

Evaluation of the Degree of Decongestion Among Patients Admitted with Acutely Decompensated Heart Failure Utilizing the Novel HEMOTAG Cardiopulmonary Assessment System

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Introduction

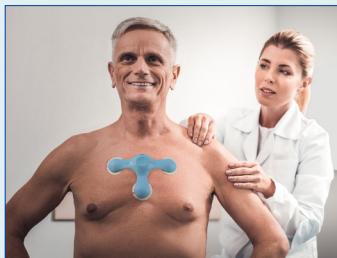
The HEMOTAG device, as part of the HATS-OFF (Hemotag Assessment for Short-term Outcomes of heart Failure) clinical trial, non-invasively measures cardiac time intervals in the assessment of heart failure. The isovolumetric contraction time (IVCT) is validated as a marker of congestion among patients with heart failure. As part of the phase 2 clinical trial, we assessed the degree of decongestion achieved at time of hospital discharge utilizing both the IVCT as measured by HEMOTAG with comparisons made to NTproBNP levels.

Methods

Patients were prospectively recruited as part of the on-going NHLBI clinical trial. Data at the time of discharge, including IVCT as measured by the HEMOTAG device and NTproBNP levels, were assessed. Exploratory analyses were made assessing degree of decongestion at time of discharge. Patients were defined as having markers of congestion with IVCT > 40 ms and NTproBNP \geq 1800 pg/mL.

Results

A total of 42 patients were analyzed of which the mean age was 67 years with a mean body mass index of 35. Twenty four (57%) of patients had an elevated NTproBNP \geq 1800 pg/mL (mean 10349 pg/mL, SD 9646) suggesting a higher than normal level of congestion at the time of discharge and IVCT timings noted to generally be over the elevated threshold of 40ms (mean 49ms, SD 13ms). Eighteen (43%) of the patients were discharged with an NTproBNP < 1800 pg/mL (mean 930, SD 462) and the IVCT timings detected for those patients were mostly under the elevated threshold of 40ms (mean 27ms, SD 11ms) levels.



The image showcases the application of HEMOTAG Vitals. Once the device is positioned on the patient's chest, a 30-second recording begins through the HEMOTAG App. The patient receives an alert upon completion of the reading, and the data is automatically uploaded to our HIPAA-compliant, secure cloud system for processing. A comprehensive structural heart health report is then generated and accessible to the provider through the Clinician Dashboard. This enables the provider to assess the patient and optimize their care.

Conclusion

As part of the on-going clinical trial, our exploratory data demonstrate that the majority of patients admitted with ADHF are discharged from the hospital with a higher than normal level of congestion. Our results suggest that traditional markers of decongestion may not be sufficient in the patient evaluation and that the HEMOTAG device can predict higher than normal levels of congestion at time of discharge.

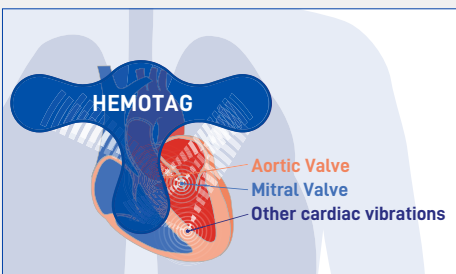
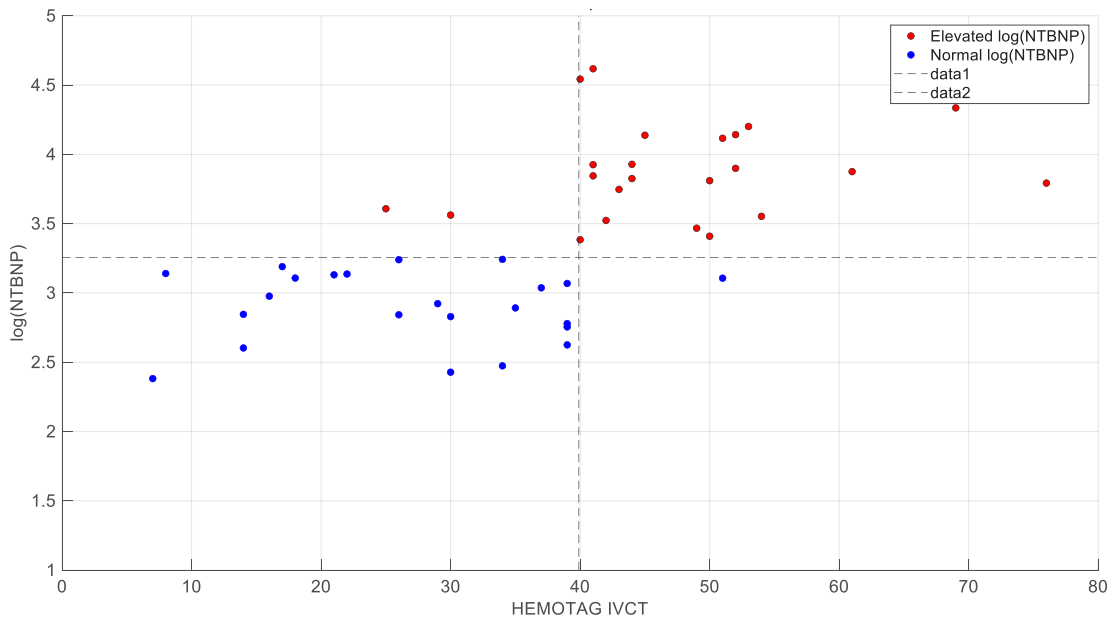
Table 1.

HEMOTAG efficacy to detect elevated NTproBNP (NTproBNP \geq 1800 pg/mL)

Sensitivity	92
Specificity	96
Negative Predictive Value	92
Positive Predictive Value	96

An IVCT \geq 40ms recorded by HEMOTAG™ has high sensitivity and specificity to detect higher than normal level of congestion. NTproBNP \geq 1800 pg/mL was used as an objective surrogate of higher than normal level of congestion.

NT pro NTBNP: Sensitivity = 92%, Specificity = 96%
NPV = 92%, PPV = 96%



About HEMOTAG Vitals

HEMOTAG Vitals is the future of non-invasive cardiac hemodynamic monitoring. Providing vitals using our proprietary non-invasive quad sensing vibration technology, which previously were available only through surgical procedures or blood draws. Aventusoft/HEMOTAG sees beyond the gold-standard invasive procedures and implantable devices, with our mission to revolutionize the way we can respond to structural heart disease and heart failure (HF) in the coming decade.