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Technical Performance of Continuous Pressure Insufflators Versus Traditional Insufflators in the Presence of Leaks During Laparoscopic Surgery

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Abstract

Background. New insufflators have been developed to manage leaks emanating from the working cavity during laparoscopic surgery. Little data have been published to show the performance of these insufflators. This study evaluates the performance of 2 modern continuous pressure insufflators in various leak conditions. *Methods*. Performance of a new continuous pressure insufflator, EVA15 (Palliare, Galway, Ireland), was compared with that of a continuous pressure insufflator, Airseal intelligent Flow System (iFS) (CONMED, Utica, NY), and a traditional intermittent pressure insufflator, Endoflator 40 (KARL STORZ, Tuttlingen, Germany). Six different leak scenarios were created in a swine model to create different dynamic leak profiles of between 5 and 15 L/min. Pressure deviation from setting was measured for each insufflator tested. The following were calculated: (a) mean absolute difference of measured insufflation pressure vs. the insufflator pressure setting for the 50 second measurement period (MAD) and (b) standard deviation of the absolute differences (SD). *Results*. The average mean absolute pressure difference between the EVA15 and Airseal is .27 mmHg. However, the average mean absolute pressure difference between the EVA15 and Endoflator 40 is 2.62 mmHg. *Conclusions*. Continuous pressure insufflators provide superior pressure delivery performance in leak situations when compared against a traditional intermittent pressure insufflator. No clinically significant performance difference was observed when comparing the EVA15 and Airseal iFS insufflators in the tested leak situations.

Keywords

laparoscopic insufflators, insufflator performance, leaks

Background

Recent years have seen the introduction of a new class of laparoscopic insufflators which provide continuous pressure insufflation in the face of large leaks such as those that may typically be introduced during robotic surgery, repeated suction in the cavity in complex procedures, or during smoke evacuation. An example of this class of insufflators is the Airseal (CONMED, Utica, NY) insufflator. These continuous pressure insufflators differ from their intermittent pressure insufflator counterparts, by virtue of the fact that there is no periodic cessation of flow delivery to measure pressure. This permits them to respond more quickly to leak situations by instantaneously supplementing insufflation flow to compensate for the leak. A further purported advantage of these continuous pressure insufflators is that they permit insufflation at lower pressures, which, it is proposed, offers an opportunity to reduce postoperative pain.[1] Whereas benchtop studies have been published,[2] there is little animal or human data published to date on the performance of continuous pressure insufflators in animal or human studies, nor comparative performance studies against the more common intermittent pressure insufflators which have been used over the past 20 years. The principal objective of this study was to evaluate the performance of a new continuous pressure insufflator, EVA15 (Palliare, Galway, Ireland) in a swine model, under simulated leak conditions, and to compare its performance both with the Airseal continuous pressure insufflator and a traditional

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intermittent pressure insufflator, in this instance the Endoflator 40 (KARL STORZ, Tuttlingen, Germany).

Methods

One male pig (*Sus scrofa domesticus*-weight: 35 kg) was involved in this experimental non-survival study. The protocol was approved by the local Ethical Committee for animal use and care (ICOMETH No. 38.2018.01.108) and by the French Ministry of Superior Education and Research (MESR) (APAFIS #15430-2018060814456804). Animal study informed consent is not applicable. The animal was managed according to the directives of the European Community Council (2010/63/EU), housed and acclimatized for 48 hours in an enriched environment, respecting circadian cycles of light–darkness, and with constant humidity and temperature conditions, fasted 24 hours before surgery, with ad libitum access to water, and finally sedated (zolazepam + tiletamine 10 mg/kg IM) 30 minutes before the procedure to decrease stress. Anesthesia induction was achieved by means of intravenous (18 G IV catheter in ear vein) propofol 3 mg/kg and maintained with rocuronium .8 mg/kg along with inhaled isoflurane 2%. After the procedure, the animal was sacrificed with an intravenous injection of a lethal dose of euthanized with a lethal dose of pentobarbital (40 mg/kg).

