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Study of Arrhythmia Prevalence in NUVANT Mobile Cardiac Telemetry System Patients

Jonathan M. Engel, *Member, IEEE*, Vipin Mehta, Richard Fogoros M.D., Abhi Chavan, *Senior Member, IEEE*

***Abstract*—The Corventis NUVANT™ Mobile Cardiac Telemetry system is an innovative solution in the field of continuous monitoring of symptomatic and asymptomatic cardiac abnormalities to help physicians diagnose and treat non-lethal cardiac arrhythmias. As an FDA cleared product on the market for more than 2 years, the collected body of patient data represents a unique and powerful source of clinical information. Analysis of a sample of 951 NUVANT patients has revealed interesting statistics on the prevalence of various cardiac arrhythmias in the patient population. The population is non-randomized and largely consists of US patients where a traditional Holter Monitor study was negative. The analysis here is focused on classifying the detected arrhythmias using potential therapy solutions as a classifier. Across the total population, 2.2% of patients presented arrhythmias indicating assessment for clinically significant tachycardia, 19% indications of potential bradycardia, 20% had indications of atrial fibrillation, 1% indicating arrhythmias requiring other conditional treatment, and 58% presenting arrhythmias likely not requiring treatment.**

I. Introduction

LOW-cost, high-impact wearable health care technologies such as mobile patient monitoring systems are being rapidly introduced to the market as the convergence of low cost, high performance electronics, sensing, miniaturization, processing power, and algorithm development technologies enable small and affordable wearable devices. Companies such as Toumaz, Proteus, iRhythm and Corventis have developed or are developing on-skin wearable non-invasive devices to address a number of health conditions. Of these, Corventis is the only company with cleared, market introduced mobile cardiac outpatient telemetry (MCOT) and mobile patient monitoring (MPM) systems that are applied to the patient's skin to collect electrocardiogram (ECG) signals [1]-[4]. Additionally, past studies have shown these non-invasive devices which impose minimal restriction on patient lifestyle during wear enjoy high levels of patient compliance which is critical for clinical success [5].

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All authors with Corventis, Inc, Saint Paul, MN 55108 USA. Corresponding author: Jonathan Engel. Phone: 651-925-3808; fax: 651-389-3251; e-mail: jonathan.engel@corventis.com).

Such wearable systems are poised at the confluence of technological and economic feasibility, and with the push for lower health care expenditures are likely to make an impact in the way medicine is practiced. Reliable remote rather than in-hospital monitoring of patients is a key factor in overall cost reduction and wearable devices are likely going to play an important role in addressing upcoming legal mandates intended to contain cost and help get healthcare institutions to focus on better outcomes. One such example in the US is the upcoming Medicare mandate to reduce readmissions for patients with congestive heart failure. Corventis' FDA cleared AVIVO™ MPM system is targeted to help manage patients living with heart failure and may assist health care providers in meeting these targets.

Wearable MCOT and MPM systems generate large volumes of data, in a low-cost seamless fashion which can be analyzed to provide additional benefits. This could include features customized to patient populations, improved diagnostic yield, and in the long term help characterize and track the health of large patient populations as well as provide input into health infrastructure investment decisions and regulations. One particular area of interest is the distribution of arrhythmia types in patients undergoing MCOT monitoring from a downstream therapy viewpoint. Several examples of studies of arrhythmia presentation and prevalence based on general population studies as well as MCOT system data exist in the literature [1], [6], [7]. However, these studies predate the availability of low-cost, external, continuously wearable, high performance systems

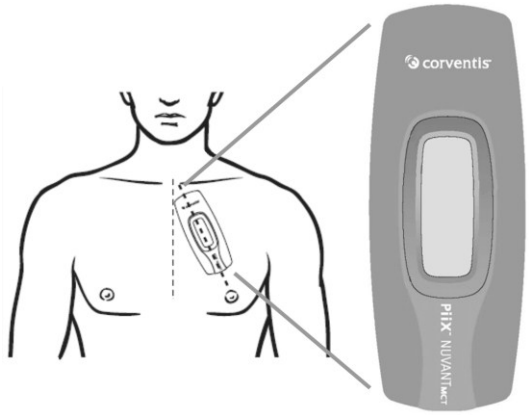

Fig. 1. Application site for Corventis NUVANT PiiX™.

