RESEARCH PAPER

Effect of cleaning status on accuracy and precision of oxygen flowmeters of various ages

Q9

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Abstract

Objective To evaluate oxygen flowmeters for accuracy and precision, assess the effects of cleaning and assess conformity to the American Society for Testing Materials (ASTM) standards.

Study design Experimental study.

Methods The flow of oxygen flowmeters from 31 anesthesia machines aged 1–45 years was measured before and after cleaning using a volumetric flow analyzer set at 0.5, 1.0, 2.0, 3.0, and 4.0 L minute^{-1}. A general linear mixed models approach was used to assess flow accuracy and precision.

Results Flowmeters 1 year of age delivered accurate mean oxygen flows at all settings regardless of cleaning status. Flowmeters ≥5 years of age underdelivered at flows of 3.0 and 4.0 L minute^{-1}. Flowmeters ≥12 years underdelivered at flows of 2.0, 3.0 and 4.0 L minute^{-1} prior to cleaning. There was no evidence of any beneficial effect of cleaning on accuracy of flowmeters 5–12 years of age ($p > 0.22$), but the accuracy of flowmeters ≥15 years of age was improved by cleaning ($p < 0.05$). Regardless of age, cleaning increased precision, decreasing flow variability by approximately 17%. Nine of 31 uncleaned flowmeters did not meet ASTM standards. After cleaning, a different set of nine flowmeters did not meet standards, including three that had met standards prior to cleaning.

Conclusions Older flowmeters were more likely to underdeliver oxygen, especially at higher flows. Regardless of age, cleaning decreased flow variability, improving precision. However, flowmeters still may fail to meet ASTM standards, regardless of cleaning status.

Clinical relevance Cleaning anesthesia machine oxygen flowmeters improved precision for all tested machines and partially corrected inaccuracies in flowmeters ≥15 years old. A notable proportion of flowmeters did not meet ASTM standards. Cleaning did not ensure that they subsequently conformed to ASTM standards. We recommend annual flow output validation to identify whether flowmeters are acceptable for continued clinical use. Q1

Keywords anesthesia, durable medical equipment, equipment maintenance, oxygen flowmeters.

Introduction

Anesthesia machine flowmeters are vital to procedures that require that specific oxygen flows be delivered to breathing circuits—for example, in low flow or closed circuit systems (Lowe & Ernst 1981) or when multiple gases such as nitrous oxide or medical air are administered (Dorsch & Dorsch 2008). Most often, these flowmeters are of a variable-orifice design characterized by a graduated vertical glass tube with an internal taper toward the bottom. Within the tube, a freely moving indicator ball or bobbin rises in the tube with increasing oxygen flow.

Frequently, it seems to be assumed that oxygen flowmeters are accurate. In fact, based on the author's review of hospital records, flowmeters are often in service for decades without maintenance or flow validation. Exceptions are when an obvious defect has been detected, for example, a crack in the flow tube or an indicator that does not move (Sadove et al. 1976; Dorsch & Dorsch 2008), or a dislodged float stop (Dorsch & Dorsch 2008). Less obvious defects such as leaks, accumulation of static charge, or internal debris are likely to go undetected (Waaben et al. 1978). Routine in-house maintenance may be discouraged by the manufacturer (Datex Ohmeda 2001).

Lack of validation is not attributable to the absence of a methodology to do so. Several approaches have been developed to assess anesthesia machine oxygen flowmeter calibration, including the bubble meter method and serial master flowmeters (Sadove et al. 1976; Waaben et al. 1978), and gasometer precision spirometry and dry gas meters (Stromme & Hammel 1968). A key piece of calibration equipment is the master flowmeter, a calibrated rotameter of similar design to the flowmeters being tested that serves as a standard against which all others are compared. The flowmeter under scrutiny is connected in series with the master flowmeter, and the output of the former causes the indicator to rise in the latter. Master flowmeters can be certified by the National Institute of Standards and Technology (NIST) National Voluntary Laboratory Accreditation Program (NIST 1998) or the United Kingdom Accreditation Service (UKAS 2009). The accuracy for a currently available model is certified to be ±2% (MPB Q2 2014). Calibration assessed using the bubble meter method (Levy 1964; Waaben et al. 1978, 1980) is reportedly accurate to within ±1.8% when compared with high-accuracy master flowmeters (Waaben et al. 1980). Gasometer methods are also still used with high accuracy [American Society for Testing Materials (ASTM) 2015], although more recently, piston calibrators have proven to be accurate and more convenient (MesaLabs 2013).

Standards for assessing oxygen flowmeter performance on anesthesia machines are available. The ASTM has stated that, for flowmeters, the limits of error for flow rate at 20 °C and 760 mmHg must be within 10% of the flow setting (ASTM 2005). The International Organization for Standardization (ISO) has an equivalent standard of ±10% of the indicated value for anesthetic gas delivery systems at ambient temperature and pressure (ASTM 2005; ISO 2011).

Nonetheless, the most recent study evaluating the accuracy of anesthesia oxygen flowmeters dates back more than 35 years (Waaben et al. 1980). Database searches in the contemporary literature yielded no recent studies on this subject, despite the fact that the earlier studies raised concerns. Waaban et al. (1978) documented deviations from ASTM standards at flow rates <1.0 L minute^{-1}, and Sadove et al. (1976) found that flow rates <2.0 L minute^{-1} deviated by 20−150% from the indicated range.

The goals of this study were to assess the accuracy and precision of oxygen flowmeters on anesthesia machines across a range of service ages. We hypothesized that flowmeters would be accurate within ±10% of the indicated flow, conforming to ASTM standards. Furthermore, we hypothesized flow accuracy would be improved with cleaning.

Materials and methods

Equipment

Thirty-one oxygen flowmeters on anesthesia machines in clinical use for small animal patients at the College of Veterinary Medicine, Kansas State University, KA, USA, were tested. Each machine was identified by a serial number, and its age was defined as the number of years in service. The machines were connected to the same constant pressure pipeline oxygen outlet for all testing. Line pressure was verified daily and remained constant.

Oxygen flows were measured using a piston-based gas flow analyzer (Defender 530; Mesa Laboratories, NJ, USA; Fig. 1). The calibration certificate indicated an accuracy of 0.06−0.24% (MesaLabs 2014). This was validated by the manufacturer in accordance with ISO 17025 (ISO 2010) by calibration at ambient conditions against a more highly accurate positive displacement primary piston prover set for volumetric assessment.

Experimental protocol

The experiment was conducted at room ambient conditions. The barometric pressure (P_B) was measured in the clinical pathology laboratory of the hospital. Before starting data collection for each flowmeter, the room temperature was recorded from an ASTM-certified thermometer (Mercury thermometer model 8N146; Brooklyn P-M Thermometer Company, NY, USA). The same individual (SF) performed all measurements and cleanings. Blinding to cleaning status was not possible because of the before-and-after nature of the question.

Flow settings of 0.5, 1.0, 2.0, 3.0 and 4.0 L minute^{-1} were tested in random order for each flowmeter. Randomization was accomplished with standard functions available through the data worksheet software (Excel 2013; Microsoft, WA, USA). For each flow setting, 1 minute was allowed for the indicator to stabilize, then a locally fabricated, handheld sight guide aligned the investigator's eye with the widest part of the ball or top surface of the

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