Accuracy and Long-Term Outcomes from First Multi-Center Registry Experience for Non-Invasive Localization

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BACKGROUND

Correct localization of the origin of premature ventricular complexes (PVC) and ventricular tachycardia (VT) is key to successful catheter ablation. We sought to review the accuracy of non-invasive electrocardiographic imaging (ECGi) localization and long-term outcomes (12 months post ablation) in a real world setting when using VIVO.

METHODS

Device Description

VIVO™ (View Into Ventricular Onset) is a non-invasive mapping tool that localizes the earliest site of ventricular activation from a standard 12 lead ECG. Precise location of the ECG electrodes are obtained from a 3D image of the body surface, which is merged onto a patient-specific model of the heart and torso created from MRI/CT scan images (workflow Figure 1).
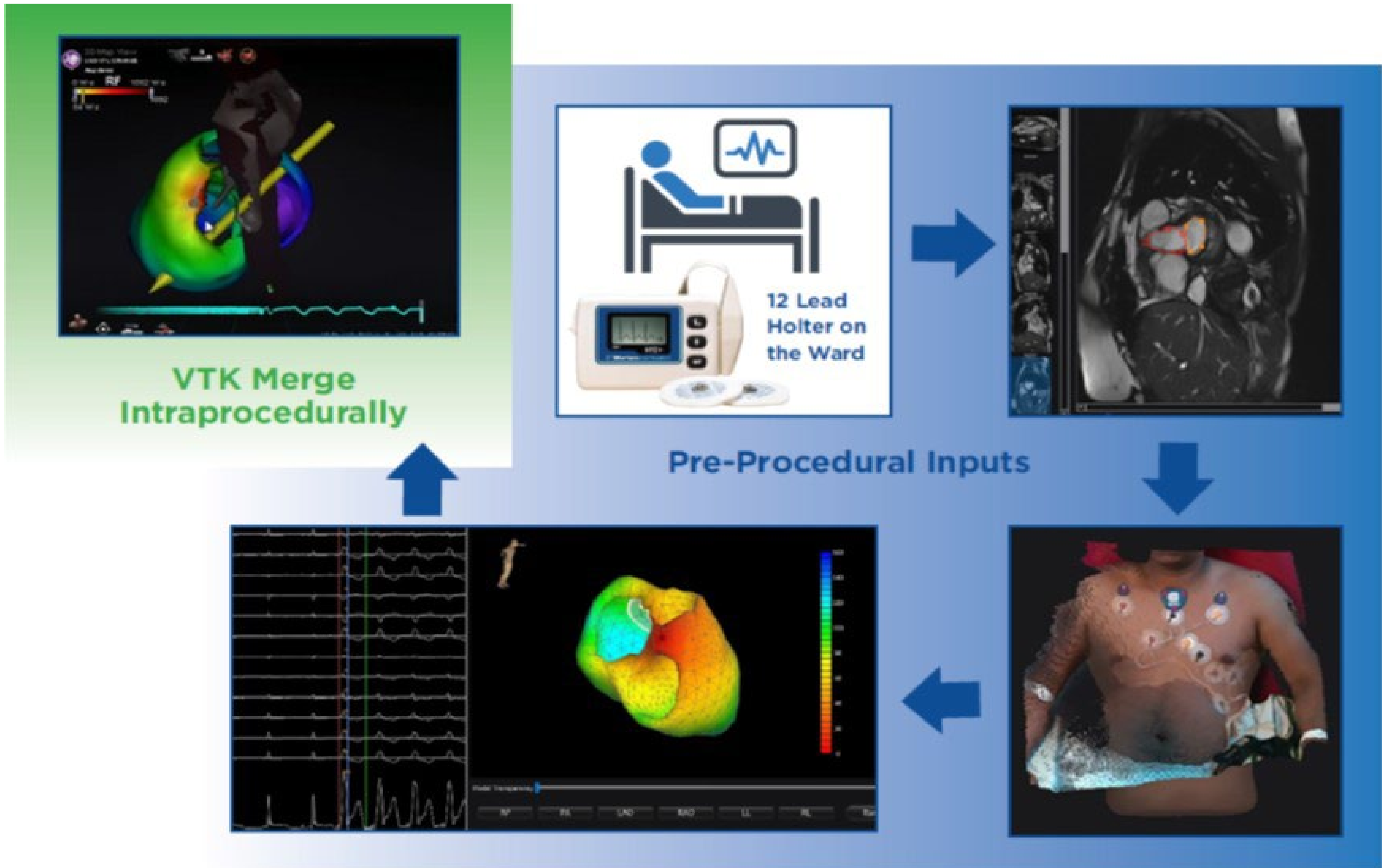

