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Non-invasive TensorTip MTX Hemoglobin Measurement Validation Study

Non-invaziv TensorTip MTX Hemoglobin Ölçümü Validasyon Çalışması

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Abstract

Objective: Point of care devices are fast and easy to use but their true potential is still waiting to come up. TensorTip MTX is a non-invasive medical device can measure various bioparameters, including hemoglobin. Purpose of this study is to measure the correlation between TensorTip MTX and our routine laboratuvary analysis of hemoglobin and to see that device is useable in emergency department settings for situations like gastroinstestinal bleeding and acute traumatic hemorrhages.

Methods: In the month after the ethical board approval, we conduct our study in 147 patients. Their hemoglobin levels were already measured while their course of emergency department visit. To gather accurate data of hemoglobin measurement of TensorTip MTX, device put on the ring finger of the patients and wait at least 45 seconds for measurement. All measurement documented and recorded by researcher. Measurements from blood samples and TensorTip MTX device are compared with intraclass correlation coefficient (ICC) and Pearson correlation coefficient.

Results: In 147 patients; 61.2% (n=90) were male, 38.8% (n=57) were female and ages are between 18 and 89. Mean age is 55.72±20.30 years; 23.1% (n=34) of them is under 35 years old, 76.9% (n=113) over 35 years. Statistically, the correlation between hemoglobin levels measured by the reference method and TensorTip was found to be 42.4%, which is statistically signficant (p=0.001; p<0.01) [ICC: 0.424; 95% confidence interval (CI): 0.281-0.548]. Correlation between hematocrit level measurements is 46.9% significantly compatible (p=0.001; p<0.01) (ICC: 0.429; 95% CI: 0.333-0.586).

Conclusion: Our study showed that correlation between reference measurement and TensorTip MTX device is fair (ICC: 0.424 for hemoglobin and 0.429 for hematocrit). Further studies needed to determine that this device is suitable or not to identify the need of blood transfusion and management of patients with acute hemorrhages in the emergency settings for now.

Keywords: Non-invasive, hemoglobin, emergency

Öz

Amaç: Hasta başı ölçüm yapabilen cihazların kullanımı kolay ve hızlıdır ancak tam potansiyelleri halen ortaya çıkmamıştır. TensorTip MTX non-invaziv olarak hemoglobin de dahil olmak üzere pek çok vital parametreyi ölçebilen bir cihazdır. Bu çalışmanın amacı TensorTip MTX adlı cihazın ölçtüğü hemoglobin değerlerini rutin laboratuvar analizleri ile karşılaştırarak, bu cihazın acil serviste gastrointestinal kanama ve akut travmatik kanama gibi durumlarda kullanılabilirliğini değerlendirmektir.

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Öz

Yöntem: Etik kurul onayı alındıktan sonraki ay içinde çalışmaya dahil edilen 147 hasta üzerinde ölçüm yapılmıştır. Acil servise başvuruları sorasındaki süreçte venöz kandan hemoglobin değerleri ölçülmüştür. TensorTip MTX cihazı ile doğru ölçüm yapabilmek için, 45 saniye boyunca hastaların yüzük parmağından ölçüm yapılmıştır. Toplanan her veri araştırmacı tarafından kaydedilmiştir. Kan örneklerinden ve TensorTip MTX ile ölçülen hemoglobin seviyeleri sınıf içi korelasyon katsayısı (ICC) ve Pearson korelasyon katsayısı ile karşılaştırılmıştır.

Bulgular: Toplamda 147 hastanın %61,2'si (n=90) erkek, %38,8'i (n=57) kadın ve yaş aralığı 18 ile 89 arasındaydı. Ortalama yaş 55,72±20,30; %23,1'i (n=34) 35 yaş altındaydı, %76,9'u (n=113) 35 yaşın üstündeydi. Referans değer ile TensorTip hemoglobin ölçümleri arasındaki %42,4 düzeyinde istatistiksel olarak anlamlı uyum saptandı (p=0,001; p<0,01) [ICC: 0,424; %95 güven aralığı (CI): 0,281-0,548]. Referans ile TensorTip hematokrit ölçümleri arasındaki %46,9 düzeyinde istatistiksel olarak anlamlı uyum gözlendi (p=0,001; p<0,01) (ICC: 0,429; %95 CI: 0,333-0,586).

