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Predicting accuracy of pocket- chemhemog hemoglobinometer in the measurement of hemoglobin and hematocrit levels in children aged 1 month-12 years

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Abstract

Background: Anemia presents a significant global health challenge, notably affecting pediatric populations in India, where children aged 6-59 months face an alarming 58% prevalence . Accurate hemoglobin assessment is pivotal for diagnosing anemia, underlining the critical need for accessible point-of-care devices in regions with limited resources. The Pocketchem Hemog emerges as a promising solution, poised to transform diagnostic approaches, especially in pediatric healthcare settings. Beyond anemia, monitoring hemoglobin and hematocrit proves crucial in diseases such as dengue in Pediatric critical Care Units (PCCUs). Objectives : This study aims to evaluate the Pocketchem Hemog device's accuracy compared to an automated hematology analyzer, and exploring its potential in rapid detection anemia and identifying the severity of dengue . **Methodology**: This nine-month prospective study was conducted at a tertiary hospital which included 250 children between the age 1 to 12 months. The subjects were assessed for hemoglobin and hematocrit count using a pocketchem hemog and comparing them with the automated analyzer findings. Serial hematocrit assessments were done in dengue

patients admitted in PICU using capillary blood with hemog and it was compared with the venous blood HCT using automated analyzer in the lab. The data was noted and analyzed for association and correlation using SSPS software.

Result:

The mean Hemoglobin (Hb) values from capillary prick by Pocketchem Hemog and laboratory measurements the means are 11.0 and 11.75 mg/dl, (p = 0.0027) .The mean values between Hb in venous blood by Pocketchem Hemog and lab are 11.8 g/dl and 11.75g/dl,(p value of 0.000). Comparisons of mean Hematocrit (HCT) values between HCT Prick and HCT Lab yielded mean values of 33.25 % and 34.37 % (p=0.000), as well as HCT Venous Blood with Pocketchem Hemog and HCT Lab gave the man values of 34.34 % and 34.37% respectively (p = 0.0034). Strong positive correlation was observed in serial HCT measurements which further prove the positive statistical association thereby establishing the reliability of the device.

Conclusion: Pocketchem hemog is a reliable method for hemoglobin and hematocrit estimation which can be done bedside, time saving and cost benefiting. Studies with more sample size in various geographical locations are necessary to validate it as a clinically reliable tool.

Key words: PocketChem Hemog Hemoglobinometer , Anemia , Hematocrit , Hemoglobin , Dengue

Introduction

In countries like India which are still developing, anemia is more prevalent in pediatric population. The prevalence of anemia increases with age and peaked at the ages of 12 to 17 months for male babies (72.35 % in NHFS -4 and 81.74 % in NFHS 5) [1] and 18 to 23 months for female babies (69.01% in NFHS 4 and 79.17 % in NFHS -5) [2].

Hemoglobin assessment is a very reliable indicator for anemia. It is widely used as a screening investigation for detection of anemia and also for assessing the response to treatment[3]. Since the prevalence of anemia is so high, we need a point-of-care device for hemoglobin estimation for screening purpose. The pocketchem hemog is such a device which can be used in healthcare facilities.

Dengue fever is caused by dengue virus. It is transmitted by Aedes mosquitoes. It has a wide clinical course that differs from a self- limiting moderate clinical course to potentially severe illness that leads to death.[4] A rise in hematocrit in dengue is a sign of plasma lea kage whereas lower hematocrit indicates hemorrhage. Hence hematocrit monitoring plays an important role in the management of dengue in PICU settings.[5] Since it requires frequent sampling which is cumbersome for both doctors and patients, a point of care device for the monitoring of hematocrit will make the work easier for all.

