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REGULAR ARTICLE

Home INR monitoring of oral anticoagulant therapy in children using the *CoaguChek™ S* point-of-care monitor and a robust education program

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Abstract

Introduction: Management strategies such as self-monitoring of anticoagulant therapy have been reported with increased frequency. Whilst patient education is frequently mentioned, details regarding the educational interventions employed are scarce. This study aimed to improve the outcomes of home monitoring of warfarin therapy in children through the development and implementation of a robust intervention, based upon the PRECEDE model of education.
Materials and methods: Participating parents had to complete an intensive education and training program. After demonstrating practical and theoretical competency, parents commenced home monitoring. Every second scheduled home INR (H-INR) required a paired INR on the same day, obtained by a trained pathology collector (C-INR). Demographic and statistical outcome data was collected.
Results: Parental understanding of warfarin therapy improved significantly following the educational intervention ($p<0.0001$). 65.5% of H-INRs and 64.4% of C-INRs were within the target range (ns). Lin's correlation coefficient between H-INRs and C-INRs was 0.949. There were no warfarin-related adverse events.

Abbreviations: INR, International Normalised Ratio; POC, point-of-care; RCH, Royal Children's Hospital, Melbourne, Australia; PRECEDE, predisposing, reinforcing and enabling causes in educational diagnosis and evaluation; H-INR, Home INR; C-INR, Control INR; TTR, time in therapeutic range.

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Conclusion: This study demonstrated a significant improvement in parental knowledge following participation in a robust educational intervention. Furthermore, compared to previous reports in children, a greater level of correlation between home and hospital-based INRs was achieved by participating parents. The use of similar educational interventions may serve to improve the outcomes of similar management strategies.

Regular blood monitoring of patients receiving warfarin is imperative for the safe and effective use of this agent [1—6]. The literature demonstrates that children receiving warfarin require more frequent monitoring than their adult counterparts due, in part, to the complexity of their underlying medical conditions [7]. The gold standard method for monitoring warfarin therapy is the Prothrombin Time, expressed as an international normalised ratio (INR), collected via venipuncture. In paediatric patients, the ability to perform venous monitoring tests is significantly reduced due to poor venous access relative to the frequency of testing required [7]. This has serious implications for the maintenance of effective therapy.

The development of point-of-care (POC) INR monitoring methods has introduced a potential solution to the issue of obtaining frequent, non-traumatic INR tests in children. Previous studies suggest that home monitoring of warfarin therapy offers patients and families improved outcomes regarding self-efficacy, quality of life measures and stability of therapy [8—11]. A recent review of POC monitoring of warfarin therapy in children suggested that the decreased correlation previously reported between POC INR results generated by parents compared to clinicians [7] may reflect the education programs upon which home monitoring programs were based [12]. This study is the first to report the outcomes of a home INR monitoring program for children based upon a robust education program that adhered to a validated model of health education.

Materials and methods

We hypothesised that greater correlation between Home INR and hospital-based INR results could be obtained if parents completed a validated education and training program before commencing home INR monitoring in their child.

Participants

Families of children whose warfarin therapy was managed by the Haematology Department at the Royal Children's Hospital (RCH), Melbourne were invited to participate in this study.

This protocol incorporated the conduct of the parent education program and the home monitoring study. The study was approved by the RCH Ethics in Human Research Committee.

Education and training program

The *P*redisposing, *R*einforcing and *E*nabling *C*auses in *E*ducational *D*iagnosis and *E*valuation (PRECEDE) [13] model of health education was used to facilitate the design and delivery of parental education. The program incorporated oral presentation, group discussion, practical demonstrations and the provision of written material.

The goal of the education program was to increase the level of control of warfarin therapy in children by increasing the percentage of time children spent in their target therapeutic range. This goal was to be achieved by parents demonstrating competency in five sub-objectives:

- Performance of POC INR tests using the *CoaguChek™ S* monitor (*Roche Diagnostics, Castle Hill, NSW, Australia)*.
- Increased knowledge regarding warfarin's action.
- Increased knowledge regarding the rationale for regular blood monitoring.
- Increased knowledge regarding confounders of stable warfarin therapy.
- Increased knowledge regarding warfarin-related adverse events.

Participants attended two half-day group education sessions and two one-hour individual sessions at RCH. Parents were taught the *CoaguChek™ S* monitor's mode of operation, maintenance and use in performing INR tests.

Knowledge and competency assessment

Practical and theoretical competency needed to be demonstrated before the commencement of home monitoring. Theoretical competency was evaluated by a twelve-point questionnaire, administered

prior to the educational intervention and at its completion. Failure to achieve a 75% pass mark on the questionnaire necessitated ongoing education on an individual basis. Practical competency was determined based upon the accurate performance of an INR test on the Principal Investigator (FN). Failure to demonstrate competency necessitated ongoing practical training.