Sonuç: Çalışmamız gösterdi ki referans ölçümler ile TensorTip MTX cihazı arasındaki korelasyon orta düzeydedir (hemoglobin için ICC: 0,424, hematokrit için ICC: 0,429). Eldeki verilerle şu an için kan transfüzyonu yapılmasına karar vermekte ve akut kanamalı hastaların acil servis yönetiminde bu cihazların kullanımının uygunluğunu değerlendirmek için daha fazla çalışmaya ihtiyaç duyulmaktadır.

Anahtar Kelimeler: Non-invaziv, hemoglobin, acil servis

Introduction

Anemia can present with several symptoms that require emergency care. Anemia caused by trauma, gastrointestinal bleeding, and chronic diseases requires immediate and accurate diagnosis in the emergency department. Prompt treatment is essential. Anemia may not always be detectable by physical examination; therefore, evaluation of hemoglobin and hematocrit values is necessary. It is often impossible to determine these values at the patient's bedside. Delaying the diagnosis of anemia can affect patient outcomes. Devices that can continuously measure at the patient's bedside can assist clinicians in monitoring and guiding treatment for various diseases. Pulse oximeters, which are widely used in clinics today, are pioneering bedside measurement devices.

Devices that enable bedside measurements are easy to use, portable, fast, and inexpensive, making them highly suitable for emergency departments or disaster situations. The rapid results obtained with these devices allow clinicians to use their time more efficiently, thereby accelerating the diagnosis and treatment process.

Although there was initial skepticism when pulse oximeters were first used, years later, Severinghaus noted that there was a 90% decrease in anesthesia-related deaths coinciding with the introduction of pulse oximeters. Rapid and continuous measurement of vital parameters, such as pulse oximeters, is crucial for clinical decision-making[1].

Continuous monitoring of hemoglobin levels in a fast and non-invasive manner in the clinic can provide significant benefits in cases such as trauma and gastrointestinal bleeding. With these devices, excessive transfusions can be avoided in patients with active bleeding or those undergoing surgery.

In this study, we aimed to determine the correlation between the hemoglobin and hematocrit values measured using the TensorTip MTX device (CNoga Medical Ltd., OrAkiva, Israel) and the laboratory values obtained from venous blood to enable faster detection and treatment of anemia in the emergency department.

The history of the oximeter began in 1876 in the city of Tübingen, Germany, where Karl von Vierordt at the university measured the spectral changes in light passing through the tissue when the circulation was cut-off. However, these studies were ignored until Ludwig Nicolai developed a device in 1931 to measure the transmission of red light. In 1939, Karl Matthes introduced an ear oximeter that balances red and infrared light. Squire was the first to notice the change in transmission of red and infrared light in the hand when he cut-off circulation using a pressure cuff in 1940. The pulse oximeter can be considered a continuation of Squire's device and idea[1].

The development of oximeters gained momentum during World War II to protect fighter pilots from dangerous hypoxia. The term "oximeter" was coined in 1942 by Glen Millikan, who developed lightweight, red, and infrared ear oximeters[1].

