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CLINICAL RESEARCH

Health-related quality of life correlates with time in therapeutic range in children on anticoagulants with International Normalised Ratio self-monitoring

Corrélation entre la qualité de vie et le temps dans la zone thérapeutique cible chez les enfants sous anticoagulants et participant à un programme d'éducation thérapeutique de l'International Normalised Ratio

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Abbreviations: CHD, Congenital heart disease; INR, International normalised ratio; TTR, Time in therapeutic range; QoL, Quality of life; PedsQL[TM], Pediatric Quality of Life Inventory; VKA, Vitamin K antagonist.
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Summary

Background. — Managing oral anticoagulant therapy with vitamin K antagonists remains challenging in paediatric medicine.

Aims. — This study aimed to assess the correlation between time in therapeutic range and quality of life in children participating in a non-selective International Normalised Ratio self-monitoring and vitamin K antagonist education programme.

Methods. — Children aged from 2 to 18 years and receiving vitamin K antagonist therapy were eligible for this prospective multicentre study. Clinical and demographic data were collected. Health-related quality of life was assessed using the PedsQL™ 4.0 questionnaire. Correlations between quality of life scores and time in therapeutic range were measured.

Results. — A total of 121 children were included in the study (mean age 9.6 ± 4.9 years). Cardiac conditions were the predominant indication for vitamin K antagonists. The mean time in therapeutic range was 0.78 ± 0.15 overall, and 0.76 ± 0.24 over the 3-month period before quality of life assessment. The mean total quality of life score was 76.2 ± 18 in self reports, 71.4 ± 22 in mother reports and 73.5 ± 19 in father reports. The time in therapeutic range correlated with the total quality of life scores in self reports ($r = 0.22$; $P = 0.04$), mother reports ($r = 0.23$; $P = 0.02$) and father reports ($r = 0.28$; $P = 0.02$). The time in therapeutic range predominantly correlated with school functioning in self reports ($r = 0.38$; $P = 0.002$) and mother reports ($r = 0.40$; $P < 0.001$), and with physical functioning in father reports ($r = 0.28$; $P = 0.03$).

Conclusions. — Time in therapeutic range correlated with quality of life in children participating in a non-selective International Normalised Ratio self-monitoring and vitamin K antagonist education programme. Regular assessment of quality of life in patient education programmes contributes towards understanding the concerns and needs of patients.

Résumé

Contexte. — Chez l'enfant, la gestion des anticoagulants reste difficile en pratique.

Objectifs. — Cette étude évalue la corrélation entre le temps dans la zone thérapeutique cible de l'*International normalised ratio* et la qualité de vie des enfants sous anti-vitamine K participant à un programme d'éducation thérapeutique avec automesure de l'*International normalised ratio*.

Méthodes. — Les enfants agés de 2 à 18 ans et sous anti-vitamine K étaient élegibles à cette étude prospective et mulicentrique. Les données démographiques et cliniques ont été collectées. La qualité de vie a été évaluée à l'aide du questionnaire PedsQL™ 4.0. La corrélation entre le temps dans la zone thérapeutique cible et la qualité de vie a été étudiée.

Résultats. — Au total, 121 patients âgés de 2 à 18 ans (âge moyen $9,6 \pm 4,9$ ans) ont été inclus. Les pathologies cardiaques représentaient la principale indication des anti-vitamine K. Le temps dans la zone thérapeutique cible moyen était de $0,78 \pm 0,15$. Le temps dans la zone thérapeutique cible durant les 3 mois précédents l'évaluation de la qualité de vie était de $0,76 \pm 0,24$. Les scores moyens de la qualité de vie étaient de $76,2 \pm 18$, $71,4 \pm 22$ et $73,5 \pm 19$ estimés respectivement par les enfants, leurs mères et leurs pères. Le temps dans la zone thérapeutique cible corrélait avec le score total de la qualité de vie estimé par l'enfant ($r = 0,22$; $p = 0,04$), par la mère ($r = 0,23$; $p = 0,02$) et par le père ($r = 0,28$; $p = 0,02$). Le temps dans la zone thérapeutique cible était principalement corrélé à la fonction scolaire de la qualité de vie mesurée par le patient ($r = 0,38$; $p = 0,002$) et par la mère ($r = 0,40$; $p < 0,001$), et à la dimension physique de la qualité de vie mesurée par le père ($r = 0,28$; $p = 0,03$).

