Improving Outcome Assessment in AF Ablation Trials

a Core Lab Perspective

Alexei Shvilkin, MD, Ph.D.

Clinical Electrophysiologist,
Associate Director, Arrhythmia Monitoring Laboratory,
Beth Israel Deaconess Medical Center;
Director of Research,
ECG and Arrhythmia Core Laboratory of
Harvard Clinical Research Institute,
Boston, MA

Standardizing AF Ablation Trial Designs

HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation: Recommendations for Personnel, Policy, Procedures and Follow-Up

A report of the Heart Rhythm Society (HRS) Task Force on Catheter and Surgical Ablation of Atrial Fibrillation.
Developed in partnership with the European Heart Rhythm Association (EHRA) and the European Cardiac Arrhythmia Society (ECAS); in collaboration with the American College of Cardiology (ACC), American Heart Association (AHA), and the Society of Thoracic Surgeons (STS).
Endorsed and Approved by the governing bodies of the American College of Cardiology, the American Heart Association, the European Cardiac Arrhythmia Society, the European Heart Rhythm Association, the Society of Thoracic Surgeons, and the Heart Rhythm Society.

Hugh Calkins, MD, FHRS; Josep Brugada, MD, FESC; Douglas L. Packer, MD, FHRS;
Riccardo Cappato, MD, FESC; Shih-Ann Chen, MD, FHRS; Harry J.G. Crijns, MD, FESC;
Ralph J. Damiano, Jr., MD; D. Wyn Davies, MD, FHRS; David E. Haines, MD, FHRS;
Michel Haissaguerre, MD; Yoshito Iesaka, MD; Warren Jackman, MD, FHRS; Pierre Jais, MD;
Hans Kottkamp, MD; Karl Heinz Kuck, MD, FESC; Bruce D. Lindsay, MD FHRS;
Francis E. Marchlinski, MD; Patrick M. McCarthy, MD; J. Lluis Mont, MD, FESC; Fred Morady, MD;
Koonlawee Nademanee, MD; Andrea Natale, MD, FHRS; Carlo Pappone, MD, PhD;
Eric Prystowsky, MD, FHRS; Antonio Raviele, MD, FESC; Jeremy N. Ruskin, MD; Richard J. Shemin, MD

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Misdiagnosis of Atrial Fibrillation by 12-lead ECG Reading

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Causes of errors in the electrocardiographic diagnosis of atrial fibrillation by physicians

Jorge Mario Davidenko, MD, FACC,[a,b,c,*] Lisa Simonettta Snyder, RN, MSN, FNP[b]

- 35,508 consecutive ECGs screened; 2809 true AF tracings
- 54 Primary ECG readers in a single hospital
  - All Board-Certified in Internal Medicine
  - 35 Board-Certified Cardiologists
  - 2 Board-Certified Electrophysiologists

Davidenko JM et al. J.Electrocardiol, 2007;40(5):450-6

Misdiagnosis of Atrial Fibrillation by 12-lead ECG Reading

(n=2809)

	False-positive	False-negative	Total
No V pacing	4.5 %	2.4 %	7.8 %
V pacing	6.1 %	3.2 %	9.3 %

