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Patterns of Use of Cardiac Troponins Amongst Clinicians within Public Sector Health Care Facilities in KwaZulu-Natal, South Africa

Evette L. Subramoney [1,2], Ashandree Reddy [1,2] and Verena Gounden [1,2,3,*]

[1] Department of Chemical Pathology, National Health Laboratory Service, Inkosi Albert Luthuli Central Hospital, Durban 4001, South Africa
[2] Department of Chemical Pathology, School of Laboratory Medicine and Medical Sciences, College of Health Sciences, University of KwaZulu-Natal, Durban 4001, South Africa
[3] Department of Clinical Biochemistry, University Hospital Galway, Newcastle Road, H91YR71 Galway, Ireland
* Correspondence: verenagounden@yahoo.com

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Abstract: Background: The data evaluating troponin utilisation and requesting practices in comparison to best practice guidelines is limited in developing and middle-income countries. This study aimed to assess the ordering practices of high sensitivity cardiac troponins amongst clinicians within public sector health care facilities in KwaZulu-Natal (KZN), South Africa. Methods: Requisition details and results of all cardiac troponin (cTn) requests for individuals older than 18 years analysed by the National Health Laboratory Services (NHLS) across KZN during the period 1 January 2018 to 31 December 2019 were extracted from the NHLS Central Data Warehouse. Time interval between the baseline and consecutive measurement was calculated for those who underwent serial sampling and delta troponin (percent change) determined for those samples with time interval <3 hours. Each cTn request was also assessed for concomitant requests for other cardiac biomarkers. Results: 75% of all cTn requests were analysed using a high-sensitivity assay. A serial sampling strategy (18.6%) was only observed in hospital settings with a relatively similar frequency amongst emergency departments, high care and general wards. Only 3.5% of samples represented serial samples collected within 3 h of each other. Moreover, 69% of all cTn requests had an associated request for other cardiac biomarkers, whilst 65% of CKMB requests did not have an associated cTn request. Conclusion: Awareness and adherence to clinical guidelines for the evaluation of chest pain is essential to reduce the variability of requesting practice for troponin assays.

Keywords: myocardial infarction; troponin; biomarkers; high-sensitivity; acute coronary syndrome

1. Introduction

Since 2000, ischaemic heart disease (IHD) has contributed to the highest number of deaths, accounting for 16% of all deaths worldwide [1]. The surge in metabolic risk factors in recent years due to rapid urbanisation and globalisation in low- and middle-income countries are among the factors driving the rising cases of IHD [1].

In 2000, the joint European Society of Cardiology (ESC) and the American College of Cardiology (ACC) committee redefined myocardial infarction. In this revised definition, biomarkers of myocardial necrosis (viz. myoglobin, creatine kinase myocardial band (CKMB) and cTn I and T became the key determinant for the

diagnosis of AMI [2]. During 2007, the Global MI Task Force was established, and a revised Expert Consensus Document for the Universal Definition of Myocardial Infarction (UDMI) was released. cTn was recommended as the preferred biomarker for myocardial injury (defined as cTn values above the assay-specific 99th percentile upper reference limit (URL)) with emphasis on serial sampling to document rising/falling values in the setting of acute myocardial ischaemia as well as the need for better precision at the 99th percentile URL [3]. Following the advent of high-sensitivity cTn (hs-cTn) assays, the 2012 Third UDMI document included criteria for hs-cTn assay use and shorter 3-hour (h) algorithms [4]. The latest 2018 Fourth UDMI provides guidelines on the use of hs-cTn assays, particularly for differentiating myocardial injury due to ischaemic causes versus non-ischaemic conditions as both can cause elevated cTn concentrations. In addition, analytical issues of cTn assays, benefits of hs-cTn assays, considerations for rapid rule-out/rule-in algorithms for diagnosing myocardial injury and concerns about delta troponin for using hs-cTn assays are addressed [5].

At present, hs-cTn assays are in routine use in many clinical laboratories and are characterised by two criteria namely; the ability to measure significantly lower cTn concentrations at or below the 99th percentile URL with minimal variability (i.e., % coefficient of variation (CV) of ≤10%) in more than 50% of normal healthy individuals [5–7].

