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Quality of life assessment in children commencing home INR self-testing

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ABSTRACT

Introduction: Management of oral anticoagulant therapy (OAT) in children is complex and frequent testing of the International Normalised Ratio (INR) is a significant burden. This study evaluates the impact of a home INR self-testing (home ST) program on the quality of life (QoL) of children and their families. The aim of the study was to determine if participation in a home ST program improves QoL for children requiring long-term OAT and their families.
Materials and Methods: Children aged eight to 18 years requiring long-term OAT and parents of children participated. Quantitative methods comprised three validated QoL questionnaires; the anticoagulation specific PAC QL©, the PedsQL™ and the PedsQL FIM™. Questionnaires were completed before commencing home ST and 6–12 months later. Qualitative methods consisted of open-ended questions which participants answered when completing the questionnaires for the second time. Results of INRs tested at home were collected.
Results: Fifty-five parents and 35 children participated. The percentage of time the children's INRs were in their target therapeutic range was 71.3. Parents reported statistically significant improvements in QoL for themselves (mean increase 6.9), their family (mean increase 8.6) and their child (mean increase 11.1) following the commencement of home ST (difference $p \leq 0.003$ on all questionnaires). The children did not report a statically significant improvement in QoL.
Conclusion: Parents reported significant improvement for their child's QoL, their QoL and the families' function following commencement of home ST. Children did not report a significant improvement in their QoL, but clearly identified satisfaction with home ST.

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Introduction

Improved outcomes for children with chronic disease across the last two decades have led to an increase in the number of children requiring oral anticoagulation therapy (OAT). OAT is complex to manage in children and the burden of frequent blood monitoring can be significant [1–3]. Quality of life (QoL) is a recognised and validated measure of the burden of treatments for children [4]; yet, there is a lack of data about the impact of long-term OAT on QoL in children and families.

In this paper, QoL will refer to both health-related QoL (HRQoL) and QoL as defined by the following definition of heath related QoL, specific to young people with chronic illness:

> *Health-related QoL (HRQoL) in young people with chronic illness is subjective, multi-dimensional and dynamic. This involves the achievement of goals and aspirations and the constraints imposed through ill health and treatment* [5] (p.1831).

Multiple studies have investigated the success of home international normalised ratio (INR) self-testing (home ST) of children requiring OAT in terms of safety and efficacy [3,6–9]. This is the first study to evaluate the impact of a home ST program on the QoL of the child and their family. The aim of the study was to determine if participation in a home ST program improves QoL for children requiring long-term warfarin therapy and their families.

Abbreviations: HRQoL, health-related quality of life; ICC, intraclass correlation coefficient; INR, International Normalised Ratio; MCID, minimal clinically important difference; OAT, oral anticoagulant therapy; PAC QL©, Pediatric Anticoagulation Quality of Life inventory©; PedsQL™, Pediatric Generic Core Scales Quality of Life inventory™; PedsQL FIM™, Pediatric Quality of Life Family Impact module™; QoL, quality of life; ST, self-testing; TTR, time in therapeutic range.

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Materials and Methods

This prospective cohort study evaluated the impact of a home ST program on the QoL of children and families within an Australian pediatric tertiary hospital. QoL was assessed immediately prior to and then six to twelve months following the intervention.

Eligibility criteria for entry into the Anticoagulation Service's Home ST Program included:

1. The child required OAT for more than 12 months duration
2. The child commenced OAT more than 3 months prior to entering the program.
3. Parents and/or the child had English language proficiency.

All parents/carers with a child eligible to commence participation in the Home ST Program were eligible to participate in the QoL study. Children aged eight years and older were also eligible to participate in the QoL study. This age limit was necessary as the child QoL questionnaires used were designed only for children eight years and older [10]. Acceptance into the Home ST program was not contingent on participation in the QoL study. A purposive sampling method was used. If a family fulfilled the eligibility criteria, they were invited via letter to attend the next planned home ST training day and to participate in the QoL study. Ethics approval was granted from the hospital's Human Research Ethics Committee. All participants 18 years and older (parents) signed a Participant Information and Consent Form. Participants 12 years and older were offered the opportunity to give consent, in addition to their parent/guardian providing consent.

Intervention

Commencement on the Home ST Program requires a parent/guardian and children aged 8 years or older to attend a one-day group training and education session incorporating both practical and theoretical training [3]. All participants had to demonstrate competence in performing an INR test using the CoaguChek XS™ monitor (Roche Diagnostics, Castle Hill, NSW) prior to commencing home ST [3]. The training and education program for this study was conducted in accordance with the previously implemented and validated program [3].

