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Equipment Monitoring Abstracts

Contents

Accuracy of the NOVA StatStrip® Glucometer in Patients Undergoing Abdominal Surgery: A Prospective Observational Study

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INTRODUCTION

While the Nova StatStrip® Glucose Hospital Meter System (Nova Biomedical, Waltham, MA, USA) is the newer glucometer technology with hematocrit correction[1] and approved for point-of-care testing (POCT) in critically ill patients,[2] its use during abdominal surgery has not been evaluated. The purpose of this study was to assess the accuracy of the Nova StatStrip® glucometer in patients undergoing major hepatobiliary procedures using the Parkes error grid (ISO15197:2013)[3] and criteria defined by the Clinical and Laboratory Standards Institute (CLSI) POCT12-A3 guideline.[4]

METHODS

This study was a *post hoc* exploratory study of blood samples that were obtained from abdominal surgical patients in a prospective randomized-controlled trial on infectious outcomes after hepatobiliary surgery. With the approval from the institutional Research Ethics Board and after obtaining written informed consent, patients aged 18 or older and scheduled for elective liver and pancreatic surgery between October 2018 and May 2022 were enrolled. Arterial blood samples were collected at baseline (before surgery), 1h after baseline, 2h after baseline and 3h after baseline. Blood glucose levels were measured by the Nova StatStrip® glucometer using a 3-mL syringe and the GEM® Premier™ 5000 (Instrumentation Laboratory Company, Bedford, MA, USA) blood gas analyzer using a 3-mL lithium heparin blood gas syringe for reference blood glucose. Accuracy of the StatStrip® glucometer was analyzed using the Parkes error grid for type 1 diabetes mellitus[3] and the Clinical and Laboratory Standards Institute (CLSI) POCT12-A3 criteria.[4] The primary outcome was the accuracy of the Nova StatStrip® glucometer meeting the Parkes error grid criteria. The Parkes error grid was divided into five risk zones. When 99% of samples were within zones A and B on the Parkes error grid, clinical accuracy was acceptable.

RESULTS

We assessed 187 patients of which 15 refused to participate. Surgery had to be rescheduled in 17 patients. Twenty of the remaining 155 consenting subjects were excluded, because the surgical procedure was not performed as planned (“open and close”). The Parkes error grid plotted results are shown in Fig. 1. All samples at all time-points were within zones A and B. In addition, the Nova StatStrip® glucometer also satisfied CLSI POCT12-A3 criteria at all time-points.

DISCUSSION

The Nova StatStrip® glucometer was accurate in patients undergoing major upper abdominal surgery.

REFERENCES

1. Karon BS, Griesmann L, Scott R, et al. Evaluation of the impact of hematocrit and other interference on the accuracy of hospital-based glucose meters. Diabetes Technol Ther 2008; 10: 111-20.
2. StatStrip® GLU Nova Hospital Glucose Monitoring System. Available from URL; http://www.novabio.us/statstrip-glu/ accessed Sep 29 2018.
3. Parkes JL, Slatin SL, Pardo S, Ginsberg BH. A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. Diabetes Care 2000; 23: 1143-8.
4. Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities, 3rd Edition, 3 ed: CSLI; 2013.