In Table 1 below, a summary of endorsed rapid predictive algorithms using hs-cTn assays for the early rule-out/rule-in of MI are outlined.

Table 1. Rapid rule-in/rule-out algorithms for AMI using hs-cTn tests [8–11].

ESC (2015) [8]	• A rapid rule-out protocol at 0 h and 3 h is recommended if hs-cTn tests are available • A rapid rule-out and rule-in protocol at 0 h and 1 h is recommended if a hs-cTn test with a validated 0 h/1 h algorithm is available. Additional testing after 3–6 h is indicated if the first two troponin measurements are not conclusive and the clinical condition is still suggestive of ACS.
ESC (2020) [9]	• ESC 0 h/1 h with blood sampling at 0 and 1 h is recommended if a hs-cTn test with a validated 0 h/1 h algorithm is available • Additional testing after 3 h is recommended if the first 2 cTn measurements of the 0 h/1 h algorithms are not conclusive but the clinical condition is still suggestive of ACS • As an alternative to the ESC 0 h/1 h algorithm, it is recommended to use the ESC 0 h/2 h algorithm with blood sampling at 0 and 2 h, if a hs-cTn test with a validated 0 h/2 h algorithm is available • As an alternative to the ESC 0 h/1 h, a rapid rule-out and rule-in protocol with blood sampling at 0 h and 3 h should be considered, if a high-sensitivity (or sensitive) cTn test with a validated 0 h/3 h algorithm is available
American College of Emergency Physicians (2018) [10]	• A single hs-cTn result below the limit if detection (LoD) on arrival to the emergency department (ED) or negative serial hs-cTn result at 0 h and 2 h predicts a low rate of a major adverse cardiovascular event
Consensus statement of Ethics and Guidelines Standing Committee of the South African Heart Association (2012) [11]	• Initial hs-cTn level below 99th percentile URL in a patient with a reliable history of chest pain onset more than 6 h prior to sampling, rules out MI • Initial hs-cTn value above specified WHO cut-off values, rules in MI • Initial hs-cTn value between 99th percentile URL and WHO cut-off levels, a rapid 0 h/3 h rule-in algorithm is recommended with delta troponin criteria specific for each cTn isoform

Audits assessing the use of cTn assays in clinical settings have shown variable adherence to guidelines regarding repeat timed measurements. Some audits noted inappropriate ordering of cTn as a routine test in the ED due to a lack of awareness of appropriate use [12–14]. Others identified a majority of requests that were submitted without any clinical information and inappropriate timing of samples [14]. At the time of this study, there were no data concerning the pattern of cTn use across multiple health care facilities within South Africa (SA).

South Africa has a unique dual health care system. The public sector (Department of Health, DoH), which is state-funded, caters to the majority (72%) of the population while the private sector, which is largely funded through individual contributions to medical aid schemes or health insurance, serves around 28% of the population [15,16]. Laboratory services to all public health facilities within SA are provided by the National Health

Laboratory Service (NHLS), which is a separate public entity from the DoH. There are over thirty NHLS laboratories across KwaZulu-Natal (KZN) based at the various levels of health care facilities.

The objective of this study was to investigate the cTn use pattern among clinicians from the public sector health care facilities of KZN, the second most populated province in SA with a population of over 10 million residents and where up to 80% of its population rely on public health care facilities [15,16]. A further objective was to assess whether their patterns of practice aligned with the recommendations outlined in the Fourth UDMI.

2. Methods

We performed a retrospective analysis of all cTn results provided by KZN NHLS laboratories during the period 1 January 2018 to 31 December 2019.

Sample collection date and time, patient demographics, clinical history, name of health care facility and department, and assay method (as indicated by the test set code) for each cTn result were extracted from the NHLS Central Data Warehouse. Troponin requests with concomitant requests for other cardiac biomarkers, such as CKMB, Total creatine kinase (CK), serum myoglobin and natriuretic peptides (BNP or NT pro-BNP) were also retrieved from the database. All patients ≥18 years of age who had a Troponin T and/or Troponin I result for the period under review were included, while those <18 years of age and those with no age information were excluded.

