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Research Article

Feasibility of Non-Invasive Advanced Haemodynamic and Cardiac Output Monitoring (ClearSightTM) in Guiding Goal Directed Therapy During Medical Emergency Team Response: A Pilot Study

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Abstract

Purpose: This study evaluated the feasibility of goal directed therapy (GDT) in a general ward setting for haemodynamically unstable patients who triggered a medical emergency team (MET) call.

Methods: This prospective, observational, pilot study was conducted at a specialist teaching hospital, Peter MacCallum Cancer Centre, Melbourne following ethics approval. A continuous, non-invasive cardiac output monitor (Clear Sight™ - Edwards Life Sciences, Irvine, CA, USA) was available to guide MET management via assessment of patient fluid responsiveness. Utility of the Clear Sight™ system in the ward environment was assessed. The MET was free to implement or disregard GDT guidelines and each fluid management decision was recorded.

Results: Twenty patients were recruited and satisfactory Clear Sight™ output data was obtained in 80% (16/20). Median Clear Sight™ mobilization and set up time was 18.5 minutes. Twenty-eight fluid management decisions were made in thirteen patients. In seven of twenty-eight (25%) decisions the patient was identified as fluid-responsive and fluid was administered in each (7/7 decisions). In the remaining twenty-one (75%) decisions the patient was identified as non-fluid-responsive, yet the MET administered fluid in 95% (20/21 decisions) contrary to GDT guidelines. Of the sixteen patients with satisfactory Clear SightTM output data, 56% (9/16) required ICU admission for further haemodynamic management.

Conclusions: Our data supports the feasibility of Clear Sight™ in delivering ward based GDT and in guiding MET management. Given that only 29% (8/28) of MET decisions were concordant with GDT guidelines, our data supports the need for a larger multicentre prospective study to further evaluate GDT in the ward setting.

Keywords: *Advanced Haemodynamic Monitoring; Emergency Response Team; Failure to Rescue*

Introduction

The goal of all resuscitation is prevention and/or treatment of end-organ dysfunction and cellular injury by optimising tissue oxygen delivery to meet metabolic demand and optimization of intravascular volume to ensure maximization of tissue oxygen delivery remains a

cornerstone. Fluid therapy is a complex intervention with both insufficient and over resuscitation with intravenous fluid being associated with adverse outcomes [1].

Manipulation of the macro-circulation to defend capillary autoregulation and microcirculatory oxygen delivery relies heavily on advanced haemodynamic monitoring to optimise volume state and cardiac function [2]. Early initiation of goal directed therapy (GDT) in the resuscitation of haemodynamically unstable patients with septic shock has been shown to reduce mortality [3] and has been integrated into international practice guidelines [4].

It is estimated that only about 50% of haemodynamically unstable patients are fluid responsive [5,6]. This suggests the application of standard empiric fluid therapy may lead to fluid overdose in a substantial proportion of unstable ward patients.

Ward based GDT would help medical emergency teams (MET) to manage fluid therapy more accurately, may help prevent fluid overdose and may identify non fluid responsive patients who would benefit from other haemodynamic strategies e.g. vasopressors or inotropes. Non-invasive cardiac output monitoring offers the potential for safe, ward based GDT, with the ability to rapidly discern fluid-responders from non-fluid-responders and to tailor appropriate (fluid/vasopressor/inotropic) therapy to reduce episodes of 'failure to rescue' and thereby improve patient outcomes.

We conducted a pilot study trialling the use of the Clear Sight™ (Edwards Life Sciences, Irvine, CA, USA), technology that utilises a non-invasive finger cuff with volume clamping and pulse contour analysis to derive beat-by-beat blood pressure and cardiac output measurements, to guide GDT in haemodynamically unstable patients meeting institutional Medical Emergency Team (MET)/Rapid Response Team criteria in an in-patient ward setting.

The primary objective for this pilot study was to assess ease and rapidity of acquisition of advanced haemodynamic monitoring data through the Clear Sight™ system. As a condition of ethics committee approval this was to be a pragmatic trial, with advanced haemodynamic data being made available to the Medical Emergency Team, but its use in the management of individual patients was left to clinician discretion. Secondary objectives, therefore, were to assess if there was alteration in fluid management strategy when advanced haemodynamic monitoring parameters were available to the treating team to see if there was a difference in the end points of resuscitation and disposition in terms of volume of intravenous fluid administered.

Methods

Patient population

This prospective observational pilot study was conducted at Peter MacCallum Cancer Centre, a metropolitan specialist teaching hospital in Melbourne, Australia, after obtaining ethical approval from the local ethics committee (Peter MacCallum Centre Project 14/181L). All patients who received a MET call between 24/04/15 and 24/06/15 were considered for the study. The need for informed consent was waivered due the emergent nature of the patient population.

