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A Dual-Valve System to Minimize Loss of Pneumoperitoneum in Laparoscopic Surgery

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ABSTRACT

Background and Objectives: Loss of visualization of the surgical field due to pneumoperitoneum deflation when CO_2 insufflator cylinders become empty can occur at key moments during laparoscopic surgery. The purpose of this study was to examine the incidence of intraoperative cylinder exhaustion in the United Kingdom, determine its impact on patient safety, and design and test a novel device to minimize the phenomenon.

Methods: We performed a national cross-sectional survey of U.K. surgeons, inviting all members of the Association of Surgeons of Great Britain and Ireland (ASGBI) and the Association of Upper GI Surgeons (AUGIS) to participate. We designed and tested a novel dual-valve system to allow rapid intraoperative exchange of CO_2 cylinders.

Results: Eighty-five percent of the U.K. surgeons surveyed reported loss of surgical visualization at critical times during laparoscopic surgery, caused by the decrease in pneumoperitoneum during CO_2 cylinder exchange. Eighty-four percent said that the process contributed to the surgeon's stress, and 63% said that a device that maintains uninterrupted pneumoperitoneum would reduce the risk of intraoperative complications. In our locale, a timed cylinder exchange was, on average, 30 times quicker with the novel dual valve than by conventional cylinder exchange (mean conventional exchange time, 61.3 ± 7.3 s vs. novel device, 2.0 ± 0.2 s; $P \leq .0001$) and could be performed just as rapidly by staff unfamiliar with the device (2.2 ± 0.3 s vs. 1.9 ± 0.4 s $P = .1945$). We suggest that this simple, low-cost system could be developed for use in a clinical setting to enhance patient safety.

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INTRODUCTION

Laparoscopic techniques have been rapidly accepted across the surgical specialties, bringing significant benefits to patients.[1–3] As skills and technologies have improved, the scope and complexity of laparoscopic operations have advanced.[4,5] Maintaining uninterrupted pneumoperitoneum is important for adequate visualization and safe operative progression.[6,7] However, loss of pneumoperitoneum may occur for various reasons, including exhaustion of the CO_2 supply in the insufflator cylinder at crucial times during the laparoscopic procedure. Few data have been published on how this common problem and requirement for intraoperative CO_2 cylinder exchange might affect patient safety and the surgeon's stress. In our experience, the time taken to change cylinders and reestablish pneumoperitoneum varies from less than a minute to a few minutes, depending on the expertise of the operating room staff and the proximity of a replacement cylinder. The loss of pneumoperitoneum can be particularly rapid if it occurs during times when suction is being used—for example, when bleeding occurs. Most surgeons stop operating until pneumoperitoneum is reestablished and visibility of the surgical field is regained. This interruption can lead to disturbance of the surgeons' concentration and loss of surgical rhythm and can delay the effective control of bleeding, which in turn has the potential to lead to serious complications. The surgeon's stress can be transferred to staff responsible for the cylinder exchange, creating a tense atmosphere for the rest of the operation. This survey of laparoscopic surgeons in the United Kingdom was designed to assess the incidence and impact of loss of pneumoperitoneum because of CO_2 cylinder exchange during laparoscopic procedures. We also evaluated a simple prototype dual-valve system in a nonclinical setting that can potentially maintain uninterrupted pneumoperitoneum while the empty gas cylinder is exchanged.

MATERIALS AND METHODS

The Survey

An online questionnaire (SurveyMonkey, www.surveymonkey.com/s/XWG5X77) was designed to assess the incidence and impact of losing pneumoperitoneum as a result of the exhaustion of the CO_2 in the cylinders during laparoscopic surgery. All members of the Association of Surgeons of Great Britain and Ireland (ASGBI) and Association of Upper GI Surgeons (AUGIS) were invited by e-mail to participate. Inquiries were made on the laparoscopic workload of the surgeons, whether they experienced loss of pneumoperitoneum at critical points of the operation due to the CO_2 cylinder's becoming empty, and the length of time needed for their surgical staff to change the cylinder. A Likert scale was used to obtain views on whether losing pneumoperitoneum contributed to the length of operation, the surgeon's stress levels, and risk of complications. Respondents were asked if they would be interested in a novel device to reduce cylinder exchange times and also were invited to provide comments and feedback. All responses were treated anonymously, and no financial compensation was given.