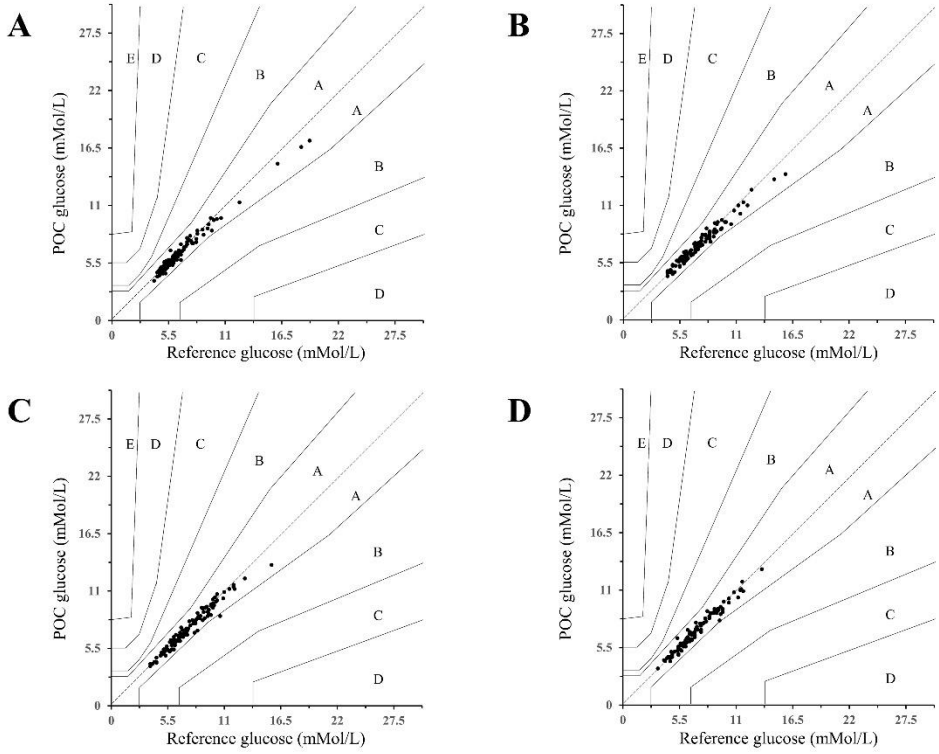

Fig. 1 Error grid analysis for arterial glucose obtained by the Nova StatStrip® glucometer and reference glucose values as demonstrated by the Parkes error. A = Baseline; B = 1h after baseline; C = 2h after baseline; D = 3h after baseline. Clinical accuracy is acceptable when 99% of samples must are within zone A or zone B. POC = point-of-care

Decreasing Environmental Impact and Costs of Using Inhalational Anesthetics by Replacing Chemical Absorbers with an Innovative Carbon Dioxide Membrane Filter System: Preliminary Results from a Prospective, Randomized, Clinical Trial

AUTHORS

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INTRODUCTION

Memsorb™ is a device that uses a semipermeable polymeric membrane to remove carbon dioxide (CO_2) from anesthesia circuits. CO_2 flows down a concentration gradient into the hollow lumen of the fibers and is continuously flushed out of the circuit by an air/oxygen gas mixture. This device can effectively eliminate CO_2 using the GE Datex-Ohmeda Aisys CS2 anesthetic machine in-vitro[1]; its use in a clinical setting has not been established. This prospective randomized clinical trial was designed to (1) examine the efficacy of the Memsorb™ system at CO_2 elimination in-vivo and (2) determine anesthetic gas usage when using the device with GE Datex-Ohmeda Aisys CS2 anesthetic machines.

METHODS

This study protocol was reviewed and approved by the local research ethics board. 87 patients were enrolled in this prospective randomized controlled trial since 2021. Inclusion criteria were patients with age >18, ASA I – III, undergoing elective surgical procedures. Exclusion criteria included severe respiratory disease, raised intracranial pressure, use of anesthetic agents other than sevoflurane, use of fresh gas flow (FGF) less than 2 L/min, laparoscopic surgery, or self-reported pregnancy. The primary outcome measure was effectiveness of Memsorb™ compared to traditional carbon dioxide absorbers at eliminating CO_2 during the maintenance phase of anesthesia, measured as end-tidal CO_2 ($ETCO_2$) and inspired CO_2 ($FiCO_2$). The secondary outcome was the amount of inhaled anesthetic used during the maintenance phase of anesthesia. A two-tailed Mann-Whitney U-test was performed to assess for statistical significance using GraphPad Prism software. Data are presented as median (25% percentile – 75% percentile; minimum, maximum).