Conclusions. — Le temps dans la zone thérapeutique cible est corrélé à la qualité de vie des enfants sous anti-vitamine K et participant au programme d'éducation thérapeutique avec automesure de l'*International Normalised Ratio*. L'évaluation régulière de la qualité de vie dans un programme d'éducation thérapeutique apporte des données utiles visant à comprendre les besoins des patients.

Background

In the paediatric population, managing oral anticoagulant therapy using vitamin K antagonists (VKAs) remains challenging. Indeed, stable VKA dosing is difficult to achieve in children, as a result of changes in diet, concomitant illnesses, drug interactions and compliance difficulties.

VKA efficacy and safety rely on International normalised ratio (INR) monitoring. Because of the absence of standard VKA doses, serial INR tests must be performed to adjust the treatment when the result is out of range [1]. Risks of haemorrhagic or thromboembolic events increase when the INR level is above or under the therapeutic window [1,2]. The time in therapeutic range (TTR) measures the percentage of time that the INR is within the appropriate range and stands as an indicator of anticoagulation control [3]. The TTR reflects the optimal balance between thrombosis prevention and the occurrence of bleeding events, which depends on the INR variability [4].

Recurrent blood tests are a significant burden in children, and laboratory INR monitoring has been progressively replaced by self-monitoring using home devices [5—8]. In parallel, educational programmes have emerged to manage VKA therapy and INR self-monitoring in paediatrics, aiming to improve the TTR, as well as children's quality of life (QoL).

INR self-monitoring in children has shown safety and reliability, allowing high TTR values and low rates of haemorrhagic and thromboembolic adverse events to be obtained [5,6,8,9]. Within 10 years of existence, our INR self-monitoring and VKA education programme has contributed to the attainment of a mean overall TTR > 80% in our paediatric patients, while improving the health-related QoL of children on anticoagulants [10,11]. Our educational programme is non-selective, and includes individual and group sessions dedicated to the child and their family. This programme aims to improve autonomy, disease knowledge, self-management and, ultimately, QoL [11].

Nowadays, health-related QoL assessment stands as a reliable patient-related outcome, reflecting the burden of care and management for children [12]. In children with congenital heart disease (CHD), we showed that their QoL was mainly impacted by the severity of the disease, and predominantly correlated with their exercise capacity [13,14]. However, children on anticoagulants represent a specific group of patients with severe medical conditions, including CHD, but also various extracardiac pathologies. Several studies have highlighted the contribution of INR self-monitoring in terms of TTR or QoL, but none has investigated the relationship between these two outcomes. Indeed, the determinants of QoL are multiple and complex to analyse, but identifying an association between TTR and QoL would contribute to the promotion of non-selective educational programmes dedicated to the overall population of children on VKAs. Therefore, this study aimed to assess the correlation between TTR and QoL in children participating in a non-selective INR self-monitoring and VKA education programme.

Methods

Study design and population

This prospective cross-sectional study was carried out from April 2012 to February 2017 in three paediatric tertiary hospitals: the Paediatric Cardiology Department of Paris—Necker University Hospital; the Paediatric and Congenital Cardiology Department of Montpellier University Hospital; and the Paediatric Cardiology and Rehabilitation Unit of St-Pierre Institute in Palavas-Les-Flots, France.

Children aged from 2 to 18 years requiring VKA treatment for more than 3 months, regardless of the indication, were eligible to participate in the study; they were screened during their participation in the first session of the VKA education programme.

The following clinical data were collected: demographic details; indication for VKA therapy; INR range and target; the existence of any underlying medical conditions; and the number and type of VKA education sessions. At each education session, values of INR were automatically collected from the self-monitoring device, using CoaguChek® XS Connect software (Roche Diagnostics, Maylan, France).

Indications for VKA therapy included cardiac conditions (dilated cardiomyopathy, Fontan circulation, Kawasaki disease with coronary aneurysm and valve replacement) and extracardiac conditions (stroke, pulmonary arterial hypertension, systemic lupus erythematosus, antiphospholipid syndrome and deep vein thrombosis).

INR self-monitoring and VKA education programme

After common training in therapeutic patient education, the investigators from all three centres designed a common non-selective education programme. The structure of this education programme was built as recommended by the current guidelines, and adapted to our practice in patient education, as previously reported [10,11].