The population cohort was stratified into five age categories based on age in years, viz. 18–24, 25–39, 40–59, 60–74 and ≥75; while the troponin requests were categorised per health care (HC) facility and clinical setting. Each HC facility was delineated according to the level of service provided as designated by the DoH (i.e., Level 1—clinics, community health centres (CHCs) and district hospitals, Level 2—regional hospitals, Level 3—tertiary hospitals and Level 4—central and specialised hospitals). Clinical departments were subdivided into ambulatory encounters (i.e. outpatient departments (OPD), which included both specialist and non-specialist clinics, and emergency departments (ED)) and hospital admissions (coronary care units (CCU), intensive and high care units (ICU/HCU) and all other wards). CCUs were analysed separately from general ICU/HCUs as the nature of disease in the patient population from the latter departments were more heterogeneous and often multi-system.

Serial sampling analysis for a single encounter was identified based on the time interval between the baseline and subsequent request as well as the respective department of origin. When the initial request originated from an outpatient setting (i.e. OPD and ED), serial sampling was considered if the subsequent request was within 24 h. Whilst in the case of an initial request originating from an inpatient setting, a time interval of 72 h to the second request was deemed a single encounter. Those who had more than two serial samples within an inpatient encounter were identified as having successive requests within 24 h of each subsequent request. The time interval between the baseline and second request was determined and classified as: <3 h, 3–6 h, 6–12 h, 12–24 h or >24 h.

One of three cTn assays were used at the various laboratories within KZN during the period of the study. Information regarding the assay method employed for each cTn result was confirmed through the test set code assigned on the laboratory information system (LIS) at the time of sample analysis. Two of these were hs-cTn assays with their respective manufacturer specifications for the 99th percentile URL, LoD and WHO rule in values as follows: Siemens ADVIA Centaur cTnI (Siemens Healthcare Diagnostics Inc. Tarrytown, New York, United States of America): 40 ng/L; 6.0 ng/L; 600 ng/L and Roche Elecsys cTnT (Roche Diagnostics International Ltd., Rotkreuz, Switzerland): 14 ng/L; 5.0 ng/L; 100 ng/L. There were no gender specific cut-offs for the 99th percentile URL reported by the laboratories during this period. The third was the semi-quantitative point-of-care (POC) Roche Cobas h232 Troponin T (Roche Diagnostics International Ltd., Rotkreuz, Switzerland) assay with an analytical range of 40–2000 ng/L, medical decision point of 50 ng/L (%CV 9.3%) and WHO rule-in value of 100 ng/L. All samples that were analysed using the high-sensitivity assays were serum based, whilst heparinized plasma samples were used for the POC assay.

Delta troponin was determined for all hs-cTn data that were associated with a second result within 3 h of the initial request. Myocardial injury was established based on either value exceeding the 99th percentile URL of the respective hs-cTn assay. Acute myocardial injury was defined according to the recommendations of The National Academy of Clinical Biochemistry, i.e., a dynamic change of ≥20% in patients with baseline elevations in cTn or ≥50% in those with baseline levels below the 99th percentile URL [5,7].

Data Analysis

Continuous data were presented as mean ± standard deviation (SD) and categorical variables were presented as proportions. Cross-sectional analyses were performed using pivot tables and graphs on Microsoft Excel 2016 (Microsoft Corporation, Redmond, Washington, United States).

This study was approved by the University of KwaZulu-Natal Bioethics Committee (BREC/00001783/2020) and did not include any studies involving human participants.

3. Results

3.1. Population Demographics

During the study period, 41591 cTn requests for 32,395 patients were received at KZN NHLS laboratories. Female patients represented 54.2% of the cohort, exceeding the requests for male patients most notably in the age group >60 years by an average of 37%. The greatest proportion of requests were from the 40–59-year-old group with a relatively close distribution of requests across both genders in this category (Figure 1). Overall, the mean (SD) age of the cohort was 55 years (17.5).