Davidenko JM et al. J.Electrocardiol, 2007;40(5):450-6

Factors Resulting in AF Misdiagnosis

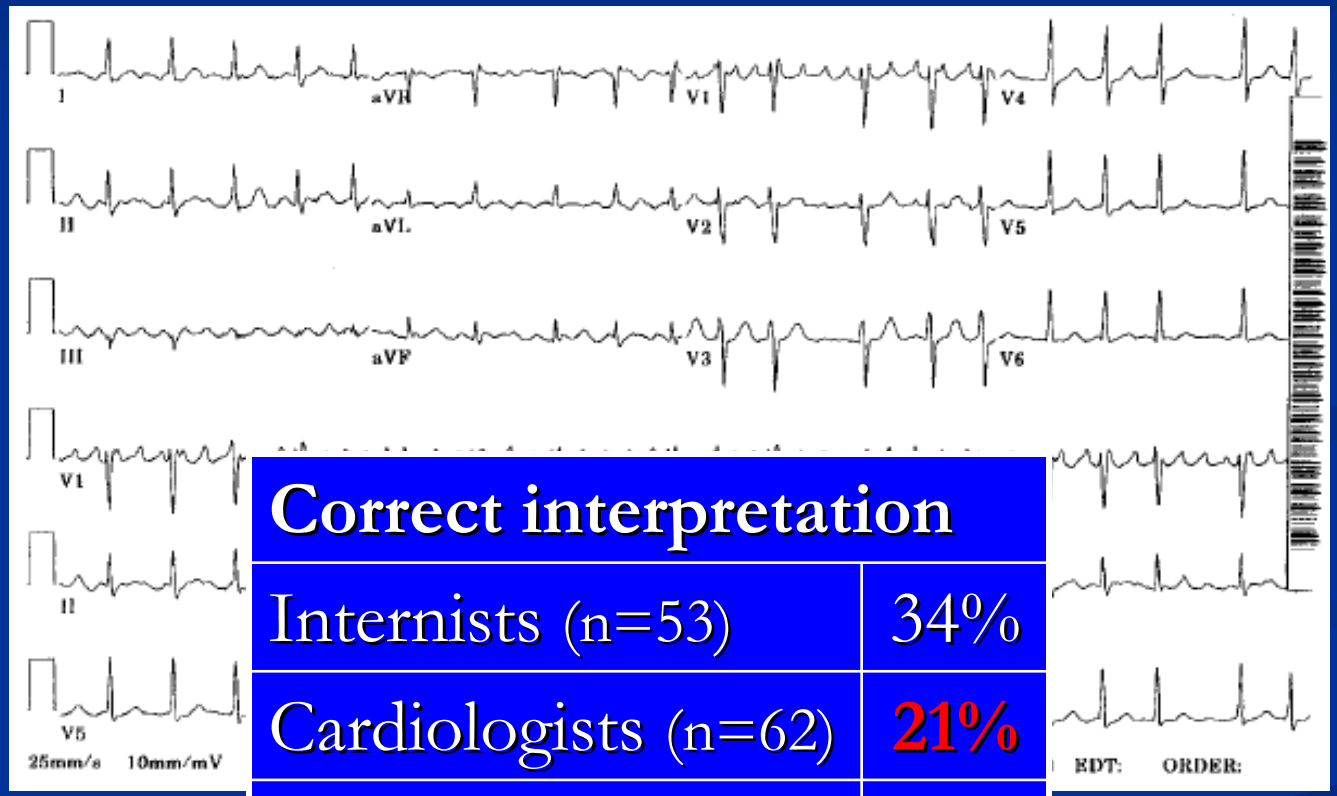
AF missed

- Regular V rate (CHB or V pacing)
- High amplitude A activity (misdiagnosed A flutter)

AF overdiagnosed

- Baseline artifact
- Low amplitude A activity
- Ventricular rate >130

Survey Study of AF ECG Interpretation



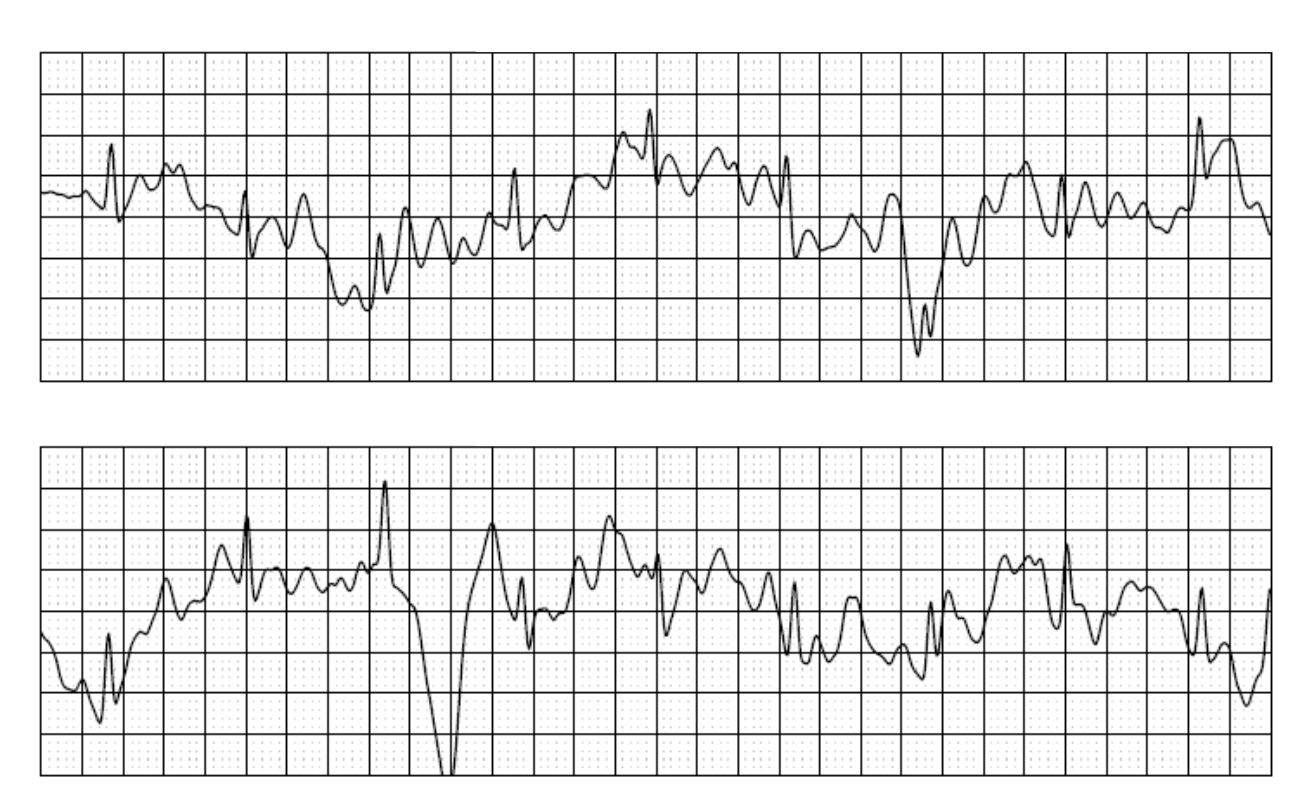
Correct interpretation	
Internists (n=53)	34%
Cardiologists (n=62)	**21%**
Overall	31%

