

Wellysis S- PATCH versus Conventional HOLTER Ambulatory Electrocardiographic Monitoring (The PACER Trial)

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ABSTRACT

This is a prospective, interventional, non-randomized, single group assignment, diagnostic sub study with intention to treat. This sub study aims to compare the diagnostic yield, or ability to detect arrhythmias - especially paroxysmal atrial fibrillation (PAF) - of the conventional Ambulatory Holter monitoring device with the Wellysis S Patch, a novel, dual-lead, low-profile device.

Background: It is widely recognized that technology can improve the health of populations in countries around the world. Smartphone technology is at the forefront of innovation in low, middle and high-income countries. The Smartphone technology has already improved the doctor-patient interaction, reducing costs and improving care for patients.

Methods: Patients referred for ambulatory electrocardiographic (ECG) monitoring wore both devices simultaneously for 24-48 hours and the incidence of clinically significant arrhythmias were compared. Patients who satisfied the eligibility criteria as well as referred for ambulatory ECG monitoring were consented and enrolled prospectively to have the Holter monitor and the Wellysis S Patch device placed simultaneously. A patient satisfaction survey was given to the patient and parent/guardian after completion of the study to compare the comfort, interference with daily activities, adverse events (such as skin irritation or if either device fell off), and preference for each device. The overall performance (comfort of wearing, ease of use, efficiency and durability, clarity of recorded signals)

Results: When it comes to comfort of wearing, ease of use, efficiency and durability, clarity of recorded signals of Wellysis S Patch was found to be superior to conventional Holter (feedback from patients, paramedical staff, clinical staff regarding the comfort of wearing, usability, operational efficiency) by Mc Nemars analysis, which revealed odds ratio of 8.75 with a 95% CI 4.205 to 21.060, $P < 0.0001$.

Conclusion: Multi lead ambulatory Holter monitoring remains the gold standard for arrhythmia detection in stroke patients. However Wellysis S Patch device has a definite complementary role in the detection of paroxysmal atrial fibrillation (PAF) in stroke patients. However with advances in technology a paradigm shift is possible.

BIOGRAPHY

Satyanarayana Upadhyayula is a Consultant Cardiologist in Medanta Hospital, New Delhi. He completed his MBBS from Kakatiya Medical College in 1986. In 1990 he completed his M.D. from All India Institute Of Medical Sciences - Biophysics, worked in Cardio Vascular Physiology, Hemodynamics, Nuclear Medicine and Nuclear Cardiology. Fellowship in Emergency Medicine (FEM) July 2007 - June 2008 (Royal College of General Physicians, UK). Life Member - Indian Academy of Echocardiography. American Heart Association (AHA) Certified Instructor in Basic Life Support (BLS), Advanced Cardiac Life Support (ACLS) and International Trauma Life Support (ITLS) Fellowship in Echocardiography Apollo Hospital. Fellow International Medical Sciences Academy (FIMSA).

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