The first individual education session involved the child and their parents (or legal guardians), and included theoretical training on VKA therapy and practical training on the self-monitoring device (CoaguChek XS®; Roche Diagnostics, Meylan, France). The programme required all families to demonstrate competence in performing INR self-measurement before starting home testing. A group session was held 12 weeks after the start of INR self-monitoring, and then every 6 months. Reinforcement education sessions were provided when necessary. Results of INR tests were transmitted to each referral centre. The referring physician indicated to the family the therapeutic adjustment to perform and the date for the next INR check.

As required by health authorities in France since 2008, the INR self-monitoring and VKA education programme was expertised in each of the three centres, and received approval from its regional health agency.

Health-related QoL assessment

We used the Pediatric Quality of Life Inventory (PedsQL™) questionnaire, a generic paediatric health-related QoL instrument, designed for children aged from 2 to 18 years. The PedsQL™ questionnaire has four multidimensional scales: physical functioning (eight items); emotional functioning (five items); social functioning (five items); and school functioning (five items). The three summary scores are: total scale score (23 items); physical health summary score (eight items); and psychosocial health summary score (15 items). Each item uses a 5-point Likert scale from 0 (never) to 4 (almost always). Items are reversed scored and linearly transformed to a 0—100 scale, higher scores indicating a better QoL. This instrument was validated by Varni et al. in healthy and patient populations, and its psychometric properties showed reliability, validity and responsiveness to clinical change over time [15]. The translation and cultural adaptation into French was performed by the MAnagement de Projets Insu (MAPI) Research Institute (www.mapi-trust.org; French project management support network), following the international guidelines [16]. The psychometric properties of the French version of the PedsQL™ appeared to be acceptable [17]. We have previously shown the good sensitivity of the PedsQL™ in controlled prospective QoL studies among healthy controls and children with various chronic diseases [10,18].

According to the child's age, we used the following versions of the PedsQL™: proxy reports for children aged from 2 to 4 years; and self and proxy reports for children aged from 5 to 7, 8 to 12 and 13 to 18 years. Parents and children completed the QoL questionnaires at each visit planned as part of the education programme. Children aged 5 years and older completed the PedsQL™ self-questionnaire under the supervision of a trained nurse. Both parents could participate, and they completed the PedsQL™ proxy questionnaire separately.

Statistical analysis

Patient characteristics are presented using means and standard deviations for continuous variables, and frequencies and proportions for qualitative variables. QoL scores were calculated with the parametric Student's t-test when the distribution was Gaussian, and with the Mann—Whitney test otherwise, for the following variables: sex; indication for VKA; and type and number of therapeutic education sessions attended.

The TTR was calculated using the method described by Rosendaal et al., using linear interpolation to measure the percentage of TTR [4]. This method allocates an INR value to each day, including days between INR tests. TTR measurement requires the INR value, the date of the INR test and the values of the target therapeutic range predefined by the clinician. In the study population, two INR ranges were defined, as in our previous studies: from 2.5 to 4 in a mechanical mitral valve; and from 1.8 to 3.2 in other cases [11]. For each patient, the TTR was calculated for the overall participation in the education programme, and over the 3 months preceding QoL assessment.

Correlations between QoL scores and TTR measured over the 3 months preceding QoL assessment were studied using Pearson's or Spearman's coefficient, and were performed independently for children, mothers and fathers. The statistical significance was set at 0.05, and analyses were performed using Statistical Analysis Systems software, version 9 (SAS Institute, Cary, NC, USA).

Formal aspects of the study

This study complies with the declaration of Helsinki; it was approved by the Sud-Méditerranée IV Ethics Committee (2011-A01466-35), and registered on ClinicalTrials.gov (number NCT01587053). Written informed consent was obtained from all parents or legal representatives. When parents or legal guardians refused to participate in the study, their child underwent the same educational programme, as part of their routine follow-up, but no data were collected for the purpose of the study.

Results

Patient characteristics

During the study period, 158 children on VKA therapy participated in the INR self-monitoring and VKA education programme in one of the three participating centres. After gaining consent from their parents or legal guardians, a total of 121 children were included in the study (mean age 9.6 ± 4.9 years; 58% male patients). Cardiac conditions were the predominant indication for VKA (e.g. valve replacement and Fontan circulation), and extracardiac conditions accounted for 12% of the population. All patients underwent at least one group education session, and nearly 80% underwent two or more education sessions (initial session and reinforcement sessions).

