User Evaluation of a Novel Smart Insufflator for Laparoscopic Surgery-The EVA-15

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ABSTRACT

Introduction: There is resurging interest in the importance of effective, nuanced insufflation and personalised pneumoperitoneal pressure-management during laparoscopy. Here, we present user-evaluation data from a regulated, prospective, multispecialty study of a new insufflator (EVA-15, Palliare, Galway, Ireland) which provides high-frequency pressure-sensing, built-in smoke evacuation with pedal activation and highly responsive, high-flow gas provision.

Methods: With institutional ethics and regulatory body approval, a non-randomised, prospective clinical investigation was performed on 30 subjects undergoing laparoscopic surgery using an EVA-15 device. Cases were selected from a variety of specialties on a near-consecutive basis without specific exclusion criteria. Users (both surgeons and operating room nurses) completed a survey at case completion to capture ordinal categorical data on a 5-point Likert agreement scale (1 – Strongly disagree to 5 – Strongly agree) concerning (i) Settings and Setup Evaluations, (ii) Alarms and Displays Evaluations, (iii) Short Instruction Guide, and (iv) Insufflator Performance along with any additional feedback.

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Results: Operations on 30 patients (mean age 54 y, 15 males) were studied with a questionnaire completed by operating room teams after individual consent. The procedures included general (n=13), upper (n=3) and lower (n=6) gastrointestinal surgery, bariatric (n=3), hepatobiliary (n=2) urology (n=2, both robotic prostatectomy) and gynaecology (n=1) operations. In all cases, the laparoscopic component was completed capably with the use of the EVA-15 device. The insufflator evaluation score across all categories was a median of 4, demonstrating satisfactory use and performance in all regards.

Conclusion: The EVA-15 is a smart insufflator system that is capable of satisfactory performance across a spectrum of cases among different specialties.

INTRODUCTION

After a period of relative quiescence, the technology and practice of laparoscopic pneumoperitoneum initiation and management has recently become a subject of great interest. This is driven by a combination of factors including the increasing role of robotic platforms for abdominopelvic surgery (where total gas usage tends to be higher),[1] the potential benefits of adopting a low-pressure approach to surgery,[2] increased awareness of the environmental impact of surgical practice,[3] and, perhaps most precipitously, the COVID-19 pandemic (wherein there has been concern that the health care team could become infected from aerosols generated during minimally invasive operations).[4] For these reasons, the surgical community has refocused its attention on methods and means of gas intra-abdominal pressure and volume management including smoke management and gas leaks.[5] Alongside improved practice guidelines and adjunct smoke-management technologies, the benefits of high-frequency gas pressure-monitoring and responsiveness are becoming increasingly realised.

Here we provide data obtained in a user-assessment clinical study regarding a new FDA-approved smart insufflator, the EVA-15 (Palliare, Galway, Ireland), as part of a regulated trial prior to CE-marking. The system provides separate tubing for gas insufflation, continuous pressure-monitoring and smoke evacuation that attach to separate standard trocars via luer connections (Fig. 1). Smoke evacuation can be activated by the surgical team using a foot pedal placed alongside the diathermy pedal, and the compensatory increase in flow rate is capable of managing suction in the order of 40 L/min. The evacuatory tubing contains a ULPA filter and a second filter can be attached to the back of the device to ensure maximum purification of the gas entering the operating room. The device has a relatively small footprint and weight and a simplified display that shows only the most relevant data to the operating room team.

