Symptom/Rhythm Correlation With Patient Owned Device: Insights Into Practice And Challenges

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Abstract
Capturing symptom/rhythm correlation is crucial in patients who have rhythm-related symptoms. Evolving technology has led from 24 hour and 14 day Holter monitors to now external loop recorders to capture symptom/rhythm correlation. In patients with very infrequent and short-lived symptoms, the only recourse is an implantable recording device. Recently, patient activated recording devices have become available. These have the potential to significantly increase the duration for monitoring symptom/rhythm correlations. We report cases of using such devices to demonstrate some of the uses and challenges of this new ECG recording technology.

Introduction
Patients who have rhythm-related symptoms usually have a need to record symptoms and rhythms in the same time frame. The use of an ambulatory ECG or Holter monitor for symptom evaluation has a diagnostic yield proportional to symptom frequency and with evolving technology has led from 24 hour and 14 day Holter monitors to now external loop recorders to capture symptom/rhythm correlation. The arrival of external loop recording devices in the late 1980’s increased the diagnostic yield to approximately a 25% range,1 again related to the symptom frequency and the ability of the patient to tolerate continuous or intermittently applied skin electrodes.

In patients who absolutely require the recording of rhythm prior to infrequent but short-lived symptoms, the only recourse is an implantable recording device. In the last years, patient activated recording devices have become available. These have the potential to significantly increase the duration during which patients may have a tool for monitoring symptom/rhythm correlations. As well, given their ability to be used in the very long term, such devices offer an opportunity to consider longitudinal assessment of drug effects. Such devices can be used in the long term for atrial fibrillation detection in groups deemed to be at risk for such an arrhythmia based on epidemiological (age plus hypertension) or clinical features (post CVA with normal carotid Doppler assessment).2-4

We report four typical cases of using such devices to demonstrate some of the uses and challenges of this new and potentially disruptive advance in patient and marketing driven ECG recording technology.

Device Description
A handheld ECG device that captures a modified lead II ECG recording was used. The device has two contact electrodes for each thumb and records a modified lead II ECG which is uploaded to a central recording site or can be recorded to the patients desktop. Record duration is 30 seconds (with storage of up to 20 recordings). The validity of a thumb electrode record to accurately reflect a modified lead II has been established.5 Patients are capable of making record whenever symptoms occur. Further details about the current iteration of this device can be found at the manufacturers URL (http://www.theheartcheck.com/products/pen_device.html).

Case 1
A 52-year-old triathlete presented with a 5-year history of sudden onset/offset rapid heart palpitations. Episode duration is minutes at a time causing significant symptoms at peak exercise while training. Over the years three, 2 weeks external loop recorders (ELR) failed to correlate symptoms with rhythms. The patient was bothered, by his rare rhythm related events but never pre-syncopal and was not offered an implantable monitor. Using a home athletic heart rate monitor, he recorded his heart rate changes during symptoms. After a cool down period he engaged in vigorous exercise. A sudden step increase in heart rate to 230 bpm followed by an equally sudden decrement back to basal rate 160 bpm was seen (Fig 1a). Based on this, he underwent diagnostic electrophysiology study in January 2010. This revealed intermittent dual AV node physiology with isolated atrial
ectopy at extremes of stimulation with Isoproterenol infusion. Since no rhythm was ever documented it was opted not to perform empiric slow pathway ablation.

He acquired a hand held ECG device in March 2014 and 10 months later was able to induce and record index symptoms followed by a recording of rhythm when he returned to normal (Fig 1b). The rhythm recorded is suggestive of typical atrioventricular nodal re-entrant tachycardia (AVRNT) as a cause of symptoms witha small retrograde deflection seen after each QRS at a rate 200 bpm. He was booked for redo procedure with planned empiric slow pathway ablation to be performed even if no arrhythmia is induced.

**Case 2**

A 29-year-old man morbidly obese otherwise healthy, presented to Emergency Room with rapid atrial fibrillation. By history he was thought to have a rapid regular rhythm that then degenerated to an irregular rhythm. Echo, stress echo, and Holter were unrevealing and normal. On September 19, 2004 an electrophysiogical study documented a difficult to induce typical AVNRT at rate of 250 bpm. An uncomplicated slow pathway ablation procedure was performed with the unproven hypothesis that typicalAVNRT preceded bouts of atrial fibrillation.

