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Original article

Validation of Safety and Efficacy of Real Time Multi Vital Remote Monitoring in Patients with Chronic Ischemic Heart Disease

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Abstract

Background: The emerging role of technology in health settings is paving the pathway for novel ways to manage chronic diseases. In recent times, continuous remote monitoring of vital signs using wearable devices has gained immense interest because it enables real-time access to patient data from anywhere. ***Aim:*** The objective of this study was to correlate the vital parameters; including ECG, pulse rate, respiratory rate, temperature, heart rate, oxygen saturation, and blood pressure; derived from Real Time Multi vital remote monitoring (RTMVRM) solution and standard vital monitoring methods in chronic ischemic heart disease patients, stable on medication. ***Methods:*** A total of 199 patients with confirmed diagnosis of chronic ischemic heart disease, stable on medication, presenting to the Department of General Medicine in ESIC Medical College and Hospital, Hyderabad, were enrolled into the study. The data for Vital parameters was obtained from the subjects at prespecified time points for a 24 hr duration using both RTMVRM and standard methods under direct and continued supervision of the physician. The Spearman's rank coefficient of correlation was used to evaluate the correlation between the data obtained from RTMVRM solution and standard measurements. The study also examined the safety and efficacy of the RTMVRM using the Vigo Vitals solution. ***Results:*** The vital parameters showed statistically significant ($p<.0001$) positive correlations (spearman) between the RTMVRM solution and standard measurements for pulse rate (0.9418), respiratory rate (0.96766), temperature (0.82103), heart rate (0.98522), systolic BP (0.97468), diastolic BP (0.90832) and SpO2 (0.99620) at 24th hour. The ECG data showed statistically significant ($p<.0001$) positive correlations (spearman) between the RTMVRM solution and standard measurements for P-wave 0.94749, PR-interval 0.93432, QRS-complex 0.95305, RR-interval 0.66011, QT-interval 0.77310, ST-segment 0.97749 and T-wave 0.95881 at 24th hour. Vigo vitals solutions reported 99% accuracy with 99% sensitivity and 100% capture rate. No device related serious adverse events were reported during the study. ***Conclusion:*** The results of this study validated the remote monitoring technology of RTMVRM, a cloud technology based vital monitoring solution. With its ability to offer access to continuous vitals in real time, RTMVRM may enable quick clinical decisions, prevent complications, and enable care providers to stay ahead of the disease. Both the clinician and the patient's satisfaction were guaranteed by the solution, with accuracy and precision in vital monitoring and a decluttered monitoring experience.

Keywords: ***Ischemic Heart Disease, Vital Monitoring, Remote monitoring, Electrocardiogram, Vigo vitals solution***

Introduction

Ischemic heart disease (IHD) is one of the common cardiovascular diseases. According to World Health Organization (WHO), it is estimated that IHD is responsible for 8.9 million deaths in 2019, accounting for 16% of total deaths worldwide. According to Global burden of disease data, IHD accounts for the loss of >182 million disability-adjusted life-years (DALYs) and >176 million years of life due to premature mortality in 2019 alone. Thus, it is important to continuously monitor patients with chronic ischemic heart disease [1-3].

Rapid advances in technology with five foundational techniques like semi-conductors, networking, cloud computing, data analytics has revolutionized various fields including medical care, healthcare, and clinical research fields, which is evincing keen interest in the application of technology [4]. The COVID-19 pandemic has also played a part in pushing healthcare systems worldwide to their limits, thus highlighting the glaring critical

demand for reliable, efficient, and accurate remote healthcare services to fill the inevitable gaps in healthcare [5].

Remote patient monitoring belongs to the telemedicine category of eHealth applications and offers the benefits of improved access to care, early detection of health issues, enhanced patient engagement, improved health outcomes, and cost-effective management of chronic conditions. Remote patient monitoring involves the monitoring of patients and transmission of medical data such as vital parameters to the health care providers through a centralized command center. This technology helps clinicians to monitor the data in real time [6].

Cardiac arrhythmia is one of the serious medical conditions that needs early detection. Remote monitoring of the electrocardiogram (ECG) can help detect elevated heart rate and rhythm changes in people with palpitations or paroxysmal atrial fibrillation. The RTMVRM Vigo care solution distinguishes itself from comparable products in the market by offering ECG recordings and immediate real-time ECG analysis.

