A New Paradigm for Value: Point-of-care Testing for High-sensitivity Troponin I

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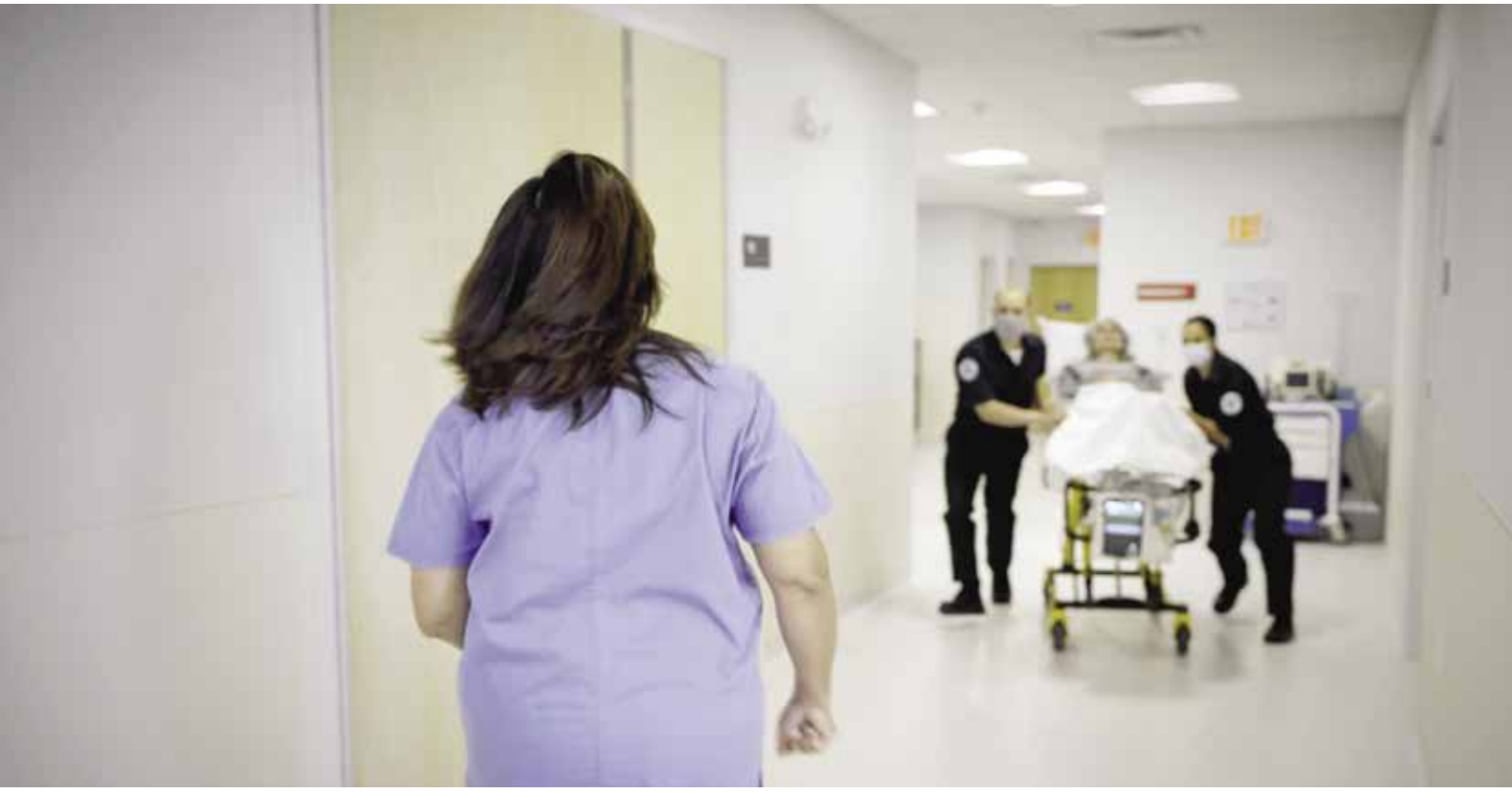
Introduction

