Non-invasive 12 Lead ECG Assessment As Compared To Physician 12 Lead ECG Assessment

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BACKGROUND

Accurate localization of PVC and VT arrhythmias is often difficult and time consuming. Current methods rely on a 12 lead ECG interpretation by the physician. Several methods, using body surface mapping, have been developed to improve upon the current method, but they remain cost prohibitive and time consuming as compared to the standard 12 lead ECG. Despite its wide acceptance, the interpretation of the 12-lead ECG is based off assumptions and continues to have inaccuracies.

Non-invasive localization should be easy to use, affordable and improve upon clinically accepted methods of arrhythmia localization. VIVO™ (Catheter Precision, Mt. Olive, NJ USA) is a novel electrocardiographic imaging (ECGi) system that utilizes the standard 12 lead ECG.

In a multi-center study, the accuracy of VIVO to localize a PVC or VT was compared to the physician's interpretation of a 12 lead ECG.

METHODS

Device Description

VIVO is a non-invasive localization system. It combines standard clinical inputs from a MRI or CT, 12-lead ECG and a 3D photograph of the electrode placement. The VIVO workflow is described in Figure 1.

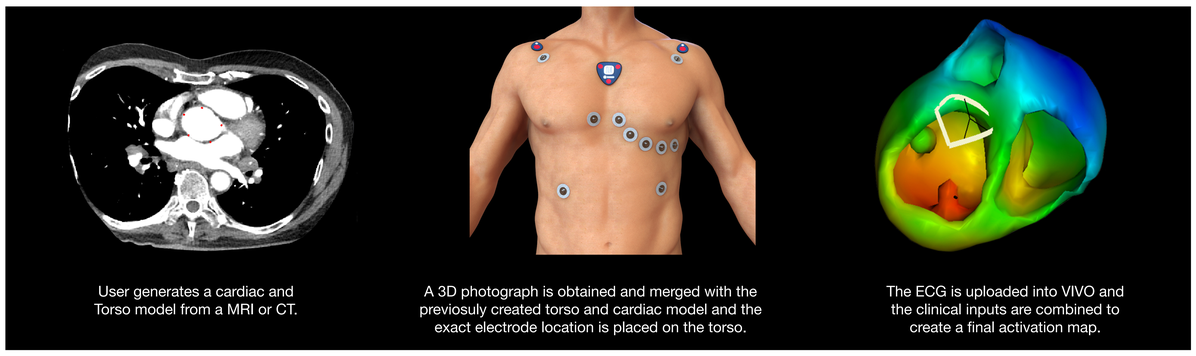

Figure 1: VIVO Workflow

Protocol

The VIVO study was a prospective, non-randomized study conducted at 6 investigational site.

For patients undergoing PVC or VT ablation, a physician assessment of the standard 12 lead ECG was recorded prior to the ablation procedure.

For the same subjects, a patient specific 3D model of the ventricles and torso were created from standard MR or CT scans. This model was merged with a 3D photograph of the standard 12 lead ECG electrode placement and ECG recordings from the investigational site's recording system were uploaded into the VIVO system for analysis.

The final VIVO analysis, identifying the location of the PVC/VT, was compared to the physician's assessment of the 12 lead ECG depicting the same PVC/VT. To determine if VIVO or the physician was more accurate in the localization of the PVC/VT, both the physician assessment and VIVO analysis were compared to the successful ablation location.

All data was reviewed and confirmed by an expert Committee* consisting of three physicians that were not involved with the clinical evaluation.

*Adjudication Committee: Steve Kutalek, MD (Drexel University); Edward Platia, MD (Washington Hospital Center); Binu Philips, MD (Mount Auburn Hospital)

RESULTS

A total of 45 subjects comprised the intent-to-treat cohort. Demographics are described in Table 1.

Demographic		Percent (N)
Gender	Male	46.67% (21)
	Female	53.33% (24)
Age (mean ± SD)		56.4 ± 14.9

Table 1: Subject Demographics

Physician Assessment

VIVO correctly identified the PVC/VT origin as better or the same than the physician assessment in 43/45 subjects (95.56%). Results are detailed in Table 2.

Performance Standard	Percent (N)
VIVO was the same as the physician guess	44.44% (20)
VIVO was better than the physician guess	51.11% (23)
The physician guess was better than VIVO	4.44 (2)

Table 2: VIVO Localization as Compared to Physician Assessment of a 12 Lead ECG

VIVO was more accurate in localizing PVC and VT arrhythmias than the physician's assessment of a standard 12 lead ECG in over 50% of the subjects. Further, the physician was only better in identifying the PVC/VT location in less than 5% of the subjects.

DISCUSSION

The 12-lead ECG is useful to localize the site of origin for an ablation procedure. Although useful, the 12-lead ECG has limitations. Current methods assume a standard anatomy and ECG electrode lead placement and does not adjust for changes to anatomy or lead placement. As a result, the 12 lead ECG may localize incorrectly, potentially requiring longer invasive mapping times.

Creating the patient specific anatomy model and ECG lead placement is not time consuming and required little training of the hospital staff. Future studies should not only observe the accuracy of VIVO but determine the impact of more accurate localization of ventricular arrhythmias on procedure times and ablation success.

CONCLUSION

VIVO may be better able to account for variances in electrode placement and patient specific anatomy. The non-invasive system can be used pre-procedurally to assist in planning an ablation procedure and may be beneficial in decreasing overall procedure time and increasing ablation success.

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