Studies that were conducted previously showed contradictory results regarding the accuracy of Hemocue hemoglobinometer in measuring hemoglobin in capillary blood and measuring hemoglobin in venous blood by automated hematology analyzer. [6]This study aims at comparing the accuracy of pocketchem hemog using venous and capillary samples with that of the automated hematology analyzer. This study also aims at finding out the accuracy of percentage increase or decrease of Hematocrit in capillary samples using pocketchem hemog with that of venous samples using automated hematology analyzer in Dengue patients admitted in PICU.

Hence our aims and objectives of the study are to compare the accuracy of pocket chemhemog using venous and capillary samples with that of the automated hematology analyzer. In addition to this we also aim to compare the accuracy of percentage increase or decrease in hematocrit values of pocket chemhemog using capillary blood samples with that of venous blood sample using automated hematology analyzer in patients with Dengue fever.

Methodology

SOURCE OF DATA:

All children in the mentioned age group of 1 month-12 years attending our OPD and admitted in wards of Vinayaka Missions Kirupananda Variyar Medical College and Hospitals , Salem who require a complete blood count.

2. Patients admitted into PICU with a diagnosis of dengue fever.

STUDY DURATION:

9 months (January 2022 to September 2022)

Ethical approval

Before the study began, ethical committee approval was obtained from the ethical committee of the Institution

SAMPLE SIZE:

250

SAMPLING TECHNIQUE :

Nonrandom-purposive sampling

STUDY DESIGN

A Cross sectional study that is prospective in nature.

INCLUSION CRITERIA:

a)All children attending pediatric OPD in age group 1 month-12 years who require complete blood count.

b)All children admitted in pediatric ward

c) Accompanying children whose parents give consent for this study

d) All Dengue patients admitted in PICU

EXCLUSION CRITERIA:

Parents who do not give consent for the study

Study Tools- POCKT CHEM HEMOG HEMOGLOBINOMETER

AUTOMATED HEMOGLOBIN ANALYZER.

Data collection methodology:

The children who fit into inclusion criteria were included in the study after obtaining informed consent from the parents. The socio-demographic data including age, sex, and history of any illness in the past, history of medications were noted. This data is recorded into a Microsoft excel spread sheet for correlation before analysis. After explaining the procedure the tip of the left

middle finger was pricked with a lancet and first drop of blood was wiped with cotton. A standard microcuvette was used to collect the capillary blood and immediately assessed with Pocketchem hemog device for analysis. The Hb results were displayed numerically in g/dL and hematocrit in percentage was noted manually in the data sheet immediately after measurement. After explaining the procedure samples were collected from venous blood in children enrolled for the study. The investigator made sure that the child was in a comfortable position, blood about 3ml was collected and transferred to EDTA containing vacutainers by following standard guidelines. The tubes were gently inverted 4-5 times and transferred into a cold box maintained at 4-8ºC. Venous blood was also subjected to testing by Pocketchem hemog and values were noted. The samples were transferred to the laboratory on the same day and processed. The automated hematology analyzer was used and the complete blood picture of the specimen was performed. Values of hemoglobin & hematocrit were noted. The quality control checks for Pocketchem hemog system was performed weekly as per manufacturer instructions. Repeat hematocrit was performed with hemoglobinometer on capillary blood for patients requiring repeated hematocrit assessments, especially patients with dengue fever.

STATISTICAL ANALYSIS:

The data from the proforma was recorded into MS-Excel . IBM SPSS Version 26.0 was used for analyzing the data statistically. For continuous variables, the data value is expressed as Mean±SD (Standard Deviation). To assess the mean difference of means between the two groups, student's t-test (Paired sample t-test) was used and to test linear relationship between the groups, Pearson's correlation coefficient (r-value) was used. To estimate the bias and limits of agreement between the pocketchem hemog and automated hematology analyzer, Bland-Altman plot was used. All the p values having less than 0.05 were taken to be statistically significant.