that promise to allow large patient population sampling due to lower barriers for wide market adoption. The retrospective analysis presented here is a first step in that direction, providing results from an analysis of cardiac arrhythmia data from a sample of 951 NUVANT MCOT system patients, representing more than 250,000 individual ECG strips and 450,000 hours of continuous arrhythmia monitoring

II. The NUVANT System

As a pioneer in the field of mobile patient monitoring, Corventis has developed the NUVANT mobile cardiac telemetry system, which includes a patient wearable device (PiiX™) that provides near real time feedback on cardiac arrhythmias and heart rate [2], [8]. These signals are relayed via wireless link to a networked gateway, the zLink, which transmits the patient data to the Corventis monitoring center (CMC) where the data is reviewed, annotated, and made available to the attending physician. Following the instructions for use (IFU), either the patient, or caregiver (physician or medical professional) prepares the skin site and applies the adherent PiiX to the skin in upper left quadrant of the chest. (Fig. 1).

The typical NUVANT patient is prescribed the NUVANT system after a traditional Holter monitor study has not provided adequate clinically actionable data. Problems with compliance, signal interference, wear duration, patient lifestyle, and other factors plague Holter deployments. These shortcomings are addressed by the NUVANT system, which allows for high patient compliance and designed to be inconspicuous during use. NUVANT is cleared for up to a 30 day prescription, with each adherent PiiX device providing up to 180 hours of monitoring.

III. Methods

The PiiX adherent device includes a sensor suite for the purpose of measuring a variety of relevant health data (NUVANT and/or AVIVO) such as patient posture, sleep orientation, activity duration and intensity, respiration rate, fall detection, underlying tissue impedance, as well as a single lead electrocardiogram (ECG). Of interest for this analysis, the PiiX continuously monitors the patient and when the device detects cardiac data of interest the ECG strip data is packaged and transmitted for CMC review. Retrospective analysis of these archived transmissions and subsequent CMC arrhythmia classification grouped into areas of potential therapy forms the basis of the presented study. Actual treatment prescribed and clinical outcomes based on the transmitted arrhythmias are not presented.

De-identified data collected from 951 NUVANT patients was analyzed to generate relevant statistics on the patient population demographic and diagnosed arrhythmias. Demographic criteria consist of age and gender. Arrhythmias were grouped into 5 classes consistent with their most applicable post-diagnosis therapy. These groups include arrhythmias indicating assessment for (1) ventricular tachycardia (VT), (2) potential bradycardia or sinus pause

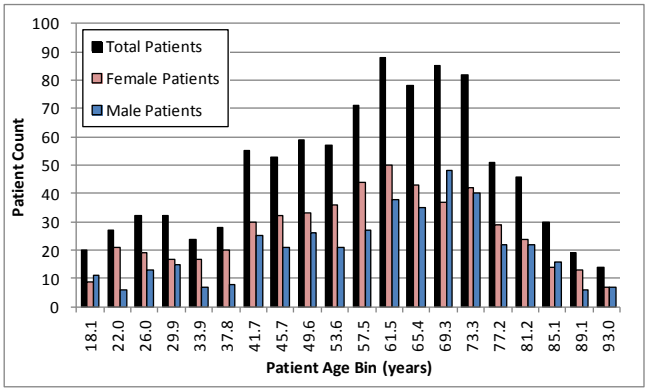

Fig. 2. Patient population histogram representing 951 NUVANT prescriptions, with 537 female and 414 male patients.

(BR), (3) atrial fibrillation (AF), (4) other arrhythmias which will likely require treatment (LT) (e.g. 2nd degree AV blocks), and (5) arrhythmias not likely requiring treatment (NLT) (e.g. sinus tachycardia and nonconducted PACs). The arrhythmia groups were also prioritized in the order listed above, such that a patient exhibiting both VT and LT type arrhythmias would be listed under only the VT category. To reflect clinical practice, sinus bradycardia arrhythmias (heart rate < 40 bpm) were also ignored for patients younger than 60.