Home INR monitoring study procedure

Once competency was demonstrated, the parent and child attended RCH at pre determined intervals to correlate their results with those generated by in hospital testing. For the purposes of this study, the Home INR (H-INR) refers to the INR test performed by parents in the home. The Control INR (C-INR) refers to the INR performed by experienced staff in the Pathology Collection Department. C-INRs were performed on the same day as every second H-INR, with a comparison being made between the H-INR and C-INR results generated.

The H-INR was deemed to be accurate if the difference between the H-INR and the C-INR was $\leq \pm 0.2$ INR units. Frequency of INRs was determined as per usual clinical practice. Fig. 1 depicts the testing schedule associated with participation in the home monitoring study. Parents kept a log of all H-INRs performed and the Principal Investigator kept a log of all C-INRs. Clinical management was based upon the H-INR unless the difference between the H-INR and C-INR was $> \pm 0.2$ INR units, in which case the C-INR determined management decisions.

Data analysis

Assessment of knowledge

Knowledge outcome data was analysed descriptively using percentages and means (plus standard deviations, confidence intervals and/or ranges). The results of knowledge assessment at the different time points were analysed using paired *t*-tests. A *p* value of less than 0.05 was considered to be statistically significant. Data generated was analysed using a statistical software package, STATA, release 8.1 (Stata corporation, College Station, TX).

Assessment of Home INR monitoring performance

Demographic details of study participants were presented descriptively. For the purpose of this study, warfarin-related adverse events included all thrombotic episodes and major bleeding events. Major bleeding was defined as an event requiring the transfusion of red blood cells, hospital admission or a drop in Haemoglobin of ≥ 2 g/L. Data is presented descriptively using means and/or medians with standard deviations and 95% confidence intervals ($\pm$ ranges) using the previously mentioned statistical package.

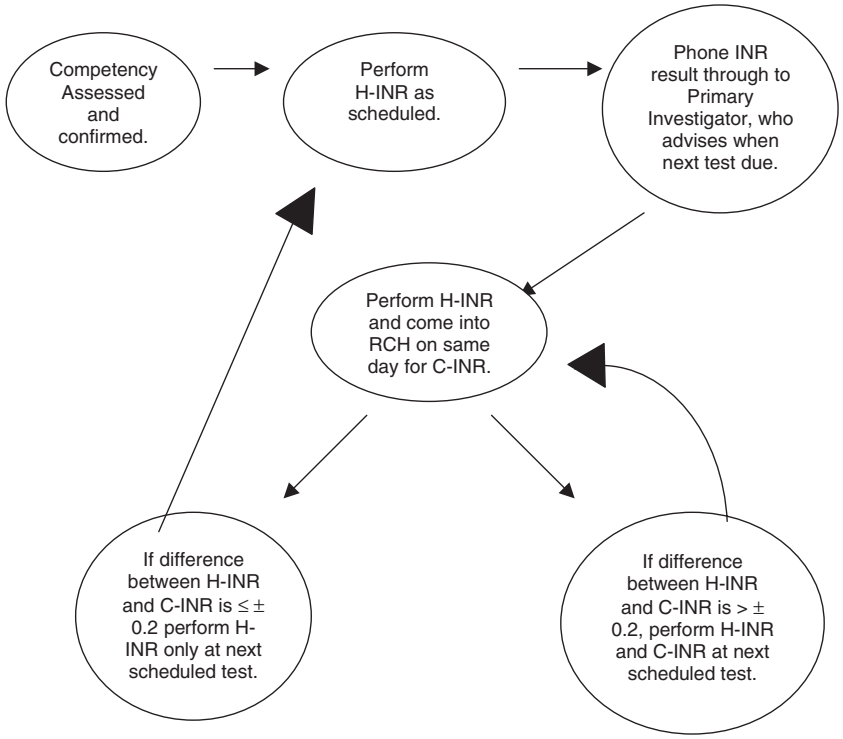

Figure 1 Home monitoring study testing schedule.

Cross-over significance of differences in the H-INR and C-INR was investigated to determine how frequently management decisions would have altered based on discrepant results. Analysis was performed comparing the percentage of time that the H-INR was within the target therapeutic range compared with the C-INR.

Parent satisfaction with performing INR monitoring at home was determined at the conclusion of the study in an effort to quantify parents' perceptions as to the benefits of such a program and whether they would want to participate in an ongoing home INR monitoring program.

