INTERNATIONAL NORMALISED RATIO MONITORING IN CHILDREN: COMPARING THE ACCURACY OF PORTABLE POINT-OF-CARE MONITORS TO STANDARD OF CARE LABORATORY MONITORING AT RED CROSS WAR MEMORIAL CHILDREN'S HOSPITAL

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INTRODUCTION AND OBJECTIVES

Monitoring the international normalised ratio (INR) is an integral part in management of children on long-term oral anticoagulant therapy. Point-of-care INR monitors such as the Mission® PT/INR monitor provide advantages in efficiency and accessibility but have not been evaluated for accuracy in the South African paediatric setting.

We undertook a feasibility study with the aim to evaluate the accuracy of the Mission® PT/INR Monitor in comparison to standard laboratory INR measurement, in children presenting for INR testing at a tertiary paediatric facility in Cape Town, South Africa.

MATERIAL & METHODS

Study design and participants

Children between the ages of 1 year to 17 years were eligible for enrolment. Children under 12 months of age and critically ill children were excluded from enrolment.

Study protocol

Blood samples for INR analysis were obtained consecutively by venepuncture for collection in citrated tubes for measurement on the Sysmex CS-2100i coagulation analyser in the laboratory and then by fingerprick for measurement on the Mission® PT/INR device.

Main outcome measures

We compared the accuracy of the Mission® PT/INR monitor to the Sysmex CS- 2100i laboratory analyser. We also described secondary variables, including patient demographics and disease profile.

Figure 1. The Mission ® PT/INR monitoring device

RESULTS 1

Thirty-seven (37) participants were enrolled into the study, with forty (40) paired POC INR and laboratory INR values. **Table 1** shows the demographic profile of the study sample.

Table 1. Demographic profile of study sample

Total number of participants n=37 N (%)	N (%)
Gender	
Male	23 (62)
Female	14 (38)
Age (years, months)	
Youngest	1y 1m
Oldest	17y
Mean	8y
< 5 years	10 (27)
5 - 6 years	5 (13.5)
>7 years	22 (59.4)
Hospital admission status	
Inpatient	14 (38)
Outpatient	23 (62)
Primary Place of Residence	
Cape Town Metropole	26 (70)
Western Cape (other than Cape Town)	7 (19)
Not from Western Cape	4 (11)
Place of Sample Collection	
Outpatient clinic	4 (11)
Inpatient Wards	15 (40)
Ambulatory Medicine department	3 (8)
Laboratory phlebotomy department	15 (40)

Table 2. Disease profile of study sample

Total number of participants n=37	N (%)
Primary indication for INR testing	
CARDIAC	7 (19)
Fontan/Glenn circulation	1 (2.7)
Dilated cardiomyopathy	2 (5.4)
Prosthetic Valve	3 (8.1)
Kawasaki Disease	0
Primary Pulmonary Hypertension	0
Other	1 (2.7)
Known cardiac patient?	5 (13.5)
NON-CARDIAC	30 (81)
Liver Disease	13 (35.1)
Renal Disease	2 (5.4)
Venous Thromboembolism	1 (2.7)
Arterial Thromboembolism	0
Other	14 (37.8)
Comorbid illnesses	6 (16.2)
HIV	0
TB	1 (2.7)
Renal	0
Liver disease	0
Malignancy	1 (2.7)
Haematological	0
Other	4 (10.8)

Table 2 summarises the disease profile of the participants in the study sample. The minority of participants had their INRs tested for primary cardiac indications (19% vs 81%). Five patients (13.5%) were on anticoagulant therapy including four on warfarin therapy and a fifth on aspirin.

Non-cardiac indications for INR testing predominated in the study sample. The vast majority of these patients had liver disease as the primary indication for INR testing, most of whom had chronic liver disease related to biliary atresia.

RESULTS 2

Method comparison analysis

The mean INR values for the Mission® PT/INR and the laboratory method compared favourably with means of 1.49 (SD 0.73) and 1.39 (SD 0.69) respectively. This represents a slight overestimation of INR values by the Mission® PT/INR device. Non-parametric tests showed that this slight overestimation was statistically significant (p-value 0.0012). 92.5 % of INR readings INR results on the POC INR device were within 0.5 units of the laboratory value.

The limit of agreement between the two methods of INR measurement are represented in the Bland-Altman difference plot (**Figure 2**) - this revealed good agreement with mean difference of 0.13 (-0.33; 0.58). Only two values were outside the 95% limits of agreement.