Knight BP et al, J.Electrocardiol, 1999; 32 (4):315-9

Features of Trans-telephonic Event/Holter Monitor Recordings

- Single/Few leads
- Lower sampling rate and signal resolution
- Often low- and high frequency noise
- Few electronic filtering options

A Sample Event Recorder Strip



HCRI Core Lab Experience with Discrepant Rhythm Readings

- Atrial fibrillation vs Atrial Flutter
- Ambiguous **Atrial Fibrillation/Flutter** statement
- Atrial flutter vs Sinus Tachycardia
- Atrial fibrillation vs Sinus Rhythm+APBs+noise

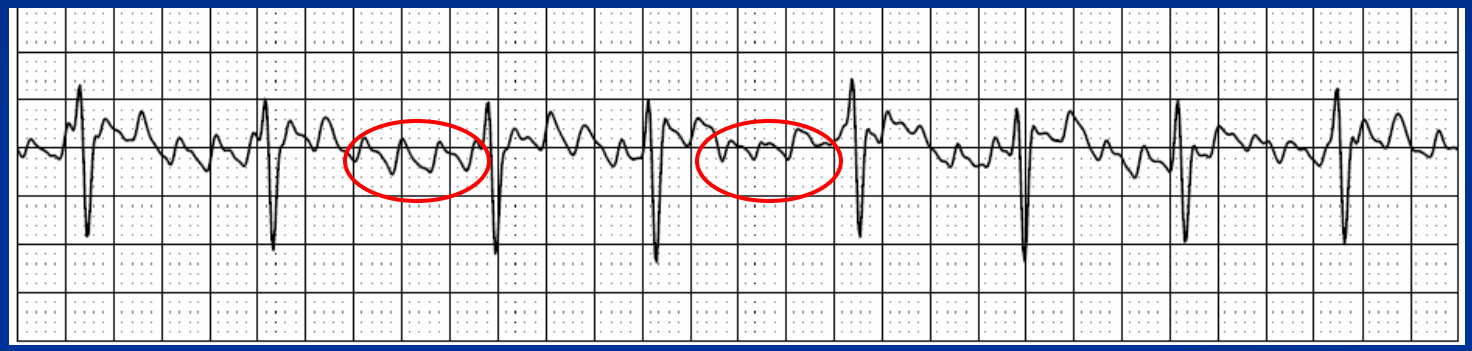
Hypothesis: Rhythm interpretation can be significantly improved by:

- Reinforcement of basic EP concepts through in-service training and continuous feedback
- Streamlining and standardization of rhythm nomenclature
  - Elimination of non-essential/misleading diagnoses

AF/Flutter Differentiation

1. Stability of morphology and cycle length of atrial signal in atrial flutter (adequate atrial signal)
2. RR interval patterns in multi-level AV block (poor atrial signal)