Earl Wood and his student J. E. in 1949, Geraci combined Millikan's ear device with Squire's pressure cuff in 1949. Wood expanded and mathematically developed Squire's idea by measuring the ratio of red to infrared light intensity under pressure and reperfusion[1]. The pulse oximeter was invented in 1974 by Takuo Aoyagi at Nihon Kohden, but its

clinical use was intially limited due to accuracy concerns regarding oxygen saturation (SpO_2). Initial studies showed differences of >6% during normoxia and 10-20% during hypoxia between arterial blood oxygen saturation (SaO_2) and SpO_2, and familiar signal decreases and errors were observed during movement or low perfusion. Despite these limitations by the late 1980s, pulse oximetry has become a standard in healthcare. In 1989, Tremper and Barker reported that pulse oximetry was one of the most important developments in non-invasive monitoring because it continuously and rapidly evaluates oxygen saturation[1]. Years after these studies, the reliability and benefits of the oximeter have made its routine use essential for patient monitoring in clinics. Devices capable of non-invasive hemoglobin measurement appear to follow a similar path.

Currently, various devices are available for non-invasive hemoglobin measurement, including the NMB200 (OrSense Ltd., NesZiona, Israel), Radical-7, Rad-87, Pronto-7, and Pronto (Masimo Corp., Irvine, CA, USA). However, the practical use and reliability of these devices are limited. In a study conducted by Rice et al.[2] in 2013, it was concluded that the Radical-7 system was insufficient for making transfusion decisions. Similarly, in a study conducted by Lindner and Exadaktylos[3] in 2013, Masimo systems were used for continuous hemoglobin measurement; promising results were obtained when compared with HemoCue capillary measurements and routine laboratory analyses, suggesting that they could help improve patient management. The TensorTip MTX device in our study uses the color distribution of peripheral blood tissue to measure specific vital parameters and biomarkers.

TensorTip MTX Device Structure

a) Hardware: The device consists of a soft gel cover containing the upper part of the finger compartment and a base on which the sensor is protected by a lens located at the bottom. A monitor screen was placed behind the cover. The device contains 4 light emitting diode (LED)s in four different wavelengths, from visible light to infrared (625-950 nm). The image sensor detects light spectra between 350 and 1200 nm. A rechargeable battery can also be used as a power source[4].

b) Software: The device consists of a medical subsystem and microcontroller unit (MCU) containing the color image sensor, LEDs, and digital signal processor (DSP), and a control subsystem containing four buttons, a screen, and additional sensors. The DSP software is responsible for image acquisition, image processing, light control testing, and the collection of clinical parameter values. The MCU software is responsible for user interfaces, process management, data storage, and power management[4].

Indications for Use

The non-invasive TensorTip MTX, produced by Cnoga Medical, is a small, lightweight, portable device developed to measure and display blood pressure (systolic and diastolic), oxygen saturation (SpO_2), peripheral pulse rate, hemoglobin, hematocrit, mean arterial pressure, partial O_2 pressure (PO_2), partial CO_2 pressure (PCO_2), cardiac output, pH, red blood cell count, and some additional parameters. Measurements were performed using capillary finger tissue (excluding the thumb). The ring finger is recommended for this procedure. The device was designed for home use and can be used in blood donor clinics[4].

Materials and Methods

Our study was conducted prospectively in the Emergency Department of University of Health Sciences Turkey, Kartal Dr. Lütfi Kırdar City Hospital within one month of obtaining ethical approval on 14.01.2016 (decision number: 2016/514/75/7).

Patients aged >18 years who presented to our emergency department and agreed to participate in the study by signing an informed consent form were included in the study. Patients who did not provide consent, were under 18 years of age, were pregnant, or could not undergo measurements on their fingers due to physical limitations were not included in the study.

Two milliliters of venous blood was taken in an ethylenediaminetetraacetic acid vacutainer (Becton, Dickinson and Company, Franklin Lakes, NJ, USA) from patients participating in the study for their current treatments, or tests were measured in the LH 780 analyzer (Beckman Colter, Inc., Brea, CA, USA) to determine reference values. For LH 780, the accuracy of device measurements with control samples was tested twice a day. The TensorTip MTX device was placed on the patients' ring fingers as specified in the user manual, and hemoglobin and hematocrit values were measured within 45s. The data obtained were recorded by the researcher, and no changes were made to the patients' treatments or interventions.