RESULTS

72 patients met the inclusion criteria and were included in the analysis. The groups were similar with respect to age, sex, body mass index, or comorbidities. $ETCO_2$ was measured to be 39.2 (36.7 – 40.8; 33.5, 48) mmHg in the control group compared to 38.7 (36.5 – 41.5; 32.6, 55) mmHg in the Memsorb™ group. $FiCO_2$ was higher in the Memsorb™ group at 4 (3 – 5; 0.8, 8) mmHg compared to 1 (0.7 – 1.1; 0, 3) mmHg in the control group ($P<0.0001$). Minute volume (MV) ventilation was 5.7 (4.7 – 6.6; 3, 8.4) L/min in the control group

compared to 5.9 (5.1 – 7.0; 3.5, 9.4) L/min in the Memsorb™ group. More sevoflurane inhalational agent was used in the Memsorb™ group at 0.34 (0.27 – 0.43; 0.13, 0.71) ml/min compared to 0.27 (0.21 – 0.33; 0.15, 0.53) ml/min in the control group (P=0.0097).

DISCUSSION

Our study shows that this device can be successfully used with the GE Datex-Ohmeda Aisys CS2 anesthetic machines in a clinical setting. Despite higher $FiCO_2$ levels, no MV changes were required to maintain equivalent $ETCO_2$. We observed higher sevoflurane usage with this device, similar to a recently published study[2] but contrasting with findings published by the developers of this device[3]. This observation may be related to flushing air/oxygen mixture used to reduce the $FiCO_2$. Further studies are underway examining the impact of increased $FiCO_2$ on $PaCO_2$, as well as the effectiveness of the device in laparoscopic surgery and low-FGF anesthesia.

REFERENCES

1. Banik, S., Enk, D., Payne, S. & Noppens, R. Comparison of the Novel Membrane-Based Carbon Dioxide Filter Memsorb® with a Chemical Granulate Absorbent Using a Lung Simulator Device: A Prospective, Randomized, In-Vitro Feasibility Trial. *CAS Annual Meeting* https://www.cas.ca/CASAssets/Documents/Annual-Meeting/Abstracts/2021/2021-CAS-VAM_Abstract-Case-Report_Series_EQUIPMENT-MONITORING.pdf (2021).
2. Eerlings, S. A. *et al.* Memsorb™, a novel CO2 removal device part II: in vivo performance with the Zeus IE®. *J Clin Monit Comput* **36**, 1647–1655 (2022).
3. Schmidt, M., Wilfart, F., Ford, Z., Roach, D. & Hung, O. Low, minimal and metabolic anesthesia using a novel membrane technology instead of chemical absorbents for carbon dioxide removal - clinical data. *CAS Annual Meeting* https://memsorb.com/sites/default/files/2020-08/ESA2019.pdf (2019).

Invasive Hemodynamic Monitoring During Anesthesia: Is There a Better Way?

AUTHORS

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INTRODUCTION

Patients undergoing complex surgery require strict blood pressure monitoring to minimize hemodynamic fluctuations as these have been linked to increased post-operative mortality, morbidity, delirium, and stroke[1]. The current gold standard for blood pressure monitoring is the placement of an intraarterial catheter. While this technique provides continuous blood pressure readings, the insertion of this monitor is painful, time consuming, and carries a risk of infection, bleeding, nerve, and arterial injury[1]. An alternative device called ClearSight by Edwards LifeSciences allows for beat-to-beat blood pressure monitoring using a non-invasive finger microcuff. A previous study comparing the accuracy of the ClearSight and arterial line systems in cardiac surgery patients used a handful of time points per patient for their analysis[2]. In this study, we sought to compare continuous blood pressure measurements collected by ClearSight and arterial line systems in elective cardiac surgery patients for the duration of their surgery.