Under general anesthesia, 3 laparoscopic trocars were inserted in the peritoneal cavity of the pig in supine position. Abdominal pressure was measured by attaching a Model PS309 (Validyne, Northridge, CA) pressure transducer to 1 trocar, calibrated in the range of +/− 50 mmHg, and connected to a National Instruments USB-6003 data acquisition device and PC, which sampled pressure readings every 10 msec. Pressure data were imported into Microsoft Excel and plotted.

Standardized protocols do not exist for evaluating the leak performance of insufflators and therefore were developed as part of this study. After insertion of three 12 mm trocars in a 35 kg pig, 6 different leak scenarios, each encompassing a 50 second sample period, were created to test the responsiveness of the insufflators. They were as follows:

1. Opening and shutting of a trocar luer port every 10 seconds (opening at T = 10, 20, 30, and 40 seconds and shutting at T = 15, 25, 35, and 45 seconds),
2. opening and closing of a trocar luer port for a 20 second period (opening at T = 5 seconds and shutting at T = 25 seconds),
3. opening of a trocar luer port for 40 seconds (beginning at T = 10 seconds) but not closing the port,
4. introducing and removing a Veress needle from a trocar sealing valve every 10 seconds (introducing at T = 10, 20, 30, and 40 seconds and removing at T = 15, 25, 35, and 45 seconds),
5. introducing and removing a Veress needle from a trocar sealing valve for a 20 second period (introducing at T = 5 seconds and removing at T = 25 seconds), and
6. introducing a Veress needle through a trocar sealing valve for 40 seconds (introducing at T = 10 seconds) but not removing it.

Testing on the EVA15, Airseal, and Endoflator 40 insufflators was conducted at 15 mmHg pressure setting.

Statistical Analysis

The following were calculated for each test case for each insufflator:

1. Mean absolute difference of measured insufflation pressure vs. the insufflator pressure setting for the 50 second measurement period and
2. standard deviation of the absolute differences (SD).

Results

Three insufflators, the EVA15, Airseal, and Endoflator 40, were tested for leak performance at 15 mmHg insufflation pressure in accordance with the study protocol, and the results are presented in Table 1, with pressure traces shown in Figure 1. The average mean absolute pressure difference between the EVA15 and Airseal, from Table 1, for the 6 test cases, is seen to be .27 mmHg, 1.8% of target insufflation pressure, a difference statistically significant but not considered to be clinically significant, given the pressure delivery accuracy specification for the EVA15 insufflator is +/−1 mmHg. The average mean absolute pressure difference between the EVA15 and Endoflator 40, for the 6 test cases, is seen to be 2.62 mmHg (nearly ten times higher than the mean absolute pressure

Table 1. MAD and SD of Pressure Readings for Leak Test Conditions A–F Comparing EVA15 and Airseal.

	EVA15		Airseal			
Test Case	MAD	SD	MAD	SD	Difference	p
A	.99	.78	.71	.49	.28	<.001
B	1.18	.91	.65	.39	.53	<.001
C	.74	.59	.70	.41	.04	<.001
D	1.03	.84	.80	.51	.23	<.001
E	1.24	.93	.71	.43	.53	<.001
F	.84	.70	.82	.44	.02	.09

Abbreviations: MAD = measurement period.

