AMPS-QT

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AMPS-QT is a quarterly journal dedicated to all the people and organizations involved in the world of cardiac safety. Published by AMPS LLC, it covers all aspects of methodology and software technology related to clinical trials and Thorough QT studies.

Editorial

One of the areas of cardiac safety we never covered before in this magazine is telemedicine, a term widely used to define the use of telecommunication and information technologies in order to provide clinical health care at a distance. During the past few years AMPS has developed a platform to provide remote cardiology services over various network means (Internet, GSM, GPRS, etc). This technology nowadays allows several European clinics and hospital based cardiology departments to monitor residents in senior and nursing homes, pharmacy customers, and, in general, patients of general practitioners in need of an opinion from an expert cardiologist in geographical situations where none is available nearby. Dr Antonio Sanzo, resident cardiologist at the Humanitas Clinic in Castellanza, is an expert and enthusiastic adopter of the technology and the author of this issue's essay on Telemedicine which focuses on the advantages of remote cardiology services. Happy reading!

A Noteworthy Contribution:

Remote Monitoring in Cardiology: Clinical Overview

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Remote patient monitoring is a form of ambulatory care in which mobile device collect biomedical parameters and deliver them to care givers in real time. Remote patient monitoring promises to contain burgeoning costs of health care provision, to improve therapy implementation by patients, to hasten the identification of complication [1,2]. Remote patient monitoring still in its infancy. We have conflicting evidence of value in the literature, which partially reflects inadequate definition (terminology) and classification (patients), so optimization of remote patient monitoring needs better classification of system and patients and risk-based stratification of patients.

Home Monitoring Systems

There are conflicting evidences from literature: there are meta analyses and single centre studies demonstrating that remote patient monitoring is effective and cost effective, but there are also multi centre studies with opposite conclusions. The evidences are conflictual because the same label was used for different intervention in different cohorts.

Telemedicine has a complex structure. There are several components: the device, the data transmission and processing system, the algorithm of analysis of information and the response to the patient. If one element changes, the intervention is different and each element is crucial for the success of the service. Until now most efforts were dedicated to the device although technology alone does not guarantee the success and the sustainability of a new telemedicine service. It is important to select the proper physiological parameters to monitor, improve the connection of different devices with the data centre and implement accurate algorithms for analysis.

Remote patient monitoring devices evolved over the past years and changed from phone-based acoustic coupling systems to more automated external, wearable or implantable device.

Home based portable technology can collect cardiovascular parameters e.g. blood pressure, weight, heart rhythm, ECG [2,3,4]. The level of precision is clinically important and should be tailored to the specific disease being monitored. Indeed, the level of precision of measurement of body weight is more important for a patient with heart failure than in hypertension [5]. This aspect is important also for economic aspects that cannot be neglected [6].

Multi-sensor and non-invasive wearable devices have the advantage of continuously monitoring the patient; this technology was proved to be promising in the MUSIC

study which monitored heart rate, thoracic impedance, respiratory rate and volume, activity duration and intensity in patient with heart failure [7].

At present, the role of non-invasive remote monitoring remains unclear. Implantable haemodynamic monitors have been developed [8]. If used alone or in combination with implantable cardioverter defibrillator (ICD) or cardiac resynchronisation therapy (CRT) devices, they may provide useful information for clinical management of heart failure patients. A recent guideline update for CRT advocates the use of remote monitoring in this high risk group of patient for the detection of clinical problems and technical issues [9].

Telemedicine can be synchronous (data flow delivered real time) or asynchronous (data is stored and forwarded later). Ideally, the telemedicine system should transfer the information synchronously to the telemedicine centre. This information should then be analyzed automatically by an algorithm and, upon detecting a critical situation , generate an alarm for medical staff to promptly act upon. In this ideal setting the synchronous transfer and algorithm play a key role.

