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Use of decision aids for shared decision making in venous thromboembolism: A systematic review ☆

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ABSTRACT

Background: Optimal care of patients with venous thromboembolism requires the input of patient preferences into clinical decision-making. However, the availability and impact of decision aids to facilitate shared decision making in care of venous thromboembolism is not well known.
Objectives: To assess the availability, clinical impact and outcomes associated with the use of decision aids in patients with or at risk for venous thromboembolism.
Patients/methods: A systematic review of the literature was performed exploring the use of decision aids in patients with venous thromboembolism. Criteria for primary inclusion required use of patient values clarification in the decision aid. A secondary review without the requirement of a patient values clarification was performed to be more inclusive. The data was summarized such that knowledge gaps and opportunities for enquiry were identified.
Results: The primary review identified one study that explored the decision to extend anticoagulation in patients with a recent venous thromboembolism beyond the stipulated 3-month duration. The secondary review identified an additional study exploring the decision to undergo computer tomography testing in patients at low risk for pulmonary embolism in an emergency department setting. Both studies were of modest quality given a lack of control group for comparison analysis.
Conclusions: Despite numerous calls to increase use of shared decision-making, a paucity of data exists to help patients engage in the treatment decisions for venous thromboembolism. Future studies of additional VTE clinical decisions with longer-term clinical outcomes appear necessary.

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1. Introduction

Venous thromboembolism (VTE), including deep venous thrombosis (DVT) and pulmonary embolism (PE) is a common medical condition with an incidence of approximately 1–2 per 1000 people annually [1]. Each phase of VTE prevention or care requires a number of clinically important decisions. Equipoise exists for many of these decisions, such as the need for diagnostic testing in low risk patients, the choice of oral anticoagulant and need for shorter vs. extended (beyond 3–6 months) anticoagulation after a first VTE event. Numerous society guidelines and recommendations call for incorporating patient preferences in a shared decision model for the care of VTE patients [2–8]. Additionally, the Institute of Medicine included patient-centered care as one of six key quality domains for healthcare delivery [9].

Shared decision-making incorporates multiple steps [10]. First, physicians must describe to patients their diagnosis and the benefits and harms of the treatment options. In so doing, patients can begin to understand the consequences of the decision at hand. Second, patients must communicate their goals, values and preferences to physicians. Finally, patients and their physicians discuss the medical evidence and the patients' values and goals so as to come together to agree on a treatment that incorporates the best of both worlds for patients.

Decision aids are tools that [1] assist patients and providers in fully describing the risks and benefits of a clinical decision [2], include a process or exercise to help clarify a patient's values for a particular

medication decision, and [3] facilitate a mutually agreed upon decision between the patient and provider [11,12]. Many of these tools take the form of a paper handout or pamphlet while others are Internet- or video-based [13–15]. Additional criteria have been proposed to evaluate the quality of a decision aid, assessing domains of information, probabilities, values clarification, decision guidance, development, evidence, disclosure, language, and evaluation [16,17].

Even though the importance of shared decision making is highlighted in multiple guidelines and recommendation statements, whether evidence supporting the use of decision aids in patients with VTE exists is not known [2–4,6–8]. To explore this knowledge gap, we systematically reviewed the literature regarding use of a decision aid in any phase of VTE care (prevention, diagnosis, acute treatment and extended/chronic treatment).

2. Materials and methods

2.1. Information sources and search strategy

We followed the PRISMA recommendations when performing this systematic review [18]. With the assistance of a medical research librarian (M.L.C.), we searched MEDLINE via Ovid, EMBASE, CINHAL, Web of Science and PsycInfo databases without date limits. The search included published conference proceedings from these databases. Our search strategy is a combination of controlled vocabulary terms for relevant databases (e.g., Medical Subject Headings for MEDLINE searching) and appropriate keywords to represent the concepts of venous thromboembolism, pulmonary embolism, or deep vein/venous thrombosis and shared decision-making (Online appendix). Additionally, we utilized proximity searching in databases that supported it to capture additional citations related to VTE and patient and physician decision-making. No additional filters were used. To identify additionally relevant decision-aids, we also manually reviewed the Ottawa Research Institute Patient Decision Aid Inventory [19]. We contacted communicating authors for any missing data or clarifying questions. In addition, we also reviewed the 115 studies identified from the 2014 Cochrane Review of decision aid use [12]. The literature search was last updated in May 2015. We registered our study protocol with PROSPERO (CRD42014014832) prior to beginning the systematic search of the literature. This study was deemed not regulated by the Institutional Review Board Medicine at the University of Michigan.