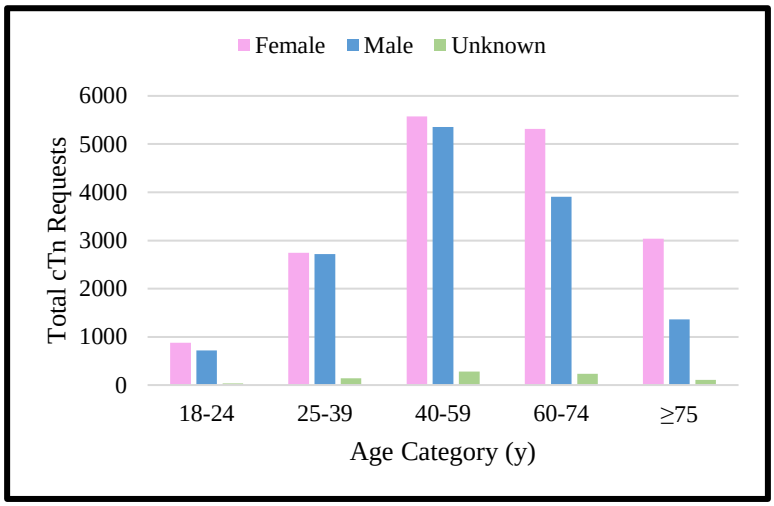

Figure 1. Age and Gender distribution of troponin requests.

3.2. Health Care Facilities

Overall, the majority of cTn requests emerged from hospitals dominated by level 2 HC facilities (37%) followed by level 1 HC facilities (29%). Of note, clinics and CHCs comprised <3% of requests from level 1 HC facilities while overall, up to one-quarter of results from level 1 HC facilities were from OPD. On the whole, cTn requests arising from the ED accounted for half of all requests, whereas requests for in-patients comprised 35%. However, the majority of these requests were from wards not requiring critical care (24%). Furthermore, the number of requests emanating from the ED (39%) and wards (34%) at level 2 HC facilities were relatively close (Table 2).

Table 2. Distribution of cTn requests according to level of health care and clinical department.

	ED	**OPD**	**CCU**	**ICU/HCU**	**WARD**	**Total**	
	n	*n*	*n*	*n*	*n*	***n***	**%**
Level 1	7279	2994	0	149	1766	12,188	29
Level 2	5967	2627	801	694	5313	15,402	37
Level 3	7262	649	50	549	1881	10,391	25
Level 4	243	144	319	2077	827	3610	9
Total *n*	20,751	6414	1170	3469	9787	41,590	
%	50	15	3	8	24		100

Summary of origin of cardiac troponin requests processed in KwaZulu-Natal, South Africa, 1 January 2018 to 31 December 2019. Number of requests (*n*) per department and level of health care facility. Proportions of requests (%) per department (last row) and per level of health care facility (last column) as a percentage of all requests. ED, emergency department; OPD, outpatient department; CCU, coronary care unit; ICU/HCU, intensive care unit/high care unit; Ward all non-ICU/HCU wards.

3.3. Additional Cardiac Biomarkers

More than two-thirds of all cTn requests had an accompanying request for additional cardiac biomarkers (Figure 2). Among them, CK (53%) and CKMB (33%) requests were the most frequent, while <1% had an

associated request for serum myoglobin. However, there were 27,100 CKMB requests without an accompanying order for cTn and only 13% of cTn requests had an associated request for natriuretic peptides.

