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Original article

Effects of home prothrombin international ratio (PT-INR) management in children with mechanical prosthetic valves – Importance of individual correlations between laboratory and CoaguChek device PT-INRs

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ABSTRACT

Background: Warfarin administration is essential but requires difficult management and frequent clinic visits in patients with mechanical prosthetic atrioventricular valve replacement (MPAVVR). This study investigated how home prothrombin international ratio (PT-INR) monitoring with CoaguChek[®] (Roche Diagnostics, Basel, Switzerland) safely reduced clinic visits in children with MPAVVR. We also compared individual correlations between the CoaguChek and laboratory PT-INR.

Methods: This study included four pediatric patients who started frequent warfarin home-monitoring after MPAVVR (three mitral valves and one tricuspid valve). We collected information regarding the number of outpatient clinic visits and measurements of PT-INR before and after starting home CoaguChek monitoring (each one year) from medical records. We also compared individual correlations between laboratory and CoaguChek PT-INR in three patients.

Results: No major clinical events were encountered during the study period. The ratio of outpatient clinic visits in the second year to those in the first year was decreased in all patients (0.30–0.66). The ratio of the numbers of home measurements to all PT-INR measurements in the second year ranged from 0.55 to 0.64 indicating that CoaguChek home monitoring approximately halved the number of outpatient clinic visits. CoaguChek measurements tended to be slightly overestimated in two patients but were greatly underestimated in one patient.

Conclusions: CoaguChek home monitoring in children with MPAVVR reduced the number of their clinic visits without compromising the safety of warfarin management. Given considerable individual differences in correlations between CoaguChek and laboratory PT-INR, individual correlation needs to be identified to fairly interpret the CoaguChek PT-INR values.

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Introduction

Anticoagulation therapy using warfarin [1], a vitamin K antagonist, remains essential in patients with mechanical prosthetic atrioventricular valve replacement (MPAVVR) [2,3]. The effect of warfarin has been quantified by prothrombin international ratio (PT-INR) [4,5]. Effects of warfarin doses greatly vary

between patients. It can also fluctuate in the same patient depending on food intake, patients' condition, other drug usage [3], and undefined factors. Such fluctuation is greater in children [6]. However, the optimal range of PT-INR [2] is narrow. The risk of thrombotic events will increase with the attenuated effect of warfarin, while the risk of bleeding events will increase with the excessive effect of warfarin. Thus, frequent outpatient clinic visits have been required to optimally manipulate warfarin dosage for keeping PT-INR within the narrow acceptable range. However, frequent outpatient clinic visits may increase the chance of infection. It may also increase burden in patients and their family members [7].

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The CoaguChek® portable device (Roche Diagnostics, Basel, Switzerland) is available for point of care measurements of PT-INR [7,8]. It is easy to use and it takes only about 1 min to obtain measurement results. Only 10 µL of capillary blood sample is needed to allow the measurement. Capillary sampling induces less pain than venipuncture because puncture is completed in a moment. While venipuncture requires special skills, capillary puncture does not require such skills [6]. A number of validation studies were performed to report its usefulness and consistent results between CoaguChek and laboratory PT-INR [8–10]. Home monitoring and control of anticoagulation has been reported in adults [4] as well as in children [11] indicating improvement in their quality of life (QOL) [12] and familial function [13].

However, it remains unclear whether and how home CoaguChek monitoring reduces the number of clinic visits between patients. It is also undetermined whether personal discrepancy is present in correlation between CoaguChek and laboratory tests. This study tested the hypothesis that home CoaguChek monitoring reduces clinic visits in children with MPAVVR without compromising safety. We also assessed if there are any individual differences in the correlation between the CoaguChek and laboratory test of PT-INR. Finally, we described individual experiences of trouble-shooting home CoaguChek monitoring.

Methods

Patients

As shown in Table 1, this study included four pediatric patients with MPAVVR receiving warfarin anticoagulant therapy (5–10 years at the inclusion of this study, three male and one female).

Table 1
Included patients.

	Patient 1	Patient 2	Patient 3	Patient 4
Sex	Male	Male	Female	Male
Age (years)	10	7	6	5
Valve replacement	Mitral	Mitral	Mitral	Tricuspid
Type and size of prosthetic valve	Carbomedics 19 mm	Carbomedics 16 mm	Carbomedics 16 mm	ATS AP 16 mm
Years after current valve replacement	9	5	5	2
Disease	Congenital MS PH	VSD, MS, MR	MR RMCT	HLHS
CoaguChek target range	2.0–3.5	2.0–3.5	2.0–3.5	1.5–3.0
Years after valve replacement	9	5	5	2
Days in admission: first year/second year	9/0	0/0	5/0	86/83
(A) Outpatient clinic visits: first year	46	35	31	38
(B) Outpatient clinic visits: second year	14	15	16	25
(C) Outpatient clinic visits ratio=(B)/(A)	0.30	0.43	0.52	0.66
(D) Home measurements during the second year	17	20	21	45
(E) Measurements during second year, (B)+(D)	31	35	37	70
(F) Ratio of home to all PT-INR measurements during the second year=(D)/(E)	0.55	0.57	0.57	0.64
Ratio of home measurements within the target range	12/17(71%)	16/20(80%)	17/21(81%)	40/45(89%)
Medications other than warfarin at the study entry				
Aspirin	+	+	+	+
Clopidogrel	–	–	–	+
Diuretics	Tracemide Spironolactone Trichlormethiazide	–	–	Tracemide Spironolactone Trichlormethiazide
Pulmonary vasodilator	Bosentan/Tadarafil/Beraprost	–	–	Bosentan/Sildenafil
Other drugs	Carvedilol Candesartan Sodium ferrous citrate	–	–	Pimobendan Isosorbide dinitrate Famotidine Potassium L-aspartate Zonisamide Herbal medicines (Dai-kenchu-to Sho-kenchu-to)

MS, mitral stenosis; PH, pulmonary hypertension; VSD, ventricular septal defect; MR, mitral regurgitation; RMCT, the rupture of mitral chordaetendinae; HLHS, hypoplastic left heart syndrome.

Included were three patients with mitral valve replacement in biventricular circulation and one patient with tricuspid valve replacement in hypoplastic left heart syndrome (HLHS) after Fontan operation. In the last patient, the first replaced tricuspid valve was stuck and re-replacement was performed two years before the inclusion in this study. Written informed consent was obtained from the parents of all patients, and the study was approved by the institutional review board of Saitama Medical Center of Saitama Medical University.

Educational protocol and home monitoring

The target PT-INR range in CoaguChek was decided as 2.0–3.5 for patients 1–3. That for patient 4 was decided as 1.5–3.0 because this patient had a different correlation between CoaguChek and laboratory PT-INR as described later. Laboratory PT-INR was measured by Roche STA-R revolution (Roche Diagnostics).

Participants were required to complete an educational program before starting home PT-INR monitoring using CoaguChek XS system. Their understanding and procedures that included at least three PT-INR measurements were evaluated using the predefined checklist (Table 2) in the outpatient clinic. The checklist included step-by-step procedural details such as clean and safe puncture, collecting and stopping the blood, and proper handling of CoaguChek. After attending physician had agreed that the educational program was completed with enough quality, home PT-INR measurements with CoaguChek were started. A small dosage of warfarin (e.g. 0.05 mg) was prescribed to increment warfarin dosage at home if small amount of increase of warfarin was needed. Parents recorded PT-INR values as well as warfarin dosage in special notebooks designed for warfarin control. Parents reported PT-INR values to their attending physician by telephone.

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