Emergency departments (EDs) worldwide are striving to improve safety and the quality of care in the face of increased demand and periodic crowding. In addition to interventions targeted to improve processes related to triage, care transitions, observation units, and other process redesigns, the use of point-of-care testing (POCT) has been mapped as a strategy to improve ED performance.[1] Improvements in the ED performance measures of ED length of stay (ED-LOS)[2] and cost savings or cost-effectiveness[3] have been documented for high-sensitivity cardiac troponin (hs-cTn) versus standard troponin (cTn).[4]

Hs-cTn assays have revolutionized clinical decision making by their ability to measure very low values to identify patients at low risk of 30-day adverse events and to safely rule out MI in more than 20% of patients who present to the ED with ischemic symptoms.[5] However, the value of implementing hs-cTn on a POCT platform has not yet been fully characterized. In order for such an assay platform to be compatible with current clinical diagnostic strategies, and therefore acceptable to clinicians, the POCT assay must have comparable analytical performance with the standard hs-cTn performed in the central laboratory setting and must have a direct impact on clinical decision making.[5] To be acceptable to hospital administrators, it must also provide cost savings or cost-effectiveness (value/cost) compared to the standard, central laboratory hs-cTn assays.

The Siemens Healthineers Atellica® VTLi Patient-side Immunoassay Analyzer using the Atellica VTLi hs-cTnI Reagent Cartridge has been shown to provide robust sensitivity, specificity, and negative predictive values when compared to clinically adjudicated diagnosis of MI.

Diagnostic accuracy was evaluated in a prospective study of whole blood from serial sampling of 1089 patients tested with the Atellica VTLi system. Samples were collected in a single-center study from patients 21 years or older who presented to the hospital emergency department with symptoms suggestive of MI, such as chest discomfort. Using the Fourth Universal Definition of Myocardial Infarction, an independent panel of two physicians, blinded to the results of the Atellica VTLi system, determined that 91 of these patients suffered from MI (8.4% prevalence). The resulting values are shown below based on the 99th percentile URL cutoff.



Population	99th URL (ng/L)	Timepoint	Subjects		Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
			Non-MI	MI				
Overall	22.9	Baseline	998	91	64.8% (54.6–73.9%)	85.7% (83.4–87.7%)	29.2% (25.0–33.8%)	96.4% (95.3–97.2%)
		2 hours	998	91	81.3% (72.1–88.0%)	84.6% (82.2–86.7%)	32.5% (28.7–36.4%)	98.0% (97.0–98.7%)
Male	27.1	Baseline	615	56	67.9% (54.8–78.6%)	86.2% (83.2–88.7%)	30.9% (25.5–36.9%)	96.7% (95.3–97.7%)
			615	56	80.4% (68.2–88.7%)	84.7% (81.7–87.3%)	32.4% (27.6–37.5%)	97.9% (96.5–98.8%)
Female	18.5	Baseline	383	35	65.7% (49.2–79.2%)	85.4% (81.5–88.6%)	29.1% (22.6–36.6%)	96.5% (94.5–97.7%)
		2 hours	383	35	82.9% (67.3–91.9%)	84.3% (80.4–87.6%)	32.6% (26.8–38.9%)	98.2% (96.3–99.1%)

Emergency Department Length of Stay

POCT has been shown to reduce ED-LOS in a variety of contexts.

Several groups have provided evidence that the use of POCT panels including analytes such as electrolytes, renal function tests, metabolites, blood gases, CO-oximetry, lipids, liver function tests, hematology tests (blood counts, coagulation, cardiac markers, endocrinology, diabetes screening), and urinalysis in the ED can reduce the time of ED-LOS. A group in Thailand found significantly shorter time from arrival to decision and ED-LOS for the POCT group than for the central lab group.[6] Following POCT implementation in rural Australian EDs, more patients with a circulatory system illness were treated and discharged from the ED within 4 hours than before POCT implementation, and after controlling for clinically important factors (patient age, triage category, and the arrival day and time at the ED), the ED-LOS tended toward shorter average times following POCT implementation but did not reach statistical significance.[7] In two separate reports, Kankaanpaa et al.[8,9] evaluated POCT panel testing in ambulatory ED patients and found that the use of POCT decreased time to results and ED-LOS for patients compared to testing conducted in the central lab. In a meta-analysis of the impact of panel POCT in ambulatory care, Goyder et al.[10] found differential diagnoses could be made on average 40 minutes faster with the use of POCT, with a reduction in ED-LOS of 34 minutes, with no difference in mortality. Finally, Weihser et al.[11] showed a 54% reduction from baseline ED-LOS following implementation of panel POCT as part of an evidence-based lean service redesign, and additionally reported a drop from 4.5% to 0.7% in 30-day mortality rates with the improved service design.