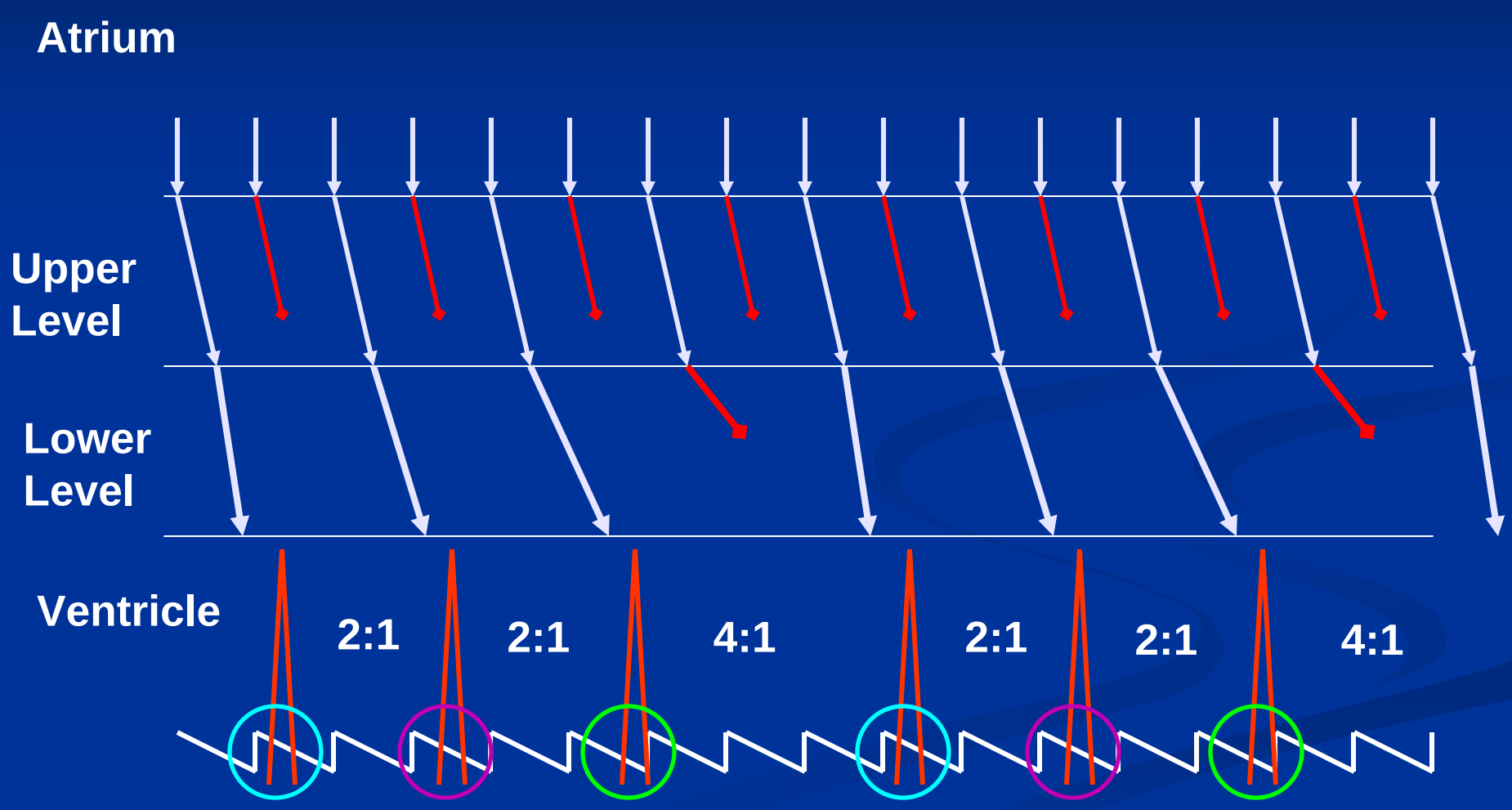
AF



Flutter

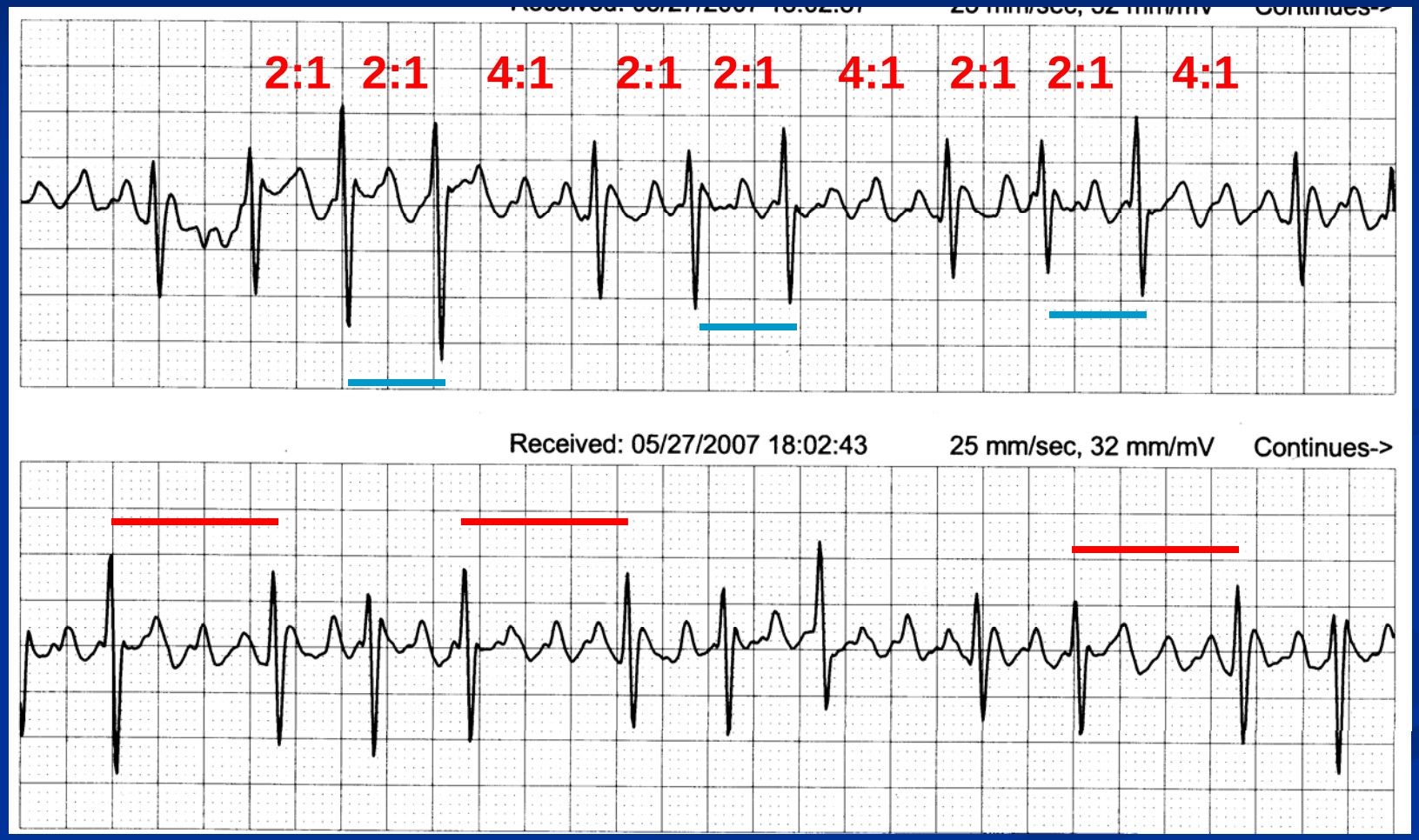
Multi-level AV Block in Atrial Flutter:

Upper Level 2:1; Lower Level 4:3



Atrial Flutter with Two Levels of Block

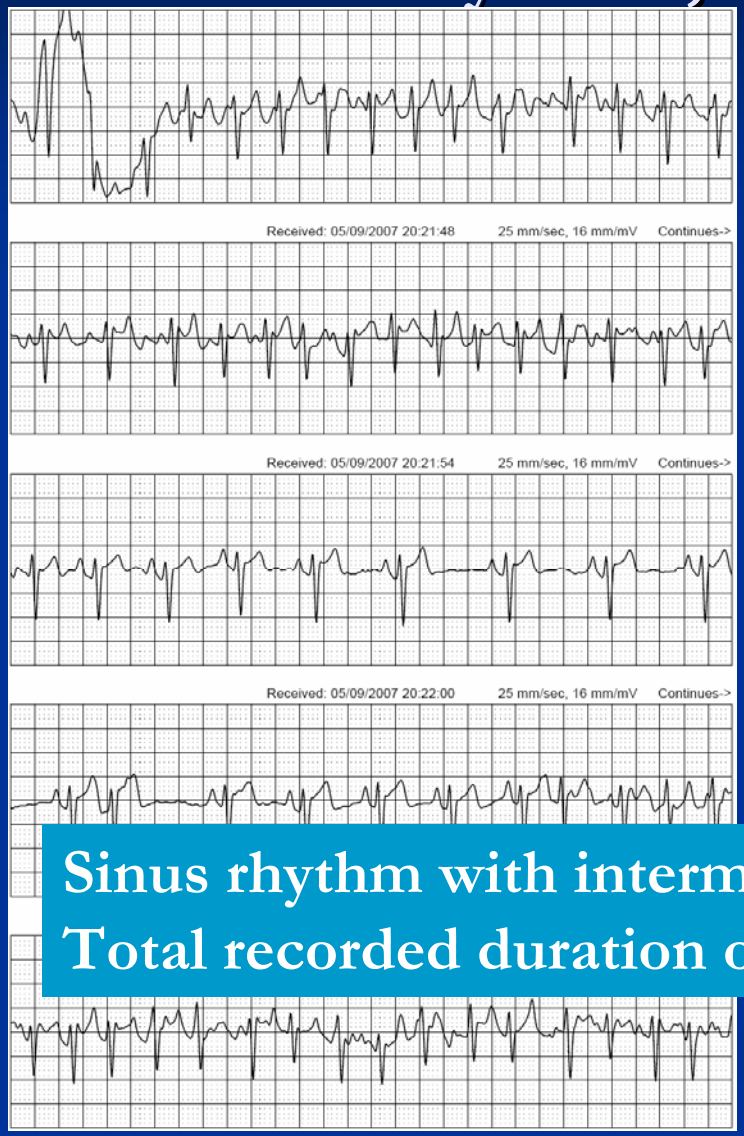
(2:1 upper, 4:3 lower)