Figure 1: VIVO Workflow

Protocol

- Each patient had a CT or MRI, a standard 12 lead ECG and a 3D photograph of the torso completed prior to creating a VIVO analysis map
- The pre or intraprocedural location was compared to the hospital's EAM system for accuracy.
- This was indicated by using a 27-segment heart-model and determining the segment to which VIVO predicted the localization and the segment to where the EAM located the successful ablation site. Segments were considered a match when the segment was the same for both EAM and VIVO or when the segments were adjacent to each other (segmental accuracy) as shown in Figure 2.

RESULTS

Long-Term Follow-up

- 76 patients had procedural success and were then followed up to 12 months, but only required one follow-up visit
- 60 (83.33%) patients had long-term procedural success (no recurrence or continued reduction)
- Patients had recurrence of the same arrhythmia at the same rate as the development of a new arrhythmias (N=6 and N=6).

Interval		Continued Reduction	No recurrence	Recurrence Same	Recurrence New
3 Months	N	2	12	0	1
	%	13.33%	80.0%	0%	6.7%
6 Months	N	3	8	0	0
	%	27.0%	73.0%	0	0
12 Months	N	10	25	6	5
	%	20%	50%	12%	10%
Overall	N	15	45	6	6
	%	20.8%	62.5%	8.3%	6.9%