Statistical Analysis

The NCSS (Number Cruncher Statistical System) 2007 program was used for the statistical analysis. Descriptive

statistical methods (mean, standard deviation, median, frequency, ratio, and minimum and maximum) were used to evaluate the study data.

The Pearson correlation analysis was used to evaluate the relationship between hemoglobin levels and hematocrit measurements. The intraclass correlation coefficient (ICC) was used to evaluate the pairwise agreement between the LH 780 and TensorTip measurements. Statistical significance was evaluated at $p<0.01$ and $p<0.05$.

Results

The study was conducted with a total of 147 cases at the University of Health Sciences Turkey, Kartal Dr. Lütfi Kırdar City Hospital between 14.01.2016 and 14.02.2016. The demographic characteristics of the patients are presented in Table 1.

The hemoglobin and hematocrit measurements of the subjects using both the LH 780 and TensorTip MTX devices are shown in Table 2.

The relationship between LH 780 and tensor type hemoglobin/hematocrit is shown in Table 3, and the correlation is shown in Figure 1. A moderate agreement was observed between the LH 780 and TensorTip devices for both hemoglobin (HGB) and hematocrit (HCT) measurements, with ICC values of 0.424 for HGB and 0.469 for HCT, both of which were statistically significant (p=0.001). Gender-based analysis showed stronger agreement in male patients (ICC=0.460 for HGB and 0.484 for HCT, p=0.001) than in females, where agreement was weaker, particularly for HGB (ICC=0.301, p=0.011), although it was still significant for HCT (ICC=0.400, p=0.001). Age-based analysis revealed no significant agreement for HGB in patients under 35 years of age (ICC=0.233, p=0.089), but moderate agreement for HCT (ICC=0.371, p=0.014). For individuals aged 35 years and older, the agreement was stronger, with ICC values of 0.472 and 0.492 for HGB and HCT, respectively (p=0.001).

Table 1. Age and gender distribution

Age (year)	Min-max (Median)	18-89 (59)
	Mean ± standard deviation	55.72±20.30
Age groups; n (%)	<35 age	34 (23.1)
	≥35 age	113 (76.9)
Gender; n (%)	Male	90 (61.2)
	Female	57 (38.8)

Table 2. Distribution of hemoglobin and hematocrit measurements

LH 780 HGB	Min-max (median)	2.8-17.0 (10.1) g/dL
	Mean ± SD	10.44±3.17 g/dL
TensorTip MTX HGB	Min-max (median)	5.4-17.4 (12.2) g/dL
	Mean ± SD	11.84±2.56 g/dL
LH 780 HCT	Min-max (median)	10.5-52.3 (31.1)%
	Mean ± SD	32.16±9.47%
TensorTip MTX HCT	Min-max (median)	17.0-50.0 (34.0)%
	Mean ± SD	34.46±7.25%

HGB: Hemoglobin, HCT: Hematocrit, SD: Standard deviation

Discussion

Devices that can measure hemoglobin at the bedside are suitable for use in emergency rooms or in disaster situations because of their ease of use, portability, speed, and affordability. The rapid results obtained with these devices allow clinicians to use their time more efficiently, which in turn accelerates the diagnosis and treatment process, which is of critical importance.

The emergence of devices capable of non-invasive measurement of hemoglobin levels occurred after 2010. These devices are developed for continuous hemoglobin monitoring and have been used in many different clinical applications. Studies have evaluated various areas, from identifying blood donors to continuously measuring hemoglobin levels in patients during surgery, and different results have been obtained.

All studies were conducted using major devices, but the methods and objectives of the studies varied. In their 2011 study, Miller et al.[5] performed continuous hemoglobin monitoring with Radical-7 in 20 patients undergoing spinal surgery and compared these measurements with measurements taken with arterial blood gas and HemoCue. Their study showed that non-invasive hemoglobin measurement may not be accurate enough in some patients. As expected, more accurate results were obtained as the perfusion increased. They stated that, as technology advances, these devices could be used as standard monitors for patients at risk of bleeding.