RTMVRM is a cloud technology-based integrated vital monitoring solution developed by Vigo Care Pvt. Ltd. The purpose of this study was to correlate the vital parameters including pulse rate, respiratory rate, temperature, heart rate, oxygen saturation, blood pressure, and ECG derived from RTMVRM solution and standard vital monitoring methods in chronic ischemic heart disease patients who were stable on medication.

Materials and Methods

Study design

The objective of this single-centre, prospective, multiple arm study was to validate the vital parameters using Remote Monitoring Technology in chronic IHD patients. The study was conducted in the Department of General Medicine in ESIC Medical College and Hospital, Hyderabad. All participants were educated about the study objectives before signing an informed consent form.

Participants

The eligibility of patients participating in the study was based on discrete inclusion and exclusion screening criteria. A total of 199 subjects were enrolled in the study who were aged between 18 to 65 years of either gender with known chronic IHD, stable on medication who consented to comply with all study procedures. Patients with a history of contact dermatitis or hypersensitivity to patch material, regular smokers, and expressing difficulty in abstaining from smoking for 48 hours before the study and those with clinically significant physical disability were excluded from the study.

Finally, the included patients were onboarded with vigo vitals (Vigo care pvt. Ltd., Hyderabad), a comprehensive device consisting of a chest patch (biosensor, Vivalnk model VV330) placed on chest just below the clavicle bone on the left side of the chest with an adhesive, a rechargeable axillary temperature patch (model VV200), a non-invasive BP cuff (rechargeable, model Viatom BP2A), a pulse rate and SpO2 probe (rechargeable, Viatom Checkme O2) and a bedside monitoring tab. Philips Early Vue VS30 vital sign monitor which is FDA approved medical device was used to monitor the vitals (PR, BP, RR, SpO2, temperature and HR) and a FDA approved and CE marked device was used for recording ECG (CardioCare 2000- 12 Channel ECG) as control or standard method.

The on boarding with RTMVRM solution was performed in the morning in a quiet room with controlled temperature and continued for 24 hours. The participants were then allowed to sit comfortably on a chair for 2 hours followed by vitals examination using the standard methods recorded periodically at 0, 2, 4, 6, 8, 10, 12, and 24 hours respectively. All participants were served standard breakfast after 2 hours and lunch at 6 hours post on-boarding. Subjects were in observation at the research site until 24 hours.

The primary safety end point was to evaluate contact dermatitis, discomfort or pain, infection at the site of application and allergic reactions. The secondary safety end point was to check for device dislodgement, false positives or negatives and battery related issues. The primary efficacy endpoint was to evaluate device success, sensitivity, specificity, capture rate and accuracy. The secondary efficacy end point was to analyze the duration of monitoring, user-friendly interface, false alarms and artifacts, patient comfort and compliance and technical reliability.

Definitions used in the study

Onboarding the patients with the device and capturing the required data can be considered as device success. Sensitivity is the ability of the test device to correctly classify an individual as diseased. The ability of a test to correctly classify an individual as disease- free is called the test′s specificity [7]. Positive predictive value and negative predictive value reflect the proportion of positive and negative results that are true positives and true negatives, respectively [8].

Data collection methods

Vital parameter data was collected from the study subjects through RTMVRM solution as well as the standard methods. RTMVRM is an integrated vital monitoring solution, which includes medical grade class B wireless devices, a bedside monitor, a nursing portal, a clinician app (Vigo Konnect), and a centralized command centre deployed at the research site. The product of Vigo Care Pvt. Ltd is a cloud-based technology platform that includes wireless biosensors to collect a variety of bio signals for data analysis and continuously records the vitals including pulse rate (PR), respiratory rate (RR), temperature, heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), oxygen saturation (SpO_2) and lead 2 ECG. The advantage of the solution is that it is wireless, non-restraint to day-to-day activities and offers access to continuous real-time remote monitoring of vitals, thus enabling quick clinical decisions. Both the clinician and the patient's satisfaction were guaranteed with accuracy and precision in vital monitoring and a decluttered monitoring experience. A schematic picture is depicted in Fig 1.