Outcome Measures

Quality of Life Measurement

Participants completed the suite of QoL questionnaires at two timepoints: first was during participation in the home ST training program; second was 6–12 months post-commencement of home ST. Baseline QoL questionnaires were distributed during the training session to all consenting participants. The repeat QoL evaluation was timed to coincide with the patients' annual or 6-month review in the Clinical Haematology Department. Forms were distributed at the time of clinic attendance, and could be completed at that time or taken home for completion.

KIDCLOT Pediatric Anticoagulation Quality of Life Inventory©. The KIDCLOT Pediatric Anticoagulation Quality of Life Inventory © (PACQL©) was developed specifically to assess QoL in children requiring long-term OAT and has undergone preliminary validation [10]. The inventory, suitable for children aged eight years and older (36 items), includes a parent-proxy inventory (38 items). Validation of the scoring formula was completed within a Canadian cohort study [12]. Scores are presented as percentages; a higher score is indicative of a higher impact of anticoagulation on QoL and lower scores indicate that anticoagulation has a lower impact on QoL. A pilot study was conducted separately, prior to the commencement of the current study to ensure that the PACQL© was reliable for use in an Australian population. Seven parents and five children consented for the pilot study and completed the appropriate PACQL© at two time points, approximately three months apart. The inventory was reliable; data analysis showed a Cronbach's alpha coefficient of greater than 0.8 for 74.6% of the items on the questionnaires (range 0.79 to 0.91). Internal consistency was measured for the parent proxy and child versions of the PACQL© at baseline and post-home ST. Cronbach's alpha for the parent proxy version was 0.843 at baseline and 0.874 post home ST. The child version achieved 0.828 at baseline and 0.784 post-home ST. The intraclass correlation coefficient (ICC) indicated good reproducibility of the questionnaire, with results of 0.436 and 0.614 for the parent and child versions of the PACQL©, respectively [13].

Pediatric Quality of Life Inventory™. The Pediatric Quality of Life Inventory™ Generic Core Scales (PedsQL™) questionnaire comprises 23 items and has demonstrated reliability and validity in a variety of paediatric populations [14]. As the PACQL© is suitable for children aged eight to eighteen years, this study used the PedsQL™ questionnaire versions available for the eight to 12 years and 13–18 age groups and the paired parent proxy questionnaires for those two age groups. When assessing QoL following an intervention, a minimal clinically important difference (MCID) is desired [15]. The PedsQL™ states the MCID between pre and post intervention QoL scores for parents is 4.5, with a difference of 4.4 for children [15,16].

Pediatric Quality of Life Inventory Family Impact Module™. The PedsQL™ Family Impact Module (PedsQL FIM™), only available as a parent proxy questionnaire, contains 36 items and has been validated [17,18]. The PedsQL FIM™ produces three final scores, including a total, parent HRQoL and family functioning score.

Qualitative Measures

Four open-ended questions appropriate for children and four questions appropriate for parents were developed to elicit responses directly about the Home ST program. This additional method of data collection was utitiised to explore a different aspect of QoL, thus increasing the likelihood of capturing each participant's subjective perception of their own or their child's QoL. As the questions had never been used before, a pilot study was undertaken with families already participating in the Home ST program. The goal of piloting the open-ended questions with families who had extensive experience with home ST was to ensure the questions provide useful information about how parents and children feel about home ST. As these questions were developed specifically for this study, asking families already participating in the home ST program was a reliable means of determining the validity of these questions. Six parents and five children consented to participate in the pilot study and returned the questions. Thematic analysis was used to identify three themes that were inherently relevant to home ST; preference for home INR testing (identified by all participants); feasibility and logistics of home ST (identified by all parents and four children); and family psychosocial wellbeing and empowerment (identified by all children and five parents). Results from the pilot study demonstrated the questions were appropriate and provided relevant information about the participants' feelings and attitudes towards home ST.

Descriptive Measures

Secondary outcomes measures such as participants' home INR results, frequency of INR testing and OAT-related adverse event rates were collected prospectively. Adverse events include bleeding or a thrombotic event whilst on OAT. Major bleeding and clinically relevant non-major bleeding in children have been defined by The International Society on Thrombosis and Haemostasis (ISTH) [11]. All other types of bleeding reported were noted as minor.

Statistical Analysis

Data were analysed using Statistical Package for the Social Sciences software (SPSS) (Chicago, USA, Version 18) and NCSS (Kaysville, USA,

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