When the lens is focused on cTn assays, data support reduced ED-LOS with the POCT version compared to central lab testing. An early study using a cTn POCT reported overall hospital stay and non-coronary care unit stay were significantly shorter for those randomized to the POCT group, with no difference between POCT and central laboratory results for diagnostic accuracy or mortality.[12] Blick et al.[13] reported that laboratory turnaround time was a rate-limiting factor in ED-LOS. Implementing POCT as part of Six Sigma initiatives and central laboratory automation resulted in cutting in half the time to cTn results: 30-minute turnaround for POCT compared to 60 minutes from the central lab. Additionally, they identified a 35% increase in productivity (ratio of paid hours per test).

Finally, with the advent of hs-cTn, studies narrowed the focus of cTn testing ever further. Chew et al.[14] reported results from a randomized control trial comparing a 1-hour hs-cTn testing protocol with a standard, 3-hour cTn testing protocol and found that the 1-hour protocol using hs-cTn enabled more-rapid discharge from the ED of patients who were suspected of having acute coronary syndrome (ACS).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Patient Test Result
Result
cTnI
8.3
ng/L
Repeat
Next
Atellica VTLi

Cost Comparison

Hs-cTn has been shown to be a cost-effective alternative to standard cTn testing in a number of settings independently of findings that show reduced ED-LOS.

The initial studies compared central lab testing for both standard and high-sensitivity tests, with RATPAC suggesting that hs-cTn testing in general is cost-effective (i.e., cheaper, and more effective) compared with standard testing.[15] Substantial hospital cost reductions were observed in a number of studies that compared the high-sensitivity version of cTn testing to the standard version. Reported cost reductions included a $490 savings per patient with 25% fewer unnecessary cardiac admissions,[16] 42% reduction in avoidable chest pain admissions, which saved the hospital £21,000 per month over a 2-year period,[17] and a significant decrease in hospital cost for patients admitted with chest pain or dyspnea when using a lowered cTn cutoff at the 99th percentile of 14 n/L for NSTEMI.[18] For the early rule-out of AMI in people presenting to the ED with acute chest pain and suspected ACS, Health Technology Assessment results published by Westwood et al.[3] indicate that hs-cTn testing in general may be cost-effective compared with standard cTn testing.

Hs-cTn has allowed for faster evaluation periods by shortening the time to diagnose NSTEMI and observation periods for ED patients from 9–12 hours to 3 hours or less,[19] and is likely cost-effective compared to standard 10-hr cTn.[20] Furthermore, hs-Tn testing is very likely to be cost-effective compared to standard assessments in a non-emergent population for assessing cardiovascular risk, in which patients determined to be at high risk are referred to preventive treatments.[21]

$490

Savings per patient

42%

Reduction In avoidable chest pain admissions

£504,000

Over a 2-year period

Takeaways

Although results of a direct comparison of hs-cTn testing between POCT and central lab testing are not yet published, there is substantial evidence that, in general, the use of POCT testing can reduce ED-LOS, especially when combined with process redesign using Six Sigma or a similar approach. Considering that in 2007 an extended ED stay (>11.4 hours) cost an additional $1600 ($2000 in March 2021),[22] reductions in ED-LOS translate to substantial hospital cost savings. Additionally, cost evaluations have shown hs-cTn testing to be cost-effective for hospitals compared to standard cTn testing.

When the two premises are combined, i.e., the cost-effectiveness of hs-cTn testing and the reduction in hospital cost for ED-LOS with the use of POCT, it follows that a POCT version of hs-cTn will prove to be an added value for hospitals overall. The Atellica VTLi Immunoassay Patient-side Analyzer combined with the hs-cTnI Reagent Cartridge does just that—it gives clinicians the speed and proximity to the patient of POCT and the clinical benefits of high-sensitivity results and alleviates the need to compromise between speed and accuracy.

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