Inclusion and exclusion criteria

Adult patients at Peter MacCallum Cancer Centre who presented with unexpected haemodynamic instability in the in-patient ward setting who met institutional MET call criteria for haemodynamic instability (heart rate < 60 or > 120 beats per minute, systolic blood pressure < 90 mmHg) and were for active management including invasive organ support in a critical care unit were deemed eligible for this pilot study. Exclusion criteria included: uncooperative patients, inability to apply the Clear Sight™ finger cuff to patients, patient receiving palliative care only, and patients with significant tachyarrhythmia (e.g. atrial fibrillation or atrial flutter) with heart rate >140 beats per minute.

Data collection

The time of initiation of a Medical Emergency Team (MET) call was noted at T1 (Figure 1). The Clear Sight™ monitor was brought from the ICU when eligible patients were identified. An appropriate cuff size was selected and attached to the patient and patient data (age, gender and weight) were entered for calibration of the Clear Sight™. The time point at which an adequate non-invasive arterial waveform trace was acquired was noted as T2. The Clear Sight™ trace was identified as 'absent', 'poor', 'acceptable' and 'good'. Patients with 'absent' or 'poor' Clear Sight™ trace were excluded from further study as the accuracy of output data could not be confirmed. At T2 the initial Clear Sight™ Mean Arterial Pressure (MAP) and Stroke Volume (SV) were recorded and the first 250 ml intravenous fluid bolus was commenced as soon as possible at time B1. The initial bolus was delivered as quickly as possible and on completion the Clear Sight™ MAP and SV were again recorded and fluid responsiveness was then assessed.

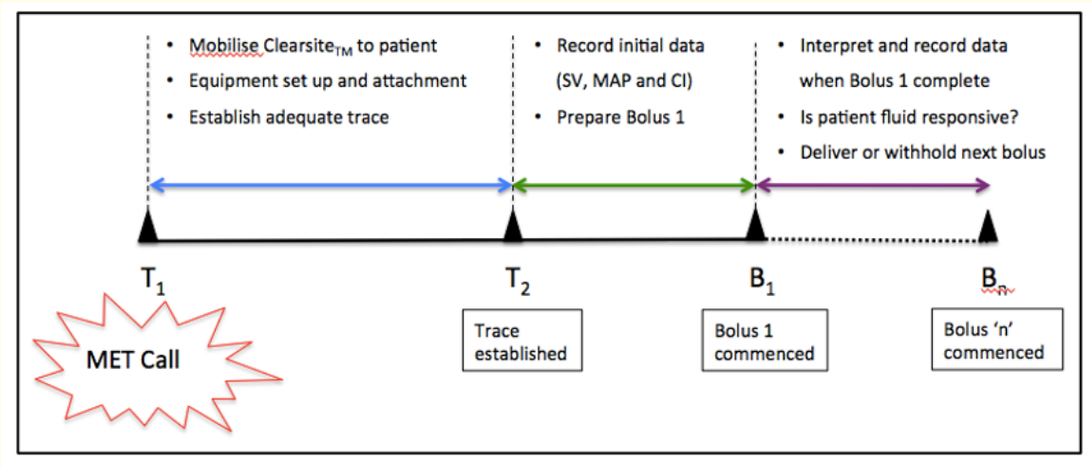

Figure 1: *Summary of time intervals.*

Patients demonstrating an increment of 10% or greater in their SV in response to the fluid bolus were deemed to be fluid responsive [7]. Decision on further fluid management and/or transfer to the Intensive Care Unit (ICU) for formal invasive haemodynamic monitoring, further fluid management, vasopressors, inotropes or any other resuscitation measures deemed appropriate in the clinical context was left to the discretion of the Medical Emergency Team. If further fluid was given, the commencement time of each subsequent intravenous bolus (Bn) was recorded and fluid responsiveness was assessed in the same way. An Excel based data collection form was completed during each MET call (Figure 2).

Patient ID **Age** **Gender**

MET alert time **(T_1)** Trace established time **(T_2)**

SV at T_2: MAP at T_2:

	Time	**SV (post bolus)**	**MAP (post bolus)**	**Fluid responsive (Y/N)**	**Further fluid given (Y/N)**
Bolus 1	(B_1):				
Bolus 2	(B_2):				
Bolus 3	(B_3):				
Bolus 4	(B_4):				
Bolus 5	(B_5):				
Bolus 6	(B_6):				
Bolus 7	(B_7):				
Bolus 8	(B_8):				

Disposition following MET call:
Problems encountered:
24 hour follow up:

Figure 2: *ClearSightTM Record Sheet.*

Data was analysed using Microsoft Excel (Microsoft Inc, Redmond, VA, USA). The mean arterial pressures (MAP) recorded using conventional non invasive blood pressure (NIBP) measurement equipment available in the ward and by the Clear Sight™ probe were simultaneously recorded for each patient. Linear regression between the two MAP data sets was performed and a line of best fit plotted.