METHODS

Ethics approval was obtained from the Biomedical Research Ethics Board. In this prospective observational study, we recruited 30 patients scheduled for elective cardiac surgery. We compared systolic (SBP), diastolic (DBP), and mean arterial blood pressure (MAP) measured by the ClearSight system (ABP) versus the arterial radial line (ART). We simultaneously recorded ABP and ART measurements every 20 seconds from induction to incision closure, except during cardiopulmonary bypass. The accuracy of the ClearSight system was determined based on the accepted threshold (±5 mmHg, standard deviation of <8 mmHg) recommended by the Association for the Advancement of Medical Instrumentation[3]. For SBP, DBP, and MAP, we used one-sample t-tests to assess for the difference between ABP and ART, and ordinary least-squares linear regression to test for proportional bias. Due to the large sample size, we considered effect size (Cohen's d and r) to interpret results. Bland-Altman[4] plots were created with limits of agreement (LOA), where confidence intervals were adjusted for multiple observations per individual[5]. Data was further analyzed with percentage error (PE), agreement tolerability index (ATI), and interchangeability. Lastly, a paired samples t-test was used to compare time to placement of ABP and ART.

RESULTS

Our analysis included 17,502 SBP, 17,899 DBP, and 17,957 MAP data points. Fixed bias was present in differences between ART and ABP with SBP (mean difference=8.66, p<0.001, Cohen's d=0.705) and DBP (mean difference=-2.03, p<0.001, Cohen's d=-0.236), but was not present in MAP (mean difference=-0.29, p<0.001, Cohen's d=-0.032). Proportional bias was significant in SBP (B=0.043, p<0.001, r=0.056, r-squared=0.003), DBP (B=-0.107, p<0.001, r=0.124, r-squared=0.015), and MAP (B=-0.043, p<0.001, r=0.211, r-squared=0.045), but had a small influence on the data. Though LOA intersected with 0, distance from the mean was >5 mmHg for SBP, DBP, and MAP. PE for SBP, DBP, and MAP were lower than the PE cutoff calculated from the ART data. ATI for SBP, DBP, and MAP were all <1, indicating acceptable agreement. Average interchangeability rates show SDP 37.52%, DBP 50.23%, and MAP 49.65%. It was significantly faster to place the ABP (1.69.5±0.57 min) in comparison to ART (5.64±4.15 min; p<0.001).

DISCUSSION

Based on the data, ABP is not an acceptable replacement for ART when considering the clinically acceptable mean difference in blood pressure of 5 mmHg. However, according to statistical standards, there is evidence to suggest ABP may be interchangeable with ART. This, combined with the ease of placement and setup of the ClearSight microcuff (in comparison to the intraarterial catheter), allows for quicker onset of surgery and may benefit emergent patients where time is critical.

REFERENCES

1. Rogge, D. et al. Continuous non-invasive arterial pressure monitoring in obese patients during bariatric surgery: an evaluation of the vascular unloading technique (ClearSight system). Anesth Analg. 2019;128(3):477-83.
2. Wang, Y. et al. A comparison of ClearSight noninvasive cardiac output and pulmonary artery bolus thermodilution cardiac output in cardiac surgery patients. Perioper Med. 2022; 11, 24.
3. Stergiou, G. et al. A universal standard for the validation of blood pressure measuring devices: association for the advancement of medical instrumentation/European society of hypertension/international organization for standardization (AAMI/ESH/ISO) collaboration statement. J Hypertens. 2018; 36(3):472-78.
4. Bland, J.M. & Altman, D.G. Agreement between methods of measurement with multiple observations per individual. J Biopharm Stat. 2007; 17(4), 751-82.
5. Zhou, G.Y. Confidence interval estimation for the Bland-Altman limits of agreement with multiple observations per individual. Statistical Methods in Medical Research. 2011; 22(6), 630-642.

Replacement Endotracheal Tubes did not Exhibit Clinically Relevant Differences in Bending Stiffness Despite Stiffer "Pinch" Test

AUTHORS

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INTRODUCTION

Recent supply disruptions due to the COVID-19 pandemic and other factors have impacted many hospitals, with almost no drug or equipment class unaffected.[1] Recent shortages have interrupted the supply of endotracheal tubes (ETT) at our hospital, necessitating substitution of ETTs sourced from other vendors.

