Tropsensor : A Rapid Non-Invasive Transdermal Solution For Troponin Measurement

Jitto Titus[1], Alan HB Wu[2], Siddharth Biswal[1], Atandra Burman[1] and Allan S Jaffe[3]
[1] RCE Technologies, Carlsbad, CA
[2] Zuckerberg San Francisco General Hospital, San Francisco, CA
[3] Mayo Clinic, Rochester, MN

Background and Objective

Over 10 million patients present at the ED with chest-pain, with the majority due to non-cardiac causes, resulting in unnecessary burdens for Emergency Departments (ED)[1].

Current biochemical biomarker testing relies on labeling the cTn with turnaround times often an hour or more[2].

Point-of-care solutions reduce the test time, but still depend on the proper handling of samples and blood processing techniques that could lead to difficulties[3].

Solution: Tropsensor[4,5] provides a rapid (5-min) non-invasive alternative to standard of care (SOC) hs-cTn measurements without the need for a blood draw.

Methods and Materials

Study site: Zuckerberg San Francisco General Hospital

Cohort size: 26 patients

Recruitment mechanism: Patients presenting with ACS-related symptoms at the ED

Technology tested: Tropsensor, a wrist-worn vibrational spectroscopy-based, noninvasive transdermal troponin sensor

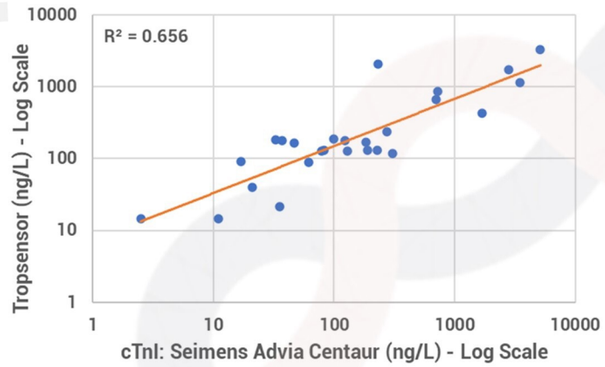
Comparative technology: Siemens ADVIA Centaur[6] high sensitivity troponin-I assay via a blood draw.

Summary

A three-layer neural network was used to train regression and binomial classification models.

This neural network contains three 1-D convolutional layers stacked with batch normalization and Rectified Linear Unit (ReLU)[7] layers.

The neural network is trained using Adaptive Movement (ADAM)[8] stochastic optimizer employing a cross entropy loss function.



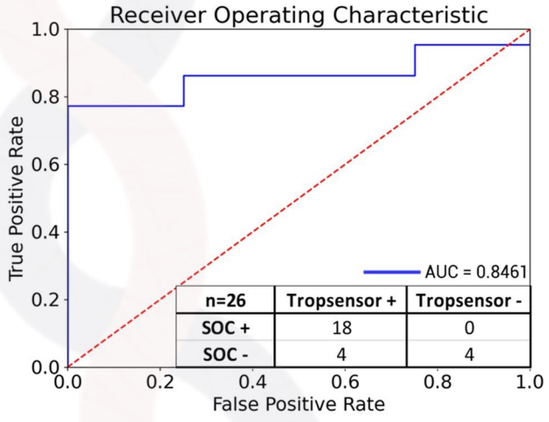
The 99th percentile[6] cutoff for the SOC Seimens Advia Centaur assay is 47.34 ng/L

Conclusion and Discussion

Tropsensor output correlates significantly with SOC hs-cTn assay

Implications:

- accelerated assessment of patients presenting with chest pain
- since blood draw is not required, Tropsensor could provide a rapid, safe, standardized and reliable source for cTn while allowing bedside serial trending.
- potential for streamlining cardiac care workflow by ruling-out many non-cardiac patients and identifying those with high values who are at risk.



n=26	Tropsensor +	Tropsensor -
SOC +	18	0
SOC -	4	4

Sensitivity = 1, Specificity = 0.5, PPV = 0.8182, NPV = 1,
Correlation = 0.8228, Accuracy = 0.8461

REFERENCES

1. Herren, K. & Mackway-Jones, K. Emergency management of cardiac chest pain: a review. Emergency Med. J. 18, 6–10 (2001).
2. Michel, J. B. & Schussler, J. M. The trouble with troponin. Proceedings 31, 238–239 (2018).
3. Collinson, P. Cardiac biomarker measurement by point of care testing—Development, rationale, current state and future developments. Clin. Chim. Acta 508, 234–239 (2020).
4. Titus, J., Wu, A.H.B., Biswal, S. *et al.* Development and preliminary validation of infrared spectroscopic device for transdermal assessment of elevated cardiac troponin. *Nature Commun Med* **2**, 42 (2022). https://doi.org/10.1038/s43856-022-00104-9
5. Burman, A. & Titus, J. in USPTOUS 16/597,933 (ed. USPTO) (RCE Technologies, Inc., USA; 2020).
6. Musetti, V. et al. Evaluation of the analytical performance of a new ADVIA immunoassay using the Centaur XPT platform system for the measurement of cardiac troponin I. Clin. Chem. Lab. Med. (CCLM) 56, e229–e231 (2018).
7. Si, Jiong, Sarah L. Harris, and Evangelos Yfantis. "A dynamic ReLU on neural network." 2018 IEEE 13th Dallas Circuits and Systems Conference (DCAS). IEEE, 2018.
8. Zhang, Zijun. "Improved adam optimizer for deep neural networks." 2018 IEEE/ACM 26th International Symposium on Quality of Service (IWQoS). Ieee, 2018.

DISCLOSURES

Presenter: Jitto Titus
RCE Technologies: VP & Optical Scientist, Equity holder
Co-author: Alan HB Wu
UCSF: Chief, SFGH Clinical Chemistry and Professor of Laboratory Medicine, Scientific Advisor for RCE, Equity holder
Co-author: Siddharth Biswal
RCE Technologies: Data Scientist, Equity holder
Co-author: Atandra Burman
RCE Technologies: Founder & CEO, Equity holder
Co-author: Allan S Jaffe
Mayo Clinic: Professor, Cardiovascular Division and Chair of the Division of Core Clinical Laboratory Services, Scientific Advisor for RCE, Equity holder

rce
Abstract: 12766
Scientific Sessions
American Heart Association.
November 5-7, 2022
Chicago, IL + Virtual