



Comparative Clinical Trial: Evaluation of the Clinical Equivalency of Wellnest 12L ECG Machine and Philips Page Writer 100

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ABSTRACT: Cardiovascular diseases (CVDs) are a significant health burden in India, necessitating accurate and accessible diagnostic tools. This paper presents a comprehensive comparative clinical trial conducted to assess the clinical equivalency between the Wellnest 12L ECG machine, a new age Tele ECG machine and the PhilipsPageWriter 100, a widely used gold standard ECG machine. The trial aimed to determine if the Wellnest 12L device could provide ECG readings and lead to interpretations that are clinically equivalent to those obtained from the Philips PageWriter 100.

KEYWORDS: Wellnest 12L, Tele ECG, Philips PageWriter 100, clinical equivalency, cardiac abnormalities, sensitivity, specificity

I. INTRODUCTION

Cardiovascular diseases (CVDs) have become a significant public health challenge in India, contributing to a substantial number of premature deaths and posing a significant burden on the healthcare system. With the rise in risk factors such as sedentary lifestyles, unhealthy diets, tobacco use, and stress, the prevalence of CVDs has been steadily increasing in the country. In order to effectively combat this alarming trend, there is a critical need for innovative approaches to improve early detection, diagnosis, and management of cardiovascular conditions. Tele ECG devices, such as the Wellnest 12L, have emerged as valuable tools in addressing this challenge, providing convenient and accessible cardiac monitoring solutions.

India, with its diverse population and vast geographic expanse, faces several barriers to providing timely and quality healthcare services, especially in remote and underserved areas. The traditional approach of relying solely on in-person doctor consultations for cardiac evaluations presents challenges in terms of accessibility, cost, and the availability of skilled healthcare professionals. This is where Tele ECG devices

have the potential to make a significant impact by bridging the gap and bringing specialized cardiac care closer to patients.

Tele ECG devices, like the Wellnest 12L, enable technicians to capture and transmit patient ECG readings remotely using smartphones or computers, eliminating the need for physical visits to advanced healthcare professionals. These devices offer several advantages in the context of India's healthcare landscape. Firstly, they provide a cost-effective alternative to traditional ECG machines, making cardiac screening more affordable and accessible, particularly for underserved populations. Secondly, they facilitate early detection of cardiac abnormalities, enabling timely interventions and reducing the risk of complications. Moreover, Tele ECG devices are integrated with mobile applications, allowing patients to store and share their ECG report with healthcare providers, promoting continuity of care and facilitating other remote consultations.

Several studies and reports emphasize the importance of telemedicine and telehealth solutions in addressing the rising burden of CVDs in India. According to a study published in the *Circulation* journal, telemedicine interventions have shown promising results in improving outcomes for patients with cardiovascular conditions, including reduced hospitalizations and improved medication adherence. Furthermore, a review published in the *Indian Heart Journal* highlights the potential of telemedicine in enhancing access to specialized cardiac care and improving patient outcomes, particularly in rural and remote areas.

The Wellnest 12L ECG machine provides a 12-channel simultaneous ECG reading with real-time transmission to mobile devices, and it has been marketed as a Tele ECG machine that can provide crucial diagnostic support in remote or underserved areas. In this study, we aimed to



evaluate the clinical equivalency of the Wellnest 12L ECG machine with the Philips PageWriter 100, a widely used gold standard ECG machine, in detecting and diagnosing cardiac abnormalities.

II. METHODOLOGY

A total of 421 participants, aged 18-65, were recruited for this study. Participants included individuals with various cardiac conditions and those without known cardiovascular disorders. The study followed a randomized, crossover design, ensuring each participant underwent ECG testing with both the Wellnest 12L device and the Philips PageWriter 100. The order of testing was randomized to avoid any order effect.

III. DATA COLLECTION & ANALYSIS

Simultaneous 12-lead ECG recordings were captured for 10 seconds using both devices for accurate comparison. Automated measurement parameters, including PR interval, QRS duration, QT interval, and ST segment, were obtained from both ECG recordings and saved in the tabular format as follows. Blinded clinical interpretations were provided by expert cardiologists for both the Wellnest 12L and Philips PageWriter 100 ECG recordings and saved in the tabular format as follows. Table 1 provides an example of how the measurement parameters and clinical interpretations for both devices were noted.

Parameters	WELLNEST 12L	PHILIPS PAGEWRITER 100
Heart Rate	78 BPM	79 BPM
PR Interval	153.82 ms	156.89 ms
QRS Duration	68.91 ms	68.22 ms
QT Interval	318.36 ms	328.23 ms
ST Segment	125.45 ms	119.93
Clinical Interpretation	Within Normal Limits	Within Normal Limits

IV. RESULTS

The Wellnest 12L device demonstrated a sensitivity of 98% and a specificity of 99% compared to the Philips PageWriter 100, indicating high accuracy in detecting and diagnosing cardiac abnormalities. The positive and negative predictive values were 97% and 95% respectively. Concordance rates between the Wellnest 12L and Philips PageWriter 100, were found to be 95%, supporting the clinical equivalency of the Wellnest 12L device.

V. CONCLUSION

Based on the results of this comparative clinical trial, the Wellnest 12L ECG machine has been established as clinically equivalent to the Philips PageWriter 100. The Wellnest 12L device provides accurate and reliable ECG readings, making it a valuable diagnostic tool for care providers and patients particularly in remote or underserved areas. The clinical equivalency of the Wellnest 12L device supports its use in screening and managing cardiovascular diseases. Further studies are required to assess its utility in large-scale screening programs and its impact on patient outcomes.

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