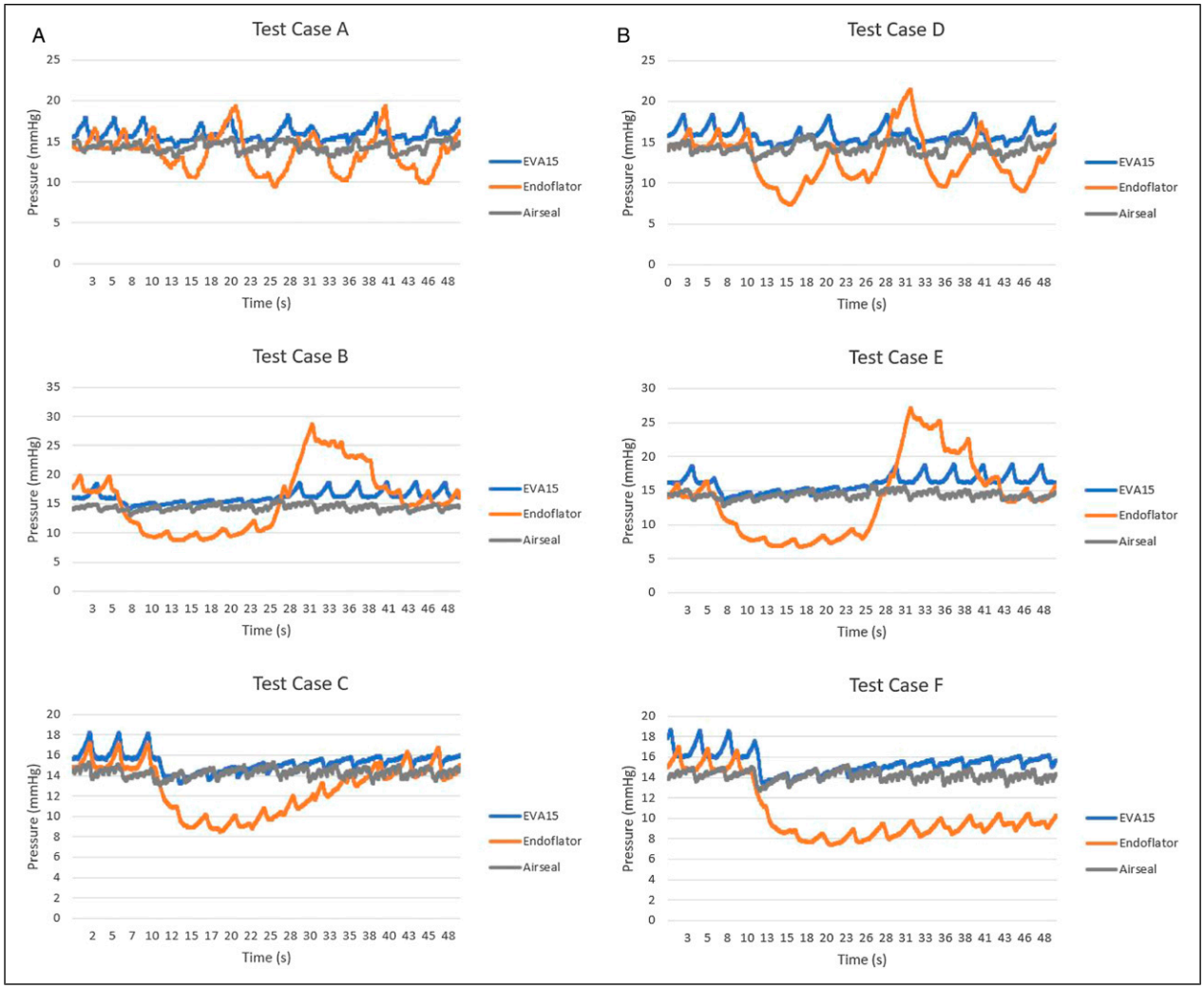

Figure 1. EVA 15, Pressure tracing of EVA 15, Airseal and endoflator 40 tested for leak performance at 15 mmHg insufflation.

difference between the EVA15 and Airseal insufflators), representing 17.5% of target insufflation pressure, a difference both statistically and clinically significant (Table 2).

Discussion

This is the first study to publish performance data of the EVA15 continuous pressure insufflator, which compares the performance of 2 different classes of continuous pressure insufflators, the EVA15 and Airseal intelligent Flow System (iFS), under simulated leak conditions. The EVA15 operates with a standard trocar, whereas the Airseal IFS employs a customized trocar with an open port designed to create an air barrier when tools are removed. The Stryker Pneumosure similarly offers a continuous pressure insufflation option with standard trocars. As tools and techniques of surgery advance, new needs emerge. Nowadays, there is increased utilization of robotic surgery, complex procedures, and there is a greater focus on the need to remove smoke from the surgical cavity, both to improve visibility within the working field and for environmental health reasons. These 2 developments both lead to an increased amount of leaks

Table 2. MAD and SD of Pressure Readings for Leak Test Conditions A–F Comparing EVA15 and Endoflator 40.