He did well for the next 9 years. In September 2013 he had bouts of what were consistent with typical atrial fibrillation not documented. He was given an ECG recording and ultimately recorded an example of atrial fibrillation in November 2013 with ongoing infrequent episodes.

He was offered and declined pulmonary vein isolation (PVI) procedure and given the symptoms burden, risks and expected benefit statistics opted for medical management. Flecainide 100 mg bid was offered along with aggressive efforts for weight control. Sleep studies showed no OSA. He did not want beta-blocker and flecainide mono-therapy was used. He acquired an ECG recording device to record recurrent rhythm symptoms (Fig 2). This allowed the recording of recurrent symptoms while on flecainide. Recurrent bouts of atrial fibrillation were recorded. His symptoms were not radically different and the arrhythmia was not showing signs of organization. Larger dose beta-blocker was added and he moved onto an uncomplicated PVI with on going ECG monitoring for symptom-rhythm correlation using the same device in follow up continuing.

**Case 3**

A 35-year-old with long-standing proximal perimembranous restrictive VSD, which produces a high velocity peri-cuspal small left to right shunt. On MRI, the shunt jet causes prolapase of right coronary cusp into the right ventricle (RV). The lesion has been long term and stable. MRI shows a normal RV and QP/QS 1.8.

He has long-standing highly symptomatic ventricular ectopy and on 12 lead ECG suggestive of right ventricular outflow tract (Left bundle morphology, inferior axis, transition lead V3, coupling interval 390 ms). Ectopy has been shown on the Holter monitor to be isolated, typically less than 500 beats per 24 hours with no diurnal variation. Symptom – rhythm correlation using a home ECG recording revealed that some but not all symptoms are related to ectopy. His highly symptomatic but infrequent ectopy was a source of psychological stress, mitigated in his view by the ability to obtain and document a signal of on-going reassurance from an ECG recording apparatus. He has been offered and declined an ablation option for rhythm management. He has intolerance or inefficacy to trials of rhythm suppression and symptom control with bisoprolol, sotalol, verpamil and diltiazem. Flecainide at initially 50 b.i.d. and escalated to 100 mg bid has improved symptoms while ongoingrhythmdocumentation occurs showing no significant QRS prolongation, allows symptom-rhythm correlation and no clear signal of pro-arrhythmia (Fig 3).

**Case 4**

A 54-year-old man with infrequent paroxysmal atria fibrillation in
the setting of mild treated hypertension, no structural heart disease, no inducible ischemia and with normal BMI and a normal sleep study. Episodes of sustained arrhythmia are rare, once in 3 years. He was offered and declined a PVI ablation or continuous medical therapy for prevention of highly bothersome but infrequent bouts of arrhythmia. He preferred a pill-in-the-pocket- oral pharmaco-conversion approach to management with an intent to take flecainide 300 mg as a single stat oral dose in the event of rhythm recurrence. He received a recording device in February 2013. With this device he frequently documents bouts of nonsustained atrial tachycardia. He has been taught how to recognize and be reassured by their occurrence and is satisfied with his sense of control of rhythm and symptoms (Fig 4).

Discussion

The era of new devices has arrived. The embrace by some patients (or their concerned families) of novel technologies has started. The use of such devices, directly marketed to patients, may exceed clinical experience, familiarity or even proven clinical evidence of efficacy on hard outcomes such as symptom control, prevention of health resource utilization, or as a guide to treatment. There is certainly the possibility that the use of such devices may in some patients encourage and promote a technologically driven somatoform behaviour. Alternatively and for many patients it may provide a tool to enhance autonomy, provide reassurance and a sense of control, and serve as a tool for drug monitoring, therapy assessment, allay diagnostic ambiguity and potentially decrease health resource utilization resource. The four cases illustrate many of these issues. In case 1, the device allowed a decision to consider empiric slow pathway ablation. Case 2 and 4, highlight the potential role such devices may have for pharmacological surveillance with the documentation of rhythm recurrence while on flecainide a potentially pro-arrhythmia medication. Although not used in these cases, such devices have been speculated to have a role in areas of concern for drug induced malignant arrhythmia with a QT signal that can be followed over time. This may have a role for pharmaco-surveillance using agents with very rare but potentially devastating long QT concerns, such as certain psychotropic medications or macrolide antibiotics.