Results

The study comprised of 250 subjects among them, 43 (17.2%) were dengue positive. When the mean values between Hb prick and the lab, HCT prick and lab, Hb venous blood hemoglobinometer and Hb lab, and HCT venous blood hemoglobinometer and HCT lab (Tab 1, 2, 3 & 4) were compared , the means were more or less close to each other which was statistically significant suggesting pocket meter is a reliable measure. Table 5 shows the moderate to strong positive correlation was obtained with respect to Hb% and HCT levels which was statistically significant. Table 6 shows a that correlation was strong and positive between serial hematocrit levels .

1. **Comparison of mean values between Hb prick and Hb Lab:**

The mean hemoglobin (Hb) values obtained from capillary prick and laboratory measurements were 11.10 and 11.75 g/dL, respectively. The t-value was 66.30, indicating a statistically significant difference. However, the 95% confidence interval (10.99 to 11.43) and the p-value of 0.0027 suggest a relatively small difference between the two methods .

2.The comparison between hemoglobin (Hb) levels in venous blood measured by the hemoglobinometer and laboratory measurements yielded the following results:

- The mean Hb value done on venous blood using the hemoglobinometer was 11.48 g/dL, while the laboratory measurement yielded a mean Hb value of 11.75 g/dL. The t-value was 94.77, indicating a statistically significant difference. However, the 95% confidence interval (11.50 to 11.99) and the p-value of 0.000* suggest a relatively small difference between the two methods .

Comparison of HCT prick versus HCT lab

In comparing mean hematocrit (HCT) values between HCT Prick and HCT Lab, the Hb Prick group exhibited a mean HCT level of 33.25% with a standard deviation (SD) of 8.00. In contrast, the HCT Lab group displayed a higher mean of 34.37%, with a lower SD of 5.75. The t-value of 65.68 reveals a difference between the two groups that was significant ($p = 0.000$), the confidence interval was 95% for the mean difference ranging from 32.25 to 34.24.

Comparison of mean values between HCT Venous blood Hb meter and HCT Lab

For hematocrit (HCT) values, the mean HCT in the Hb Venous Blood Hb Meter group was 34.34% (SD = 5.77), and the HCT Lab group showed a similar mean of 34.37% (SD = 5.75). The t-value of 94.05 and p value was 0.0034, these values were significant statistically. The confidence interval was 95% . The difference between the mean was spanning from 33.62 to 35.06.

5. **Correlation of HCT repeat comparison**:

The study revealed a positive correlation that was ranging between moderate to strong between repeat hematocrit (HCT) levels. This finding is significant statistically and it indicates consistency in the measurement of hematocrit values using the Pocketchem Hemog Hemoglobinometer and the automated hematology, supporting the device's reliability in assessing hematocrit .

Table 1: **Comparison of mean values between Hb prick and Hb Lab**

	Mean	SD	t value	95% confidence interval		P value
				Lower	Upper	0.0027*
Hb Prick	11.10	2.64	66.30	10.99	11.43	
Hb Lab	11.75	1.96	94.97	11.50	11.99	

Table 2: Comparison of mean values between HB Venous blood HB meter Prick and HB Lab

	Mean	SD	t value	95% confidence interval		P value
				Lower	Upper	0.000*
Hb Lab	11.75	1.96	94.77	11.50	11.99	
Hb Venous blood Hb meter	11.48	1.91	94.95	11.25	11.72	

Table 3: **Comparison of mean values between HCT Prick and HCT Lab**

	Mean	SD	t value	95% confidence interval		P value
				Lower	Upper	0.000*
Hb	33.25	8.00	65.68	32.25	34.24	

Prick						
Hb Lab	34.37	5.75	94.43	33.65	35.09	

Table 4: **Comparison of mean values between HCT Venous blood Hb meter and HCT Lab**

	Mean	SD	t value	95% confidence interval		P value
				Lower	Upper	0.0034
Hb Venous blood Hb meter	34.34	5.77	94.05	33.62	35.06	*
HCT Lab	34.37	5.75	95.43	33.65	35.09	

