

Comparison of Arrhythmia Prevalence in NUVANT Mobile Cardiac Telemetry System Patients in the US and India

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Abstract—The Corventis NUVANT™ Mobile Cardiac Telemetry System provides continuous monitoring of symptomatic and asymptomatic cardiac abnormalities to help physicians diagnose and treat non-lethal cardiac arrhythmias. Analysis of a sample of 2231 US and 1053 Indian NUVANT patients has revealed interesting statistics on the prevalence of various cardiac arrhythmias in the patient populations of the two nations. The population is non-randomized and consists of US patients where often a traditional Holter Monitor study was negative and self-pay Indian patients. Mean age was 61.3 for the US and 57.8 for India with 57% of US patients and 32% of India patients being female. Presentation of specific arrhythmia types was similar across populations with the exception of atrial fibrillation and flutter being more prevalent in the older US population as well as increased prevalence of symptomatic atrial and ventricular ectopic rhythms in all patients and SVT for female patients in India. Utilization as defined by the number of patient triggers was 50% higher for Indian patients.

I. INTRODUCTION

WEARABLE technologies such as fitness monitors, wearable computers, heads up displays, mobile phone peripherals, and medical mobile patient monitoring systems are seemingly maturing as products are released almost daily. In the medical space, Corventis has FDA cleared, market introduced mobile cardiac telemetry (MCT) and mobile patient monitoring (MPM) systems that are applied to the patient's skin to collect electrocardiogram (ECG) and other physiological signals [1],[4]. Additionally, past studies have shown Corventis' non-invasive devices impose minimal restriction on patient lifestyle during wear and enjoy high levels of patient compliance which is critical for clinical success [5].

Wearable MCT and MPM systems generate large volumes of data which can be analyzed to provide follow-on benefits. This could include customization 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 regulation. One particular area of interest is the distribution of cardiac arrhythmia types in patients undergoing MCT monitoring from a downstream therapy viewpoint. Several examples of studies of arrhythmia presentation and prevalence based on general population studies as well as MCT system data exist in the literature [1], [6-9]. However, these studies do not compare arrhythmia presentation across patient populations, specifically across geographic and cultural boundaries which could be helpful for conducting international medical trials. The low cost, unobtrusive nature of Corventis' NUVANT MCT System is ideal for such comparison.

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 2231 (1275 female and 956 male) NUVANT MCT System patients from the US and 1053 (336 female and 717 male) patients from India, representing approximately 600,000 individual ECG strips and 36,000 days of continuous arrhythmia monitoring.

II. THE NUVANT SYSTEM

The NUVANT MCT System includes a patient wearable device (PiiX™) that provides automatic detection of arrhythmias and automatic transmission of ECG and heart rate data [2], [8-9]. These signals are relayed via wireless

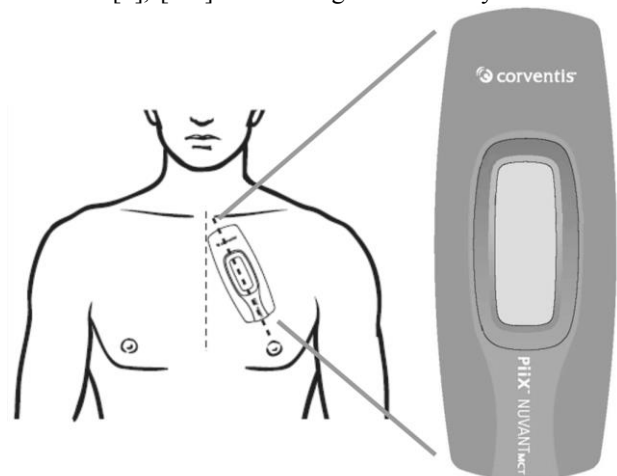


Fig. 1. Application site for Corventis NUVANT PiiX™.

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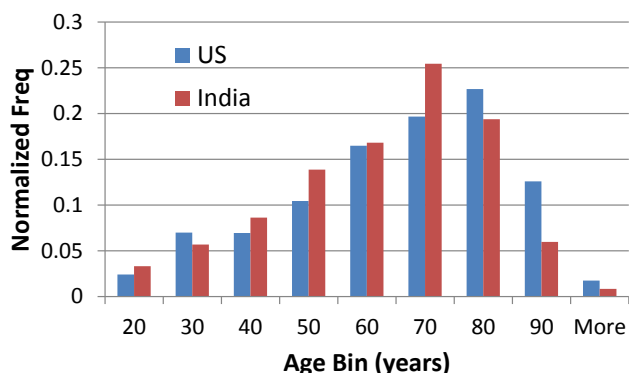


Fig. 2. Histogram of the US and India patient population by age

link to a mobile-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 prescribing physician. Either the patient or caregiver prepares the skin site and applies the adherent PiiX to the skin in upper left quadrant of the chest. (Fig. 1).