The mean overall TTR was 0.78 ± 0.15, and the mean TTR over the 3-month period before QoL assessment was 0.76 ± 0.24. No significant TTR differences were identified in terms of sex, VKA indications or type of educational programme sessions, whatever the period of TTR measurement (overall or over the 3-month period before QoL assessment) (Table 1).

QoL scores

During the study period, and considering the 121 participating children, a total of 244 QoL questionnaires were completed (83 by children, 94 by mothers and 67 by fathers). The mean total QoL scores were 76.2 ± 18 in self reports, 71.4 ± 22 in mother reports and 75.4 ± 19 in father reports. Self- and proxy-reported QoL scores, overall and in each dimension, are shown in Fig. 1.

Correlation between TTR and QoL

The TTR correlated with the total QoL scores in self reports ($r = 0.22$; $P = 0.04$), mother reports ($r = 0.23$; $P = 0.02$) and father reports ($r = 0.28$; $P = 0.02$). When considering each dimension of the QoL, the TTR predominantly correlated with school functioning in self reports ($r = 0.38$; $P = 0.002$) and in mother reports ($r = 0.40$; $P < 0.001$). Significant

Table 1 Population characteristics.

Variable	Number of patients (%)	Overall TTR (mean ± SD)	P	Number of patients (%)	3-month TTR measurement before QoL assessment (mean ± SD)	P
Number of patients	121 (100)	0.78 ± 0.15	—	83 (100)	0.76 ± 0.24	—
Sex						
Male	70 (57.8)	0.77 ± 0.16	0.72	42 (50.6)	0.80 ± 0.23	0.07
Female	51 (42.2)	0.78 ± 0.12		41 (49.4)	0.71 ± 0.24	
VKA indication						
Dilated cardiomyopathy	7 (5.8)	0.79 ± 0.14	0.89	3 (3.6)	0.83 ± 0.08	0.73
Fontan circulation	45 (37.2)	0.78 ± 0.14		29 (34.9)	0.73 ± 0.29	
Extracardiac events[a]	15 (12.4)	0.72 ± 0.83		10 (12.1)	0.66 ± 0.297	
Kawasaki disease	6 (5)	0.81 ± 0.19		4 (4.8)	0.87 ± 0.1	
Valve replacement	48 (39.7)	0.80 ± 0.19		37 (44.6)	0.79 ± 0.19	
Type of educational programme sessions						
Initial session	28 (23.1)	0.77 ± 0.18	0.80	14 (16.9)	0.78 ± 0.23	0.67
Initial and reinforcement session	93 (76.9)	0.78 ± 0.14		69 (83.1)	0.75 ± 0.24	

