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EMPoWARed: Edmonton pediatric warfarin self-management study

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ABSTRACT

Background: Patient self-management (PSM) in adults is safer and more cost effective than conventional management. Warfarin is a narrow therapeutic index drug with individual patient response to changes and frequently a long-term therapy. Children and their families are proposed to be able to effectively manage their child's warfarin therapy. Increased health related quality of life is highly associated with effective therapy in patients with chronic conditions.
Objectives: The aim of this study is to evaluate the safety and efficacy of PSM over time including HRQOL and variables that may influence PFU success at PSM.
Patients/methods: Children and their family units (PFUs) current performing patient self-testing/monitoring for ≥3 months were enrolled in this cohort study. PFUs participated in comprehensive education on warfarin testing and management followed by an apprenticeship. Socio-demographic, clinical, and laboratory data were collected to evaluate safety and efficacy and health related quality of life. Outcomes were compared between the first 6 months on PSM (phase 1) and the last 6 months data collected on PSM (phase 2).
Results: Forty-two patients performed PSM for a median of 2.7 years (range: 1.1–6.2 years). Time in therapeutic range was 90% and 92.9% ($p = 0.30$) in phases 1 and 2 respectively. All measures were strongly associated with improved heath related quality of life. PFUs socio-demographic status did not influence success at PSM. All PFUs maintained warfarin knowledge and INR testing competency. Warfarin dosing decision errors median 0 (range: 0–5, $p = 0.73$) and a median 0 (range 0–4, $p = 0.55$) per patient in phases 1 and 2 respectively. There were no adverse hemorrhagic or thrombotic events.
Conclusions: Empowering PFUs to self-manage warfarin results in increased knowledge and understanding of their health condition, improved commitment to their health care and adherence to medication regimens and is demonstrated to be sustainable over time.

1. Introduction

Improvement in patient self-efficacy via self-management strategies are demonstrated to result in behavior change, improved health status and health related quality of life (HRQOL) [1]. Self-management is the day-to-day management of a chronic condition, which is typically lifelong and ever changing. Indefinite duration warfarin therapy is frequently prescribed in children with chronic illnesses. Successful warfarin management is complex, requiring frequent international normalized ratio (INR) testing and warfarin dose adjustments, resulting in increased burden for the child (patient) and family/caregiver (patient-family unit (PFU)). Increased burden is associated with decreased HRQOL, which affects adherence [2].

Patient self-testing (PST) (INR is performed using a coagulometer and reported to the health team who make the warfarin dose adjustment) is considered to be a safe and effective method of INR testing [3, 4]. Among adults, patient self-management (PSM) of warfarin is demonstrated to improve outcomes, including reduction in major hemorrhage and thromboembolic complications, increased time in therapeutic range (TTR) and patient satisfaction [5, 6]. Several small pediatric warfarin self-management studies have demonstrated results similar to adult studies [3, 7–18].

Warfarin self-management (PSM) involves the PFU performing an INR using a coagulometer and then adjusting their warfarin dose to achieve and maintain a target INR. The EMPoWarMENT pilot study [19] randomized children to PST versus PSM and demonstrated that PFUs could successfully self-manage warfarin (non-inferior TTR and significant patient preference). In addition, PFUs described confidence in their abilities to make decisions and develop behaviors to successfully manage their warfarin therapy. The success of the EMPoWarMENT

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[19] study mandated the opportunity for PSM to be available to all PFUs. However, the sustainability of warfarin safety and efficacy and influence on PFU HRQOL with PSM has not been evaluated.

2. Objectives

The aim of this study is to evaluate the safety, efficacy and sustainability of PSM over time and the influence of PSM on HRQOL.

The primary outcome is INR time in therapeutic range (TTR). Secondary outcomes are two-fold and include safety and efficacy and PSM influence on HRQOL.

3. Methods

All patient-family unit (PFU) self-testers on warfarin for ≥3 months, who were fluent in English and demonstrated adherence to INR testing without requiring reminders more than 50% of the time to perform an INR test, were eligible to participate in the study.

This prospective cohort study enrolled eligible patients who were followed in the KIDCLOT program between May, 2008 and May, 2012 and who provided informed consent. Data was collected until August, 2014. The KIDCLOT program is a dedicated anticoagulation program at Stollery Children's Hospital, Edmonton, Alberta, Canada. Within the KIDCLOT program, the use of point of care (POC) INR meters for INR testing is standard of care.