2.2. Study eligibility and search criteria

Our study examined the question "in patients with VTE or who are at risk of VTE, what are the clinical and intermediate outcomes (e.g. satisfaction, knowledge) associated with the use of decision aids compared to no decision aid in any published study?" English language studies that involved [1] human subjects of any age [2], any phase of VTE care (e.g. initial diagnosis and risk stratification, initial treatment, ongoing/chronic treatment and prophylaxis against VTE), and [3] the use of a decision aid by the patient (with or without a physician or other provider) to make a clinical or simulated clinical decision were included.

A standard definition of a decision aid requires three components [1]: a tool to assist patients and providers in fully describing the risks and benefits of a clinical decision [2], a process or exercise to help clarify a patient's values for a particular medication decision, and [3] facilitation of a mutually agreed upon decision between the patient and provider. Given concerns that very few studies would examine decision aids that meet all three components of the definition (or the more exhaustive definition by Joseph-Williams and colleagues), a priori our search was structured in two phases (primary and secondary) [16]. In the primary review, studies that included a decision aid that 1) reviewed risks and benefits of a VTE diagnostic or treatment decision, and 2) helped patients clarify their values and wishes, were included. The secondary review did not require the values clarification exercise

as a part of the decision aid being tested. Because we expected that the use of any decision aid (even ones with just a risk/benefit discussion but no values clarification exercise) would facilitate a discussion and mutual decision between the clinician and patient, this third component of a decision aid definition was not required in our search strategy.

2.3. Database abstraction

Two authors (G.B. and B.I.) manually reviewed the title and abstract of each record to determine eligibility. Any disagreements regarding inclusion/exclusion were resolved by consensus or through a third author (A.F.). Eligible and included studies were evaluated in duplicate by two authors (G.B. and B.I.) and relevant data were extracted to a data abstraction form in accordance with the Cochrane Collaborative standards [20,21]. The data abstraction form was develop and piloted prior to any literature searches were performed. Data abstracted included study design descriptors, the specific VTE population and phase of care (e.g. diagnosis, treatment, prophylaxis) studied, type of decision aid, any assessment of patient's values as a part of the decision aid, and outcome measures.

2.4. Study quality and risk of bias

We used the Newcastle-Ottawa quality assessment scale for cohort studies and adapted the Downs and Black Study Quality checklist to assess study quality and potential bias [22,23]. For the Newcastle-Ottawa scale, studies were awarded points (zero to nine) based on patient selection, comparability of cohorts and outcomes assessed. For the Downs and Black checklist, we included items relevant to the objectives of this review and the study designs identified. The 17 included items are 1–7, 10–15, 18, 20, 25 and 27. Item 27, which assesses the power calculation, was simplified for a Yes (1 point), No (0 points) or Unable to be determined (0 points) response.

3. Results

Of 862 citations identified, one study involving 129 patients met our primary search criteria [24] and a second study involving 203 patients met our secondary search criteria (Table 1 and Fig. 1) [25].

3.1. Primary search results

Our primary search identified one study exploring the use of a decision aid (with values clarification) in the care of VTE patients. Between 2000 and 2002, Locadia and colleagues measured the preferences of 124 participants for a hypothetical scenario of extending anticoagulation therapy for two years after an initial 3 months of warfarin therapy following a VTE [24]. This study was performed at three centers in the Netherlands. They recruited patients from three groups: (1) newly diagnosed patients with a first or second episode of VTE who were being treated with warfarin, (2) patients who had experienced a major bleeding episode while on warfarin, and (3) patients diagnosed with the post-thrombotic syndrome at least 1 year after a deep venous thrombosis was identified. The participants underwent an educational review of VTE treatment risks and benefits along with a values assessment for various potential outcomes related to the decision to continue or discontinue anticoagulation treatment. The participants were then asked to advise a hypothetical friend encountering this same decision if they should stop anticoagulation after the first three months of therapy or if they should continue on anticoagulation for two additional years.

Of the 124 study subjects, 43% had experienced a prior VTE, 39% with the post-thrombotic syndrome and the remainder had experienced a major hemorrhage related to warfarin therapy. Using a paper-based decision aid to review and rate each potential health state, 25% of participants recommended cessation of treatment independent of VTE recurrence risk while 23% recommended continuation of warfarin