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Original Research Article

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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Conflict of interest: Nil

Abstract

Background: Anemia presents an important 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 ages 1 to 12 months. The subjects were assessed for haemoglobin and haematocrit count using a pocketchem hemog and comparing them with the automated analyzer findings. Serial haematocrit 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 analyser in the lab. The data was noted and analysed 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 haematocrit 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.

Keywords: PocketChem Hemog Hemoglobinometer, Anemia, Haematocrit, Hemoglobin, Dengue.

INTRODUCTION

In countries like India which are still developing, anemia is more prevalent in pediatric population. The ages of 12 to 17 months show an increased prevalence for male babies (72.35 % in NHFS -4 and 81.74 % in NFHS 5) [1]. For female babies peak prevalence is around 18 to 23 months. (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 device for easy estimation of hemoglobin for screening purpose. The pocketchem hemog is such a device which can be used in healthcare facilities.

Dengue fever 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 haematocrit in dengue is a sign of plasma lea kage whereas lower haematocrit indicates haemorrhage.

Hence hematocrit monitoring is vital in the management of dengue in PICU settings. [5] Since it requires frequent sampling which is cumbersome for both doctors and patients, a device which can be used bedside for the monitoring of hematocrit will make the work easier for all.

Studies that were conducted previously showed negative agreement between the hemoglobinometer and automated analyser in measuring hemoglobin in capillary blood and measuring hemoglobin in venous blood. [6] This study aims at comparing the accuracy of pocketchem hemog using capillary as well as venous samples with that of the automated hematology analyser (AHA). 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 analyser (AHA) 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 analyser (AHA). In addition to this we also aim to compare the accuracy of percentage increase or decrease in haematocrit values of pocket chemhemog using capillary blood samples as well as venous blood sample using automated hematology analyser in patients with Dengue fever.

Methodology:

Source of data:

1. All children aged between 1 month-12 years presenting at our OPD and admitted in wards of Nandha Medical College and Hospital Erode who require a complete blood count.
2. Patients admitted into PICU with a diagnosis of dengue fever.

Study duration: 9 months (January 2021 to September 2021)

Ethical approval: Before the study began, approval from the ethical committee was obtained.

Sample size: 250

Sampling technique: Nonrandom-purposive sampling

Study design: A Cross sectional study that is prospective in nature.

Inclusion criteria:

- All children attending pediatric OPD in age group 1 month-12 years who require complete blood count.
- All children admitted in pediatric ward
- Accompanying children whose parents give consent for this study
- 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 fulfilling the inclusion criteria were included in the study and informed consent was taken from the parents. The data which includes age, sex, and relevant history was noted. Microsoft excel spread sheet was used to record the given data for correlation before analysis. After explaining the procedure the tip of the right little finger was pricked with a needle and the first drop of blood was not used. The capillary blood is collected with a microcuvette that came with the device. 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. Vacutainers cfilled with EDTA were used to collect 3ml blood in accordance with standard guidelines. Venous blood was also subjected to testing by Pocketchem hemog and values were noted. The complete blood picture was performed in the samples using a standard hematology analyser in the laboratory. Values of hemoglobin & hematocrit were noted. Weekly Quality control checks in Pocketchem hemog system were done as per manufacturer instructions. Repeat haematocrit was performed with hemoglobinometer on capillary blood for patients requiring repeated haematocrit assessments, especially patients with dengue fever.

Statistical analysis: The data from the proforma was recorded into MS-Excel .The statistical data analysis was done using Version 26.0 of IBM SPSS. Relevant statistical analytic methods were used to analyse the data. The values of p less than 0.05 were considered significant statistically.

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 that correlation was strong and positive between serial hematocrit levels.

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. 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.

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. 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. 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 hematolog, supporting the device's reliability in assessing hematocrit.