RESULTS

Accuracy Endpoint

- 96 patients had 106 VIVO localizations
- 94.33% (N=100) segmental accuracy across all localizations
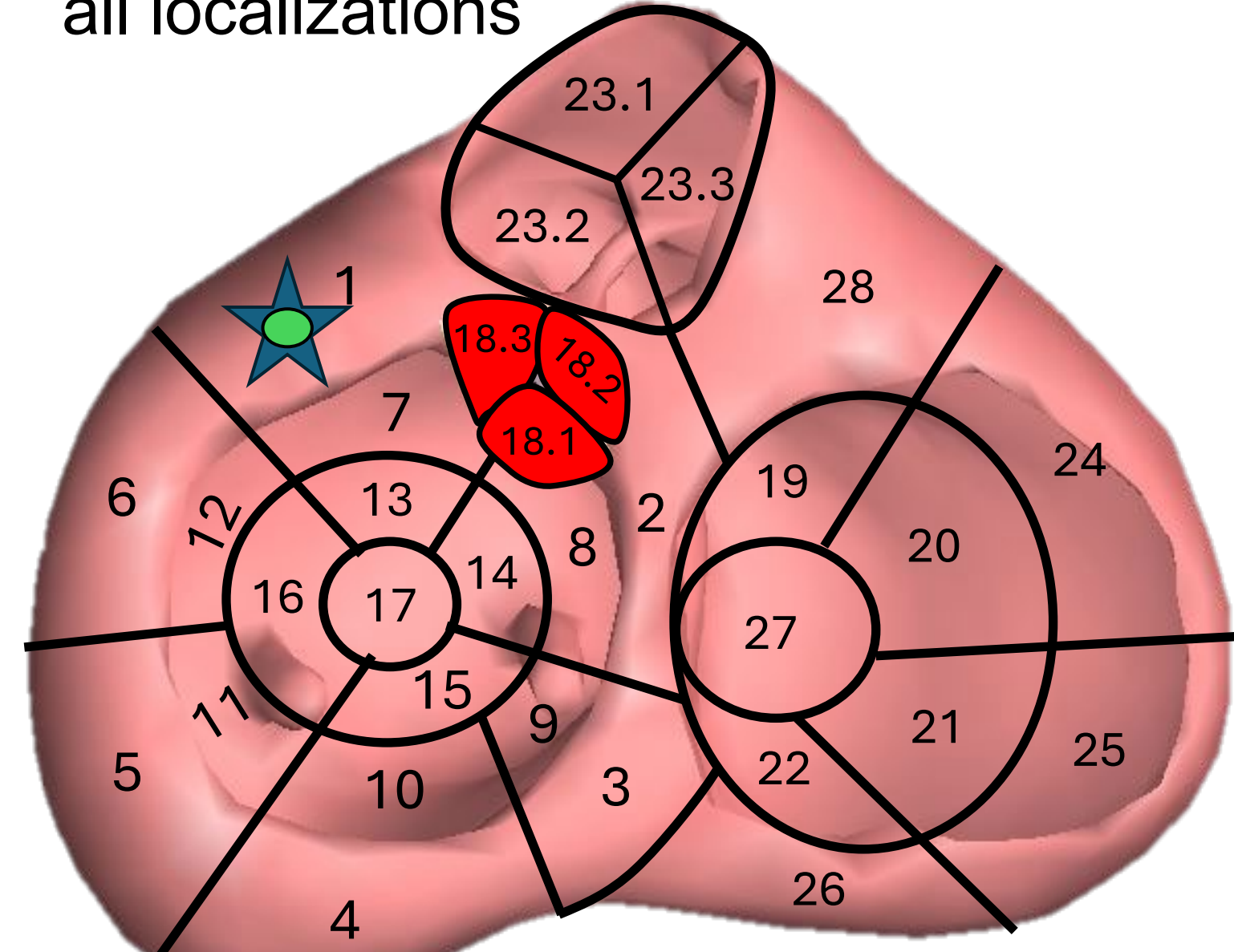