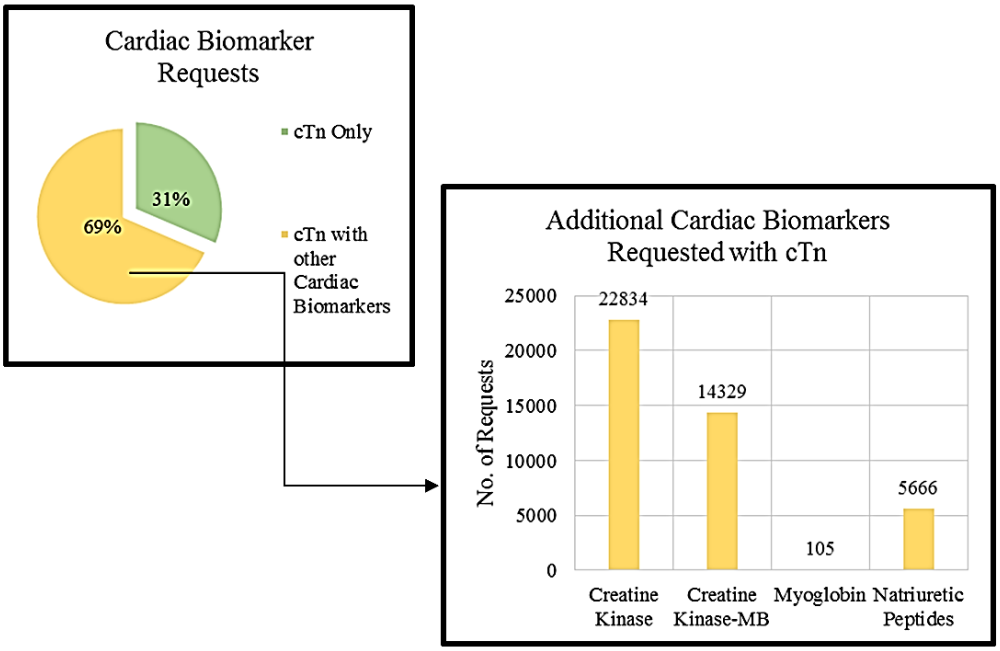

Figure 2. Cardiac troponin results with an associated request for other cardiac biomarkers including, Total creatine kinase, Creatine kinase-MB, myoglobin and natriuretic peptides (BNP and NT-proBNP) processed in KwaZulu-Natal South Africa, 1 January 2018 to 31 December 2019.

3.4. Sampling Strategy

A single sample approach was most frequently adopted with only 18.6% representing additional cTn requests within a single presentation. Serial sampling was only observed in hospital settings with a relatively similar frequency in the ED, ICU/HCU and wards. Serial sampling was infrequent in OPD and accounted for only 2.7% of the serial cTn requests. Of the 2533 patients who had serial cTn requests, 706 patients had >2 requests in a single presentation with the highest number of requests being 62. The time interval between the baseline and subsequent sample varied, and could not be determined (designated as UTC in Figure 3) for 1004 patients (43.7%) as the sample collection time for one or both samples was not indicated. Most patients (46.8%) had the second cTn request within 24 h but more than 3 h of the initial request (Figure 3).

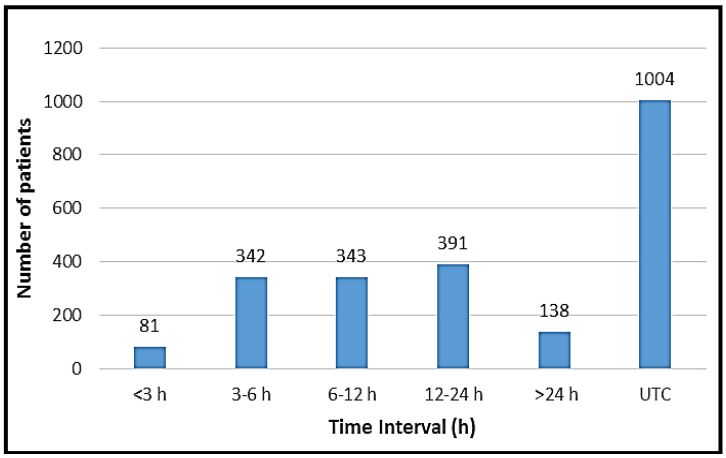

Figure 3. Patient distribution according to time interval between baseline and second troponin request for a single patient encounter, 1 January 2018 to 31 December 2019.

3.5. Application of Rapid Rule-In/Rule-Out Strategies

The bulk of cTn requests (76.7%) were analysed using a hs-cTn assay, with 19.7% of these representing serial requests for 1984 patients (Figure 4). However, only 63 (3.2%) of these patients had a second sample requested within 3 h of the initial request. Within this sub-set, a slightly greater proportion of individuals (34/63; 54%) had at least one cTn value greater than the assay-specific 99th percentile URL. However, the majority of these (19/34) did not meet criteria for a significant delta troponin. Among individuals with a baseline cTn ≤ 99th percentile URL (29/63), acute myocardial injury was inferred in only 4 patients based on delta troponin. Of note, delta troponin could not be determined in 2 cases, including one with a baseline cTn measurement exceeding the 99th percentile URL, as the successive requests were analysed using different cTn assays. Overall, at least 70 patients had serial samples for cTn that were analysed using different troponin assays.