The typical patient in the US is prescribed the NUVANT MCT 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 NUVANT MCT, which allows for high patient compliance and continuous monitoring for extended durations while remaining inconspicuous during use [5]. In developing countries where much health care spending is self-pay and access to health care is not a given, the NUVANT MCT System competes directly for consumer dollars with Holter monitors. In this environment, cost, accessibility and efficacy are the primary drivers for adoption as evidenced by the rapid growth of NUVANT MCT prescriptions in India.

III. METHODS

The PiiX adherent device continuously monitors the patient via a modified Lead II orientation and when cardiac data of interest is detected the ECG episode data is packaged and transmitted for CMC review. Retrospective analysis of these archived transmissions and subsequent CMC arrhythmia classification forms the basis of the presented study. Actual treatment prescribed and clinical outcomes based on the transmitted arrhythmias are not presented.

De-identified data from NUVANT patients was analyzed to generate relevant statistics on the patient population demographic and diagnosed arrhythmias. Demographic criteria consist of geography, age and gender. Arrhythmias were selected for their clinical relevancy, with some types only relevant when symptomatic. An arrhythmia was classified as symptomatic when it was collected in response to a patient triggering an ECG episode strip manually rather than being detected automatically by the PiiX algorithms.

CMC analysis of incoming ECG strips often identifies multiple arrhythmias in each strip. In these cases, each clinically relevant arrhythmia identified is counted in the

data set. For specific CMC classifications such as ventricular tachycardia, the annotations were used to further differentiate between sustained or non-sustained arrhythmias. Bradycardia low rate arrhythmias are only

TABLE I

PATIENT DEMOGRAPHICS

Group	n	Mean Age (years)	Median Age	Age Standard Deviation
US	2231	61.3	65	18.7
Female	1275	59.0	63	19.5
Male	956	64.4	67	17.2
India	1053	57.8	61	17.9
Female	336	54.6	59	18.1
Male	717	59.3	62	17.6
Overall	3284	60.2	63	18.5

counted as clinically relevant when they occur during waking hours which are defined as 5AM to 1AM local time. Sinus tachycardias, and ectopic atrial and ventricular rhythms (premature ventricular and atrial contractions, couplets, bigeminy, junctional beats, etc) are considered clinically relevant only when triggered by the patient, signifying a symptomatic arrhythmia.

IV. RESULTS AND DISCUSSION

Analysis of the patient population begins with patient age and region as shown in Fig. 2 and Table I. From this data we see that the patient population in India is younger and more heavily skewed towards male patients (68%) than in the US (43%). The reasons for these differences are difficult to know with certainty or control for but include cultural mores, access to health care, lifestyle, as well as socioeconomic factors. The self-pay paradigm of Indian health care is also a factor in who seeks out, can afford, or receives access to a cutting edge diagnostic tool like the NUVANT MCT System.

Investigation of presentation of specific clinically relevant arrhythmia types is highlighted in Figs.3 and 4. The US population exhibits fewer sinus tachycardia and bradycardia events and more atrial fibrillation and flutter events which would be expected of a generally older population. Fig. 4 shows the difference in percentage points not the percentage difference in an effort to avoid magnifying small differences in the rare arrhythmias such as AV (atrioventricular) blocks or ventricular tachycardias. Although purely speculation, the observed increased pause events in Indian patients may be attributable to the relatively low penetration of pacing and cardiac pharmaceutical treatments in India. Such treatments are more common in the US and would be likely prescribed to a patient exhibiting relevant pause type arrhythmias.

A hypothesis for the differences in SVT presentation does not immediately suggest itself. However, the increased presentation of atrial and ventricular ectopics in India may be due to the differences in health care utilization through patient triggers which will be discussed below or potentially

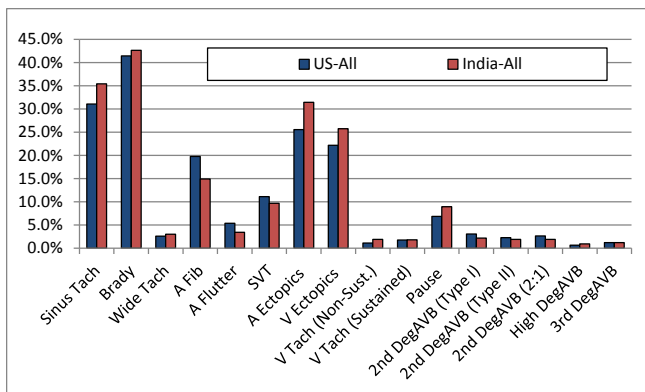


Fig. 3. Percentage of clinically relevant arrhythmia presentation for US and India Patients