New devices are also spreading in the e-Health technology context. At present, the role of these devices has not been evaluated and studies of efficacy are not yet available. Potential users are usually young people keen to adapt to technology changes, thus determining a constantly growing expectation for self monitoring. These low cost devices are spreading rapidly and could be helpful in the clinical management of patients. On the other side, their use should be regulated and algorithm and software should be developed in order to integrate these devices in clinical practice.

Patients

Patients with heart diseases are very complex: there is a broad spectrum of illnesses with different risk of hospitalisation or death. Furthermore, each patient needs a different intensity of care tailored to his/her own specific condition. Because of this, patients could be categorized according to the specific need of surveillance. The categorization could be useful in planning new studies to evaluate remote patient monitoring and cost effectiveness of the systems. Three distinct categories of surveillance could be used: high surveillance (patients with recent hospitalisation due to heart failure, myocardial infarction), medium surveillance (patient at risk for silent atrial fibrillation, chronic mild heart failure), low surveillance (hypertension, chronic atrial fibrillation). Not all approaches are the same and not every patients with heart disease will need telemedicine or the same system.

a) High surveillance patients

Heart failure is the most challenging problem in cardiology and it has an important economic impact. Important resources are directed to the reduction of hospitalisation which is the main drive of the cost for this disease. Remote patient monitoring can play a role [3-5]. In patients with congestive heart failure the risk of death is greatest in the early period after hospitalisation and is directly related to duration and frequency of hospital stay. The mortality risk after a hospitalisation for heart failure subsequently decline over time [10]. These findings suggest a role for high surveillance in the early post-discharge period after an admission for heart failure. The meta-analysis have shown the superiority of remote patient monitoring in reducing mortality and hospitalisation compared to usual care [3,4]. But these results are not conclusive because they were not confirmed by new randomised studies. These contrasting results depend on the use of non homogeneous telemedicine systems and different patients risk stratification.

More than half of all deaths due to cardiovascular disease are related to coronary artery disease. Telemedicine was copiously evaluated: in particular, ECG transmission improves health outcome in patients affected by acute coronary artery disease. However, in this contest efficacy and cost effectiveness remain to be addressed [11].

b) Medium surveillance patients

Remote patient monitoring could also play a role in the cardiac arrhythmia management [12]. Atrial fibrillation is the most common sustained cardiac arrhythmia with prevalence in general population of approximately 1%. The problem of early recognition of atrial fibrillation is greatly aggravated by the often silent nature of the rhythm disturbance (1/3 of patient with this arrhythmia is asymptomatic) [13]. The early detection of arrhythmia allows the timely introduction of therapies to prevent arrhythmia consequences. Early detection of atrial fibrillation in high risk patients (e.g. heart failure, high CHA2DS2-VASc score) is much more relevant than in low risk patients (CHA2DS2-VASc < 2, chronic atrial fibrillation). High risk patients deserve strict surveillance with implantable device or continuous external device. Patients with low risk could use less sophisticated devices for daily rhythm assessment. The monitoring of the patient after ablation for atrial fibrillation is also debated. Definitively continuous monitoring in the first period after ablation procedure is the gold standard to assess procedural success.

c) Low surveillance patients

Other cardiovascular diseases need a less strict surveillance. For example, many studies have been conducted in patients affected by hypertension and the effectiveness of telemedicine is well established [14]. In these patients the daily evaluation of blood pressure with a home device and periodical medical contact are sufficient.

Limitations

The most relevant limitation about remote patient monitoring regard legal and economic issues. Legal issues concern medical responsibilities, confidentiality and the diffusion of information respecting the privacy of the patients. Risk of failure in the data transfer due to technical issues should also be considered.
The introduction of remote patient monitoring in daily practice requires careful analysis of reimbursement policies which depend mainly on national health systems, although different sources of funding are possible (insurances, local government). Therefore, evidence supporting the value of remote patient monitoring is needed to justify the clinical and economic efforts in this field. Telemedicine might be most beneficial in patients with worsening heart disease that need strict surveillance.