3.1. Standard KIDCLOT warfarin management — patient self-testing

Children who are prescribed warfarin therapy for various indications participate in warfarin and coagulometer education [20] and are discharged home on warfarin performing PST. [13] The coagulometer used in the KIDCLOT program is the CoaguChek XS (Roche Diagnostics, Geneva Switzerland). PFUs report their INR and any changes in DIME (**D**iet, **I**llness, **M**edication changes or **E**rrors (such as missed dose)), to the KIDCLOT provider. The KIDCLOT provider then makes a warfarin dose decision and sets the next INR testing date. Based on the EMPoWarMENT pilot study results [9], including PFU feedback, the decision was made to provide the opportunity for eligible patients to participate in PSM.

3.2. Intervention — patient self-management

1) Initiation: group education
   Within one year of warfarin initiation, PFUs attend a group anticoagulation clinic appointment where they participate in comprehensive warfarin education as the commencement of PSM. The interactive classroom session (approximately 1.5 h) is followed by a brief focused individual assessment to assess and address outstanding patient needs. The education presented is child focused, and encourages participation of both the child and the caregiver to develop warfarin knowledge. Topics include:
   - 'Warfarin' what is it and how does it work, including indications.
   - Influence of **DIME** (**D**iet, **I**llness, **M**edication, **E**rror (missed doses)) on warfarin.
   - Maintaining target INR and its relationship to safety and efficacy of warfarin.
   - Patient behaviors and safety related to warfarin therapy.
   - INR reporting.
   - Recognition, reporting and management of adverse events.

2) Warfarin dose adjustments and INR testing frequency using a standardized algorithm (Table 1). Practical knowledge is taught using case scenarios and dose calculations, enabling the PFU to apply their knowledge and problem solving skills to optimize decision-making for warfarin dose adjustments when deviations from the algorithm are reasonable (i.e. missed dose).
3) Evaluation of INR testing competency using the coagulometer
   - Direct observation of PFU performing a POC INR test using the coagulometer with laboratory/meter INR comparisons is performed to demonstrate PFU competency (proper technique to perform an INR test).

4) Introduction to the kidclot.com website for web-based INR reporting.
   - The KIDCLOT© website was established as a tool for INR reporting using a secure sockets layer (SSL) address, www.kidclot.com. PFUs enter INR results into the website via computer or smart-phone. This reporting method is efficient, easily accessible, time-friendly and engaging while providing the opportunity to report on influences on warfarin therapy (DIME). Each PFU is assigned a secure identification (ID) and password to log into the site where they will enter their INR, current warfarin dose, any changes to DIME or warfarin dose, and set the next INR date. Patient and administrative staff have different levels of access; therefore no patient has access to data outside of their own profile. This security is consistent with national health privacy policies [21, 22]. The website is set up to provide reminder and out of range alerts.

5) KIDCLOT PAC QL
   - Children > 8 years and caregivers complete the KIDCLOT PAC QL and the Parent Proxy KIDCLOT PAC QL, respectively.
   - The KIDCLOT PAC QL is a valid and reliable inventory to measure the impact of anticoagulation on PFUs [23]. The inventory reports the impact of warfarin on the participant's life; therefore a higher score indicates a lower QOL.

6) Knowledge evaluation
   - PFUs complete a 25 question validated [23, 24] questionnaire evaluating knowledge of warfarin and POC INR testing. A score of >80% is acceptable. Any incorrect responses are reviewed with the PFU prior to leaving clinic to ensure PFUs have the required knowledge to begin PSM.

7) Apprenticeship of patient self-management
   - PFUs participate in a 3-month apprenticeship in warfarin management. During the apprenticeship, INRs are reported to KIDCLOT, as in PST, however also entered on-line into www.KIDCLOT.com.
   - When the INR is performed and reported, PFU's discuss their warfarin dose decision and rationale with the KIDCLOT provider. This discussion facilitates further practical teaching and learning to facilitate additional knowledge transfer on personalizing the algorithm based on the PFUs knowledge of the patient's historical warfarin response.
   - Once the 3-month apprenticeship is completed, PFUs proceed with PSM with yearly follow up.

8) Independent PSM
   - Evaluation of adherence occurs by reviewing website entries at least monthly to estimate adherence with performing INRs at appropriate intervals. Warfarin dose decisions are reviewed giving consideration to factors influencing individualized dosing, including DIME, and the value of the following INR.
   - KIDCLOT remains available for INR support, with the requirement that PFUs contact KIDCLOT if the INR is <1.6 and ≥5.
   - Out of range INRs are reviewed by KIDCLOT to ensure the dose decision made is consistent with the education provided and the dosing algorithm.