A priori it was felt that a difference of more than 10mmHg between the two measurement modalities would be clinically significant. A Bland Altman plot was produced to assess agreement between BP measurements using Clear Sight™ and ward based NIBP. Lines of agreement at 95% confidence intervals as well as at the a priori determined clinically significant levels were plotted.

Results

All patients who received a MET call within a 60-day period (2015) were considered eligible for the study. Twenty eligible patients (demographic data shown in Table 1) were deemed haemodynamically unstable and included in the study. Of these, 85% (17/20) of patients were deemed to be in cardiovascular shock on clinical examination by the Medical Emergency Team and 80% (16/20) of patients had adequate arterial pressure trace acquisition using the Clear Sight™ finger cuff. The four patients (3 in cardiovascular shock) with an inadequate non-invasive arterial trace were excluded from further analysis.

Gender	**Number (%)**
Male	6 (30%)
Female	14 (70%)
Age Range (Years)	**n**
20-29	2
30-39	1
40-49	2
50-59	3
60-69	5
70-79	5
80-89	2
Total (N)	20
Mean (SD)	60.95 (17.17)
Reason for MET call	**Number (%)**
Tachycardia	6 (30)
Hypotension	14 (70)

Table1: *Patient Demographics.*

The median time to acquisition of an adequate arterial trace and provision of advanced haemodynamic data derived from the Clear Sight™ device was 18.5 minutes (IQR 13.75: 12.5 -26.25 minutes). This included the time needed by the Medical Emergency Team to access the Clear Sight™ equipment from ICU and transport it to the patient's bedside in the ward. Of the 16 patients with at least acceptable arterial trace acquisition, adequately recorded data was available in 15 patients and allowed comparison of 17 episodes of mean arterial pressures measured simultaneously with the Clear Sight™ device and ward based techniques (manual or oscillometric automated sphygmomanometry).

The MAP measured by the two modalities is presented in table 2. Box plots (Figure 3) showed marked similarity between the two data sets and on linear regression, there was significant correlation between the values measured by the two modalities (Pearson's R = 0.73,

p-value = 0.001). The line of best fit was plotted (Figure 4) and Bland Altman plot (Figure 5) was generated to demonstrate reasonable agreement between the two modalities of MAP measurement within the a priori determined lines of agreement for clinical significance.

Measurement number	ClearSight™	NIBP
1	80	69
2	60	47
3	62	48
4	68	60
5	80	77
6	85	99
7	78	83
8	60	67
9	71	51
10	66	69
11	74	89
12	78	88
13	56	52
14	56	66
15	45	56
16	69	70
17	59	50
Mean [95CI]	67.47 [64.5,70.4]	67.12 [62.9,71.4]
SD	10.53	15.38