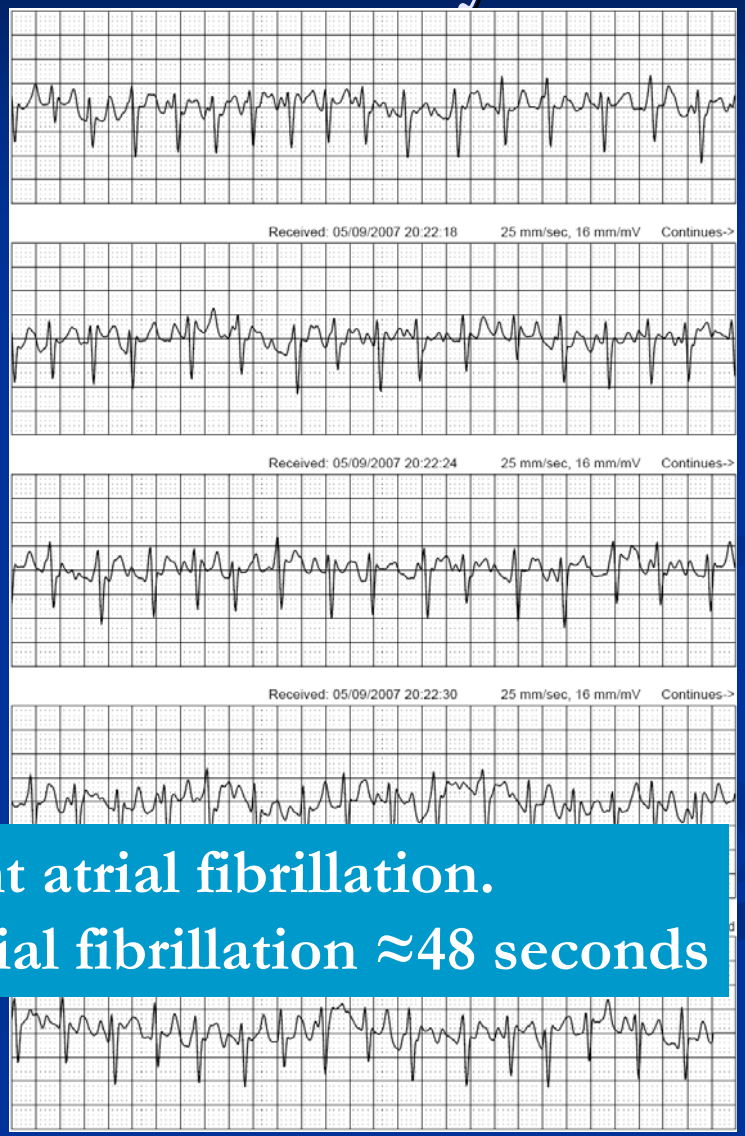


Impact of In-Service Training, Feedback, and Nomenclature Reconciliation on Discrepancies in Rhythm Interpretation

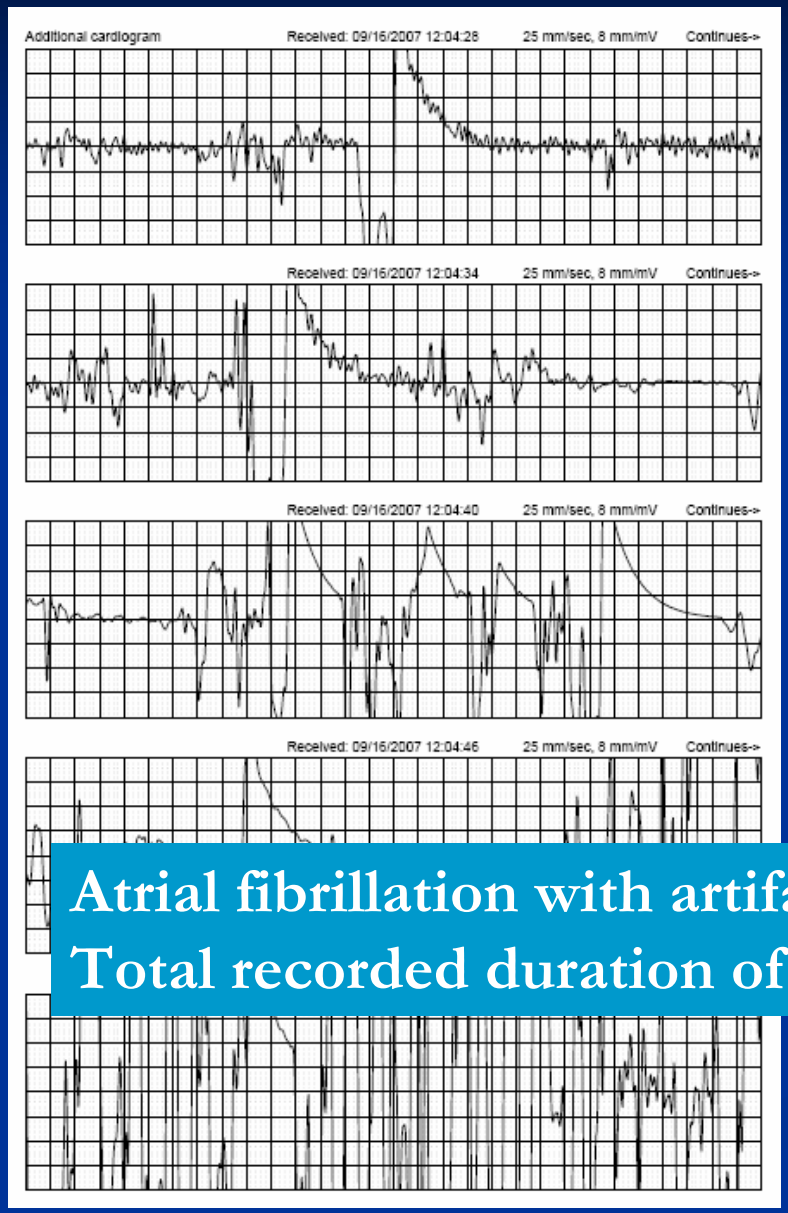
	Before	After
AF vs Atrial Flutter	≈15%	<5%
"Fibrillation/Flutter"	≈3-5%	0