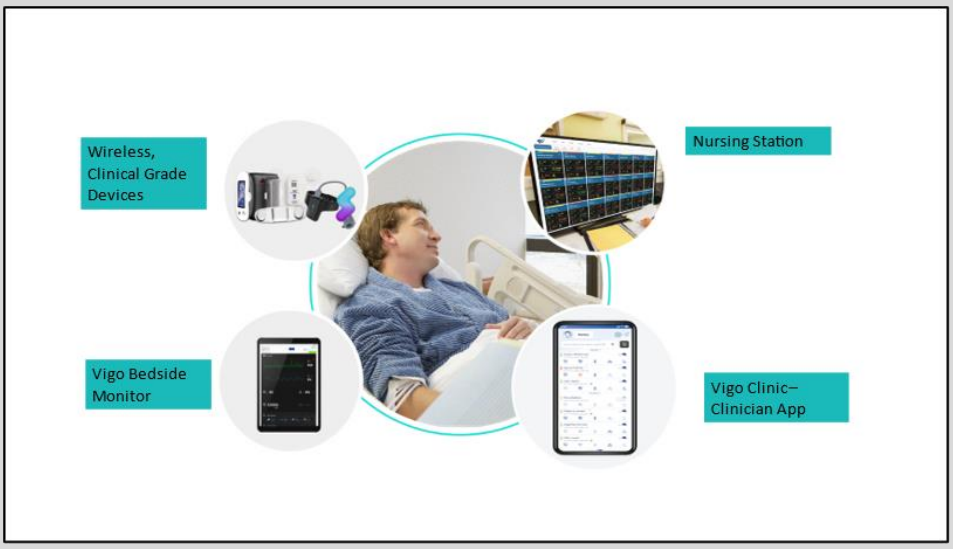

Fig 1: The schematic diagram -Vigo Vitals Solution Components

The Vigo Platform Working Model: The Scaena platform, utilizing wireless biosensors, enables real-time monitoring of vital signs and serves as the foundation for multiple built-in services for patient monitoring. Scaena is a classic Io(M)T (Internet of Medical Things) platform that enables multiple end points from Android and iOS eco systems (see Fig 2). These end points connect to various FDA approved biosensors to collect patient vitals continuously. The collected vitals are streamed continuously to the Vigo Engine at the backend running on Amazon Web Services (AWS) cloud. Vigocare Central Monitoring System (CMS) is an internal portal for Vigocare customer support staff. The portal is built using standard web development tools. CMS portal interacts with Scaena through secured Rest API layer exposed by Scaena.

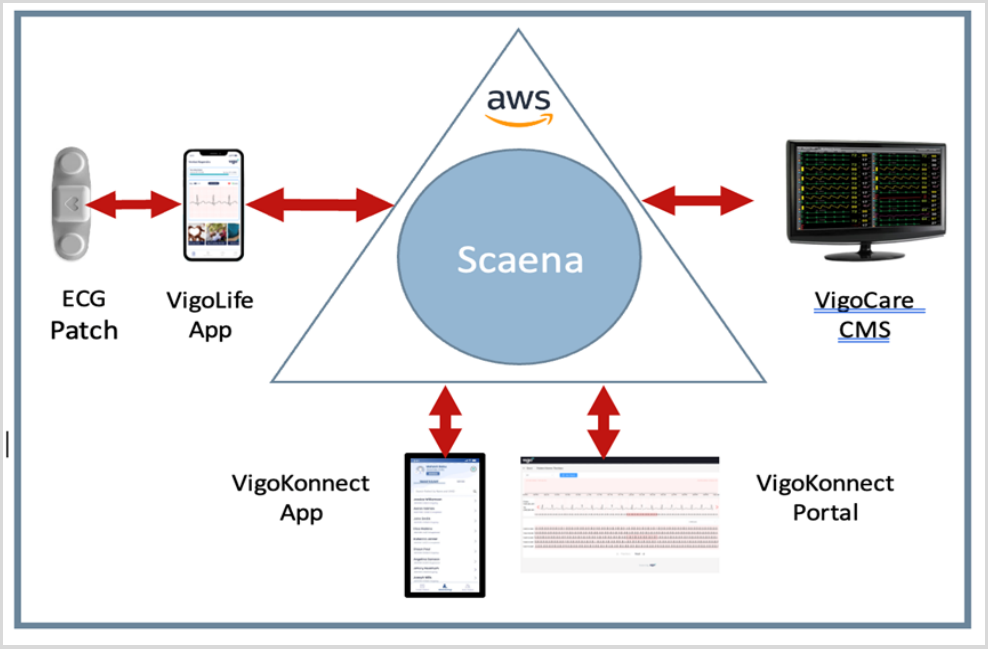

Fig 2: The Scaena Platform

Vigo Inference engine interprets the vitals and makes them available for care providers to make decisions such as

1. Present vital parameters as they are to the care givers.
2. Present interpretations like early warning alerts to care givers by utilizing various algorithms.
3. Uses internally built or FDA approved third party AI engines for data interpretation.