Table 5: **Correlations between prick and lab reports**

Correlations

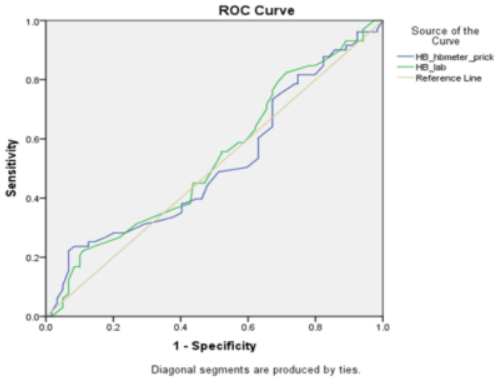
		HB_hbmeter_prick	HB_venousblood_hbmeter	HB_lab	HCT_hbmeter_prick	HCT_venous_blood_hbmeter	HCT_lab
HB_hbmeter_prick	Pearson Correlation	1	.798**	.656**	.998**	.789**	.637**
	Sig. (2-tailed)		.000	.000	.000	.000	.000
	N	250	250	250	250	250	250
HB_venousblood_hbmeter	Pearson Correlation	.798**	1	.895**	.801**	.995**	.861**
	Sig. (2-tailed)	.000		.000	.000	.000	.000
	N	250	250	250	250	250	250
HB_lab	Pearson Correlation	.656**	.895**	1	.660**	.903**	.961**
	Sig. (2-tailed)	.000	.000		.000	.000	.000
	N	250	250	250	250	250	250
HCT_hbmeter_prick	Pearson Correlation	.998**	.801**	.660**	1	.793**	.640**
	Sig. (2-tailed)	.000	.000	.000		.000	.000
	N	250	250	250	250	250	250
HCT_venous_blood_hbmeter	Pearson Correlation	.789**	.995**	.903**	.793**	1	.869**
	Sig. (2-tailed)	.000	.000	.000	.000		.000
	N	250	250	250	250	250	250
HCT_lab	Pearson Correlation	.637**	.861**	.961**	.640**	.869**	1
	Sig. (2-tailed)	.000	.000	.000	.000	.000	
	N	250	250	250	250	250	250

Table 6: **Correlation of HCT repeat comparison**

Correlations

		repeat_HCT_1_hbmeter	repeat_HCT_1_Automated analyser	repeat_HCT_2_hbmeter	repeat_HCT_2_Automated analyser	repeat_HCT_3_hbmeter	repeat_HCT_3_Automated analyser	repeat_HCT_4_hbmeter	repeat_HCT_4_Automated analyser
repeat_HCT_1_hbmeter	Pearson Correlation	1	.996**	.992**	.998**	.996**	.997**	.994**	.997**
	Sig. (2-tailed)		.000	.000	.000	.000	.000	.000	.000
	N	250	250	250	250	250	250	250	250
repeat_HCT_1_Automate danalyser	Pearson Correlation	.996**	1	.992**	.997**	.997**	.996**	.993**	1.000**
	Sig. (2-tailed)	.000		.000	.000	.000	.000	.000	.000
	N	250	250	250	250	250	250	250	250
repeat_HCT_2_hbmeter	Pearson Correlation	.992**	.992**	1	.994**	.995**	.991**	.993**	.992**
	Sig. (2-tailed)	.000	.000		.000	.000	.000	.000	.000
	N	250	250	250	250	250	250	250	250
repeat_HCT_2_Automate danalyser	Pearson Correlation	.998**	.997**	.994**	1	.996**	.997**	.994**	.997**
	Sig. (2-tailed)	.000	.000	.000		.000	.000	.000	.000
	N	250	250	250	250	250	250	250	250
repeat_HCT_3_hbmeter	Pearson Correlation	.996**	.997**	.995**	.996**	1	.997**	.994**	.997**
	Sig. (2-tailed)	.000	.000	.000	.000		.000	.000	.000
	N	250	250	250	250	250	250	250	250
repeat_HCT_3_Automate danalyser	Pearson Correlation	.997**	.996**	.991**	.997**	.997**	1	.991**	.996**
	Sig. (2-tailed)	.000	.000	.000	.000	.000		.000	.000
	N	250	250	250	250	250	250	250	250
repeat_HCT_4_hbmeter	Pearson Correlation	.994**	.993**	.993**	.994**	.994**	.991**	1	.993**
	Sig. (2-tailed)	.000	.000	.000	.000	.000	.000		.000
	N	250	250	250	250	250	250	250	250
repeat_HCT_4_Automate danalyser	Pearson Correlation	.997**	1.000**	.992**	.997**	.997**	.996**	.993**	1
	Sig. (2-tailed)	.000	.000	.000	.000	.000	.000	.000	
	N	250	250	250	250	250	250	250	250