Table 2: *MAP values recorded by ClearSight™ and ward NIBP device.*

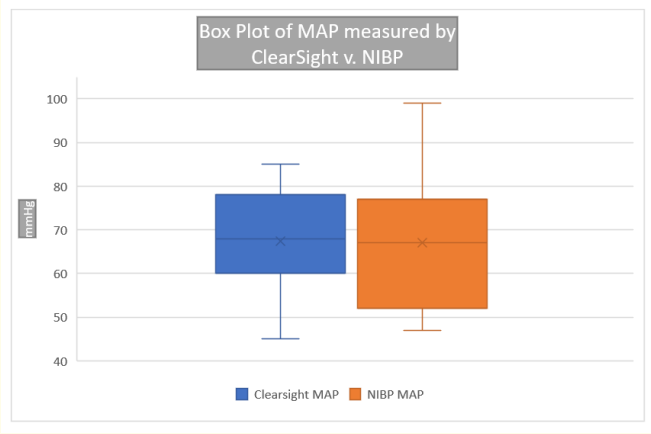

Figure 3: *Box plots of MAP data.*

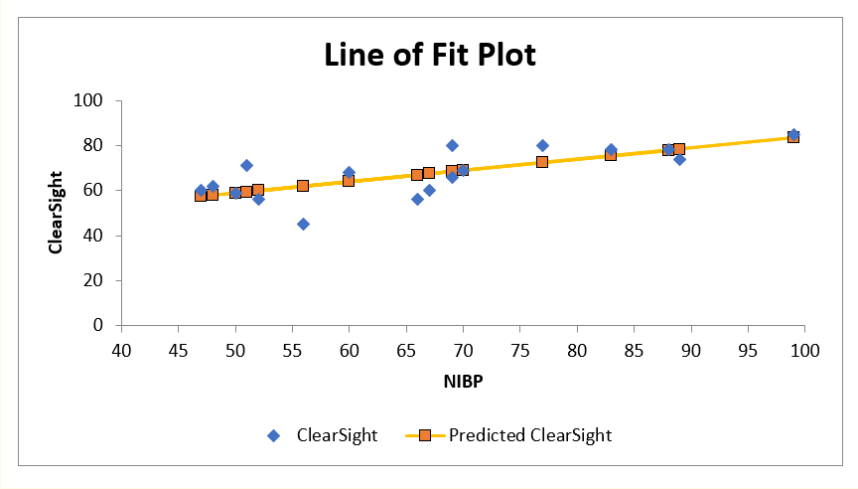

Figure 4: *Line of best fit for linear correlation of MAP data between ClearSightTM and ward NIBP measurement Pearson's R= 0.73 (p value= 0.001).*

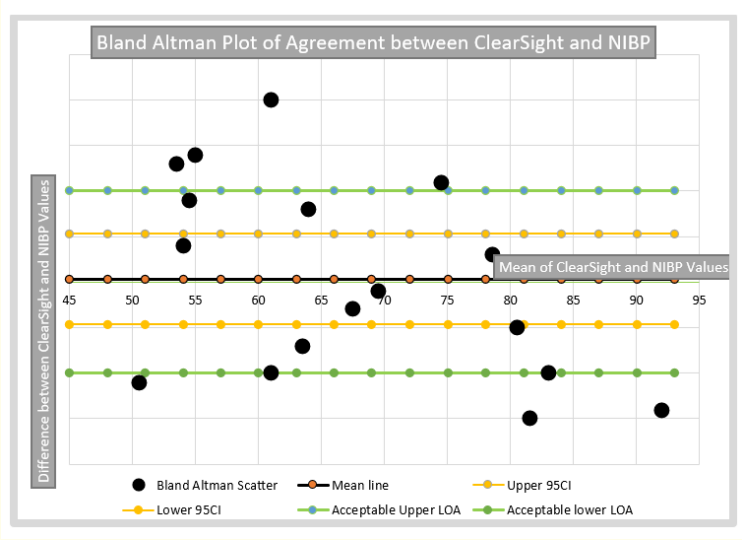

Figure 5: *Bland and Altman Plot of agreement ClearSightTM and ward NIBP measurement.*

Adequate data to determine whether patients were fluid responders or non-responders was available for only 13 patients and a total of 28 fluid management decisions were made in the study. Patients identified as being fluid-responsive were (7/7 decision episodes) managed with further fluid administration by the Medical Emergency Team. Patients identified as being non-fluid-responsive by current Clear Sight™ guidelines were still given further fluid therapy in 95% (20/21) of decision-making episodes at the discretion of the Medical

Emergency Team. As such, of the total number of decision-making episodes by the Medical Emergency Team only 29% (8/28) of decision-making episodes were concordant with current GDT Management guidelines. On follow-up 24 hours later none of the patients identified as non-fluid-responsive had radiologic evidence of volume overload, need for diuretics or ventilatory support. Of the 16 patients with a satisfactory Clear Sight™ waveform, 56% (9/16) required HDU/ICU admission for further haemodynamic management.

Brief semi structured interviews were conducted with the MET teams to identify practical barriers to the use of the Clear Sight™ device in the ward setting for GDT during MET calls. The main themes that emerged were

- Uncertainty regarding need for Clear Sight™ device at time of MET activation: Not all MET calls were appropriate for application of Clear Sight™ (e.g. MET activations in patients with respiratory distress or altered levels of consciousness)
- Logistic delays: transporting the Clear Sight™ and EV1000 monitor from ICU on a case by case basis to patient's bedside in ward, powering up, application of device to patient and initiation of trace on Clear Sight™
- Interpretation of Clear Sight™ output data: not all medical staff attending MET were confident interpreting the data or following GDT with early initiation of vasopressors for patients identified as non- fluid responsive
- Additional workload: ensuring safety of Clear Sight™ (device on loan from manufacturer, investigators liable for damage) whilst maintaining focus on the patient
- Disposition dilemma: Ward staff refusing to stand down MET call when non-concordant MAP values between devices and ward NIBP records MAP value within MET criteria and ClearSight™ does not.