QoL: quality of life; SD: standard deviation; TTR: time in therapeutic range; VKA: vitamin K antagonist.
[a] Stroke, pulmonary arterial hypertension, systemic lupus erythematosus, antiphospholipid syndrome, arrhythmia or deep vein thrombosis.
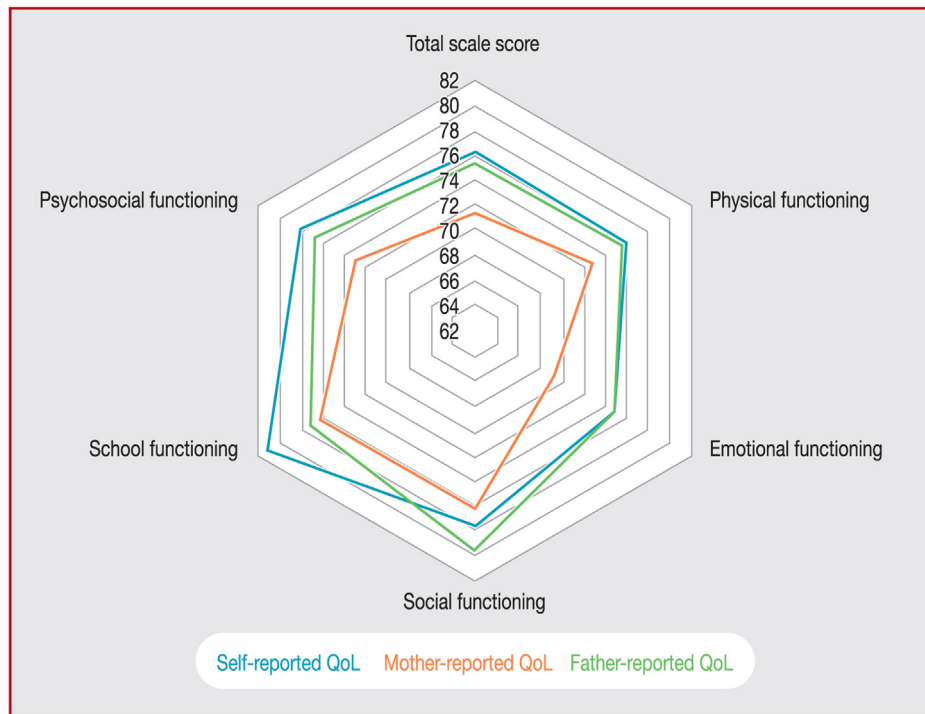
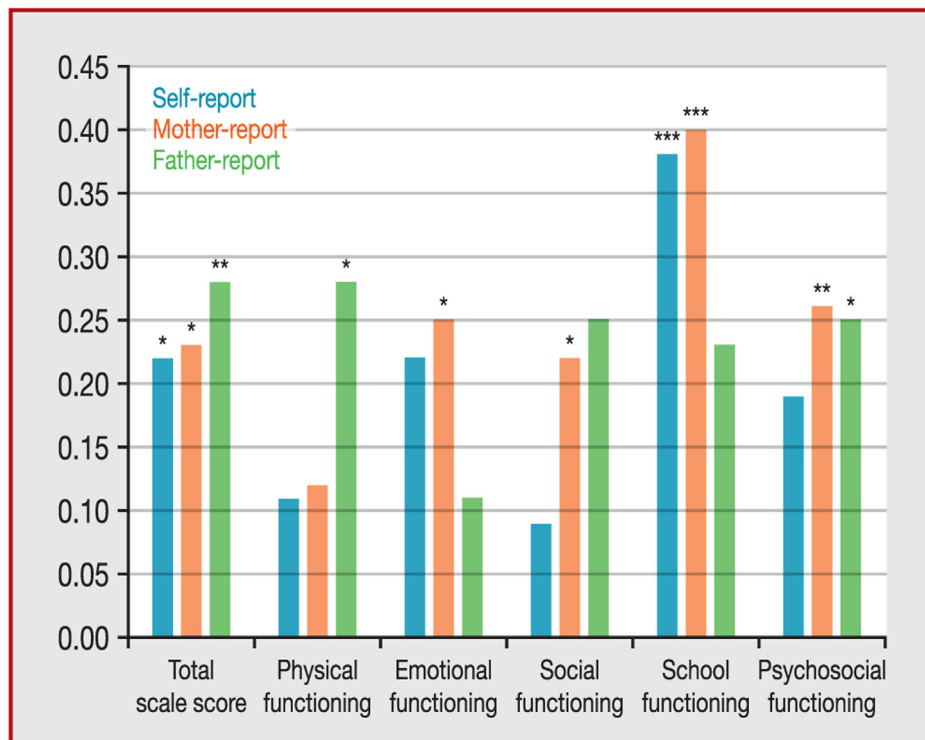**Figure 1.** Self- and proxy-reported quality of life (QoL) scores.

Figure 2. Correlation graph between time in therapeutic range and self-/proxy-reported quality of life scores. The x-axis corresponds to the quality of life dimensions. The y-axis corresponds to the correlation coefficients. The level of statistical signification is indicated as follows: * when $P \leq 0.05$; ** when $P \leq 0.01$; *** when $P \leq 0.001$.

correlations were also found between TTR and mother-reported emotional functioning ($r = 0.25$; $P = 0.02$), mother-reported social functioning ($r = 0.22$; $P = 0.03$) and mother-reported psychosocial functioning ($r = 0.26$; $P = 0.01$). In father reports, significant correlations with TTR were found with physical functioning ($r = 0.28$; $P = 0.03$) and psychosocial functioning ($r = 0.25$; $P = 0.05$). Correlation coefficients between TTR and self-/proxy-reported QoL scores, overall

and in each dimension, were always positive, as summarised in Fig. 2.

When considering the patients by groups of VKA indications, the TTR correlated significantly with QoL in children with Fontan circulation (Table 2).

Discussion

This prospective cross-sectional study has highlighted the correlation existing between TTR and QoL in a cohort of 121 children participating in a non-selective INR self-monitoring and VKA education programme.

In paediatrics, the introduction of VKA treatment usually occurs in a period of acute medical condition, such as after cardiac surgery or a thromboembolic event, or when a rare cardiac disease is diagnosed. In the long term, such a condition may result in psychological trauma among CHD survivors [19].

