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Findings from a rivaroxaban program for acute venous thromboembolism upon emergency department discharge, with focus on utility of commercially available dose pack☆

Aileen Chu, PharmD *, Jill Limberg, PharmD

Department of Pharmacy, Sharp Grossmont Hospital, La Mesa, CA, USA

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ABSTRACT

Objective: To evaluate the impact of a rivaroxaban discharge initiative on the efficacy and safety of acute venous thromboembolism treatment in emergency department patients.
Practice innovation: Patients discharged on rivaroxaban from the emergency department were provided extensive counseling along with a commercially-available medication dose pack by the ED pharmacist. Patients were contacted by phone until they had obtained outpatient follow-up and remained adherent to anticoagulation beyond the initial first month of treatment.
Methods: In this retrospective chart review over a thirteen month period, efficacy and safety outcomes were compared between patients with intervention versus those who received usual care. Efficacy was defined by reduced 90-day readmission rates due to nonadherence or treatment failure, and improved medication adherence beyond the first month from discharge. Safety was determined by comparing 90-day readmission rates due to bleeding or adverse event.
Results: 41 patients received intervention with rivaroxaban, and 34 patients received usual care, with 76% prescribed rivaroxaban and remaining patients started on enoxaparin alone (6%) or enoxaparin plus warfarin (18%). Improved treatment efficacy in the intervention group was not found to be statistically significant. Safety outcomes were similar between the two groups.
Conclusion: Home treatment of acute VTE, facilitated by medication dose pack, is a promising tactic to ensure both immediate and long-term treatment efficacy and safety. Further studies are warranted to demonstrate clinical superiority of this intervention.

1. Background

Initial home treatment of venous thromboembolism (VTE) has become increasingly common since it was demonstrated to be safe and effective over two decades ago for deep vein thrombosis (DVT) [1,2], and more recently for low-risk pulmonary embolism (PE) [3,4]. Avoidance of hospitalization is more feasible today due to the availability of direct oral anticoagulants (DOAC), which require less frequent lab monitoring and dose titration when compared to warfarin. Two of these agents, apixaban and rivaroxaban, allow patients to forgo parenteral treatment entirely.

Rivaroxaban (Xarelto™; Janssen Pharmaceuticals, Titusville, NJ, USA), a factor-Xa inhibitor, is approved for monotherapy treatment of acute VTE. Guidelines by the American College of Chest Physicians recommend DOACs over warfarin for treatment of lower-extremity DVT or PE in patients without cancer. Rivaroxaban is also a guideline-preferred agent for patients seeking to avoid parenteral anticoagulation and take once-daily therapy [5]. In low-risk VTE patients treated at home, rivaroxaban achieved higher rates of patient and prescriber satisfaction while demonstrating safety and efficacy [6,7]. Rivaroxaban has also been associated with lower cost of medical care compared to LMWH-warfarin and heparin-warfarin [8,9]. For acute low-risk PE patients, studies are ongoing to determine clinical efficacy, safety, and cost benefits of home treatment with rivaroxaban [10,11].

However, the initial dosing regimen – 15 mg by mouth twice daily for three weeks, followed by 20 mg once daily – has been prone to confusion and adverse events due to the combination of two tablet strengths, frequencies, and prescriptions. In an error reported to the Institute for Safe Medication Practice (ISMP) in November 2014, a patient took two 15 mg tablets and one 20 mg tablet concomitantly for the first ten days [12]. Anecdotally, there have also been cases of patients taking the rivaroxaban 20 mg tablet twice-daily after the initial three weeks. The Xarelto Starter Pack™ (Image 1), a blister pack with dose

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* Corresponding author at: Emergency Department Pharmacist, Sharp Grossmont Hospital, 5555 Grossmont Center Drive, La Mesa, CA 91942, USA.
E-mail addresses: aileen.chu@sharp.com (A. Chu), Jill.Limberg@sharp.com (J. Limberg).