Figure 1: **HB PRICK HB METER VS HB LAB**

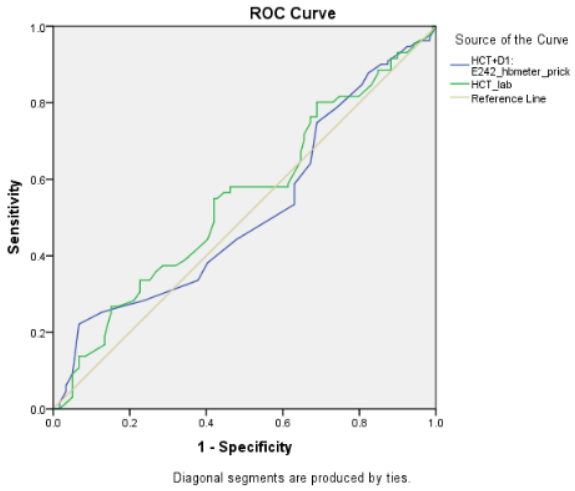


2

Area Under the Curve

Test Result Variable(s)	Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
				Lower Bound	Upper Bound
HB_hbmeter_prick	.515	.037	.674	.443	.588
HB_lab	.534	.037	.352	.462	.606

Figure 2: **HCT PRICK HB METER VS HCT LAB**

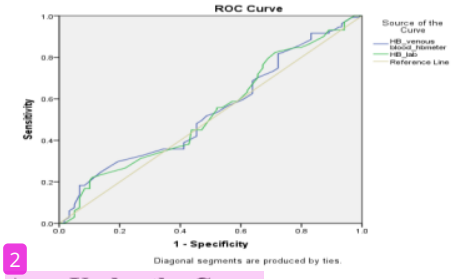


2

Area Under the Curve

Test Result Variable(s)	Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
				Lower Bound	Upper Bound
HCT+D1:E242_hbmeter_prick	.516	.037	.662	.444	.588
HCT_lab	.547	.036	.197	.476	.619

Figure 3: **HB VENOUS BLOOD HB METER VS HB LAB**

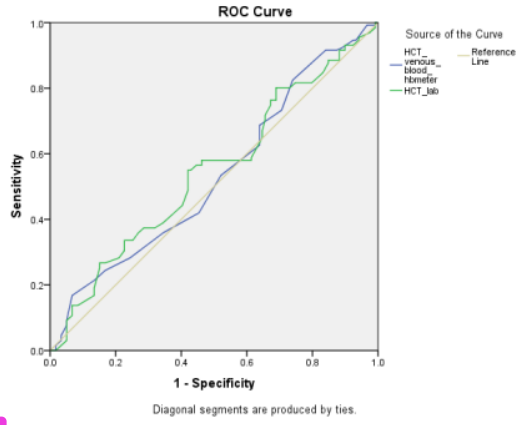


2

Area Under the Curve

Test Result Variable(s)	Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
				Lower Bound	Upper Bound
HB_venous blood_hbmeter	.539	.037	.288	.467	.611
HB_lab	.534	.037	.352	.462	.606

Figure 4: **HCT VENOUS BLOOD HB METER VS HCT LAB**



2

Area Under the Curve

Test Result Variable(s)	Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
				Lower Bound	Upper Bound
HCT_venous_blood_hbmeter	.533	.037	.375	.461	.604
HCT_lab	.547	.036	.197	.476	.619

Figure 1, 2, 3 & 4 shows the area under curve when the venous blood and capillary blood of the meter and lab, there was a moderate positive association between them suggesting the pocket meter can be used on regular basis as no much difference was noted between them.