Table 1: Comparison of mean values of 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 Prick	33.25	8.00	65.68	32.25	34.24	
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_Automatedanalyser	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_Automatedanalyser	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_Automatedanalyser	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_Automatedanalyser	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

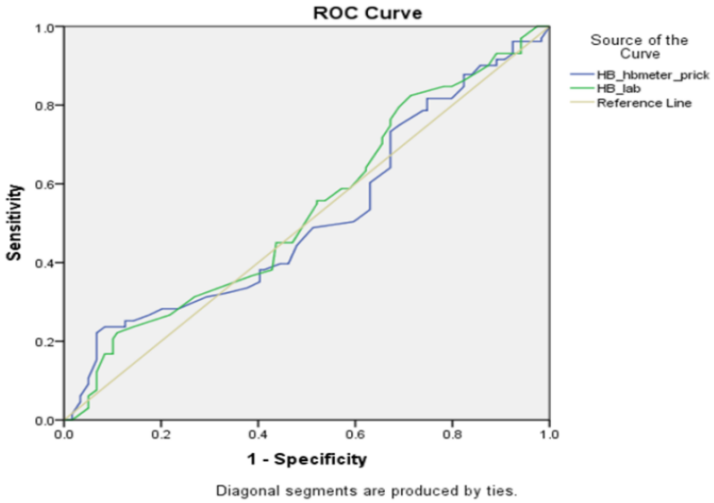

Figure 1: Hb Prick Hb Meter Vs Hb Lab

Table 7:

Area Under the Curve [AUC]					
Test Result Variable(s)	**AUC**	**Standard Error[a] :**	**Asymptotic Significance**	**Asymptotic 95% Confidence Interval**	
				Lower Bound	**Upper Bound**
HB_hbmeter_prick	0.515	0.037	0.674	0.443	0.588
HB_lab	0.534	0.037	0.352	0.462	0.606

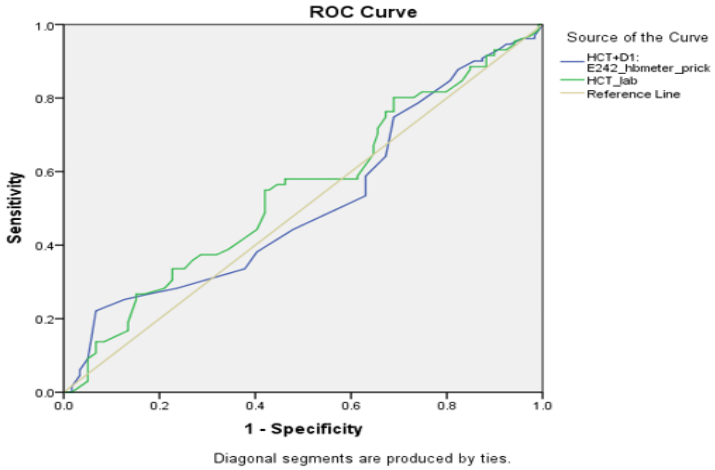

Figure 2: HCT Prick Hb Meter Vs HCT Lab

Table 8:

AUC:					
Test Result Variable(s)	**AUC:**	**Standard. Error :**	**Asymptotic Significance[a]**	**Asymptotic 95% Confidence Interval**	
				Lower Bound	**Upper Bound**
HCT+D1:E242_hbmeter_prick	0.516	0.037	0.662	0.444	0.588
HCT_lab	0.547	0.036	0.197	0.476	0.619