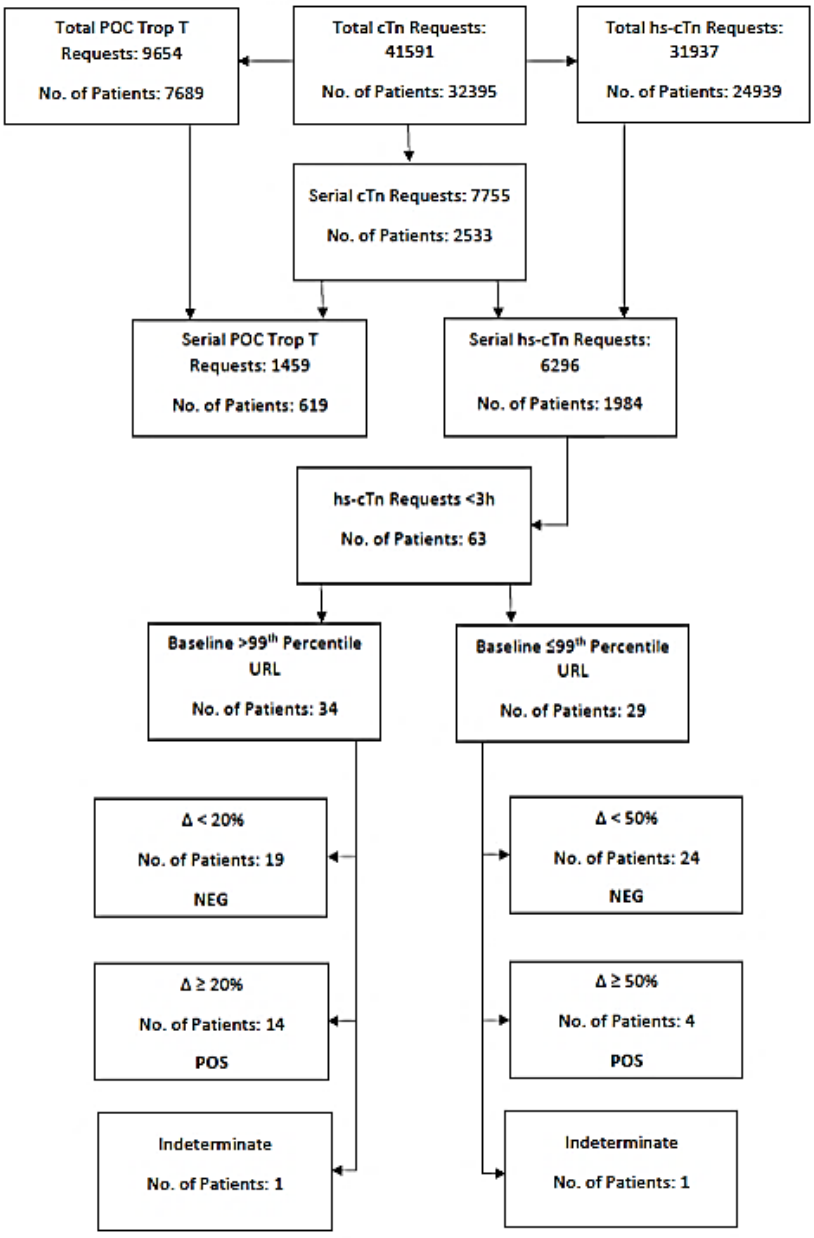

Figure 4. Flow chart illustrating total number of patients and troponin requests
Application of delta troponin was demonstrated amongst the group who had serial sample requests analysed with hs-cTn assays at presentation and at 3 h. "NEG" indicates lack of significant delta troponin; "POS" indicates significant delta troponin suggesting acute myocardial injury.

The discrepancies between total number of patients and sum of patients from individual method groups were likely because cTn requests for some patients were processed using both methods.

4. Discussion

In this study we have demonstrated the variability in practice amongst clinicians at the different levels of health care facilities across the various departments, which for the most part is not consistent with the recommendations outlined in the Fourth UDMI [5]. Our findings with regards to a low percentage of serial testing occurring following initial Troponin request has been reported in other studies focusing on emergency settings [17,18]. This study expands the clinical settings evaluated in a large population served by the laboratory services.