Discussion

In the current study, we assessed the accuracy of pocketchemhemog using venous and capillary samples with that of the automated hematology analyzer in children aged 1 month to 12 years and also compared the accuracy of percentage increase or decrease in hematocrit values of pocketchemhemog using capillary blood samples with that of venous blood sample using automated hematology analyzer in patients with Dengue fever.

The study, encompassing 250 subjects, aimed to evaluate the utility of the Pocketchem Hemog Hemoglobinometer for hemoglobin (Hb) and hematocrit (HCT) measurements in a pediatric population. A notable 17.2% of the subjects were diagnosed with dengue. The mean values between Hb and HCT measurements obtained using various methods were statistically compared, revealing valuable insights into the reliability of the Pocketchem device.

Among study participants (N=250), the capillary blood mean Hb% concentration by pocket chemhemog was 11.10± 2.64 and with automated hematology analyzer was 11.75± 1.96 while the venous blood mean Hb% concentration by pocket chemhemog was 11.48± 1.91and with automated hematology analyzer was 11.75± 1.96. Finding of our study revealed that the mean Hb obtained by automated hematology analyzer was more or less equal to that obtained by pocketchem hemog for the venous blood and capillary blood samples in our age group of participants (all p values < 0.01). Similarly, the mean HCT obtained by automated hematology analyzer was higher in comparison to that of pocketchemhemog for both venous blood (34.34 ± 5.77 vs 34.37 ± 5.75) and capillary blood (33.25 ± 8.00 vs 34.37 ± 5.75) samples in our age group of participants (all p values < 0.01). Potential reasons behind this distinction are valid physiological contrasts in Hb levels of capillary versus venous blood, contrasts in accuracy and precision of the instruments and differences in specimen collection and processing prior to analyses.

There was a statistically significantly strong correlation of Hb% values between pocketchem hemog and automated hematology analyzer in both venous blood (r value = 0.895, p value < 0.0001) and capillary blood (r value = 0.656, p value < 0.0001) samples. Also, there was a

significantly strong correlation of HCT values between pocketchemhemog and automated hematology analyzer in both venous blood (r value = 0.793, p value < 0.0001) and capillary blood (r value = 0.640, p value < 0.0001) samples. However, the difference was small but clinically significant.

Findings of our study was contrary with the findings of study done by Ashish Jain, et al.,[7] which showed capillary HemoCue estimation exhibited greater bias as well as wider limit of agreement. Variance of the differences from automated counter was significantly lower for venous HemoCue comparison compared to capillary HemoCue estimation (p value < 0.001 for each instrument).

A study done by Sarvepalli Vijaya Kumar et al[8] on comparison of hemoglobin assessment by HemoCue 301 and automated hematology analyzer using flow cytometry showed the mean value of automated hematology analyzer (11.965±1.012) was considerably higher when compared with the mean value of HemoCue Hb301 (11.697±1.312) (p=0.002). The study also showed a notably strong correlation between HemoCue Hb301 and automated hematology analyzer (r-value = 0.732, p<0.0001). These findings concur with the findings in our study. It was concluded that the HemoCue is useful in many different settings and remains a widely used method in field settings as it has several advantages and is relatively inexpensive compared with automated hematology analyzers. They have also suggested that further studies are needed to understand better about the errors occurring during measurements .