Case 3 outlines the use of the device to assess the specificity of patient driven decisions to use an outpatient oral pharmaco-conversion approach for rhythm control of atrial fibrillation. There is a burgeoning literature on long-term recording devices to identify atrial fibrillation in post stroke patients. Long-term (30 day) external loop recorder device has a 20% diagnostic yield in such patients.

Longer term implanted devices increase the diagnostic yield by virtue of longer time of recording to 60% in two years. Such devices however are cumbersome and a simple screen on a regular basis with a hand held device might ultimately allow a much longer duration of screening for briefer periods of time. Such a system has been used for a population-based survey of a circumscribed community in patients over the age of 75 with a diagnostic prevalence of atrial fibrillation at 1.5%. Similar selected patient population such as those obtaining prescrption for medications over the age of 75 have shown similar diagnostic yield prevalence of 1%

At the same time there have been advances in devices to record and generate an irregularity signal but as case 1 and 3 demonstrate documenting changes in heart rate or providing a statement of irregularity may not be adequate or equivalent to the utility of having an actual ECG signal.

For cardioembolic stroke prevention due to atrial fibrillation, the alternative is a presumption of atrial fibrillation based on Holter arrhythmic ectopy counts. Such methods have decreased diagnostic precision in predicting atrial fibrillation; to the 30-40% range in post stroke patients. The safety of new anticoagulation may allow such relatively poor diagnostic precision to still be useful as a surrogate for the decision for anticoagulation therapy in post stroke patients however this is an area of ongoing research that may be replaced by long term home ECG monitors used in this study.

There are some challenges related to the use and interpretation of the recording devices. The devices are patient self-recordings. As a result they require patient attention and certain awareness, which might be challenging when the patient is distressed with the arrhythmic event at the time of the recording. Providing patients with a recording system to monitor their own dysrhythmias can lead to neurotic behavior. Patients can become quite anxious over their heart health and may have a worsened psychological quality of life.

While interpreting theses devices, physicians sometimes face a significant number of tracings with artifact that are difficult to interpret. The large number of recordings can be cumbersome for providers to sift through. Without an automated recordings/evaluation system as with Holter’s, loop recorder, etc, providers could get overwhelmed. There are a few recording devices in the market that share the same concept of our device. AliveCor is a similar device using only lead 1 for recording. This is not an ECG device but rather a sensor that transmits information to a cell phone and it cannot store ECGs. Unlike the device discussed in our report, AliveCor does

Figure 3: Ongoing rhythm documentation showing no significant QRS prolongation, symptom-rhythm correlation and no clear signal of pro-arrhythmia.
not currently include ECG analysis software; operators can only scan the PDFs. Ultimately, the evolution of these devices might improve many of the current limitations in the near future.

Current machines have a cost to the patient directly or their insurer. The devices used in this study costs $250 CDN and it is possible that the increased use of such devices will lead to new discussions on equity of access to health technology. Such a discussion already occurs in Canada in other areas, especially in area of mental health care, medication prescriptions use and access to health care in remote areas. These technologies will force further discussion in two directions:

1. Better research to show proof in healthcare utilization benefits and the other benefits that are clinically relevant but more difficult to evaluate (health related quality of life and health care resource utilization, measures of autonomy and control, etc)
2. Ongoing discussions on costs of healthcare delivery with a device that is directly marketed to patients and families by for-profit companies.

Conclusions
The cases illustrate the utility of patient activated home recording devices in long-term assessment for both safety of medication and diagnosis of arrhythmia. These cases illustrate the complexity and the future for new techniques for symptom/rhythm correlation.

References