Within the DoH referral system, Level 1 HC facilities are deemed the first port of call when medical assistance is required but Level 2 HC facilities were found to have more cTn requests by one-fifth (21%). This may be explained by the fact that most Level 1 HC facilities are understaffed and often serviced by community service doctors whose expertise may often be limited in the management of an undifferentiated patient and restricted due to lack of knowledgeable and experienced senior medical officers/consultants.

Nevertheless, it is encouraging that at least 50% of all cTn requests emerged from the ED. On the other hand, the 15% of cTn requests from the OPD cannot be ignored where serial sampling was less frequent. Cardiac biomarkers require urgent interpretation since it is reflective of the physiological state of the patient at the time of sample collection and offers limited value when interpreted beyond this. In addition to not having access to the clinical records to determine if the results were reviewed timeously; we were not able to ascertain if patients were referred to another facility for repeat cTn testing within 24 h by using the LIS as registration details differ between facilities.

By using highly sensitive assays and the assay-specific 99th percentile URL, hs-cTn provides the necessary information to evaluate patients with suspected AMI and thus renders the use of additional biomarkers such as myoglobin and CKMB as redundant [4-7]. However, CKMB measured by mass assay is a suitable alternative when a cTn assay is not available [3–5]. In KZN, CKMB mass is not as widely available as cTn and is only performed at tertiary and some regional hospital laboratories, yet the number of CKMB requests received without a concomitant cTn request was surprisingly high. Furthermore, myoglobin and CK are not part of the national guidelines for the evaluation of acute coronary syndromes, yet were concomitant requests in just over 50% of cTn requests.. This additional testing which is divergent from recommended best practice represents a waste of resources.

Serial sampling can reduce the risk of misdiagnosis associated with assays, variations in time of presentation after onset of symptoms and other external factors that can affect optimal assay performance. Criteria for determining a pathological rise between 2 serial cTn values are assay-dependent [4-5]. Therefore, results from serial sampling to determine delta troponin is only valid if all measurements from the same patient are performed on the same specimen type and same assay [6-7]. However, a single hs-cTn result that is below the assay's LoD may be sufficient to safely discharge a patient from the ED [5–7,19]. Possible reasons for the low number of serial requests observed may include (a) an initial low result (b) poor turn-around-time (TAT) for samples sent to the laboratory, (c) shortage of clinical staff and (d) lack of knowledge regarding appropriate use/best practice guidelines.

The guidelines recommend the use of all cTn assays, including POC cTn and contemporary cTn [5,7]. POC assays may be considered for use at institutions where TAT is likely to exceed 60 minutes, provided the POC device meets the minimum analytical performance criteria i.e., %CV of ≤20% at the 99th percentile [5,8,9,19,20]. However, recommendations for use of POC platforms in accelerated assessment strategies for patients with suspected AMI is limited.

This study is the first to the authors' knowledge to review requesting practices of cTn in a South African context. Another strength of this study is that data were obtained from several health facilities across different levels of care. The findings also reflect those of a recent study examining different practices for utility and serial sampling of Troponin via a questionnaire survey across 37 European countries [21].

The limitations of this study included the following (a) limited clinical details given that data were extracted from the LIS with majority of the requests having little or no relevant clinical information and (b) we could not determine patients who may have had troponin requests from two different health care facilities within 24 h due to the referral process and differing registration details.

5. Conclusion

Our findings demonstrate limited adherence to the current clinical guidelines with regards to serial troponin sampling. Further evaluation of the reasons thereof is required though not under the scope of this paper.

Author Contributions

V.G., E.L.S. and A.R. generated the idea for this publication. E.L.S. undertook the statistical analyses. E.L.S. generated the original version and edited multiple iterations. V.G. and A.R, reviewed drafts of the manuscript. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement

Ethical clearance for this study was obtained from the Biomedical Research and Ethics Committee (BREC) of the University of KwaZulu-Natal (Ethics Clearance Certificate BREC/00001783/2020).

Informed Consent Statement

Not applicable

Data Availability Statement

The data is available from the senior author for review on reasonable request.

Conflicts of Interest

The authors declare no conflict of interest.

Use of AI and AI-Assisted Technologies

These were not used by the authors submitting this paper.

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