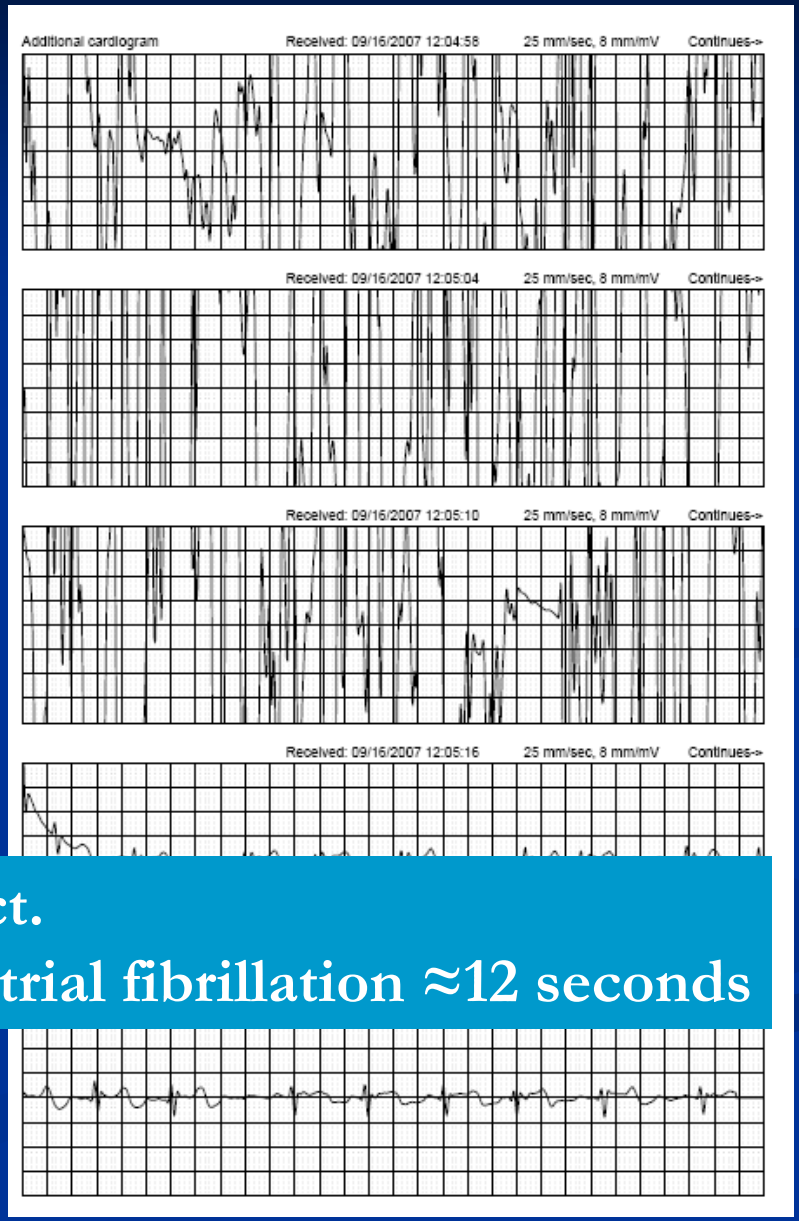
Sources of Inter-Observer Reporting Variability: Mixed Rhythms; Duration of Arrhythmia





Sinus rhythm with intermittent atrial fibrillation.
Total recorded duration of atrial fibrillation ≈48 seconds





