



BAISHIDENG PUBLISHING GROUP INC

8226 Regency Drive, Pleasanton, CA 94588, USA

Telephone: +1-925-223-8242 Fax: +1-925-223-8243

E-mail: bpgoffice@wjgnet.com <http://www.wjgnet.com>

Name of Journal: *World Journal of Methodology*

ESPS Manuscript NO: 25040

Manuscript Type: Diagnostic Advances

RE: WJC25040, Remote ECG Monitoring Using a Novel Adhesive Strip Sensor: A Pilot Study

We thank the Reviewers and Editor for reviewing this manuscript and for their encouraging comments and an opportunity to resubmit our manuscript. We have revised the discussion to address the concerns as detailed below.

Editors Comments

Comment 1: Authors' full names should be given first, then the complete name of institution, country, city, province and postcode.

Response: We have included the postcode for each author.

Comment 2: Please offer a signed pdf file with all the authors.

Response: We are submitting a signed PDF file related to the Conflict-of-Interest Statement.

Comment 3: Only one corresponding address should be provided. Author names should be given first, then author title, affiliation, the complete name of institution, detail of address (to street or avenue), city, postcode, province, country, and email.

Response: We have included details of the street address (200 First St SW)

Comment 4: Telephone and fax should consist of +, country number, district number and telephone or fax number

Response: We have included the +, country code and fax number (+1-507-255-2446, **Fax:** +1-507-255-2550)

Comment 5: Please write a summary of less than 100 words to outline the most innovative and important arguments and core contents in your paper to attract readers. Please offer the audio core tip.

Response: We have expanded the summary to be less than 100 words by outlining the most innovative and important arguments and core contents of the paper. This is included in the Core Tip section of the manuscript and reads as follows:

“The findings of this pilot study confirm that a remote monitoring system using a novel adhesive strip ECG sensor can acquire and transmit diagnostic high quality ECG data over a period of 3 days when worn by elderly subjects leading active independent lives. Automated determination of heart rate variability permitted reliable characterization of ECG strips with AF. These data have implications for long term continuous monitoring for development of atrial fibrillation in independent elderly patients.”

We have also included a Core Audio tip meeting the acceptable mp3 format that will be uploaded to the journals website.

Comment 6: Please add PubMed citation numbers and DOI citation to the reference list and list all authors.

Response: We have added the PubMed citations numbers and DOI citation to the reference list and listed all authors

Comment 7: Please provide the decomposable figure, whose parts are movable and words can be edited. So please put the original picture as word or ppt format so that I can edit them easily.

Response: We have placed the original pictures in a PPT format so that you can make necessary edits.

Reviewer #1 (Code 00236910):

Many thanks for the opportunity to review your work. This is an interesting study, the paper is well written and the results appear to be appropriately interpreted.

Response: We thank the Reviewer for this comment.

Comment 1: This reviewer struggles to identify what was the gold standard to diagnose AF in this study. It appears the authors relied on the same device to diagnose AF. It would be much better if they have a gold standard to compare such as a Holter device (or for in patients continuous monitoring). This is important because we want to know how good this new technology is comparing to the standard devices we use both as outpatients as well as inpatients.

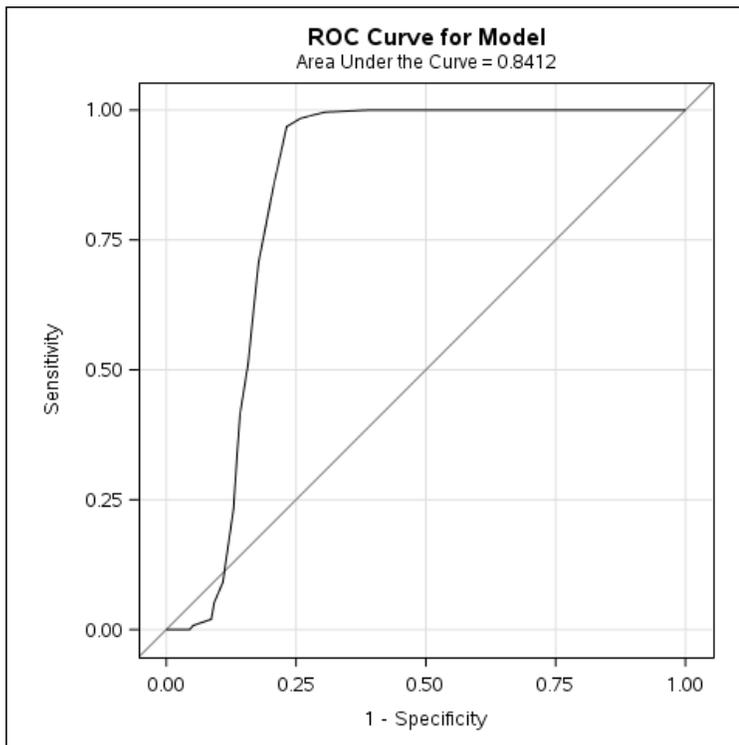
Response: The reviewer brings up an important point; however, given that this monitoring was done outside the usual care setting, it was not feasible to have any additional gold standard backup technology as a quality control. However, our in-hospital studies have indicated that we are able to detect episodes of atrial fibrillation very reliably. Furthermore, an important aspect of our studies is that we are able to detect episodes of atrial fibrillation that would otherwise go unrecognized.