The histograms of patients falling into these categories are presented showing trends within age and gender demographics and suggesting avenues for further study. Evaluation of statistical significance is carried out using paired single tail t-test. Also investigated is the time to diagnosis, which is defined as the duration in days from device application to first clinically relevant ECG strip.

IV. Results and Discussion

Analysis of the patient population begins with patient age and gender as shown in Fig. 2. Mean age for male patients is 59.3 years (σ = 18.1), for female patients is 56.8 (σ = 18.3) and overall is 57.9 years (σ = 18.2). Median age for male patients is 62.4 years, for female patients is 58.3, and overall is 60.4 years. The 951 patients are split between 414 male and 537 female patients of which 207 (50%) and 195 (36%) presented clinically relevant arrhythmias respectively during the NUVANT prescription period.

Of the total patient population, 2.2% exhibited arrhythmias indicating assessment for VT, 19% potential BR, 20% AF, 1% LT arrhythmias, and 58% likely requiring no treatment (NLT). The split by gender is shown in Fig. 3, where it is clear that male patients presented clinically significant arrhythmias at a higher rate than the female population. The above numbers present the prioritized incidence of the arrhythmias, leading to a sum total of 100%. For comparison, unprioritized incidence with patients yielding arrhythmias from multiple categories yields 2.2% VT, 20% BR, 27% AF, 3.2% LT, and 97% NLT.

Fig. 4 highlights the presentation of ventricular arrhythmias which would typically result in an

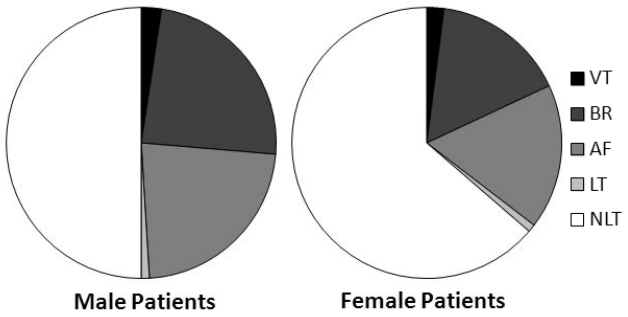

Fig. 3. Breakdown of clinically significant arrhythmia presentation for male patients and female patients.

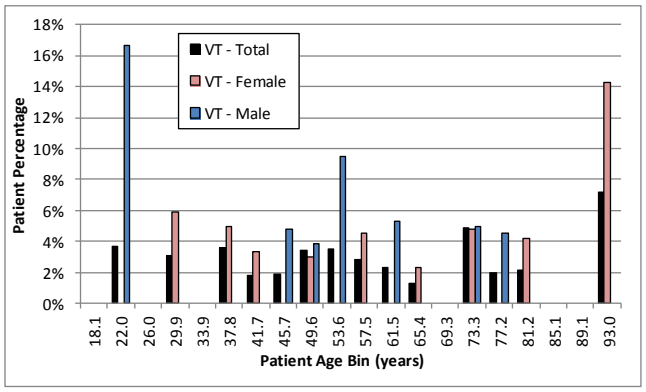

Fig. 4. Percentage of patients by age group that exhibited clinically significant tachycardia, indicating further evaluation for therapy options.