Results

Parent knowledge outcomes

Fourteen parents (12 females, 2 males) completed the education program that formed the foundation for the home monitoring study. All parents met the prerequisite theoretical competency without difficulty.

Table 1 summarises the results of key questions that were used to determine the level of parental understanding specific to warfarin therapy in children. There was significant improvement from baseline parental scores (mean 55%) on the knowledge assessment questionnaire to the assessment conducted immediately following completion of the education program (mean 83%) ($p<0.0001$).

Home monitoring outcomes

Thirteen of the participating children were female. Mean age was 14.6 years (range 6.6 years to 23 years). All patients required warfarin for long-term thromboprophylaxis. Seven patients had undergone Fontan surgery, four had prosthetic heart valves and three had primary pulmonary hypertension.

Table 1 Parental understanding of key issues pertinent to warfarin therapy in children

	Pre-education program	Conclusion of education program
Understood indication for warfarin	28% ($n=4$)	93%
Knew timing of warfarin's effect	50% ($n=7$)	100%
Understood warfarin's mechanism of action	14% ($n=2$)	80.4%
Number of known warfarin therapy complications (excluding bleeding)	0.6	3.8
Number of factors known to affect warfarin therapy	2.6	6.8

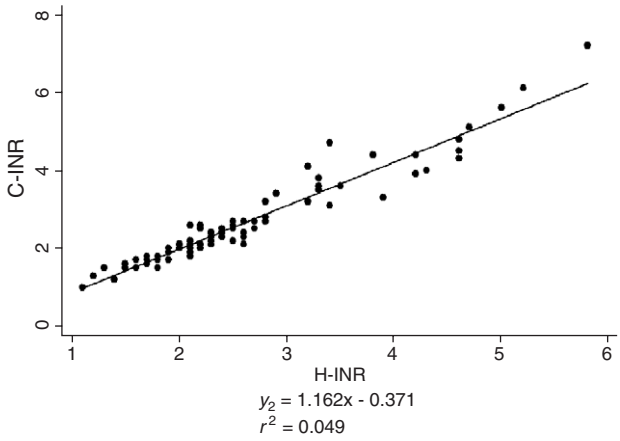

Figure 2 Correlation curves (linear regression lines) for H-INR versus paired C-INR results.

Within 4 weeks of commencing the program it became apparent that the fingerprick technique presented on the instructional video shown to parents during the education program was not ideal for smaller children. Five parents required further instruction with respect to the performance of fingerprick tests. No parent continued to have difficulty performing fingerprick tests after accessing this re-training.

Contact with the study coordinator was frequent, with parents making contact an average of 11.4 times during the 26-week study period (range 5—25 contacts). These contact points were most frequently related to the reporting of INR results, followed in order of frequency by fingerprick monitoring queries and questions relating to general warfarin management.

The mean H-INR was 2.63 (SD 0.98, 95% CI 2.42 to 2.83). The mean C-INR was 2.68 (SD 1.13, 95% CI 2.44 to 2.92). There was no statistical difference between these two means. The H-INR was higher than the C-INR on 35.6% of paired tests; lower on 41.4% of tests; and exactly the same on 23% of tests. The mean interval between INR tests performed during the study period was 15.64 days (range 7 to 28 days). During the six month study period, patients had a mean number of 7.4 (range 4 to 14) paired tests (H-INR and C-INR).

The target therapeutic range (TTR) was achieved in 65.5% of H-INR tests and 64.4% of C-INR tests.

Fig. 2 graphically represents Lin's correlation coefficient between H-INR and C-INR results. The result ($r^2=0.949$; Fisher's z-transformation 95% CI 0.926 to 0.965; $p<0.0001$) demonstrates a strong

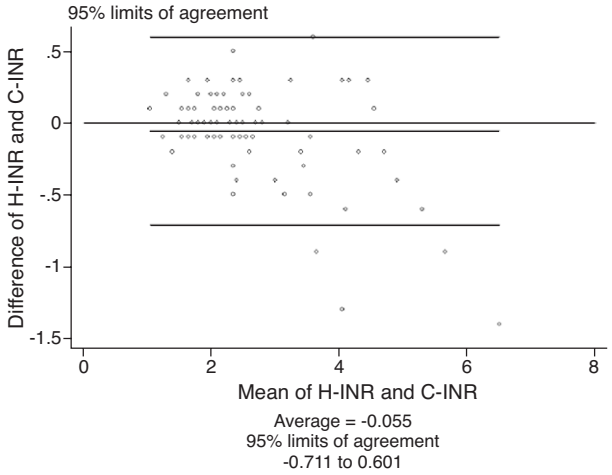

Figure 3 Bland and Altam 95% limits of agreement between C-INR and H-INR.

correlation between INR results generated at home by parents and those generated by hospital staff. Bland and Altman analysis identified an average difference of −0.055 units between the C-INR and H-INR results (Fig. 3). Only three paired INR results reached cross-over significance. In none of these instances was either the C-INR or H-INR supra-therapeutic.