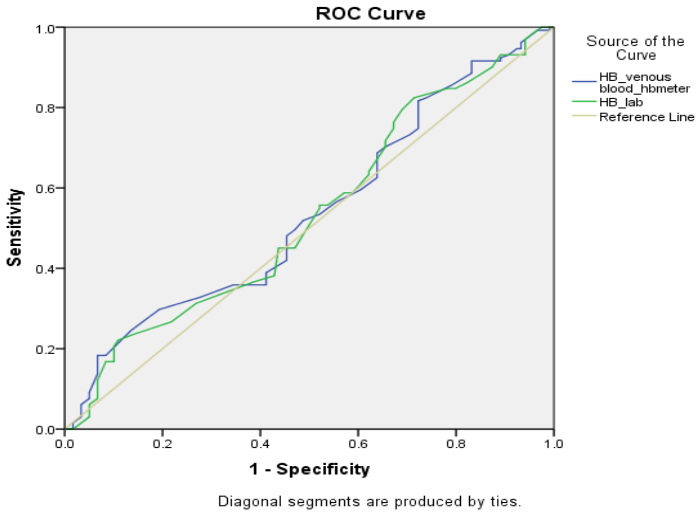

Figure 3: Hb Venous Blood Hb Meter Vs Hb Lab

Table 9:

Area Under the Curve					
Test Result Variable(s)	**AUC**	**Standard Error**	**Asymptotic Significance**	**Asymptotic 95% Confidence Interval**	
				Lower Bound	**Upper Bound**
HB_venous blood_hbmeter	0.539	0.037	0.288	0.467	0.611
HB_lab	0.534	0.037	0.352	0.462	0.606

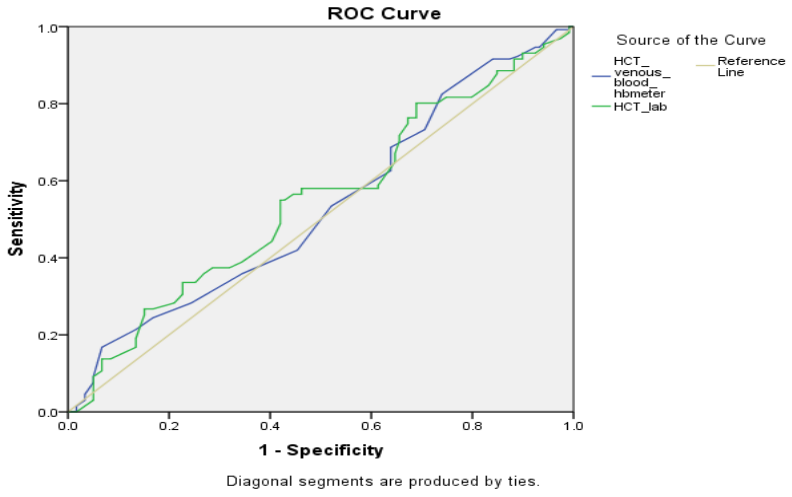

Figure 4: HCT Venous Blood Hb Meter Vs Hct Lab

Table 10:

AUC					
Variables :	**AUC :**	**Standard. Error :**	**Asymptotic Significance**	**Asymptotic 95% Confidence Interval**	
				Lower Bound	**Upper Bound**
HCT_venous_blood_hbmeter	0.533	0.037	0.375	0.461	0.604
HCT_lab	0.547	0.036	0.197	0.476	0.619

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, the precision of pocketchemhemog was estimated using samples from capillary and venous blood with that of the AHA in children aged 1 month to 12 years. We have also compared the accuracy of percentage increase or decrease in hematocrit values of pocketchemhemog using samples from capillary blood with that of venous blood using AHAin 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 analyser was 11.75± 1.96 while the venous blood mean concentration of Hb % using pocket chemhemog was 11.48± 1.91and with AHA was 11.75± 1.96.

The study result states that the mean Hb obtained by automated hematology analyser was more or less equal to that obtained by pocketchem hemog for the venous blood and capillary blood samples in our population age group (all p values < 0.01). Similarly, the mean HCT obtained by automated hematology analyser 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). The observed differentiation may be attributed to valid physiological variations in hemoglobin (Hb) levels between capillary and venous blood, differences in the accuracy and precision of measurement instruments, and variations in specimen collection and processing procedures before analysis.