In a study conducted in 2012 by Gayat et al.[6], where both the NMB-200 and Pronto-7 devices were used, they compared the measurements of the devices but stated that the clinical benefits of these devices are currently open to debate. In another study conducted in the same year, Kim et al.[7]. The reliability of the NBM-200 device with HemoCue and LH500

Table 3. LH 780 and TensorTip hemoglobin/hematocrit correlation

			LH 780/TensorTİP hemoglobin correlation	LH 780/Tensor Tip hemotocrit correlation
Total (n=147)		**ICC**	0.424	0.469
		p	**0.001****	**0.001****
Gender	**Male (n=90)**	**ICC**	0.460	0.484
		p	**0.001****	**0.001****
	Female (n=57)	**ICC**	0.301	0.400
		P	**0.011***	**0.001****
Age (year)	**<35 age (n=34)**	**ICC**	0.233	0.371
		p	**0.089**	**0.014***
	≥35 age (n=113)	**ICC**	0.472	0.492
		p	**0.001****	**0.001****

ICC: Intraclass correlation coefficient, **: p<0.01, *: p<0.05

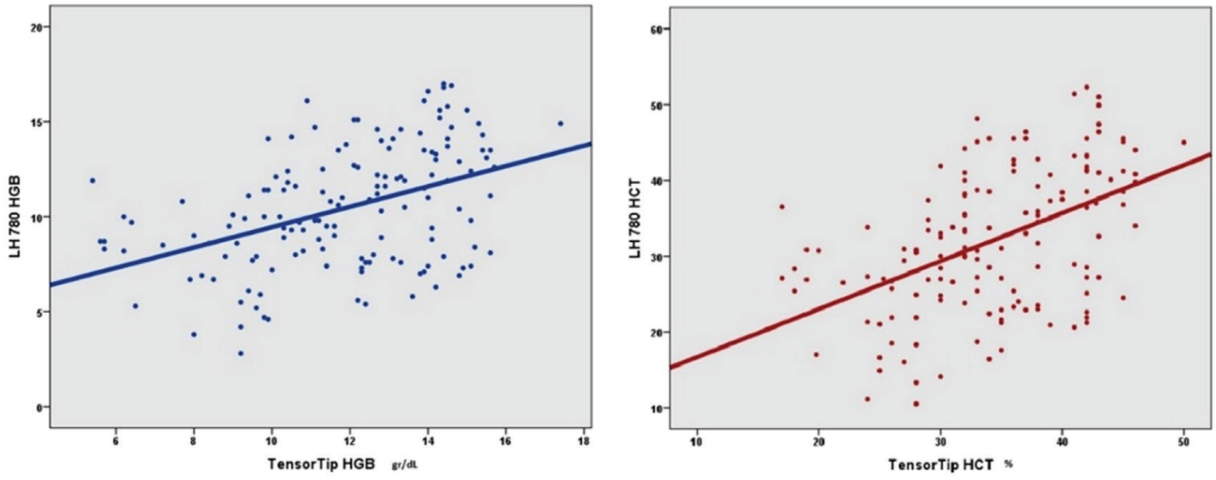

Figure 1. Correlation between LH 780 and TensorTip hemoglobin and hematocrit measurements

HGB: Hemoglobin, HCT: Hematocrit

to determine the suitability of blood donors was compared; however, they mentioned that the non-invasiveness of the device is advantageous for determining the suitability of a patient for blood donation.

Masimo Corp. devices have been used in several studies. In their study of patients in the intensive care unit in 2011, Frasca et al.[8] found that measurements made with Radical-7 were equivalent to the reference measurements. They stated that the use of this device for continuous hemogram monitoring would be beneficial in intensive care units. Rice et al.[2] evaluated the results of many studies using Radical-7 in their review in 2013 and stated that the main purpose of using these devices in operating room conditions is to determine the need for transfusion; however, with the available data, they stated that it does not currently guide clinicians when making transfusion decisions. In a study conducted by DeBarros et al.[9] in 2014 using the Pronto-7 device with the same infrastructure, the device showed a high correlation (r=0.77) with reference values, but in the same study, a weak correlation (r=0.251) was found in patients with anemia.

