Holter Umana T1 Study

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Introduction

Cardiac arrhythmias are a leading cause of morbidity and mortality. Early detection is therefore crucial for diagnosis and management. This may require ambulatory monitoring over a number of hours. While the standard Holter device provides adequate diagnostic yield, it is considered largely cumbersome and inconvenient. The Umana T1 device is a small tattoo sensor that, once validated, should offer a markedly improved patient's comfort and experience while providing the same diagnostic information.

Aims

The primary aim of this study is to demonstrate non-inferiority of the Umana device when compared to the standard Holter device (gold-standard) in detecting cardiac arrhythmias as an ambulatory electrocardiography device.

The second secondary aim to is show that the Umana device is more comfortable and convenient for the subjects undergo ambulatory electrocardiography monitoring, and is superior in this respect.

Methodology

Two thousand patients will be enrolled in this study over a period of six to nine months.

Enrolment

Patients (age over 18) who are scheduled for an elective twenty-four-hour ambulatory electrocardiography monitor at the Cardiac Lab at Mater Dei Hospital (Malta) will be asked to participate, enrolling on average ten patients per day. Information about the study will be provided both verbally and as leaflets. Those who accept to participate will be asked to sign a consent form, that is available both in English and Maltese (appendices 1 and 2 respectively).

Subjects will have set up both the standard Holter device as per current standard practice, as well as the Umana T1 device. They then do what they normally do (as per standard Holter recording) leaving hospital, and should seek to spend the day as per their normal routine. On the following morning, as is customary, they return to Cardiac lab where both devices are removed and data uploaded separately from the device to storage units. Both devices will therefore be recording the electrophysiological data of a given subject concomitantly (paired observations).

Subjects will be asked to fill in a very short questionnaire relating to their experience of both devices (Appendix 3).

The enrolment, attachment and removal of the device, as well as the questionnaires will be carried out by electrocardiographers working at the cardiac lab who have experience in the field but are not authors in this study, in order eliminate the risk of any potential bias (they will naturally be acknowledged in any subsequent report/publication).

Rhythm Analysis

The electrocardiographic rhythms collected will be analysed by qualified a team of electrocardiographers and cardiologists, and if the need arises, advise will be sought from a consultant electrophysiologist as per current practice. These health care professionals will be randomly reviewing data of different patients from both devices, in order to reduce bias. Analyses from both devices will be carried out using the respective proprietary software, which share a similar interface design. A report is generated at the end of each analyse, showing all detected cardiac arrhythmias.

Data collection

Data collected from the reports shall include the absence or presence of arrhythmias, and, where presence, their frequency. These may include:
Minimum and maximum heart rate
Maximum R-R interval
Non-conducted (dropped) P-waves
Heart blocks
Supraventricular tachycardia (SVT)
Atrial fibrillation (AF)
Premature ventricular complexes (PVC)
Sustained and Non-sustained ventricular tachycardias (NSVT)

Results will also be obtained from the questionnaire, namely paired ranking scores for each device, as well as device preference.

Statistical Analyses

For each subject, data from the standard Holter device will be paired with data from the Umana device for the same individual. The two matched data sets will then be assessed using paired student T-tests.

Results obtained from patient's ranking of each device in the questionnaire will be compared using paired student T-test.

Results of the patient's choice of device will be tested using Chi-square Analysis.

References

1. Death SC. Clinical Cardiology : New Frontiers Sudden Cardiac Death. 1998;2334–51.

2. Barold SS. Norman J. "Jeff" Holter–"Father" of Ambulatory ECG Monitoring. J Interv Card Electrophysiol [Internet]. 2005 Nov [cited 2017 Oct 8];14(2):117–8. Available from: http://link.springer.com/10.1007/s10840-005-4787-8

3. AlGhatrif M, Lindsay J. A brief review: history to understand fundamentals of electrocardiography. J community Hosp Intern Med Perspect [Internet]. 2012 [cited 2017 Oct 8];2(1). Available from: http://www.ncbi.nlm.nih.gov/pubmed/23882360

4. Smith WM, Riddell F, Madon M, Gleva MJ. Comparison of diagnostic value using a small, single channel, P-wave centric sternal ECG monitoring patch with a standard 3-lead Holter system over 24 hours. Am Heart J [Internet]. 2017 Mar [cited 2017 Oct 8];185:67–73. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0002870316302733

5. Barrett PM, Komatireddy R, Haaser S, Topol S, Sheard J, Encinas J, et al. Comparison of 24-hour Holter monitoring with 14-day novel adhesive patch electrocardiographic monitoring. Am J Med [Internet]. 2014 Jan 1 [cited 2017 Oct 8];127(1):95.e11-7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24384108

6. Turakhia MP, Hoang DD, Zimetbaum P, Miller JD, Froelicher VF, Kumar UN, et al. Diagnostic utility of a novel leadless arrhythmia monitoring device. Am J Cardiol [Internet]. 2013 Aug 15 [cited 2017 Oct 8];112(4):520–4. Available from: http://www.ncbi.nlm.nih.gov/pubmed/23672988

7. Iii JAW, Topol EJ, Steinhubl SR. New Drugs and Technologies Novel Wireless Devices for Cardiac Monitoring. 2014;573–81.