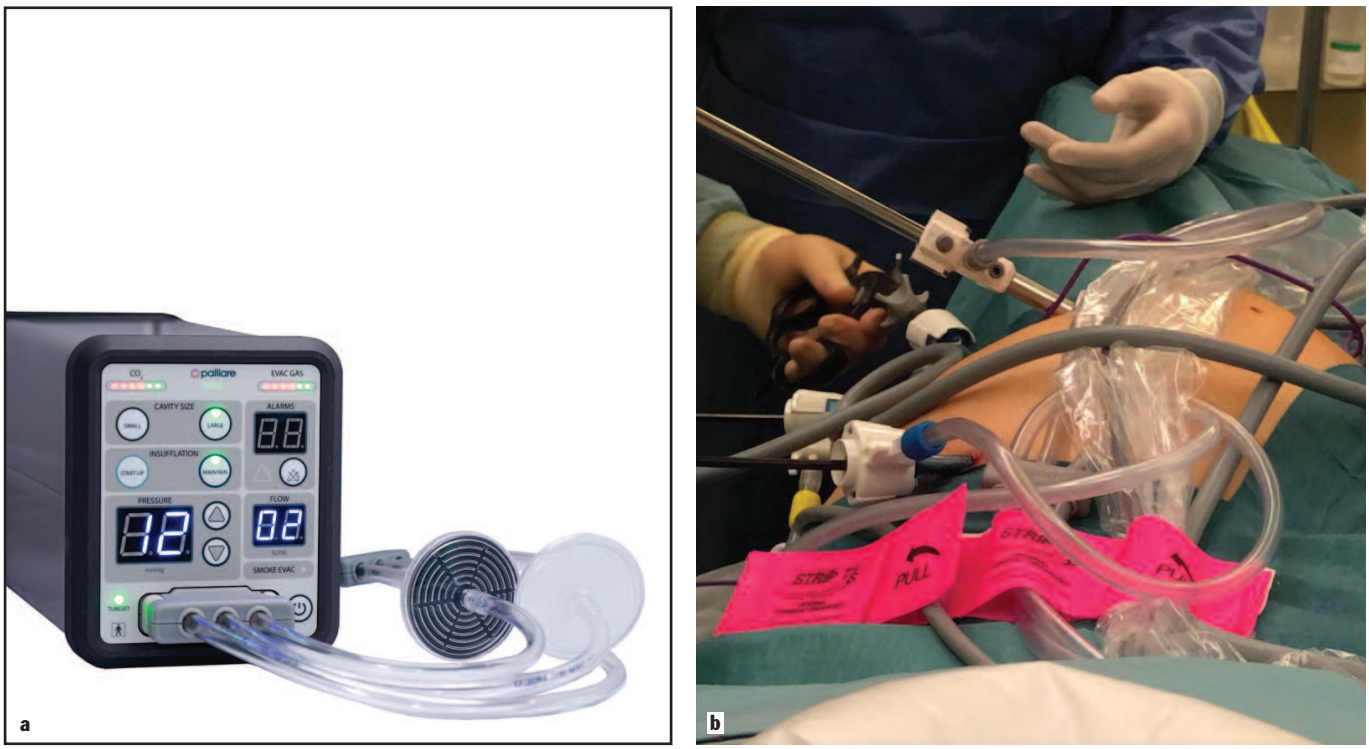

Figure 1. Photographs showing (a) the new insufflation system display and system connections and (b) the tubing in situ during a laparoscopic operation with separate connection tubes to provide highly responsive gas insufflation, pressure monitoring and smoke evacuation.

Table I
Patient demographics with procedures and specialities in the 30-case study

	Mean	Std. Deviation	Median	Range
Age (year)	54	± 15.17	55	24 - 90
Weight (kg)	83.4	± 25. 64	80	59 - 180
Gender (% Male)	50	-	-	-
Speciality	**Operation**		**Comment**	
General (n=13)	Cholecystectomy x7 Appendicectomy x2 Diagnostic laparoscopy for mesenteric cyst Hernia repair Laparoscopic adhesiolysis Drainage of splenic cyst		3 converted to open (2 cholecystectomy, one adhesiolysis)	
Upper GI (n=3)	Repair of diaphragmatic hernia Hiatal hernia repair with fundoplasty Small bowel resection		Abdominal approach	
Bariatric (n=3)	Sleeve Gastrectomy x2 Roux en Y Gastric Bypass			
Hepatobiliary (n=2)	Liver lesion ablation Liver resection (inc hiatus hernia repair)			
Lower GI (n=6)	Hemicolectomy x3 Anterior Resection Abdominoperineal resection Revision of stoma			
Gynaecology (n=1)	Bilateral Salphingectomy			
Urology (n=2)	Prostatectomy x2		Both robotic-assisted procedures	

