue warfarin, and DAPT, at the appropriate time. A comment can be included for all time-sensitive medications with specific information regarding a date for discontinuation. When reviewing medications with a patient, evaluating each medication individually is more valuable than generally asking, "Are you taking your medications?" or "Are there any changes in your medications?"

Integrating patient education, partnerships among providers and a pharmacist, and utilization of voice messaging are additional tools to increase the likelihood for patients not only to obtain and to take their medications, but also to discontinue them at the appropriate time.(5)

A written after-visit summary outlining the expectations for therapy (and, in this case, therapy duration) is another component of the EMR that could have been utilized. While the cardiologist in this case informed the patient, it may have been solely verbal and not written.

Since the patient was discharged on warfarin, referral to an anticoagulation clinic would have been appropriate. Anticoagulation clinics typically document the anticipated duration of warfarin therapy, discuss it with the patient, and enter it into a tracking system that prompts a reminder when therapy has been completed. Antiplatelet therapy is not routinely managed in an anticoagulation clinic. It is possible however to make an entry into the comments section of an anticoagulation episode that highlight the patient is taking other potentially conflicting medications or risky medications. In this case a comment could have been included about the use of DAPT and its duration. It appears that the warfarin was appropriately discontinued after 6 months; at this time the patient could have been informed regarding the appropriate duration of the DAPT. In most cases with warfarin, patients are provided an identification card, which can include the anticipated duration of therapy and might be expanded to include DAPT. The need for frequent international normalized ratio testing would have provided multiple additional encounters for reconciliation of medications.

Patients, or caregivers, must be empowered to take an active role in their care. Patients should be provided with a copy of their discharge summary, which may facilitate communication of the diagnosis and anticipated duration of therapy.

When a community or ambulatory care pharmacist receives a new prescription for a medication like clopidogrel, there is another opportunity to include a notation that authorizes refills, specific to the duration of therapy. If the desired duration of the therapy is known, inclusion of this information in the pharmacy medication profile might be useful. For example, a notation, "do not refill after a specific date" or "anticipated therapy duration is 12 months (with a specific date noted)" can provide an additional level of safety. Even if the ultimate decision were to continue therapy, inclusion of such a notation would provide a time out and facilitate a communication with the prescriber to reassess therapy.

Discontinuation of unnecessary DAPT could have been accomplished several times in this patient, including his two perioperative evaluations. Only after the PCP actively removed the drug from the patient's medication list was it truly discontinued. This case highlights the importance for improved communication among not only the providers but with the patient.

Take-Home Points

- Providers must ensure that all therapy recommendations are documented and communicated to appropriate other providers and the patient.
- Patients should be provided with specific written instructions regarding duration of therapy for select medications.
- Medication reconciliation should be accomplished at each clinic or office visit and should include a review of each individual medication.
- Integration of multiple resources, including patient education, provider–pharmacist communication, and electronic reminders, is important.
- Including the intended duration of therapy in the prescription engages the community pharmacist as another valuable resource to ensure appropriate therapy duration.

Steven R. Kayser, PharmD Professor Emeritus Department of Clinical Pharmacy, School of Pharmacy University of California, San Francisco

References

1. Hansen ML, Sørensen R, Clausen MT, et al. Risk of bleeding with single, dual, or triple therapy with warfarin, aspirin, and clopidogrel in patients with atrial fibrillation. Arch Intern Med. 2010;170:1433-1441. [go to PubMed]

2. Palmerini T, Sangiorgi D, Valgimigli M, et al. Short- versus long-term dual antiplatelet therapy after drug-eluting stent implantation: an individual patient data pairwise and network meta-analysis. J Am Coll Cardiol. 2015;65:1092-1102. [go to PubMed]

3. Mehran R, Giustino G, Baber U. DAPT duration after DES: what is the "mandatory" duration? J Am Coll Cardiol. 2015;65:1103-1106. [go to PubMed]

4. Sørensen R, Hansen ML, Abildstrom SZ, et al. Risk of bleeding in patients with acute myocardial infarction treated with different combinations of aspirin, clopidogrel, and vitamin K antagonists in Denmark: a retrospective analysis of nationwide registry data. Lancet. 2009;374:1967-1974. [go to PubMed]

5. Ho PM, Lambert-Kerzner A, Carey EP, et al. Multifaceted intervention to improve medication adherence and secondary prevention measures after acute coronary syndrome hospital discharge: a randomized clinical trial. JAMA Intern Med. 2014;174:186-193. [go to PubMed]

This project was funded under contract number 75Q80119C00004 from the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services. The authors are solely responsible for this report's contents, findings, and conclusions, which do not necessarily represent the views of AHRQ. Readers should not interpret any statement in this report as an official position of AHRQ or of the U.S. Department of Health and Human Services. None of the authors has any affiliation or financial involvement that conflicts with the material presented in this report. View AHRQ Disclaimers