	EVA15		Endoflator 40			
Test Case	MAD	SD	MAD	SD	Difference	p < .001
A	.99	.78	2.13	1.57	1.14	<.001
B	1.18	.91	4.52	3.09	3.34	<.001
C	.74	.59	2.56	2.14	1.82	<.001
D	1.03	.84	2.99	2.08	1.96	<.001
E	1.24	.93	4.76	3.29	3.52	<.001
F	.84	.70	4.78	2.43	3.94	<.001

Abbreviations: MAD = measurement period.

emanating from the working cavity, leading to the need for a new class of continuous pressure insufflation technology. Such insufflators offer stable pneumoperitoneum at low insufflation pressures, and they will be increasingly adopted to minimize leaks and reduce potential operating room staff infections due to aerosolization of virus, particularly in a post COVID-19 era.[3] Bucur et al[4] have compared the performance of the Airseal iFS to a traditional insufflator where they assessed overall degree of pressure variability and time spent within different pressure bands. The present study differs in that it compares accuracy of the insufflators against insufflator setting in dynamic leak conditions where the effects of a variety of induced leaks on performance can be directly appreciated, as opposed to the study by Mowbray et al where the assessment was over the entire duration of each case,[3] which includes many data points where leaks may not have been present. To test the performance of these insufflators, transient leaks have been created to observe the insufflator response. Broadly speaking, at 15 mmHg insufflation pressure, opening a trocar creates a leak of approximately 5 L/min, laparoscopic smoke evacuation systems evacuate at a rate of 8–12 L/min, and introducing a Veress needle into a trocar one-way valve creates a leak 15 L/min. Such leaks are variable in magnitude, transient in nature, and require constant monitoring and correction of delivered flow so as to maintain the target insufflation pressure. Traditional insufflators, by their nature sample cavity pressure every few seconds and therefore in the face of sudden leaks are much slower to respond to the initiation of the leak and the cessation of the leak. This can lead to significant pressure undershoot and overshoot. This is evidenced by the large deviation of the pressure traces of the standard insufflator as compared with the 2 continuous pressure insufflators, which had broadly similar performance in these test cases.

In this study, we found that the average mean absolute pressure difference between the EVA15 and Endoflator 40, for the 6 test cases, was 2.62 mmHg, representing 17.5% of target insufflation pressure. It might be argued whether such a mean difference is truly clinically significant. It should be noted that the mean absolute pressure difference represents the mean *across the whole experiment* and, therefore, also includes the periods between each leak challenge. The true clinical importance is observed during the leak challenges, where for instance, one can see pressure swings of 15–19 mmHg or negative swings of 7–8 mmHg with the traditional insufflator in Cases D and E.

In these test cases, it is noticeable that there were few other background sources of leak since the effect of breathing on intra-abdominal pressure could be clearly evidenced by pressure swings of 3–4 mmHg in the EVA15 and Endoflator traces. Put another way, if there is no leak, the insufflator does not have an ability to reduce the cavity pressure when it is increased by virtue of compression of cavity gas during the inspiratory phase of breathing. The Airseal device, by virtue of its seal-less trocar provides means to vent gas from the peritoneal cavity to effectively reduce the pressure during this phase. In situations where there is a leak for example, due to the trocar defect, such swings in abdominal pressure due to respiration are not seen in practice.

Conclusions

We have demonstrated and compared the performance of 2 continuous pressure insufflators and seen improved performance in leak situations when compared against a traditional intermittent pressure insufflator.

Authors Contribution

BD and AS carried out the experiment. SP wrote the manuscript and verified the analytical methods. All authors discussed the results and contributed to the final manuscript.
Study concept and design: Silvana Perretta and Bernard Dallemagne
Acquisition of data: Silvana Perretta and Andrea Spota
Analysis and interpretation: Silvana Perretta and Andrea Spota
Study supervision: Bernard Dallemagne and Silvana Perretta

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Drs Perretta and Dallemagne serve on the Medical Advisory Board of Palliare Ltd and have no conflicts of interest or financial ties to disclose. Dr Spota has no conflicts of interest to disclose.

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