METHODS

With full institutional ethics and regulatory body approval (Institutional Review Board Reference 1/378/2184), a non-randomised, prospective clinical investigation was performed on 30 subjects who were insufflated during laparoscopic surgery using the EVA-15 insufflator. The trial was performed during the current pandemic and this necessitated a change of institution during its course due to a surge that affected where elective surgery was performed. Cases were selected on each preceding day from among patients who were planned to undergo scheduled abdominopelvic surgery from a variety of surgical specialties. No specific exclusion criteria were applied and all involved patients and operating room (OR) teams gave their explicit consent prior to involvement.

All patients underwent their operation in the standard way except for use of the EVA-15 insufflator in place of existing systems. Before surgery, the OR team was given a short briefing on the system's use and an engineer from the manufacturer was present throughout the procedure. At the end of each procedure, users were given a Case Report form to complete in which a 5-point Likert agreement scale was used to provide responses to statements concerning the use and function of the insufflator in four main categories: (i) *Settings and Setup Evaluations,* (ii) *Alarms and Displays Evaluations, (iii) Short Instruction Guide,* and *(iv) Insufflator Performance.* The obtained ordinal categorical data were based on the following scale; 1 – Strongly disagree, 2 – Disagree, 3 – Neither disagree nor agree, 4 – Agree, 5 – Strongly agree or NA – Not applicable. A space was included in the form for any additional unprompted comments from the user during the questionnaire-based debrief. Forms were completed and collected at the end of each case and aggregated at the conclusion of the cohort experience.

RESULTS

The EVA-15 device performed capably in all operations and enabled the initiation, maintenance and desufflation of pneumoperitoneum in every case. Demographic information related to the patients and operations is shown in Table I. Twenty-eight percent of the procedures were commenced with a Veress needle and the remaining 72% were started by open induction (Hassan technique). The majority of cases (83%) were performed at a pressure of 12-15mmHg and the others (17%) included a component of low pressure during the procedure. Three procedures (10%) were converted to open operations but never due to issues related to insufflation: in two cases the inflammatory pathology associated with severe prior cholelithiasis meant a laparoscopic approach was not possible and in the third a planned conversion to open was performed after release of an adhesional band obstruction to suture-

Table II
Settings and Setup Evaluation

Setting and Setup Evaluation	No. of respondents	Mean (SD)	Median	Mode
Simple to change insufflation pressure setting	26	4.50 (0.58)	5	5
Clear which tube connects to which trocar	30	3.90 (1.06)	4	4
Easy to connect tubeset to insufflator	29	4.48 (0.74)	5	5
Easy to connect tubeset to trocars	28	4.61 (0.50)	5	5
Clear how to switch on the insufflator	28	4.21 (0.74)	4	4
Clear which button to press for initial insufflation	26	4.15 (0.67)	4	4
Clear which button to press for maintaining insufflation after initial insufflation	26	4.15 (0.67)	4	4
Tell when smoke evacuation is active	28	3.79 (1.32)	4	5
Tell if CO2 bottle pressure is adequate	24	3.58 (1.25)	4	4
Tell if evacuation gas pressure is adequate	27	3.74 (1.06)	4	4

User scores (5-point Likert scale) regarding the ability to change system settings, attach a tubeset and understand the information on the display upon setting up. 1 – Strongly disagree, 2 – Disagree, 3 – Neither disagree nor agree, 4 – Agree, 5 – Strongly agree, NA – Not applicable. SD= Standard Deviation

reinforce an area of perforation in the strangulated segment. Two operations were performed by a robotic-assisted approach (both prostatectomies).

Of the user respondents, 63% were surgeons and 37% were nurses. Tables II-V show the user scores related to insufflator settings and set-up (Table II), alarms and display evaluations (Table III), clarity of the supplied short instruction guide (Table IV) and insufflator performance (Table V). In addition to completion of the Likert scales, 27% of users also provided narrative feedback which generally supported the data, with additional attention being drawn to the small size of the insufflator, the attractiveness of foot pedal activation for smoke evacuation (only one user thought this latter point may need some experience for optimal use) and the ability to use the insufflator to desufflate the abdomen. One user suggested that the inclusion of a volume meter might be helpful.