The default Shiley Hi-Lo ETT (Covidien,Mansfield,USA) in our institution was routinely utilized with a Rusch Flexi-Slip 14Fr stylet (Teleflex,Dublin,Ireland). These ETTs were substituted with InTube (Intersurgical,Wokingham,UK, size 7.0,8.0) and VentiSeal (Flexcare Medical,Mountain Ash,USA, size 7.0,8.5) ETTs. Anesthesiologists perceived the replacement ETTs to be stiffer when compressing them between their fingers ("pinch" test) and expressed concerns with respect to tissue damage[2,3] due to increased bending stiffness. In addition, it was noted that styletted ETT's prepared in advance were found to have subsequently "relaxed", and did not maintain the desired curvature, potentially due to these stiffer ETT's. This caused anesthesiologists to switch to stiffer Shiley 14Fr (Covidien) stylets.

METHODS

Ethics approval was waived as this equipment study involved no patients or patient data. The study took place at a room temperature of 20° C. ETT's in all sizes supplied to our hospital were utilized with a Flexi-Slip stylet, bent to a 90° "Lightwand" bend at 8 cm[4].

Primary outcome: The force required to plastically deform the ETT/stylet, in flexion and extension, was measured with an electronic spring scale in Newtons (N). The force was measured at the Murphy eye of each ETT, with the portion of the ETT proximal to the bend fixed. A stylet was also assessed with no ETT present.

Secondary outcomes: Creep was measured every 10 minutes for 60 minutes, measured in degrees of extension of the 90° bend, as anticipated from the extension moment applied to the stylet due to the ETT's flexion deformation. Flexion deformation of the ETT/stylet would be considered negative.

Limitations: The ETT/stylet stiffness is a surrogate for potential harm outcome. The measurements were conducted by one unblinded operator, using a handheld electronic scale; one of each ETT type/size was tested. Utilizing a fixed measurement jig with multiple operators and ETT/stylet measurements could yield more accurate results.

RESULTS

The measured forces required to deform the ETT/stylets in flexion and extension are shown in Figure 1. Greater force was required to deform them in flexion than in extension, likely due the bending of the ETT in flexion, giving the ETT/stylet combination a tendency to extend, and resist the flexion force more than the extension force. Without stylets in place, larger diameter ETTs were slightly stiffer than smaller ETTs but similar between models.

The forces observed were comparable between the different ETT's and were not largely different from the forces measured for the isolated stylet. The Intube 8.0 was ~25% stiffer in flexion, but comparable in extension, the modality likely more clinically relevant during ETT insertion.

Only one ETT/stylet combination, the Venti-Seal, had measurable creep, approximately 5° over 60 minutes. This is likely not clinically relevant.

DISCUSSION

Despite the increased stiffness noted in compression (pinching), the replacement ETTs had comparable stiffness in bending moment and no clinically relevant creep of the ETT/stylet was observed over 60 minutes. As safe ETT insertion should not require transmission of significant force, the use of a stiffer stylet may be unnecessary, and could increase potential for harm, especially with videolaryngoscopy where the ETT is briefly advanced blindly between the direct oral view and indirect monitor view[5].

However, it remains advisable to check the curvature of pre-prepared ETT/stylets prior to insertion in case creep, or inadvertent "re-bending" due to handling, has occurred.

REFERENCES

1. https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency, last accessed 2023/1/2
2. Joo, HS et al, PVC tracheal tubes exert forces and pressures seven to ten times higher than silicone or armoured tracheal tubes — anin vitro study. Can J Anesth 49, 986–989 (2002). https://doi.org/10.1007/BF03016888
3. Siobal M et al, Tracheal-innominate artery fistula caused by the endotracheal tube tip: case report and investigation of a fatal complication of prolonged intubation. Respir Care. 2001 Oct;46(10):1012-8. PMID: 11572753.
4. Jones PM et al, Effect of stylet angulation and endotracheal tube camber on time to intubation with the GlideScope. Can J Anaesth. 2007 Jan;54(1):21-7. doi: 10.1007/BF03021895. PMID: 17197464.
5. Turkstra TP et al, The GlideScope-specific rigid stylet and standard malleable stylet are equally effective for GlideScope use. Can J Anaesth. 2007 Nov;54(11):891-6. doi: 10.1007/BF03026792. PMID: 17975233.

Figure 1: Forces Required to Deform ETT/Stylet