When considering each dimension of QoL, this study showed that TTR predominantly correlated with school functioning, especially in self- and mother-reported QoL. This may reflect the social impact of a severe medical condition, which in paediatrics primarily concerns school functioning. Indeed, a poor TTR in a child on VKA therapy usually requires repeated consultations and hospitalisations in order to control INR variations and prevent recurrent thromboembolic events. Therefore, in addition to the underlying chronic disease (e.g. CHD, pulmonary hypertension, cardiomyopathy, etc.), out-of-range INR variations may disrupt school attendance, integration and concentration. For example, low molecular weight heparin injection is usually required in children with a mechanical valve when INR is low, and physical activity may be forbidden when INR is high. In a recent multicentre controlled paediatric QoL study involving a cohort of 462 subjects, we showed that children with CHD were significantly more prone to grade repetition and school dropout than in the general paediatric population (30% vs. 9%, respectively) [13,20]. Furthermore, school may be a hostile environment for children with chronic diseases. Because of a supposedly vital risk, children with CHD are often hovered over by their parents and stigmatised by their teachers and peers, and often remain on the sidelines [13]; they may have psychological problems such as depression and anxiety, potentially leading to social competence and attention issues, affecting their QoL [21]. Moreover, VKA therapy in our cohort predominantly concerned children with severe CHD, such as mechanical valve replacement and univentricular heart (Fontan circulation). As reported in our previous studies, these patients are frequently associated with school dysfunction [13].

In this study, TTR was also significantly correlated with emotional and psychosocial functioning, especially in parent-reported QoL. Parents of children with CHD are at high risk of psychological and emotional problems, even a long time after diagnosis or cardiac surgery. In the literature, 30—50% of parents of children with CHD have suffered a major depressive episode in their life [19,22,23]. Parents' perception of their child's disease depends on the level of home medicalisation [24]. VKA education with an INR self-monitoring device (CoaguChek®) aims to shorten the duration of hospitalisation via home monitoring. When

we initially created this VKA self-monitoring education programme 10 years ago [11], we feared that bringing more autonomy to families might increase parental anxiety by transferring to them part of their child's medical responsibility. Fortunately, the results of this study suggest that reaching a good TTR may contribute to the family's emotional well-being. Conversely, the education programme delivers to the family the information that a low TTR is associated with a theoretical increased risk of a haemorrhagic or thromboembolic event. Therefore, a low TTR results in repeated INR measurements and dose adjustments, and probably more stress in the family circle. From a general perspective, various reports from the literature have shown that a serious health condition in children with CHD resulted in impaired psychological well-being, relationship satisfaction and financial security within the family circle [13,25—29].

In this study, TTR was associated with children's physical well-being, especially when reported by the fathers. Children on VKA therapy are usually not permitted to play contact sports (rugby, martial arts, etc.) because of the risk of injury, bruising or possibly bleeding. Therefore, our results suggest that, from a father's perspective, the QoL of their child primarily relies on their physical well-being [14]. Classically, fathers play a pivotal role in encouraging and supporting their child to participate in, be successful at and have fun when playing sport [30]. This is in line with our previous study, which highlighted the strong link between parent-reported QoL in the physical dimension and actual physical capacity (e.g. maximum oxygen uptake) in children with CHD [14]. Promotion of physical activity is included in our VKA education programme, and we always try to identify appropriate sports or physical activities for each child. Previous studies on paediatric chronic diseases have highlighted fathers' actions to ensure their children's safe participation in physical activities, such as supporting or coaching sports [31,32].

Health-related QoL assessment usually reflects the patient's clinical status over a rather short period of time before its measurement [33,34]. Our INR self-monitoring and VKA education programme starts immediately after VKA initiation, during a potential period of unstable health status, with repeated VKA dose adjustments. INR tests and dose adjustments are commonly repeated more often during the first weeks or months following VKA initiation, with frequent out-of-range INR values [35], which may impact QoL. For example, VKA dose adjustments are usually more difficult to perform in infants and young children because of high sensitivity to viral infection and diet changes. Therefore, we purposely chose to measure TTR over the 3 months preceding QoL assessment. Indeed, the mean TTR over this 3-month period of time was 76%, which is similar to the overall TTR in this study (78%), and close to the overall TTR reported previously (81%) [11]. Similar studies reported a mean TTR value of 50% immediately after VKA initiation in children [35], and a TTR increase from 54% in the first month to 75% after the first 3 months in adults [36].