Atrial fibrillation with artifact.
Total recorded duration of atrial fibrillation ≈12 seconds

Potential Computer-assisted Approaches to Improve Accuracy and Speed of Analysis

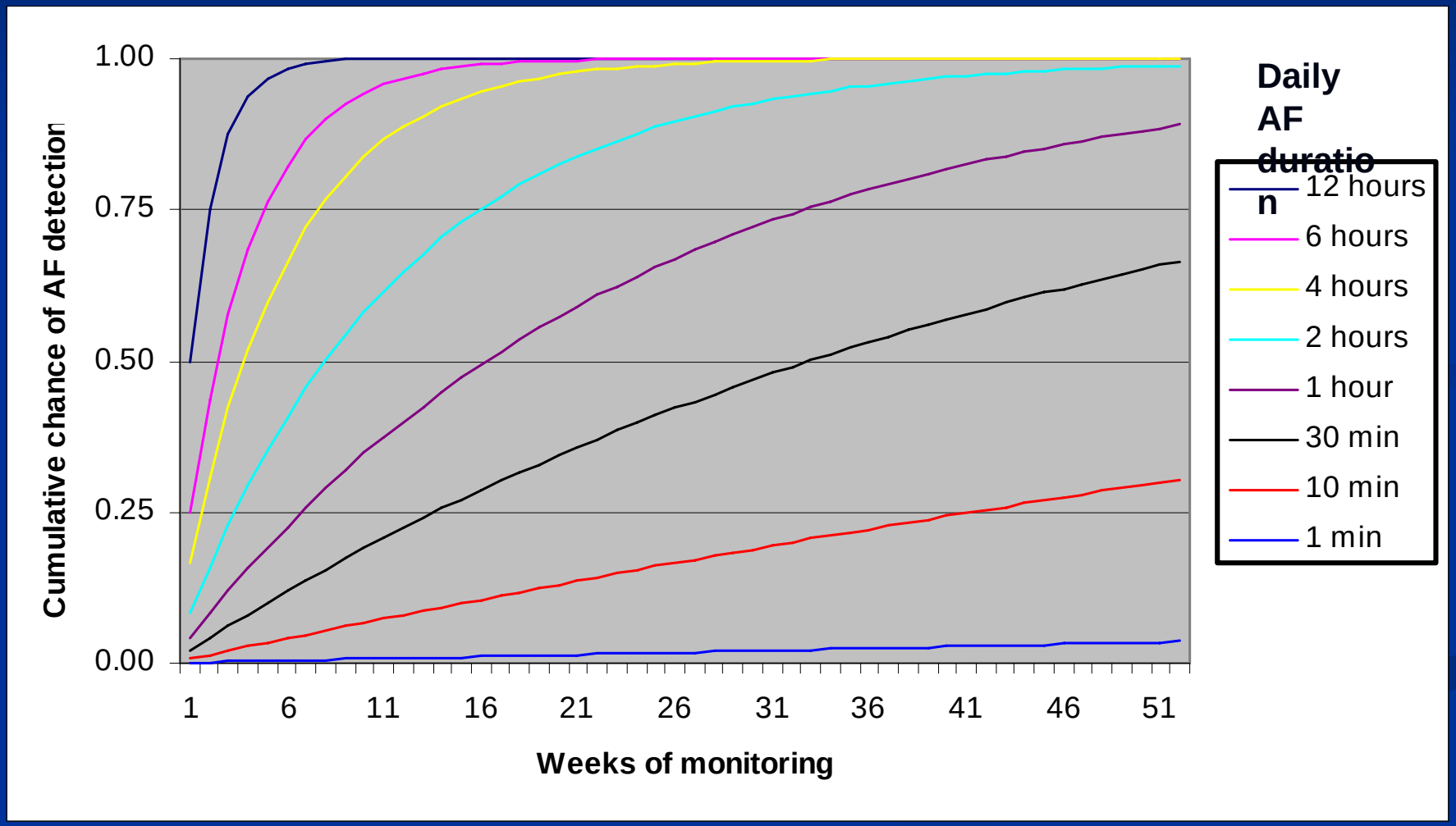
- High- and low-frequency noise – beat averaging for delineation of P-QRS relationship (or a lack of thereof)
- Spectral analysis of QRST-subtracted signal for differentiating "organized" AF and flutters
- Pattern recognition of QRS sequences/ histograms in flutters with variable conduction

Improving Assessment of Rhythm Outcomes:

- Centralized Arrhythmia Core lab (EP-staffed), especially for multi-center trials
- Training/Feedback with the monitoring technicians/primary reading sites
- Standardization of rhythm diagnoses and reporting
- Development of computer-assisted tools for improved accuracy/speed of rhythm interpretation

Thank you for your attention.

Probability of Asymptomatic AF detection by Weekly Event Monitoring



Assuming completely random asymptomatic AF occurrence on the day of monitoring