No statistical significance was identified between the age of the patient and likelihood of obtaining discrepant C-INR and H-INR results.

There were no major bleeding or thrombotic events during the study period.

On a benefit scale of 1—10 (10 being most positive), the mean parental rating was 9.4 (range 6.5—10, median 10). Only one parent expressed any anxiety about the possibility of continuing home monitoring. This anxiety related to difficulty managing an adolescent daughter who was highly critical of the parent's performance. All parents wanted to continue home monitoring of their child's warfarin therapy if an ongoing home-monitoring program was established.

Discussion

This study aimed to determine whether greater correlation between Home INR and hospital-based INR results could be generated if parents were required to complete a robust education and training program before commencing home INR monitoring in their children.

The two paediatric home-monitoring studies previously reported were components of larger studies assessing POC monitoring of warfarin therapy in children [7,14]. Whilst both of these studies made brief reference to parents receiving some form of education prior to commencing home INR monitoring, the specifics of that education were not provided and there did not appear to be any evaluation of the education-specific outcomes. Considerably more research has been conducted within the adult population regarding self monitoring and self-management of warfarin therapy. Two such papers report that patients undertook practical training programs only [15,16], with a further seven papers mentioning that patients participating in their programs were required to complete a training program incorporating both practical and theoretical components [8,10,17—21]. Whilst four of these papers stated that they assessed the subjects for practical competency prior to initiating their management intervention [10,18,19,21] not one publication stated that patients were assessed for theoretical competency. The outcomes of their education interventions with respect to impact on patient understanding therefore remain unsubstantiated. The merit of providing patients participating in warfarin management programs with theoretical education about warfarin therapy is widely accepted [22], however whether such education is meeting its objectives has largely been overlooked.

Using the PRECEDE model of health education, parents were able to significantly improve their understanding of warfarin therapy in children ($p<0.0001$). This same model of health education has been reported to have been used to guide the development of a warfarin education program for adults [23]. Although methods of statistical analysis differed between the current study and that previously reported, both confirm improved patient/parental understanding following implementation of an education program based upon the PRECEDE model.

Using three separate methods of analysis, the C-INR and H-INR compared very well, more so than previously reported in similar home INR monitoring studies [7,14,24]. In addition, target range achievement was excellent when compared with similar outcome measures for children managed by paediatric Anticoagulation Clinics [2,6,25,26]. Participation in the home monitoring program was associated with a mean interval of 15.6 days between INR tests. This finding is consistent with a previously reported study in 1995 that stated children participating in such programs required an average of three INR tests per month [14].

In any study determining INR accuracy, ideally one would compare the investigative INR to a gold standard venous INR using WHO standard thromboplastin. Our patients were extremely reluctant to

agree to a study involving venipuncture. We have recently validated our POC INR performed in hospital against venous INR [27]. Since that time, *CoaguChek*™ POC INR on capillary sample is the standard INR offered to all patients in our hospital. We therefore decided in this study to compare the home INR to our current clinical standard of care.

Children whose parents participated in this study achieved their TTR on 65.5% of INR tests performed at home during the study period. In a twelve-month audit of anticoagulant management at RCH, conducted immediately prior to this study, children managed by the RCH Haematology Department achieved their TTR on 63.4% of INR tests [25]. This program's objective of increasing the percentage of time children spend in their TTR did not reach statistical significance, but neither did home monitoring reduce the proportion of test-points children obtained within their TTR. The major limitation of this study was its inability to determine whether the goal of increasing the level of control of warfarin therapy in children was met. This limitation reflects the difficulty of conducting clinical research within this population.

The outcomes of this study suggest that home monitoring offers significant advantages to patients and families, as demonstrated by all parents expressing a desire to continue home monitoring after completion of the study. This finding is supported by several paediatric and adult papers exploring the safety and efficacy of self-monitoring in patients requiring oral anticoagulant therapy [7,10,14,17,24].

Conclusion

This study demonstrated that parents who have undergone robust education and training in preparation for performing INR tests on their child in the home were able to achieve a greater level of correlation between H-INRs and C-INRs than has been previously reported in similar populations. Ongoing research to improve the standard of education programs given to parents/patients is worthwhile. Education programs need rigorous evaluation to ensure their objectives are met.

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