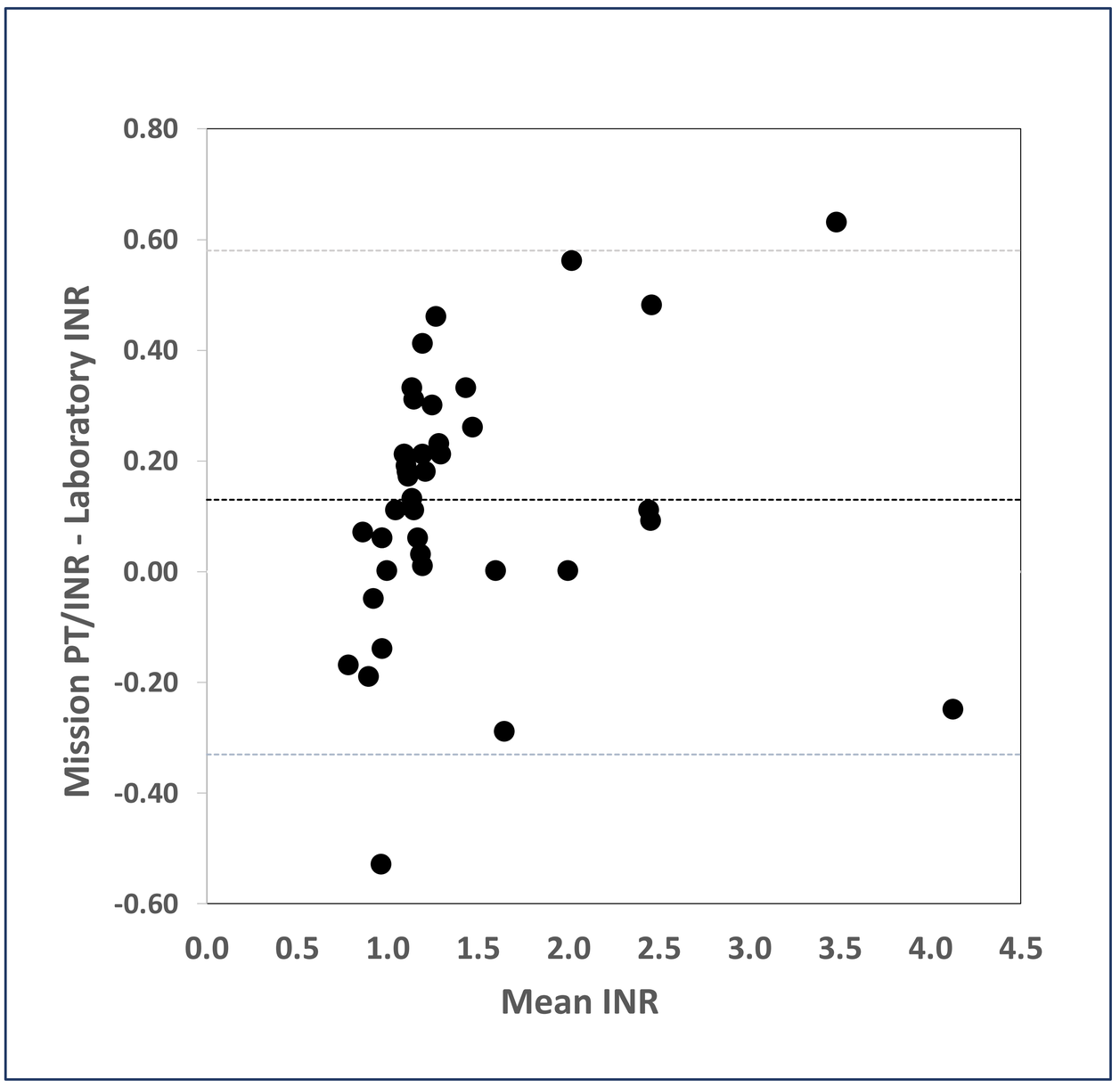

Figure 2. Bland-Altman analysis - 95% confidence intervals indicated (grey), bias (black). Markers show the difference between the two methods over the mean

DISCUSSION and CONCLUSIONS

This feasibility study showed that the majority of patients at RCWMCH who required INR testing, did so for screening purposes in non-cardiac disease, with a minority of patients on long-term oral anticoagulation.

The Mission® PT/INR has been shown to be accurate in a wide range of readings but follow-up research with a larger study sample is required to provide a power analysis of the accuracy of this device in a tertiary hospital paediatric setting.

This study has shown that this POC INR device may be implemented in an outpatient setting (including peripheral clinics) but that a detailed assessment of the infrastructure and capacity of such settings will be required to allow for appropriate and reliable quality control processes. Before implementation, staff will require training on optimal use and troubleshooting of the device, preferably according to a standard operating procedure, which should address how to proceed if INR readings fall outside of a prescribed range.

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