Conclusions

Remote patient monitoring could be pivotal in efficient cardiology management of patient. At present, this technology is promising but there are not definitive data about efficacy and cost effectiveness. In the future the telemedicine system, and not only the device, should be studied in patient stratified for their need of surveillance. Moreover, more studies are necessary to evaluate different transmission systems and algorithms to manage the burden of information. An important area of further development will be automated decision system.

References

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Products News

Latest Releases

In Q2 2014 we have released:

- Version 1.1.0 of AMPS CER-S (Continuous ECG Recordings Suite) including the first two platforms: the aECG Generator (Pollux) and Continuous ECG Viewer. The major features of CER-S include:
  - Continuous recordings annotation capabilities
  - Continuous recordings aECG generator
  - Ergonomic Viewer of Continuous recording

Looking forward

In Q3/Q4 of 2014 AMPS is planning to release:

- A new major version of CER-S including the following two new platforms:
  - Continuous ECG beat detection and classification
  - ECG beat editor
- A beat-to-beat continuous ECG solution

AMPS Recommends

The debate over QT/RR modelling and QT correction is far from being over. We propose an interesting publication from a Canadian group based in Montreal led by doctor Jacquemet aimed to assess differences in the QT intervals before and after catheter ablation in atrial flutter patients using a hysteresis-reduction model [1]. In the study, two groups of atrial flutter patients underwent catheter ablation while being continuously monitored using Holter ECG recordings: the first group consisted of those who were in sinus rhythm the day of the procedure and the second group of those who were in atrial flutter. When possible/applicable periods with matched RR intervals (before and after the procedure) were used (with no need of heart correction); for all the other analysis periods an effective RR interval, a rectified RR interval based on an autoregressive filter, was used instead. "In addition, the segments acquired under flutter conditions were pre-processed for flutter wave subtraction. Results indicated that the QTc interval during atrial flutter seems to be concordant with that during sinus rhythm and that it is apparently affected by catheter ablation intervention. The study thus seem to suggest that QT interval could be adequately assessed in patients affected by atrial flutter provided that wave subtraction, hysteresis-reduction and sufficiently long recordings (at least five minutes) are available.

Of note, the manuscript is followed by an editorial by Marek Malik which accompanies Jacquemet manuscript with a short summary on QT/RR hysteresis and on its implications beyond atrial flutter, suggesting how this phenomenon cannot be governed by a universal technology [2].

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AMPS Notebook

Fabio Badilini chaired a session on Telemedicine at the 8th **Conference of the European Study Group on Cardiovascular Oscillations** (ESGCO 2014), that was held in May in Trento, Italy.

Fabio also attended the 39th **ISCE Conference**, the meeting he chaired last year, that was held in Atlantic Beach, FL in April.

AMPS will be present at the Computing in Cardiology Conference that will be held in Cambridge, MA from September 7th to 10th, 2014. Here three abstracts will be presented:

- Gianfranco Toninelli, coauthored by AMPS team and the University of Brescia, will talk about "ECG Quality Assessment Using Data Mining",
- Roberto Sassi, from the University of Milan, will introduce PDF-ECG, an international long-time preservation ECG format, a cooperation between the University of Milan, AMPS, FDA and FAA,
- Dave Mortara will enlighten a paper, coauthored by Fabio Badilini, entitled "A Quantitative QT Hysteresis Model".

AMPS People

On this issue of our bulletin, we introduce the latest AMPS acquisition: Francesca Ferrari, who joined the AMPS family during the first quarter 2014.
Francesca obtained her Master degree in Engineering from the Polytechnic University of Milan in 2013, discussing the thesis titled: "Definition of an experimental set-up for the

quantification of functional limitations of the upper limb in apraxic subjects". Among other interests Francesca is also a Certified Sailing Instructor at the nearby Garda lake sailing school.
Francesca main focuses at AMPS are software testing, software documentation, and data manager for the Services department.