In an evaluation in which the studies were examined again, Lindner and Exadaktylos[3] concluded that the results of these studies are promising and could be useful in many healthcare settings in the future.

In 2015, Barker et al.[10] three studies that compared devices capable of non-invasive hemoglobin measurement were evaluated. As a result of the evaluation, the authors predicted that one day these devices would reach the accuracy of invasive hemoglobin measurements and could replace them. They also stated that continuous and real-time measurements of these devices could benefit clinicians in monitoring patients, reduce unnecessary transfusions, and save lives by identifying the need for transfusion at the right time, especially in patients with occult bleeding. They mentioned that in the future, these devices will be used as pulse oximeters are currently used[10].

These studies show that although both the NMB-200 and Masimo Corp. devices achieve promising results, they still need further development and time to be used safely in clinical applications. In the coming years, non-invasive hemoglobin monitoring will probably have an indispensable place in clinics for patient monitoring, just like the story of the same pulse oximeter. However, the use of these devices and the related studies are limited. Many clinicians are unaware of these devices or do not have access to them. The widespread use of these devices and the data obtained from these studies will undoubtedly accelerate the development of these devices. With the advancement of technology, we hope that these devices will be used safely for hemoglobin monitoring in the near future.

In 2018, Segman and Sheiman[11] reported that the TensorTip MTX device provided the best solution for the increasing need for rapid, painless monitoring devices in telemedicine, rural areas, community clinics, and homes. However, in 2023, Servaas et al.[12] found that the non-invasive measurements of Hb, Ht, pCO_2, and pO_2 made by the TensoTip MTX device were not as accurate and precise as conventional laboratory measurements, and its use was not recommended in perioperative surgical patients. Nevertheless, the device could still be useful in another setting.

Study Limitations

The many different diagnoses among the selected patients in our study can be considered a limitation in terms of standardization. Additionally, the perfusion index of the patients was not considered before the measurement. It can be anticipated that there may be deviations in the values measured by the TensorTip MTX device in patients with low perfusion index due to the hardware features of the device. In the comparison of hemograms of the sample group, statistically significant differences were not observed in the <35 years age group, which was the smallest group. This result can be attributed to the small sample size.

Conclusion

In our study, a weak correlation was found between the hemogram and hematocrit measurements performed using the reference device and TensorTip MTX (ICC: 0.424 for HGB, ICC: 0.469 for HCT). Further studies are required to evaluate the efficacy and potential benefits of using this device in emergency department settings.

Although many studies have reported the accuracy of these devices, more work and time are needed to fully exploit their potential, as in our study.

In the future, with the development of TensorTip MTX hardware and software, it may be possible to use it in the management of treatment and hemoglobin monitoring in patients with acute bleeding; however, in our study, the use of the TensorTip MTX device in ED conditions was not considered sufficient for clinical decision-making.

Ethics

Ethics Committee Approval: Our study was conducted prospectively in the Emergency Department of University of Health Sciences Turkey, Kartal Dr. Lütfi Kırdar City Hospital within one month after receiving the ethics committee approval on 14.01.2016 (decision number: 2016/514/75/7).

Informed Consent: A written informed consent form was obtained from all patients.

Footnotes

Authorship Contributions

Surgical and Medical Practices: E.G., F.S.D., G.A.U., Concept: E.G., F.S.D., Ö.G., Design: E.G., F.S.D., Ö.G., Data Collection or Processing: E.G., F.S.D., G.A.U., Analysis or Interpretation: E.G., F.S.D., G.A.U., Ö.G., Literature Search: E.G., F.S.D., G.A.U., Ö.G., Writing: E.G., F.S.D., Ö.G.

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