Classically, studies performed in patients on VKA therapy tend to associate TTR with the usual morbimortality variables. Indeed, TTR correlates with major bleeding and thromboembolism occurrence in patients on VKA treatment [37]. Similarly, a better TTR is associated with a lower

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Table 2 Correlation between health-related quality of life and time in therapeutic range in subgroups of children on vitamin K antagonists.

	Physical functioning		Emotional functioning		Relation functioning		School functioning		Psychosocial functioning		Total score	
	r	P	r	P	r	P	r	P	r	P	r	P
Self-reported quality of life												
VKA indication												
Fontan circulation	0.23	0.2	0.5	0.008	0.21	0.3	0.43	0.04	0.36	0.07	0.4	0.02
Extracardiac events[a]	−0.11	0.7	0.08	0.8	−0.29	0.4	0.09	0.7	0.12	0.7	−0.07	0.8
Valve replacement	−0.02	0.8	−0.001	0.9	0.01	0.9	0.38	0.04	0.09	0.58	0.09	0.5
Mother-reported quality of life												
VKA indication												
Fontan circulation	0.33	0.07	0.2	0.2	0.14	0.4	0.45	0.01	0.2	0.25	0.34	0.04
Extracardiac events[a]	−0.16	0.7	0.14	0.7	0.27	0.5	0.29	0.4	0.27	0.4	0.26	0.4
Valve replacement	−0.06	0.7	0.25	0.1	0.24	0.1	0.41	0.02	0.25	0.1	0.09	0.5
Father-reported quality of life												
VKA indication												
Fontan circulation	0.07	0.7	0.03	0.8	0.25	0.2	0.35	0.1	0.36	0.1	0.22	0.3
Extracardiac events[a]	0.24	0.5	−0.34	0.4	−0.18	0.6	−0.46	0.3	−0.46	0.2	0.02	0.9
Valve replacement	0.37	0.06	0.22	0.3	0.41	0.05	0.43	0.05	0.34	0.1	0.42	0.02

VKA: vitamin K antagonist.
[a] Stroke, pulmonary arterial hypertension, systemic lupus erythematosus, antiphospholipid syndrome, arrhythmia or deep vein thrombosis.

risk of adverse events in patients with newly diagnosed atrial fibrillation and renal dysfunction [3]. Furthermore, TTR is lower in VKA-naive patients than in VKA-experienced patients [38]. Various studies have demonstrated the positive impact of INR self-management in terms of reducing VKA-related adverse events in the adult and paediatric populations [39—41]. Nevertheless, none of these studies evaluated the association between TTR and patient-related outcomes, such as QoL. Yet, the implementation of INR self-management in children on VKAs has the dual objective of obtaining high TTR values and low rates of haemorrhagic or thromboembolic adverse events, as well as improving QoL for these patients and their families. Many education programmes primarily aim to improve patients' QoL, such as transition or rehabilitation programmes in teenagers and young adults with CHD. As a result, the level of evidence regarding the impact of patient education on patient-related outcomes in this population is currently improving [42—45].

Study limitations

This study was performed in tertiary care centres, and may not represent VKA indications in the general population. Indeed, complex heart diseases, such as Fontan circulation and valve replacement, were over-represented (37% and 40%, respectively), and few patients with simple conditions (catheter-related thrombosis, venous thrombosis) were included in this study.

No control group was available (e.g. children on VKAs outside the INR self-monitoring education programme), as this non-selective education programme is for all children on VKAs, and it would be currently be ethically unacceptable not to prescribe an INR self-monitoring device to paediatrics.

The results from this study come from a patient sample that included several VKA indications with different disease severities. This may explain the low degree of correlation, especially in certain subgroups. However, this sample heterogeneity fully reflects the population included in a non-selective patient education programme, especially as a large majority of families agreed to participate in this prospective study.

Conclusions

This prospective cross-sectional study has highlighted the correlation existing between TTR and QoL in a cohort of 121 children participating in a 10-year-old non-selective INR self-monitoring and VKA education programme. TTR correlated with the overall QoL scores in self, mother and father reports. When considering each dimension of the QoL, the TTR predominantly correlated with school functioning in self and parent reports, and with emotional, psychosocial and physical functioning in parent reports. Regular assessment of QoL in patient education programmes contributes to our understanding of the concerns and needs of patients.

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Disclosure of interest

The authors declare that they have no competing interest.

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