Discussion

This pilot study demonstrated the feasibility of using Clear Sight™ technology for the rapid assessment of haemodynamically unstable patients by a Medical Emergency Team in the ward setting.

Trace acquisition

Failed Clear Sight™ trace establishment is well documented in patients with the extreme low peripheral flow and/or high systemic vascular resistance associated with shock [8,9]. Given the emergent nature of MET calls it is also likely that operator error is more prevalent than in a more controlled surgical or ICU environment. We were able to obtain an adequate Clear Sight™–derived arterial waveform trace in the majority (80%) of haemodynamically unstable patients during a MET call. This is comparable to the acquisition rates of between 82-100% in ICU studies. Specifically, Fischer., *et al*. reported trace establishment success of 88% in a study evaluating continuous haemodynamic monitoring with this technology in the ICU [10], while ICU studies that assessed fluid responsiveness reported trace acquisition success rates that ranged between 82% and 100% [11-15].

Reliability of data

There was good correlation and acceptable agreement between mean arterial pressures measured by both conventional (manual or oscillometric) ward based sphygmomanometry equipment and Clear Sight™. The haemodynamic data was available fairly immediately after correct application of the finger probe and advanced haemodynamic data available to guide decision making for resuscitation during the MET for the small number of patients assessed in this pilot study.

Utilisation of advanced haemodynamic parameters during a MET call

The high incidence of non-fluid responsive scenarios (21/28 haemodynamic optimisation decision-making episodes), as determined by monitoring with Clear Sight™ device, may be a consequence of the device being applied to the sickest patients in the ward outside of the ICU setting. This pragmatic pilot study was designed to allow the MET to continue management as per usual with freedom to utilize or disregard GDT guidance. The MET decision to administer further fluid to non-fluid-responsive patients is likely multifactorial and may be ascribed to a mix of habitual MET call practice, unfamiliarity with the Clear Sight™ system, unfamiliarity with interpretation of advanced haemodynamic parameters (CO and dynamic SV response to a fluid challenge), reluctance to accept deranged physiologic variables with potential for ongoing end-organ damage from hypoperfusion, and a perceived need for temporization until vasopressors/inotropes could be initiated in the ICU setting.

Practical implications

Delay in commencement of GDT may result in fluid mismanagement during initial resuscitation during a MET call, and so minimization of delay is vital. In an elective ICU study Clear Sight™ data acquisition delay of less than 5 minutes were reported in 85% of patients [9]. We report a median time to acquisition of 18.5 minutes, which is substantially longer. This delay was predominantly attributable to the need to return to the ICU to collect and transport the Clear Sight™ device when the patient was deemed appropriate for the study. Never the less the ability to have continuous blood pressure monitoring with advanced haemodynamic parameters (SV and CO) is a significant improvement on current practice where most patients require transfer to an ICU setting for invasive monitoring. Our team found the Clear Sight™ monitor fixed to a wheeled stand cumbersome when lift access was required to reach patient wards on different hospital floors. Further, the limited area around the bed space during a MET call was also a challenge with the current Clear Sight™ system on a wheeled base. Set up and calibration of the Clear Sight™ system involved multiple steps and required task focus from the critical care liaison nurse who was also actively expected to participate in the resuscitation in a resource limited ward environment.

Limitations of the Study

This is a single center study conducted in a hospital with a specific patient population, all with primary haematologic or solid tumor cancers. This pilot study had a limited number of patients and missing data in three of sixteen patients with acceptable haemodynamic waveform acquisition. The pragmatic nature of the study in a clinical environment of a general patient ward, with a team not familiar with interpretation of advanced haemodynamic parameters and GDT principals also highlights the need for extensive education of the entire clinical team involved in haemodynamic optimisation of MET call patients.

Conclusions

Our data supports the feasibility of using Clear Sight™ technology for the rapid assessment of haemodynamically unstable patients by a MET in the ward setting.

We demonstrated clinically acceptable agreement between mean arterial pressure data obtained using conventional ward based equipment and Clear Sight™ in "real world" MET call conditions, lending credence to its role in goal directed haemodynamic resuscitation in physiologically deteriorating patients.

Given that the decision-making by the MET was only concordant with current GDT Management guidelines in 29% (8/28) of decision-making episodes our data supports the need for a larger multicentre prospective study to further evaluate the use of non-invasive advanced haemodynamic monitors to appropriately tailor early goal directed therapy, with ability to rapidly discern fluid-responders from non-fluid-responders and to tailor (fluid versus vasopressor/inotropic) therapy to reduce episodes of 'failure to rescue' and thereby improve patient outcomes.

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