The platform is designed to be device agnostic, which means that the platform's core inference engine does not depend on the specific device for a vital to be collected. The vigo platform was certified with ISO 13485:2016 and Medical Device Single Audit program (MDSAP) for quality management systems and data protection 27001. All devices integrated into Vigo Scaena platform were CE/FDA approved devices. The data was captured and stored in IoT Platform over the cloud.

Statistical Analysis

Descriptive statistics and the Spearman's rank coefficient of correlation were used to analyze the data obtained. The Spearman's rank coefficient of correlation was used to evaluate the correlation between the data obtained from RTMVRM solution and standard measurements. Statistical analyses were made using the statistical software SPSS (version 2.0, IBM, Chicago).

Results were summarized as mean and standard deviation (SD) for quantitative data and as numbers (%) for categorical findings.

Results

Demographic Characteristics

The study involved 199 patients with chronic ischemic heart disease. The age of the patients ranged from 18-69 (Mean ± SD is 42.2 ± 13.0, Median is 43.0), those aged between 18-40 years were 89 (44.7%), those aged between 41-60 years were 91 (45.7) and patients who aged >60 years were 19 (9.5%) with 158 identified as men and 39 as women. Two patients could not complete the 24hrs duration of monitoring, (see Table 1) hence leaving follow-up data for 197 patients. All the patients were successfully onboarded for monitoring vitals and ECG. The vital parameters and ECG measurements of 197 patients i.e., Mean ± SD, Median, minimum and maximum values for each parameter evaluated are summarized in Table 2.

Table 1: Summary of Demographic Characteristics

Variables	Age Range	N = 199
Age category n (%)	18 to 40	89 (44.7)
	41 to 60	91 (45.7)
	>60	19 (9.5)
	All subjects	199 (100)
Gender n (%)	Female	39 (19.6)
	Male	158 (79.4)
	Missing	2 (1.0)
Age (years)	N	199
	Mean ± SD	42.2 ± 13.0
	Median	43.0
	Min, Max	18, 69
Min = Minimum, Max = Maximum, SD = Standard deviation, N: number of Subjects		

Table 2: Summary of the Vital parameters and ECG measurements (Control vs Test)

Variable		Control (N=197)	Test (N=197)
Vital Parameters			
Pulse rate	Mean ± SD	82.5 ± 16.6	84.2 ± 16.7
	Median	82.0	84.0
	Min, Max	41, 131	42, 136
Respiratory rate	Mean ± SD	19.6 ± 4.7	20.5 ± 4.9
	Median	18.0	20.0
	Min, Max	11, 32	11, 35
Temperature	Mean ± SD	97.4 ± 1.2	97.7 ± 1.2
	Median	97.4	97.8
	Min, Max	92, 100	94, 100
Heart rate	Mean ± SD	82.9 ± 16.5	84.4 ± 16.5
	Median	82.0	84.0
	Min, Max	41, 131	42, 136
Systolic Blood Pressure	Mean ± SD	119 ± 17.1	122 ± 16.7
	Median	119	120
	Min, Max	65, 180	78, 186
Diastolic Blood Pressure	Mean ± SD	77.0 ± 13.3	79.3 ± 12.4
	Median	75.0	79.0
	Min, Max	39, 120	49, 121
Oxygen saturation SpO_2	Mean ± SD	97.6 ± 3.0	97.4 ± 3.0
	Median	98.0	98.0
	Min, Max	75, 99	75,100
ECG Measurements			
P-wave	Mean ± SD	0.078 ± 0.023	0.077 ± 0.024
	Median	0.08	0.08
	Min, Max	0.04, 0.16	0.04, 0.16
PR-interval	Mean ± SD	0.146 ± 0.037	0.142 ± 0.038
	Median	0.16	0.14
	Min, Max	0.04, 0.36	0.04, 0.36
QRS-complex	Mean ± SD	0.071 ± 0.028	0.068 ± 0.028
	Median	0.08	0.08
	Min, Max	0.04, 0.20	0.04, 0.20
RR-interval	Mean ± SD	0.766 ± 0.190	0.748 ± 0.188
	Median	0.76	0.72
	Min, Max	0.10, 1.48	0.10, 1.58
QT-interval	Mean ± SD	0.374 ± 0.062	0.400 ± 0.064

