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Scientific Sessions

Session LBS.08 - Late-Breaking Science: Artificial Intelligence at the Bedside

- Validation of a Speech Analysis Application to Detect Worsening Heart Failure Events in Ambulatory Heart Failure Patients

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Disclosures
W.T.Abraham: Advisor; ; Cordio Medical, Abbott Laboratories, Sensible Medical, Zoll Respicardia, Individual Stocks/Stock Options; ; V-Wave Medical, Speaker; ; Edwards Lifesciences, Impulse Dynamics. **R.Dragu:** None. **E.J.Ouzan:** None. **C.Lotan:** n/a. **E.Edelman:** Advisor; ; BEV (Amide, Expansion, SynLife), 4 Catalyzer, Cascade (Enright), Cipherome, Colossal, Dyad, Global Vascular Co, Peregrine Ventures, Cordio, RECMA, Tekla, CBSET, Butterfly, LuSeed, Xenter, Ownership Interest; ; Autus, BioDevek, CIC Labs, Panther, Research Funding (PI or named investigator); ; Abiomed, JnJ, Shockwave. **I.Shallom:** Employee; ; Cordio Medical Ltd.. **R.Haviv:** Employee; ; Cordio-Medical. **D.Burkhoff:** Consultant; ; Impulse Dynamics, AquaPass, Corvia Medical, Axon Therapeutics, Abiomed, Individual Stocks/Stock Options; ; Orchestra Biomedical. **S.D.Anker:** Consultant; ; Dr Anker has received personal fees from Abbott, Actimed, Amgen, Astra Zeneca, Bayer, Boehringer Ingelheim, Bioventrix, Brahms, Cardiac Dimensions, Cardior, Cordio, CVRx, Cytokinetics, Edwards, Farrad, Research Funding (PI or named investigator); ; Dr. Anker has received grants from Abbott Vascular and Vifor International., Royalties/Patent Beneficiary; ; Named co-inventor of two patent applications regarding MR-proANP (DE 102007010834 & DE 102007022367), but he does not benefit personally from the related issued patents.. **T.Ben gal:** Consultant; ; Cordio Medical, Researcher; ; Cordio Medical. **S.Pinney:** Consultant; ; Abbott, Ancora, CareDx, Medtronic, ADS, Procyrion, Restore Medical, Transmedics, Valgen Medtech, Nuwellis, Speaker; ; Impulse Dynamics. **O.Amir:** Consultant; ; Shahal telemedicine, Restore medical, Cordio medical. **J.Weinstein:** Consultant; ; Bayer, Research Funding (PI or named investigator); ; Cordio med , Speaker; ; AstraZeneca , Boehringer ingelheim , Pfizer. **D.Murninkas:** n/a. **Z.Iakobishvili:** Consultant; ; Cordio, Speaker; ; Pfizer, Astra-Zeneca, Boehringer Ingelheim, Novartis, Medison, Novo-Nordisk, Bayer. **C.Yosefy:** n/a. **M.Kleiner shochat:** n/a.

Abstract
Background: Detecting and preventingworsening heart failure events (HFEs) requiring hospitalization and/orintravenous therapies remains an unmet medical need. The objective of thepresent study was to develop and validate a practical user-friendly tool forpredicting such events in ambulatory heart failure patients well in advance ofthe requirement for hospitalization and/or intravenous therapies.
Methods: The Cordio HearO® system is a remote monitoring systemcomprised of a smartphone-based mobile speech application (App) and cloud-basedcomputing to detect changes in speech measures (SM) indicative of worseningheart failure. The Cordio HearO® Community Study was amulticenter, non-interventional, single-arm clinical study that enrolled NewYork Heart Association Class II and III HF outpatients, irrespective of

leftventricular ejection fraction. Using the App, patients recorded 5 sentencesdaily in their native language. Distinct SM, which may be indicative of heartfailure clinical status, were evaluated retrospectively in a training dataset (developmentgroup) and prospectively tested in a separate dataset (test group) to evaluatetheir ability to detect future worsening HFEs requiring hospitalization and/orintravenous therapies.

Results: In the development group, 263 patientswere enrolled between March 27, 2018 and November 30, 2021 and followed for upto 44 months or 189,406 patient-days. Recordings were provided on 158,024 days(83%). In the test group, 153 patients were enrolled between February 1, 2020and April 30, 2023 and followed for up to 31 months or 116,372 patient-days.Recordings were provided on 94,202 days (81%). In the development group, of 58first and recurrent HF events in 43 patients, 44 events (sensitivity 76.3% [SE5.8%]; 95% CI: 62.6%-86.1%) were detected prior to the event. Among the 43first events, 35 events (sensitivity 81.4% [SE 5.9%]; 95% CI: 69.8%-93.0%) weredetected. In the test group, 14 first and recurrent events occurred in 13patients, and 10 events (sensitivity 71.4% [SE 12.1%]; 95% CI: 40.8%, 90.1%)were detected, and among 13 first events, 10 events (sensitivity 76.9% [SE11.7%]; 95% CI: 54.0%, 99.8%) were detected. In both development and testgroups, events were detected approximately 3 weeks in advance, and theunexplained priority notification rate was about 3 notifications per year.

Conclusions: This novel speech analysis technology detects future worsening HF events with ahigh sensitivity and low unexplained notification rate supporting its potentialto reduce such events and improve patient outcomes.