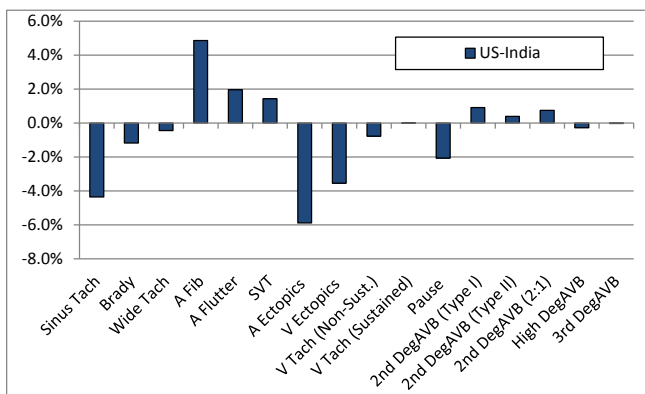


Fig. 4. Difference between US and India arrhythmia presentation. Positive means more US presentation, and negative more India presentation.

due to the market differences where Indian patients can elect to bypass the Holter for the NUVANT MCT System. This would lead to an increase in the number of patients with frequent symptoms like ectopics that are caught on Holters in the US but in India the self-pay patients are voting with their dollars to choose the more unobtrusive technology.

These comparisons continue to hold generally true when broken down by gender as well as shown in Figs. 5 and 6. However, the differences in arrhythmias such as atrial fibrillation and ectopics are more pronounced when looking at male patients while the female difference is magnified in SVTs. These differences suggest further study is needed.

As discussed, the US patient population presented is generally older. An attempt to explore and compare the arrhythmia presentation of US and India patients of similar age cohort was also made, with only patients 65 to 80 years old considered. The result is 775 patients with a mean age of 71.7 from the US and 343 patients with a mean age of 71.4 from India. Fig. 7 details the presentation of relevant arrhythmias for all patients as compared to this age-limited cohort. As can be seen in Fig. 8, the differences in arrhythmia presentation are magnified in some cases rather than reduced. Specifically the differences in atrial fibrillation between the US and India patients is much reduced when we look at a similar age cohort. However, the differences in SVTs, symptomatic ectopics, ventricular tachycardias and pause arrhythmias are all significantly magnified when comparing the 65-80 year old groups in the US and India.

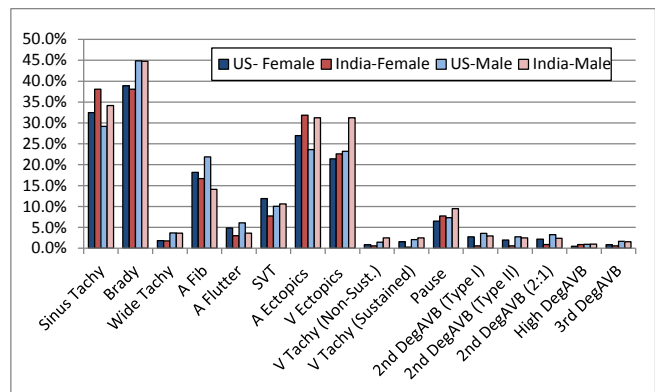


Fig. 5. Percentage of clinically relevant arrhythmia presentation for US and India Patients by gender.

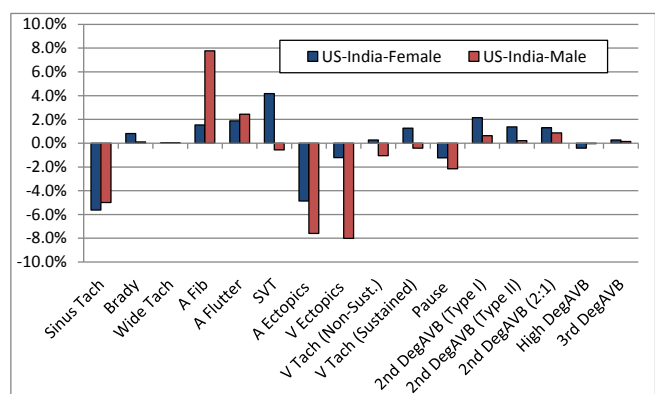


Fig. 6. Difference between US and India arrhythmia presentation by gender. Positive means more US presentation, and negative more India presentation.

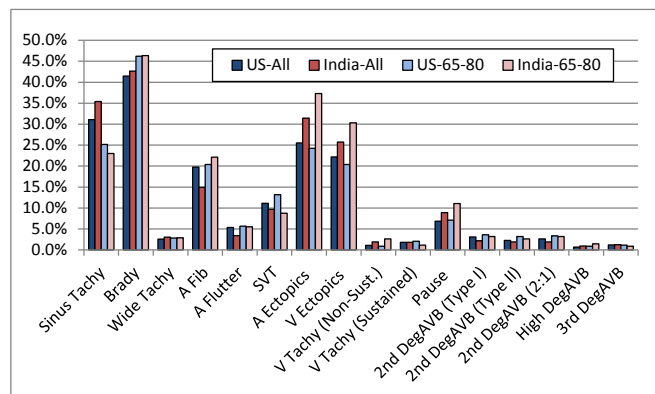


Fig. 7. Percentage of patients by region and age group that exhibited specific clinically relevant arrhythmia types.