	Median	0.36	0.40
	Min, Max	0.12, 0.60	0.12, 0.60
ST-segment	Mean ± SD	0.120 ± 0.047	0.121 ± 0.046
	Median	0.12	0.12
	Min, Max	0.04, 0.32	0.04, 0.32
T-wave	Mean ± SD	0.139 ± 0.048	0.140 ± 0.047
	Median	0.12	0.12
	Min, Max	0.04, 0.40	0.04, 0.40
Min = Minimum, Max = Maximum, SD = Standard deviation, N: number of Subjects			

Correlation between the data obtained from RTMVRM solution and standard measurements.

Vital parameters

The Spearman's rank coefficient of correlation was used to evaluate the correlation between the vital parameter data obtained from RTMVRM solution and standard measurements. The results showed that there were statistically significant positive correlations between the RTMVRM solution and standard measurements for the vital parameters measured at the 4th hour and 24th hour time points as presented in Table 3.

Table 3: Correlation co-efficient of Vital Parameters between control vs test at 4th hour and 24th hour

Parameter	4th Hour		24th Hour	
	ρ (rho) (Control vs Test)	P-value	ρ (rho) (Control vs Test)	P-value
Pulse rate	0.98745	<.0001	0.98418	<.0001
Respiratory rate	0.91751	<.0001	0.96766	<.0001
Temperature	0.94133	<.0001	0.82103	<.0001
Heart rate	0.98629	<.0001	0.98522	<.0001
Systolic BP	0.96774	<.0001	0.97468	<.0001
Diastolic BP	0.86505	<.0001	0.90832	<.0001
SpO2	0.97561	<.0001	0.99620	<.0001
ρ (rho) - Spearman correlation coefficient				

ECG measurements

Spearman's rank correlation coefficient was used to assess the relationship between ECG measurements obtained from the RTMVRM solution and the conventional measurements. The findings revealed notable and statistically significant positive correlations between the RTMVRM solution and standard measurements for the ECG data collected at the time points of 0 hours, 4 hours, and 24 hours, as outlined in Table 4.

Table 4: Correlation co-efficient of ECG between Control vs at 0, 4th, and 24th hour

ECG Measurements	0 Hour		4th Hour		24th Hour	
	ρ (rho) (Control vs Test)	P-value	ρ (rho) (Control vs Test)	P-value	ρ (rho) (Control vs Test)	P-value
P-wave	0.88154	<.0001	0.93005	<.0001	0.94749	<.0001
PR-interval	0.92481	<.0001	0.92407	<.0001	0.93432	<.0001
QRS-complex	0.88635	<.0001	0.89490	<.0001	0.95305	<.0001
RR-interval	0.62355	<.0001	0.65340	<.0001	0.66011	<.0001
QT-interval	0.67859	<.0001	0.68579	<.0001	0.77310	<.0001
ST-segment	0.97657	<.0001	0.96322	<.0001	0.97749	<.0001
T-wave	0.95991	<.0001	0.95501	<.0001	0.95881	<.0001
ρ (rho) - Spearman correlation coefficient						

From the results in Table 3 and Table 4, RTMVRM solution offered comparable outcomes in measuring the vital parameters and ECG to standard traditional devices in the market. The vigo multi vitals monitoring device showed a better patient comfort and compliance without hampering the routine activities. The performance outcomes of Vigo vitals taking the gold standard to be the decision of clinical investigators are presented below in Table 5. The outcomes were calculated over total wear time.