DISCUSSION

This prospective real-world experience of a novel insufflator system in near-consecutive cases shows its satisfactory technical performance and incorporation into the surgical workflow across a variety of users, specialities and theatre teams. While the EVA-15 was compatible with safe surgery, further experience will be needed to fully develop the potential advantages offered by this new

Table III
Alarms and Display Evaluation

Alarms and Display Evaluation	No. of respondents	Mean (SD)	Median	Mode
Understand alarms messages (with aid of short instruction sheet)	19	3.58 (1.17)	3	3
Understand the pressure being delivered by the insufflator	29	4.28 (0.80)	4	5
Understand the flow being delivered by the insufflator	29	4.34 (0.67)	4	5

User scores (5-point Likert scale) regarding the interpretation of alarms and displays on the insufflator system. 1 – Strongly disagree, 2 – Disagree, 3 – Neither disagree nor agree, 4 – Agree, 5 – Strongly agree or NA – Not applicable. SD = Standard Deviation.

Table IV
Short Instruction Guide

Short Instruction Guide Evaluation	No. of respondents	Mean (SD)	Median	Mode
Easy to understand	5	4.60 (0.55)	5	5
The length is appropriate	5	4.60 (0.55)	5	5
Able to set up the product using the instructions provided	5	4.20 (0.45)	4	4
The WARNING and CAUTION statements were clear and understandable	5	4.20 (0.45)	4	4
The sequence of information was useful and logical	6	4.50 (0.55)	4.5	4
The pictures shown were clear and understandable	6	4.50 (0.55)	4.5	4
There is no significant information missing	5	4.20 (0.45)	4	4
The terminology and measurement units used are appropriate for this application	5	4.00 (0.71)	4	4
Helpful in understanding and using the product	5	4.40 (0.55)	4	4

User scores (5-point Likert scale) regarding the interpretation of alarms and displays on the insufflator system. 1 – Strongly disagree, 2 – Disagree, 3 – Neither disagree nor agree, 4 – Agree, 5 – Strongly agree or NA – Not applicable. SD = Standard Deviation.User scores (5-point Likert scale) regarding the interpretation of the short instruction guide. 1 – Strongly disagree, 2 – Disagree, 3 – Neither disagree nor agree, 4 – Agree, 5 – Strongly agree or NA – Not applicable. SD= Standard Deviation

method of pneumoperitoneum management. This was not intended to be a trial of low-pressure pneumoperitoneum or of the benefits of the use of smoke evacuation, although such studies are clearly the next steps.

Overall, users found the system to be straightforward to understand and deploy, both during initial insufflation and while adjusting during use. A minority of users identified some areas for improvement regarding easier identification of connection tubes (addressable by labelling alongside colour coding) and further highlighting of smoke evac signalling (due to the quietness of the system), CO_2 pressure adequacy and gas pressure. These latter points are all related to insufflator engagement during the case rather than at start up, when the establishment of pneumoperitoneum is the only focus of operator attention while the other considerations arise later in the case when there are additional tasks to concentrate on (i.e., performance of the operation including addressing any unexpected findings). Furthermore, while flow and pressure are all clearly shown on the insufflator display (see Table II), gas insufflators are often positioned out of eyesight and the visibility of these readings could be improved by adding a picture-in-picture display on the operating screen. Overall, the users considered that the alarms were easy to interpret, although it is worth noting that operation of the insufflator outside of the sterile field is often best performed by the circulating nurse rather than by the scrubbed operative team. Furthermore, in the early stages of the learning curve, reference to the short user instruction sheet was needed, as some functionality was not immediately obvious from directly viewing the insufflator display.