The recent study's results contradicted those of Hinnouho G-M et al. (reference 9), revealing that mean capillary hemoglobin (Hb) levels measured with HemoCue Hb301 were notably higher than mean venous Hb levels determined by two automated hematology analyzers (Sysmex XT-1800i and Mindray BC-3000Plus). Regardless of the blood sample type (both capillary and venous), HemoCue Hb301 consistently indicated higher Hb levels compared to the automated hematology analyzers. In summary, the study concluded that the agreement between capillary and venous Hb concentrations assessed by Hemocue Hb301 was poor when compared to venous Hb measured by automated hematology analyzers, leading to significantly different prevalence rates of anemia.

In contrary to the current study, study by Toppo M et al.,[10] was conducted in a different sample population and a different setting revealed that there was only minor variation in the minimum values found by AutoAnalyzer and Digital Hemoglobinometer. Z-score of two means of both the methods was observed to be statistically non-significant. The observed difference between

the two processes was just by chance. Another study Bhaskaram et al.[11], among apparently healthy children of 1–6 years, also revealed that the mean values for hemoglobin were higher by Hemocue than by cyanmethemoglobin method. When assessed by Hemocue method the proportion of children with anemia was 66% while it was 88% with cyanmethemoglobin method, thus not similar to the current findings and does not support the use of the HemoCue in various study populations.

A study done by Silvita Fitri Riswari [12]et al compared the hematocrit values between capillary hematocrit by point of care device (Hemocue) and automated analyzer in the lab. The study showed a result similar to ours indicating a strong correlation between the two. The study has concluded that Hemocue can be used to find incidences of plasma leakages in the setting of dengue.

In a study done by Kantasit Wisanuvej[13] et al, they have compared the hematocrit values and hemoglobin values by point of care hemoglobin devices (capillary method) with automated analyzer to find a reliable and sensitive indicator for plasma leakage in dengue. It states that both hemoglobin and hematocrit by point of care devices prove to be reliable in the assessment of severity and plasma leakage in scenarios with dengue fever. The uniqueness of our study lies in serial measurements of hematocrit to test the authenticity of the device. There was a strong correlation in our study proving that pocktchem hemog values can be reliable in predicting the severity of dengue .

However when the results of our study could not be directly compared, with that of other previous studies .The comparison was limited due to several factors like, using different point of care devices, which employs different biochemical methods for estimation of Hb levels. Other influencing factors in comparing the study results were age of the study participants, setting, ethnicity and whether Hb was assessed on capillary or samples from venous blood samples or on fasting or non-fasting blood samples.

We have performed the study on both capillary and venous blood samples in comparison to venous blood samples in automated analyzer. This makes our study unique more authentic and reliable.

However, our study's focus on the pediatric population in the context of dengue represents a unique contribution. Existing literature predominantly addresses adult populations, and the scarcity of Indian studies in this domain underscores the significance of our investigation.

Clinical Implications:

The results in our study gave a strong positive correlation which makes the device more reliable to use. There are several practical advantages to the point-of-care devices that include cost effectiveness and rapid results. A positive correlation was established in repeat hematocrit levels, this strongly supports the potential use of Pocketchem Hemog Hemoglobinometer for monitoring of severity in dengue using hematocrit.

Limitations and Future Directions:

Although there were several statistically significant results that establish the accuracy of the device, there were certain limitations in the study . The sample size we have employed is relatively small and was conducted within a controlled hospital setting. Regarding generalizability, more research needs to be done with a larger sample size in much more diverse settings to better understand the actual accuracy of such pocketchemhemog devices and the operational feasibility of integration of them into current public health programs in India.

Conclusion

The pocket chem hemog has shown statistically significant accuracy in predicting haemoglobin and hematocrit levels. It has also shown strong positive correlation between serial hematocrit measurements. This makes it a relatively reliable tool to measure haemoglobin levels in community settings for screening of anemia. It also can be used for monitoring and assessment of severity of dengue and reduce the painful sampling. A larger sample size in more diverse population must be used to lend it generalizability; validate the accuracy and predictability of the device .

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