Table 5: Efficacy outcomes of Vigo Vitals

Variable	Rate
Sensitivity	99%
Specificity	100%
Positive Predictive Value	98%
Negative Predictive Value	98%
Capture rate	100%
Accuracy	99%
Duration of Monitoring	24 hrs

The vigo vitals monitoring solution has proved a user-friendly interface between the patient, physician, and the nursing personnel. There were no considerable false alarms and artifacts detected in the study that disrupted the clinical workflow or potentially lead to

unnecessary interventions and reduced trust in device reliability. Since Table 3 and Table 4 shows statistically significant correlation between the test device and the control, RTMVRM can be technically relied for remote monitoring in health care practice. Furthermore, the adhesives of the vigo vitals patches did not cause any allergic reactions or discomfort to the patients. No other serious device related adverse events were reported in the study patients.

Discussion

Vital parameters are biological indicators of the general condition and health of an individual or patient.7 RTMVRM is designed to give access to continuous vital parameters in real time to the clinicians, enabling quick clinical decisions.

The present multi arm study correlated the vital parameters; including pulse rate, respiratory rate, temperature, heart rate, oxygen saturation, blood pressure and ECG measurements derived from RTMVRM solution and standard vital monitoring methods in chronic IHD patients, stable on medication. From the study, it was observed that there were statistically significant positive correlations between the RTMVRM solution and standard measurements for all vital parameters measured at the 4^{th} hour and 24^{th} hour time points and for the ECG measurements measured at the 0, 4^{th} hour and 24^{th} hour time points.

The findings of remote vital monitoring compared with standard monitoring in healthy volunteers revealed a significant correlation and that vital parameters and ECG values were strongly and significantly correlated internally ($p>0.01$) and 100% correlated externally ($p>0.01$) [9].

The patient readily accepted the RTMVRM solution and showed no signs of discomfort. No subjects discontinued the study because of discomfort or non-adherence to the study requirements while monitoring vital parameters. Both the clinician and the patients benefited from the solution. Accuracy and precision in vital monitoring and a decluttered monitoring experience with the patient provided satisfactory utility of the solution by the clinician and patient.

Continuous monitoring of vital parameters and ECG can improve outcomes in chronic ischemic heart disease patients. The combination of medical information and artificial intelligence aided technologies have the potential to better diagnose and follow-up of cardiovascular disease patients. The problems posed by the rising need and demand for critical care services, ageing population, and qualified health care personnel shortages can be solved by adapting to and applying modern remote monitoring technologies [10-12].

The objective of the study was to validate the data obtained through the new technology and standard methods, the short 24 hr monitoring period, and the selected pool of patients were stable on medication, other more useful application of the technology like EWS was not utilized.

Study Limitations

The study was conducted at a single centre with only one indication, i.e., chronic IHD. A multi- centre study that also involves patients with other cardiac disorders and other diseases may be evaluated for more promising outcomes of RTMVRM.

Conclusions

Recent technologies in the medical field have the potential to redefine healthcare delivery and enhance patient outcomes. However, the development and adoption of AI based technologies in healthcare will be acceptable for everyone only by commencing a collaborative effort between all the stakeholders involved. This study is a step forward in that direction. The findings from the study revealed that RTMVRM and conventional methodologies for monitoring vital parameters proved a strong correlation in real-time clinical practice without compromising quality and safety.

List of abbreviations

RTMVRM: Real Time Multi vital remote monitoring
Hours: hr
IHD: ischemic heart disease
DALys: Disability-adjusted life-years
Io(M)T: Internet of Medical Things
PR: Pulse rate
RR: Respiratory rate
HR: Heart rate
SBP: Systolic blood pressure
DBP: Diastolic blood pressure
SpO_2: oxygen saturation
AWS: Amazon Web Services
CMS: Central Monitoring System
MDSAP: Medical Device Single Audit program
SD: standard deviation
IEC: Institutional Ethics Committee
ESIC: Employees State Insurance Corporation

Ethics approval and consent to participate

The study was approved by the Institutional Ethics Committee (IEC) of ESIC Medical College and Hospital and was conducted in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. The trial was registered prospectively with the "Clinical Trial Registry in India" (registry number: CTRI/2022/04/041712).

Data Availability

The patient data associated with this study is readily available and can be obtained from the author on written demand and justification.

Conflicts of Interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

Funding Statement

Funding for this project was received from Vigo Care Pvt. Ltd, Hyderabad, India.

Authors' contributions

All the authors equally involved in the execution of the study. Dr. P. Sowjanya designed the study protocol. B. Madhuri and Dr. T. Appireddy were responsible for the clinical execution of the study. Dr. A. Rajani was involved with the scientific writing of the study.

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