The EVA-15 has the potential to inject new impetus into the field of personalised pneumoperitoneal management for both the patient and OR staff. The presence of three separate tube connectors means that pneumoperitoneal gas can be exchanged without cross-contamination of the tubing and also that any liquid (blood or fluid) entering the tubing is not recycled into the insufflated gas or indeed into the system itself (once appropriately positioned above patient level). Since it can be attached to standard trocars, the EVA-15 is compatible with current surgical practice and also minimises the risks of air entrainment and gas escape associated with valve-less systems.[6-8] Use of the foot pedal to activate the smoke evacuation mode limits the waste of carbon dioxide by excessive exchange when not needed for operative progress. The high level of active insufflation responsiveness means that low-pressure laparoscopy is facilitated, and also that any inadvertent gas leaks are easily identified early on the display and so can be corrected. The small footprint of the device means it is easily positioned on existing in-theatre infrastructure, although it now can also be mounted on its own trolley. To improve reference to the device display (which was highly ranked by surgeons for providing important information that needed to be easily referenced during an operation), the EVA-15 now also is capable of projecting a picture-in-picture display, meaning that the information is observable by the entire operating team at all times during the surgery.[9]

In conclusion, the EVA-15 (Palliare, Galway, Ireland) proved to be a capable insufflator across a spectrum of users and procedures, which is encouraging for its advancement as a useful addition to clinical practice in laparoscopic surgery. Alongside its intuitive benefits, further

Table V
Insufflator Performance

Insufflator Performance	No. of respondents	Mean (SD)	Median	Mode
Initial insufflation time was too slow	30	2.23 (1.14)	2	2
Initial insufflation time was appropriate	30	3.93 (1.01)	4	4
The quality of insufflation allowed surgery to be completed effectively during higher insufflation pressures (12-15mmHg)	29	4.07 (1.10)	4	5
The quality of insufflation allowed surgery to be completed effectively during lower insufflation pressures (7-11mmHg)	14	3.64 (1.08)	4	4
Adequate insufflation was achieved during smoke evacuation during higher insufflation pressures(12-15mmHg)	29	4.03 (1.21)	4	5
Adequate insufflation was achieved during suctioning during higher insufflation pressures (12-15mmHg)	29	3.97 (1.21)	4	5
Adequate insufflation was achieved during smoke evacuation during lower insufflation pressures (7-11 mmHg)	16	3.81 (1.33)	4	5
Adequate insufflation was achieved during suctioning during higher insufflation pressures (7-11 mmHg)	15	3.67 (1.35)	4	5
Smoke evacuation was easy to activate	28	4.36 (1.10)	5	5
Smoke evacuation cleared the working cavity adequately to maintain vision during higher insufflation pressures (12-15mmHg)	28	4.18 (1.06)	4	4
Smoke evacuation cleared the working cavity adequately to maintain vision during low insufflation pressures (7-11mmHg)	14	3.86 (1.41)	4	5

User scores (5-point Likert scale) regarding insufflator performance. 1 – Strongly disagree, 2 – Disagree, 3 – Neither disagree nor agree, 4 – Agree, 5 – Strongly agree or NA – Not applicable. (Statement 1 is a negatively worded statement with a disagreement response being positive). SD = Standard Deviation.

work is needed to determine the exact degree of clinical benefits associated with its clever technology and engineering in addition to post-marketing surveillance of performance in widespread usage. STI

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AUTHORS' DISCLOSURES

RC has received speaker fees from Stryker (Amsterdam, The Netherlands), Olympus (Southend, UK), Diagnostic Green (Westmeath, Ireland) and Ethicon J&J (Somerville, NJ, USA), consulting fees from DistalMotion (Epalinges, Switzerland) and TouchSurgery (London, UK) and research funding from Intuitive (Sunnyvale, CA, USA). In addition, he holds research funding from the Irish government (DTIF, Enterprise Ireland) with IBM Research (Dublin, Ireland) and Deciphex (Dublin, Ireland) and from EU Horizon 2020 with Palliare (Galway Ireland). He is also a member of the Medical Advisory Board for Palliare (Galway, Ireland). The other authors declare that there are no conflicts of interest.

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