A statistically significant and robust correlation was observed in Hb% values between the pocketchem hemog and automated hematology analyzer for both venous blood (r value = 0.895, p value < 0.0001) and capillary blood (r value = 0.656, p value < 0.0001) samples. A notably strong correlation in HCT values was found between the pocketchemhemog and automated hematology analyzer for both venous blood (r value = 0.793, p value < 0.0001) and capillary blood (r value = 0.640, p value < 0.0001) samples. Despite a small difference, the clinical significance of the correlation remains noteworthy.

Our study results diverged from those reported by Ashish Jain et al., [7] where the capillary HemoCue estimation displayed a more pronounced bias and wider range of agreement. The disparity in differences from the automated counter was notably lower for venous HemoCue comparison when juxtaposed with capillary HemoCue estimation (p value < 0.001 for each apparatus).

Sarvepalli Vijaya Kumar et al. conducted a study (reference 8) comparing hemoglobin assessment by HemoCue 301 and an automated hematology analyzer using flow cytometry. The mean value obtained from the automated hematology analyzer (11.965±1.012) was significantly higher than that from HemoCue Hb301 (11.697±1.312) (p=0.002). Their study also demonstrated a strong correlation between HemoCue Hb301 and the

automated hematology analyzer (r-value = 0.732, p<0.0001), aligning with our study findings. The conclusion drawn emphasized the utility of HemoCue in various settings, highlighting its advantages and cost-effectiveness compared to automated hematology analyzers. They recommended further investigations to better comprehend measurement errors.

In contrast, our recent study contradicted the results presented by Hinnouho G-M et al. [9], revealing a noteworthy discrepancy. In our study, mean capillary hemoglobin (Hb) levels measured with HemoCue Hb301 were consistently higher than mean venous Hb levels determined by two automated hematology analyzers. Irrespective of the blood sample type (both capillary and venous), HemoCue Hb301 consistently indicated elevated Hb levels compared to the automated hematology analyzers. In summary, our study concluded that the agreement among Hb concentrations of capillary and venous were estimated using Hemocue Hb301 was not upto the mark in comparison to venous Hb measured by automated hematology analyzers, resulting in 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 In a separate study conducted by Bhaskaram et al. [11] on seemingly healthy children aged 1 to 6 years, it was observed that the Hemocue method yielded higher mean hemoglobin values compared to the cyanmethemoglobin method. According to the Hemocue method, 66% of the children were classified as anemic, while the cyanmethemoglobin method identified 88%, indicating a disparity from our current findings. This discrepancy raises concerns about the suitability of HemoCue for use in diverse study populations. A study done by Silvita Fitri Riswari [12] et al compared the hematocrit values betwen capillary hematocrit by Hemocue and AHA 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 haemoglobin values by point of care haemoglobin devices (capillary method) with automated analyser 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.

Nevertheless, a direct comparison between the outcomes of our study and those of prior investigations proved challenging. This limitation stemmed from various factors, including the use of distinct point-of-care devices employing different biochemical methods for estimating Hb levels. The age of study participants, diverse settings, ethnicities, and whether Hb assessments were conducted on capillary or venous blood samples, as well as fasting or non-fasting blood samples, also contributed to the complexity of comparing results.

Our study addressed this challenge by conducting assessments on both capillary and venous blood samples, comparing them with venous blood samples analyzed

through an automated analyzer. This distinctive approach enhances the uniqueness, authenticity, and reliability of our study. 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 haematocrit levels, this strongly supports the potential use of Pocketchem Hemog Hemoglobinometer for monitoring of severity in dengue using haematocrit.

Limitations and Future Directions: While the study identified several statistically significant outcomes affirming the device's accuracy, certain limitations should be acknowledged. The sample size utilized was relatively modest, and the study was confined to a controlled hospital environment. In terms of generalizability, further research with a larger and more diverse sample size in varied settings is imperative to gain a deeper insight into the true accuracy of pocketchemhemog devices. Additionally, understanding the operational feasibility of integrating these devices into existing public health programs in India requires further investigation.

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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