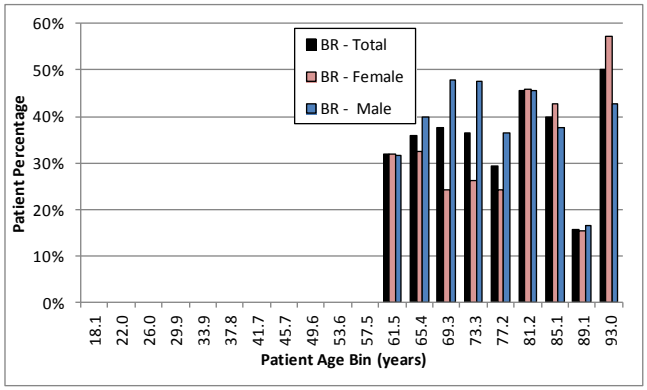

Fig. 5. Percentage of patients by age group that exhibited cardiac arrhythmias indicating abnormal rhythm and pacing issues.

electrophysiology study, which if positive typically results in an implantable cardiac defibrillator or ventricular ablation therapy. As expected, the incidence of these types of arrhythmias is very low at 2.2% of the population, since most of the symptomatic patients in this category are diagnosed through other clinic based studies and are not intentionally diagnosed using MCOT technology.

Fig. 5 details the presentation of detected arrhythmias that would typically result in evaluation for bradycardia. A key observation is that younger patients who are physically fit often present sinus bradycardia (<40 bpm) at night and are not likely to be indicated for treatment related to rhythm abnormalities. As a result, patients less than 60 years of age

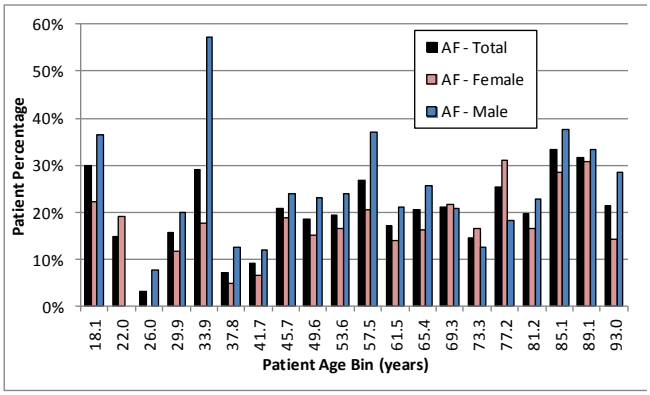

Fig. 6. Percentage of patients by age group that exhibited cardiac arrhythmias indicating atrial fibrillation.

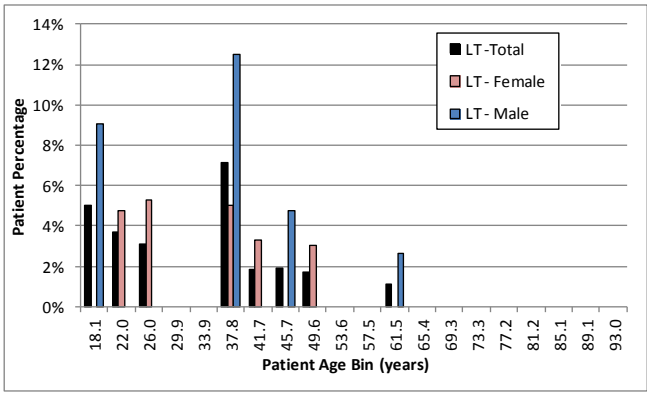

Fig. 7. Percentage of patients by age group that exhibited cardiac arrhythmias indicating likely other conditional treatment.

were excluded from the BR group.

Fig. 6 shows the rate of atrial fibrillation type arrhythmias in the patient population, with 23% males and 17% females exhibiting AF and is statistically significant (P = 0.01). As expected, the incidence of these types of arrhythmias generally increases with patient age, cresting over 30% in the older patient groups.

Fig. 7 highlights patients presenting arrhythmias likely to need treatment through other clinical methods. These patients potentially require further study, input from other testing and monitoring avenues or evaluation of other factors in the patient history.

Fig. 8 details those patients who exhibited arrhythmias that would not likely indicate further treatment. As shown, the younger patients fall into this category of relatively benign arrhythmias with a higher frequency than older patients. Since the presented patient population came to their physicians with symptomatic arrhythmias this would seem to indicate a higher incidence of clinically relevant arrhythmias with age which is not surprising.