Figure 2a: Example of exact match: VIVO indicated by the star is in the exact same location as the EAM, indicated by the black dot
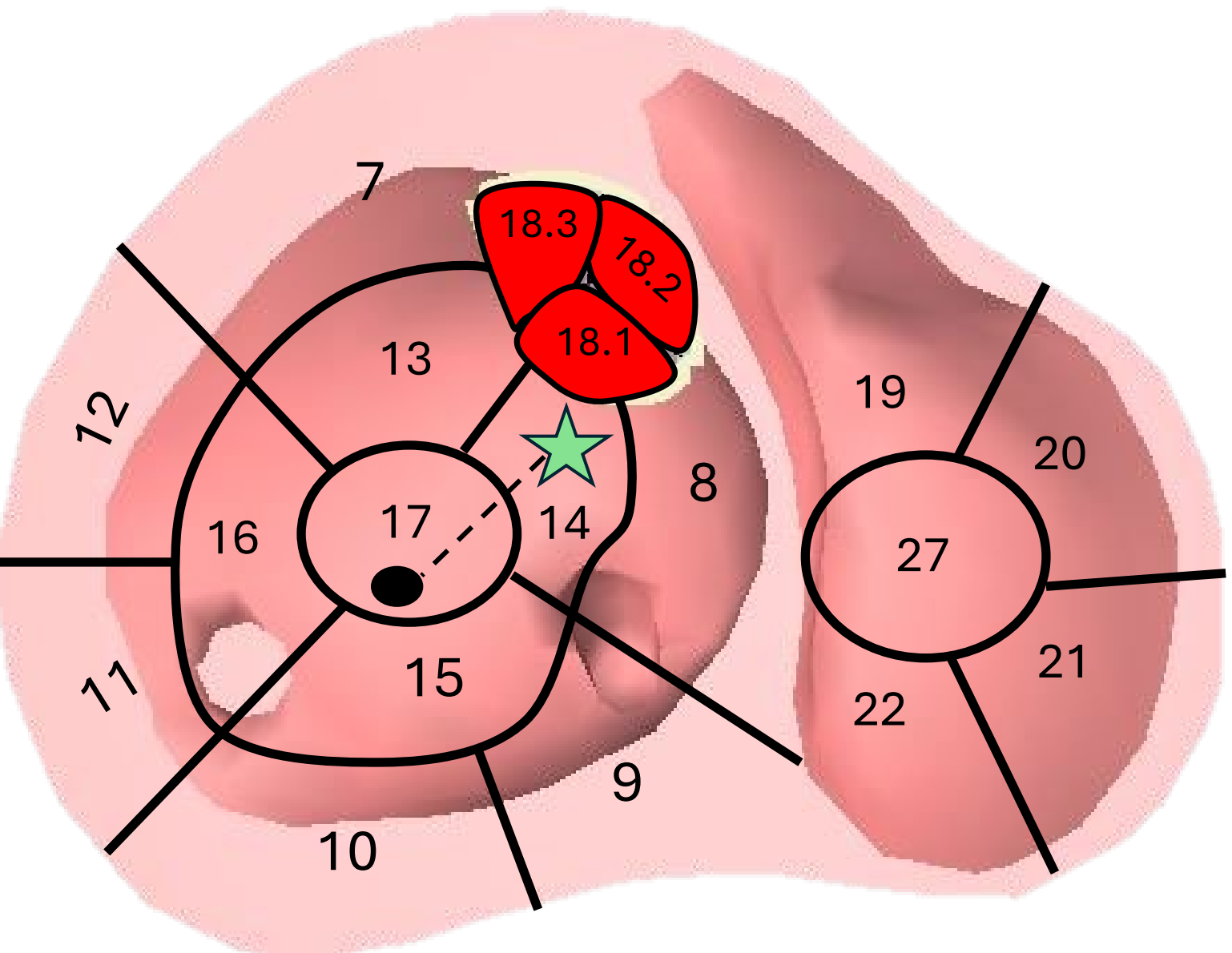

