Rapid Screening Tool for Identifying Acute Myocardial Injury:

An Exploratory Study Evaluating the Ability of a Novel, Noninvasive Device to Detect Cardiac Troponin

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Background

- Chest pain is the second most frequent chief complaint for patients presenting to the emergency department. It remains difficult to identify those having an AMI based on symptoms alone.
- The current standard of care utilizes a cardiac troponin blood assay to identify acute cardiac injury but has significant constraints based on its invasive nature and delayed result.
- The Tropsensor is a portable device used to noninvasively measure cardiac troponin with significant reduction in time to result.

Objective

Tropsensor, a noninvasive portable device using infrared spectroscopy, delivers a troponin result within minutes, significantly quicker than standard of care (SOC) assays. This pilot study assesses the correlation of the Tropsensor and high sensitivity cardiac troponin (hs-cTnI) assay results.

Methods

- This was a prospective single-site, observational study at an academic, quaternary care hospital evaluating patients presenting to the ED undergoing hs-cTnI testing with the Abbott Architect STAT (Abbott Laboratories, Chicago, IL) hs-cTnI assay.
- Recruitment of consenting patients was based on their initial troponin result being greater than the limit of detection of the SOC assay (5 ng/L).
- The output of the device, measured in Absorbance Units with a range between 0 to 1 units, was transmitted to a web-based server.
- The data compromised by noise artifacts were visually adjudicated and excluded from the analysis. This exclusion was done prior to the knowledge of SOC troponin values.
- The results of the hs-cTnI assays were compared with the output of the Tropsensor device using Kendall's *tau (τ)* measure of correlation.
- Comparison of the difference in absorbance units when stratified by a hs-cTnI value above vs below the 99th percentile upper reference limit (28 ng/L) was performed using Wilcoxon's Rank Sum Test.

Results

- Mean age of the 58 patients recruited was 60 years (60% male, 40% female).
- 26 patients were included in the final analysis. 32 were excluded:
  - 8 patients' data did not transmit
  - 8 had motion artifact
  - 9 had insufficient pressure at the contact site
  - 7 had suspected insufficient cleaning of the wrist
- Tropsensor a.u. and hs-cTnI results had moderate correlation ($\tau = 0.41$, $p = 0.0036$).

hs-cTnI value	Patients	Tropsensor Output (a.u.) *Median (IQR)*	Wilcox Rank Sum
Above 99th% URL	9	0.67 (0.61 – 0.80)	p=0.005
Below 99th% URL	17	0.50 (0.37 – 0.63)	

Table 1: Comparison of output of Tropsensor when dichotomized above or below the SOC hs-cTnI 99th% URL.

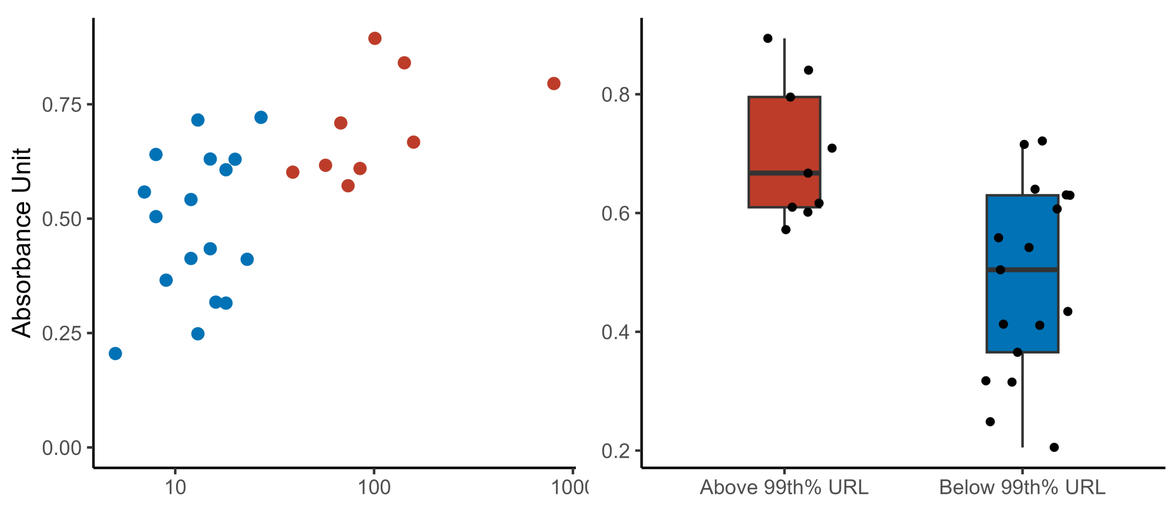

Figure 1: Left: Scatter plot showing correlation between Tropsensor output(y axis) and SOC cTnI result(x axis). Right: Comparing Tropsensor output when dichotomized above or below the SOC hs-cTnI 99th% URL

Discussion

- The Tropsensor exhibited moderate correlation to the SOC hs-cTnI assay with a significant difference found in absorbance units when stratifying hs-cTnI result by the 99th percentile URL, a threshold suggestive of cardiac injury
- A significant limitation in obtaining high-quality data was identified early during the study with future efforts focused on improving yield
- While further evaluation is needed to confirm and extend these findings, this exploratory study provides insight into the potential of a transdermal, optical device as an aid in the early risk assessment of AMI in an ED triage situation

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