Comment 2: Can the author describe whether this new ECG lead can be worn during shower, etc?

Response: Although using the BodyGuardian in the shower would affect the quality of recordings and may compromise adhesion of the electrode, it is possible to accomplish this by having the sensor covered by waterproof, plastic dressing (much like a Tegaderm transparent adhesive film), as is used to cover wound sutures.

Comment 3: In analyzing area under the ROC, it is unusual to use ROC for only one cut point. Indeed, it is a standard practice to use the predictor as a continuous predictor. If the authors really want to use one cut point to dichotomize the HRV, then sensitivity, specificity, negative and positive predictive values and likelihood ratios will be more appropriate.

Response: We have added these values to the manuscript. Due to the nature of the distribution of HRV, the ROC curves are very similar between the continuous and dichotomous variables. AUC is also similar (0.84 – curve shown below)



Reviewer #2 (Code 00214291):

Comment: Interesting new technique

Response: We thank the Reviewer for this comment.

Reviewer #4 (Code 00227355):

Comment 1: This is an interesting paper for the clinical practice. Charles J. Bruce et al. reported that a highly variable RR interval ($HRV \geq 7$) predicted AF, and the monitor acquires and transmits diagnostic high quality ECG data and permits characterization of AF. Overall the paper appears to be carefully examined and data adequately discussed. I suggest that this paper has the priority to be published in WJC.

Response: The Reviewers assessment is greatly appreciated.

Reviewer #5 (Code 00214305):

This is a pilot interesting study addressing the diagnostic utility of a new wireless ECG remote monitoring system.

Response: We thank the Reviewer for this comment.

Comment 1: The major limitation of this study is the small number of patients studied. Only one out of ten patients had an established arrhythmia (atrial fibrillation). Patients with different types of arrhythmias (supraventricular or ventricular) are missing. This is important to evaluate the reliability of this monitoring system.

Response: We agree that the sample size is limited. However, this is a pilot study directed towards evaluating the ergonomics, tolerability and effectiveness of continuous EKG monitoring, as well as identifying whether the quality of EKG recordings can be preserved over extended periods. **However, we added text to the limitations section to address your comment. It reads:**

Additionally, very few patients experienced an arrhythmia (atrial fibrillation), and patients with other arrhythmias were not included. However, this was a pilot study directed toward evaluating

the ergonomics, tolerability, and effectiveness of continuous EKG monitoring, and to determine whether the quality of the EKG recording could be preserved over extended periods.

Comment 2: The authors report that there was moderate agreement in rhythm classification between pairs of readers (median Kappa=0.65). Variability was noted in the percentages of strips rated by each reader as sinus (48-70%) while the percentages of those rated as AF was comparable across readers (11-15%). The authors should comment on this in discussion.

Response: Thank you for this comment. The moderate agreement is not being driven by disagreement over the absence or presence of atrial fibrillation, but by differences in classification between sinus and indeterminate. In table 1, one can see that the readers with lower percentages of sinus rhythm have a correspondingly higher percentage of indeterminate. We attribute this finding to the fact that some readers were more comfortable identifying sinus rhythm while others default more often to indeterminate. Regardless of this inter-reader variation, there was good agreement on the absence or presence of AF.