Figure 2b: Example of near match: VIVO is indicated by the star and the EAM location is indicated by the black dot
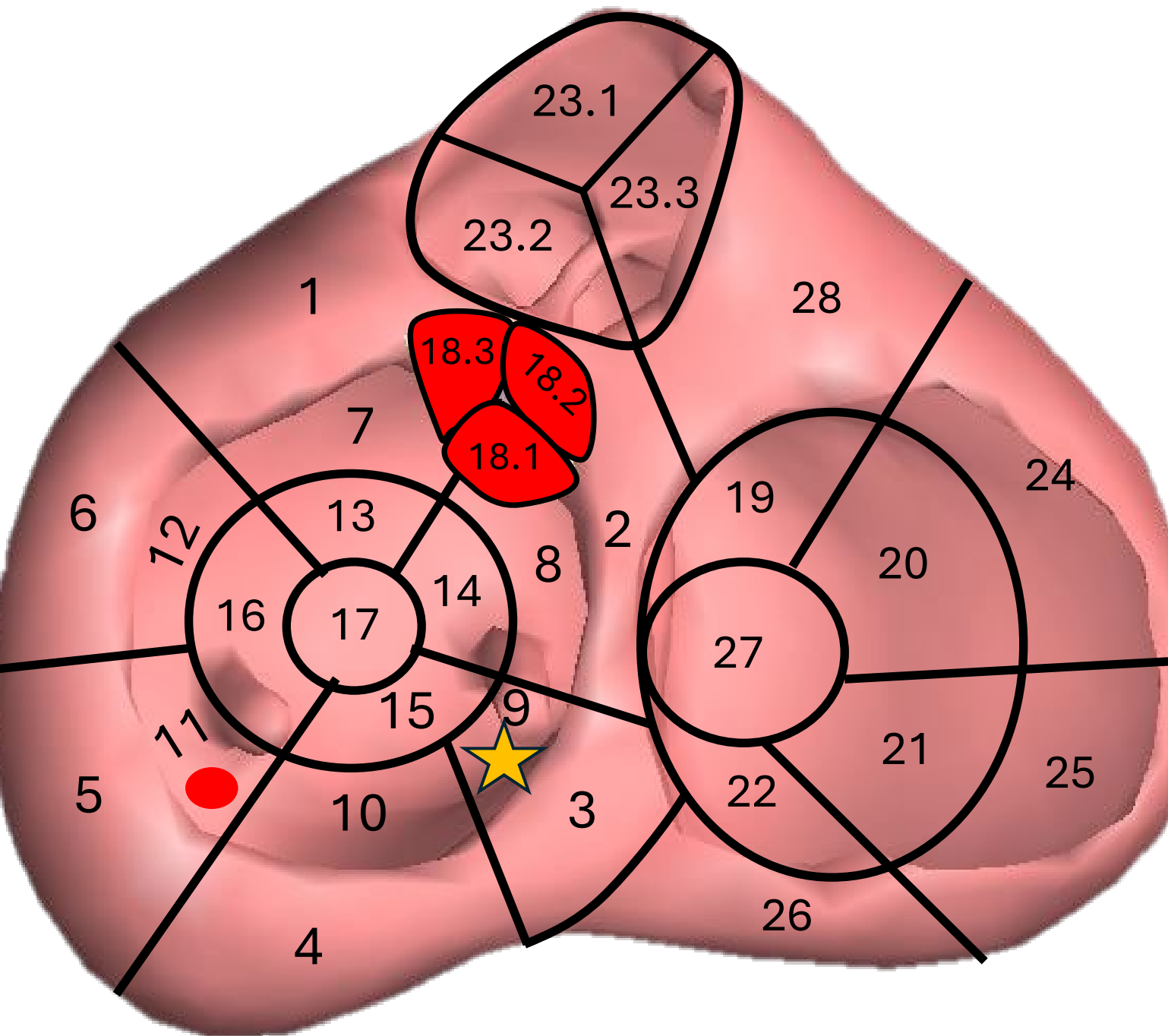

Figure 2c: Example of no match: VIVO is indicated by the star and the EAM location is indicated by the red dot

Site Number	Number of VIVO Analyses (N)	Number of Matched Segments (N)	Number of Non-Matched Segments (N)	Center Accuracy (%)
01	4	4	0	100%
02	19	18	1	94.74%
03	9	9	0	100%
04	27	26	1	96.30%
05	8	8	0	100%
06	20	18	2	90.00%
07	14	12	2	85.71%
08	5	5	0	100%
Totals	106	100	6	
%		94.33%	5.7%	

Exact Localizations Per Segment (N)			Near Match	No Match
Segment Number	N		VIVO/EAM Segment	VIVO/EAM Segment
1	9		23/1	19/18
2	2		21/23	1/4
4	1		14/17	17/12
6	2		18/1	17/12
8	2		23/28	11/9
9	4		2/23	9/22
10	4		2/18	
11	1		18/23	
12	1		2/1	
13	1		2/18	
14	2		23/18	
15	1		23/1	
18	6		4/6	
19	1		22/26	
20	1			
21	1			
22	2			
23	44			
26	1			
Totals	86		14	6

CONCLUSIONS

- VIVO is accurate and provides the physician with an area of interest to begin mapping and potentially ablating
- As VIVO only requires one beat for analysis, it is ideal for mapping several different morphologies or rarely occurring PVCs, both pre-procedurally and interprocedurally
- VIVO continues to provide accurate localization that may have positive impacts on long-term patient success, which should be further studied in future protocols