The last area of study is the time to presentation of the cardiac arrhythmia. As stated, many of the patients in the study were prescribed the NUVANT system in-lieu of or following an unsuccessful Holter prescription. As can be seen in Fig. 9, in all cases the mean patient time to arrhythmia ECG presentation is in excess of the 2-day Holter period. This highlights the need for unobtrusive, long-wear

devices with high patient compliance rates.

V. CONCLUSIONS

Based on the preceding analysis it is clear that studying the vast pools of patient data represented by wearable MCOT systems offers an interesting opportunity for learning about the makeup of the patient population with symptomatic cardiac arrhythmias. The goal of studying this data is to help drive more patient-centric custom features and functions, leading to better diagnostic yields. Further study is needed to refine the required system features based on age, gender and other co-morbidities to enable the improvement in the above mentioned outcomes.

As the availability of such data increases with market adoption, the utility of these types of analyses will increase, due to the low cost and seamless availability of the data. Improved correlation of other physiological vital signs diagnosed by the system to the arrhythmia diagnosis, coupled to disease prevalence information in various population segments may help reduce additional clinical diagnostic procedures, reduce need for manual intervention to obtain the diagnostics and lead to expedient and better guidance on potential therapies.

Specific to the patient population that was prescribed the NUVANT system, the prevalence of clinically important arrhythmia classes such as atrial fibrillation (20%) are somewhat higher than previously reported in past MCOT system studies where 17% of patients exhibited AF arrhythmias [1]. This could be due to differences in sensitivity and specificity of the systems, in patient population, or higher compliance enabled by the NUVANT system. Further study is needed to explain some of the other observations in the analyzed NUVANT data, such as the gender differences in rhythm presentation and AF.

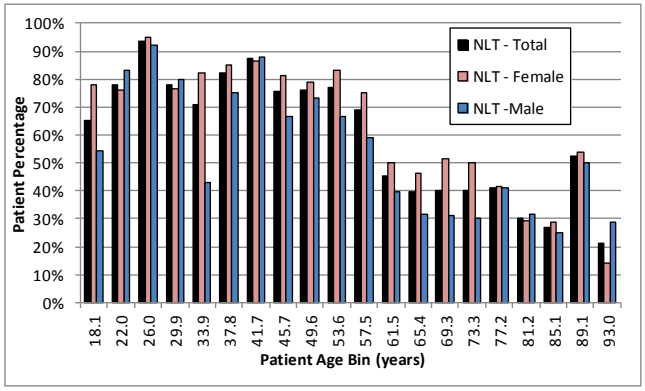

Fig. 8. Percentage of patients by age group that exhibited cardiac arrhythmias not likely requiring treatment.

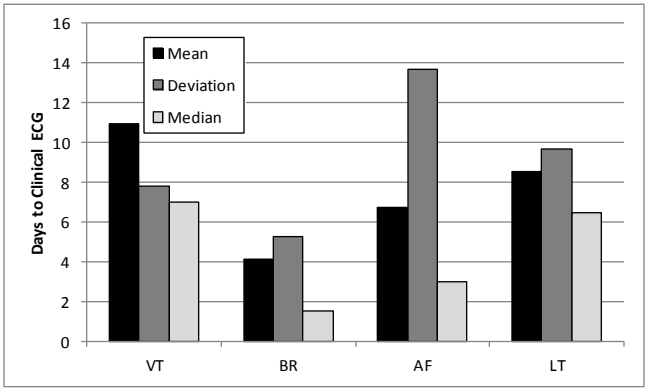

Fig. 9. Time to clinically relevant arrhythmia ECG presentation broken down by arrhythmia grouping.

Despite the limitations of retrospective studies of data provided by MCOT patient populations, the ability to analyze very large pools of data can provide information which will potentially bring additional clarity to inter-rhythm correlations and their links to other co-morbidities which are manifested by changes in physiological vital signs. The statistical data which is available seamlessly from periodic monitoring of these patients to create long term health trends will become a useful tool in identifying changes across patient populations as new treatment options take effect within large geographies. Low-cost, high-performance technologies such as the Corventis NUVANT and AVIVO systems which may enable the preventive medicine paradigm have the potential to impact health care costs as adoption increases.

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