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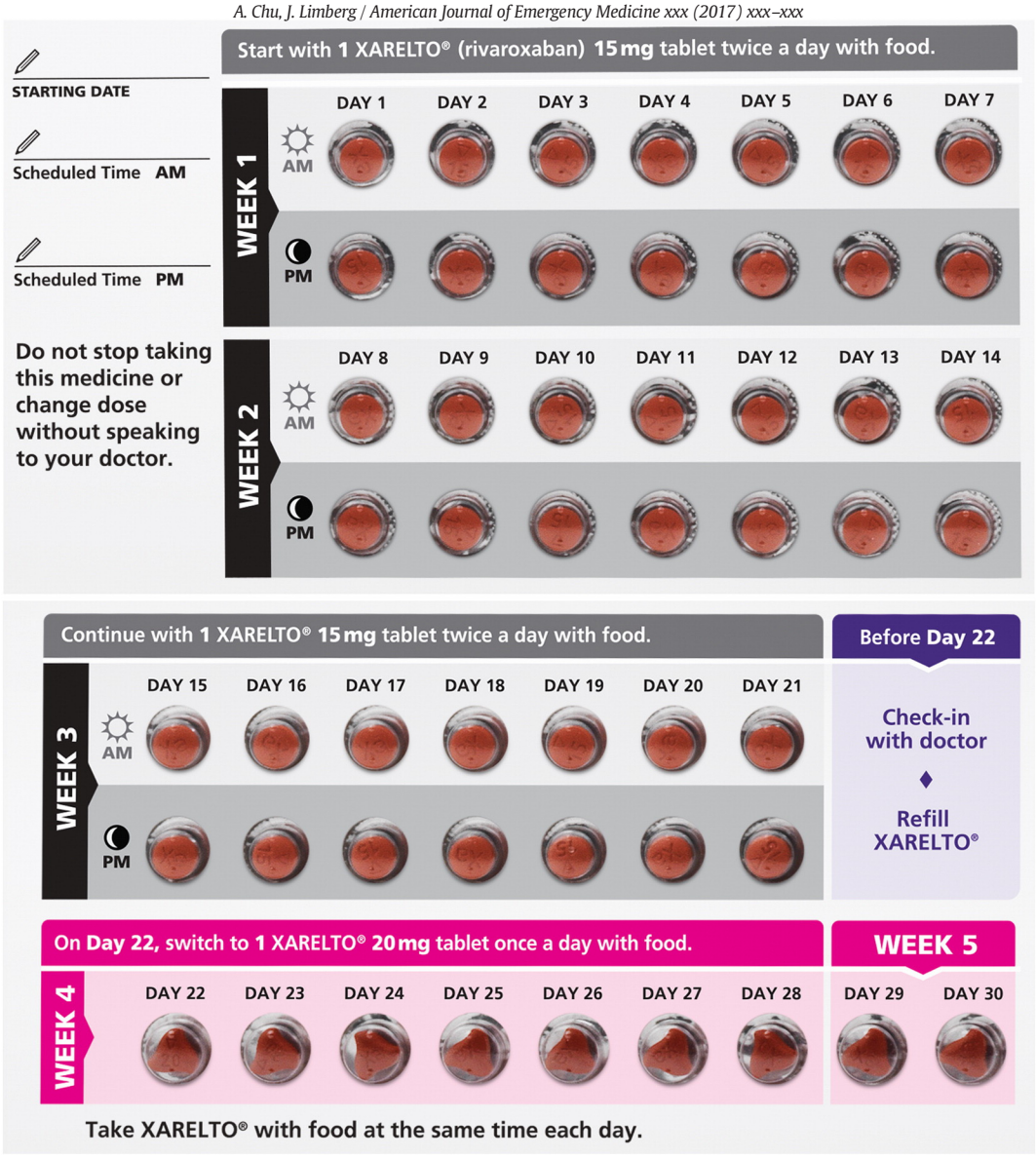

Image 1. Xarelto Starter Pack™, a blister pack with dose instructions for each of the first thirty days of VTE treatment.

instructions for each of the first thirty days of treatment, became available on the market in October 2014 with the intent to minimize such errors; its utility was endorsed by ISMP following the reported error [12]. A similar tactic, using an individualized medication box with dividers, has been employed by pharmacists to ensure patient adherence and proper dose transition [13].

Despite the clinical appropriateness of VTE treatment with DOACs, proper patient selection is imperative and oftentimes challenging. Therapeutic convenience of these medications must be weighed against barriers to access, as newer oral anticoagulants may carry substantial costs to patients with limited prescription drug coverage [5]. There is also concern for medication nonadherence due to fewer requirements for laboratory monitoring; this is inherently less problematic and easily measured with warfarin due to frequent INR monitoring and provider follow-up, particularly during the initial dose-finding period [14]. Therefore, prior to discharge with a DOAC, it is essential to ensure medication adherence through extensive patient counseling and follow-up.

2. Practice description

The authors report on an initiative that was started in late 2014 to facilitate management of patients diagnosed with acute VTE and discharged directly from the ED on rivaroxaban. Specific steps were taken to minimize errors that could potentially occur at various stages throughout the treatment process (Fig. 1).

The practice setting was an urban, community hospital with over 100,000 emergency department visits annually. Of the patients discharged from the ED, over half are either uninsured or underfunded. Therefore, adherence and affordability frequently drive decision-making for anticoagulation selection; occasionally, lack of out-of-hospital resources may result in overnight hospital admission of an otherwise uncomplicated VTE patient.

Patients discharged for home management with rivaroxaban during hours of ED pharmacist coverage – daily from 1300 to midnight – were counseled extensively and provided with a Starter Pack™ filled through the on-site outpatient pharmacy. ED pharmacists contacted patients by phone in the weeks following discharge until it was confirmed that they had obtained follow-up and remained adherent to anticoagulation beyond the initial first month of treatment.

3. Methods

In this single-center retrospective chart review, the investigators identified ED patients with discharge diagnosis of VTE based on ICD

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