This is likely due to differences in how such illnesses are treated in the two nations and the penetration of various treatments such as drugs, pacemakers and implantable defibrillators. Further study is certainly warranted.

Regarding utilization, in India the median prescription for the NUVANT MCT System is only 7 days while in the US it is 21 days. This is likely due to the self-pay nature of the Indian system favoring shorter and less costly prescriptions. Interestingly, the average number of arrhythmia episodes of all types per PiiX in both regions is nearly identical. This indicates to us that compliance, climate, cultural and other factors do not play a large role in the operation of the wearable device. A breakdown of episodes by gender shows

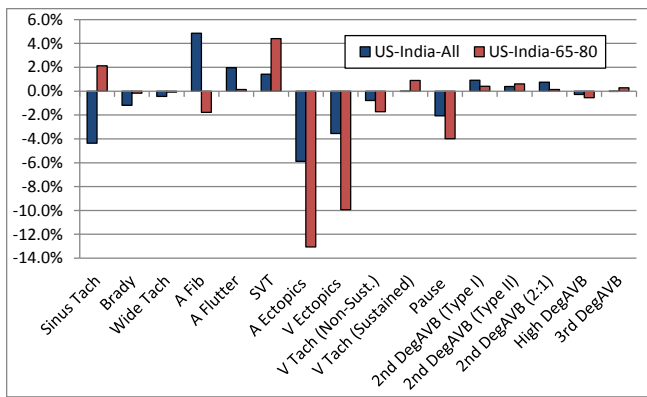


Fig. 8. Difference between US and India arrhythmia presentation in the general population and the 65-80 year old cohort. Positive means more US presentation, and negative more India presentation.

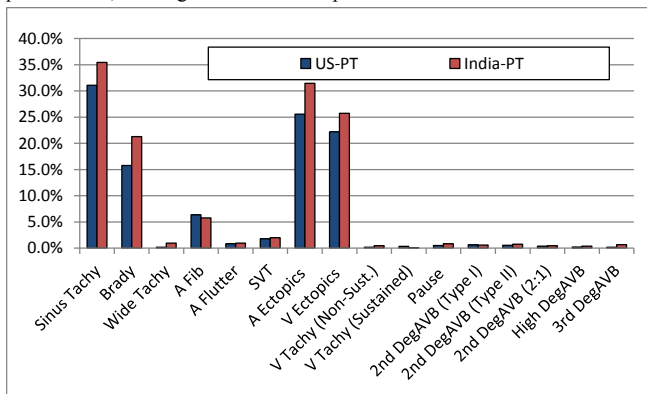


Fig. 9. Percentage of patients with symptomatic (patient triggered) clinically relevant arrhythmias.

a 20% and 34% increase in the number of episodes per PiiX for women in the US and India respectively. A hypothesis that this was due to differences in clothing and physiology for women leading to more artifact episodes was not borne out in the data and an explanation is not forthcoming.

Fig. 9 details the presentation of symptomatic arrhythmias, meaning that the patient experienced symptoms and engaged the manual patient trigger to record and transmit an ECG strip for analysis. In most cases the regional differences in symptomatic arrhythmias are slight. However, in general the utilization of the patient trigger is significantly higher in India than in the US, with Indian patients triggering on average 50% more times more than US patients. The self-pay nature of the prescription likely impacts how the patient feels about, uses, and interacts with the device.

V. CONCLUSIONS

The presented quick look at the vast amount of patient data made available by wearable medical diagnostic devices such as the NUVANT MCT System shows analysis of such data pools has potential for targeted and customized treatment of large and disparate patient populations. Studying this data also enables us to understand the limitations of comparing patient populations with vastly different demographic, healthcare, and economic circumstances. With such understanding, more rapid,

distributed, and cost effective medical trials can be envisioned as well as better patient outcomes potentially enabled.

When comparing the presented data to past studies of arrhythmia presentation [8-9], we find that the observed prevalence of arrhythmia classes like atrial fibrillation, ventricular tachycardias and pacing issues agree closely with past results. Differences in patient populations, new capabilities within the NUVANT MCT System and the CMC make direct comparisons difficult but the broad agreement is encouraging.

Specific to the patient population described above, several key questions remain. What are the primary drivers for the observed differences in presentation of such clinically relevant arrhythmias such as pause, ventricular tachycardia, SVTs, and ectopic rhythms? What can we learn about the detection and treatment of such arrhythmias from studying this aggregate data? Further study is ongoing as deployment of the NUVANT MCT System continues.

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