Prototype Device Trial

A prototype device was developed by one of the authors (ML) to connect 2 adjacent CO_2 cylinders to allow instant transition from an empty cylinder to an adjacent full one without the need to seek out a replacement cylinder for the exchange (**Figure 1**). The device is composed of a connector between the 2 cylinders with a central control switch to allow gas flow from one cylinder or the other to the insufflator. The device was assessed before testing by the staff of the local Medical Physics Department, which added a further unidirectional nonreturn valve between each cylinder and the control switch, to eliminate reverse CO_2 leakage. The device can be fitted to existing laparoscopy stack systems used in our department and widely in the United Kingdom.

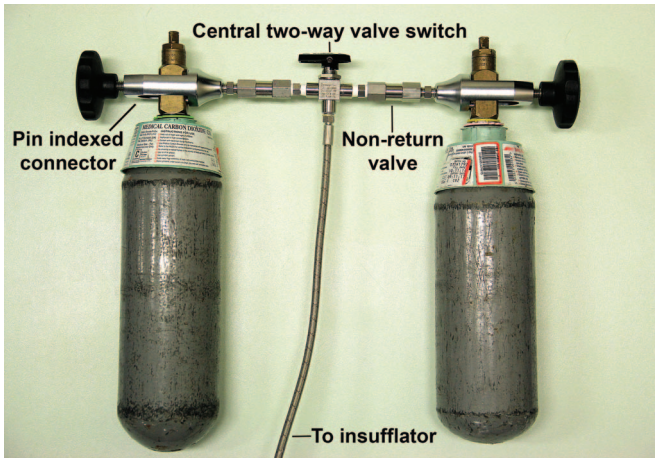

Figure 1. A novel dual-valve system to allow rapid intraoperative replacement of CO_2 cylinders, to reduce loss of pneumoperitoneum during laparoscopic surgery.

Thirty-four staff members from our district general hospital were invited to perform a timed gas cylinder exchange in a nonclinical setting. The participants consisted of trained surgical staff members, who perform regular cylinder exchange, as well as staff unfamiliar with cylinder exchange, including anesthesiology staff, surgical trainees, consultants, and administrative staff unfamiliar with the operating room environment. All staff were given a demonstration of the steps required to change the cylinder in the conventional way and the proposed method involving operation of a control switch between cylinders on the novel device. A trial run was permitted before the timed procedure. An unopened CO_2 cylinder was kept immediately at hand for the conventional exchange method. All data are expressed as the mean ± SEM. Statistical analyses were performed with Prism software (GraphPad, San Diego, California).

RESULTS

The Survey

Two hundred thirty-seven U.K. surgeons responded to the online survey request. Three percent (8/237) of the responding surgeons were not laparoscopy surgeons and did not take further part in the survey. The laparoscopic workload ranged from 22% (53/237) of respondents, who performed 25% of their caseload laparoscopically, to 25% (59/237), who performed >75% of their procedures laparoscopically (**Figure 2A**). Eighty-five percent (196/229) of the surgeons had lost pneumoperitoneum at crucial times during surgery due to the exhaustion of the contents of the gas cylinder (**Figure 2B**). Sixty-three percent (141/223) estimated that surgical teams took between 1 and 5 min to change the gas cylinder. Thirty percent (67/223) estimated that their teams took between 30 and 60 s, and 3% (6/223), less than 30 s (**Figure 2C**).

Eighty-seven percent (200/229) of the surgeons surveyed agreed or strongly agreed that it is important to maintain uninterrupted pneumoperitoneum; 62% (143/229) agreed

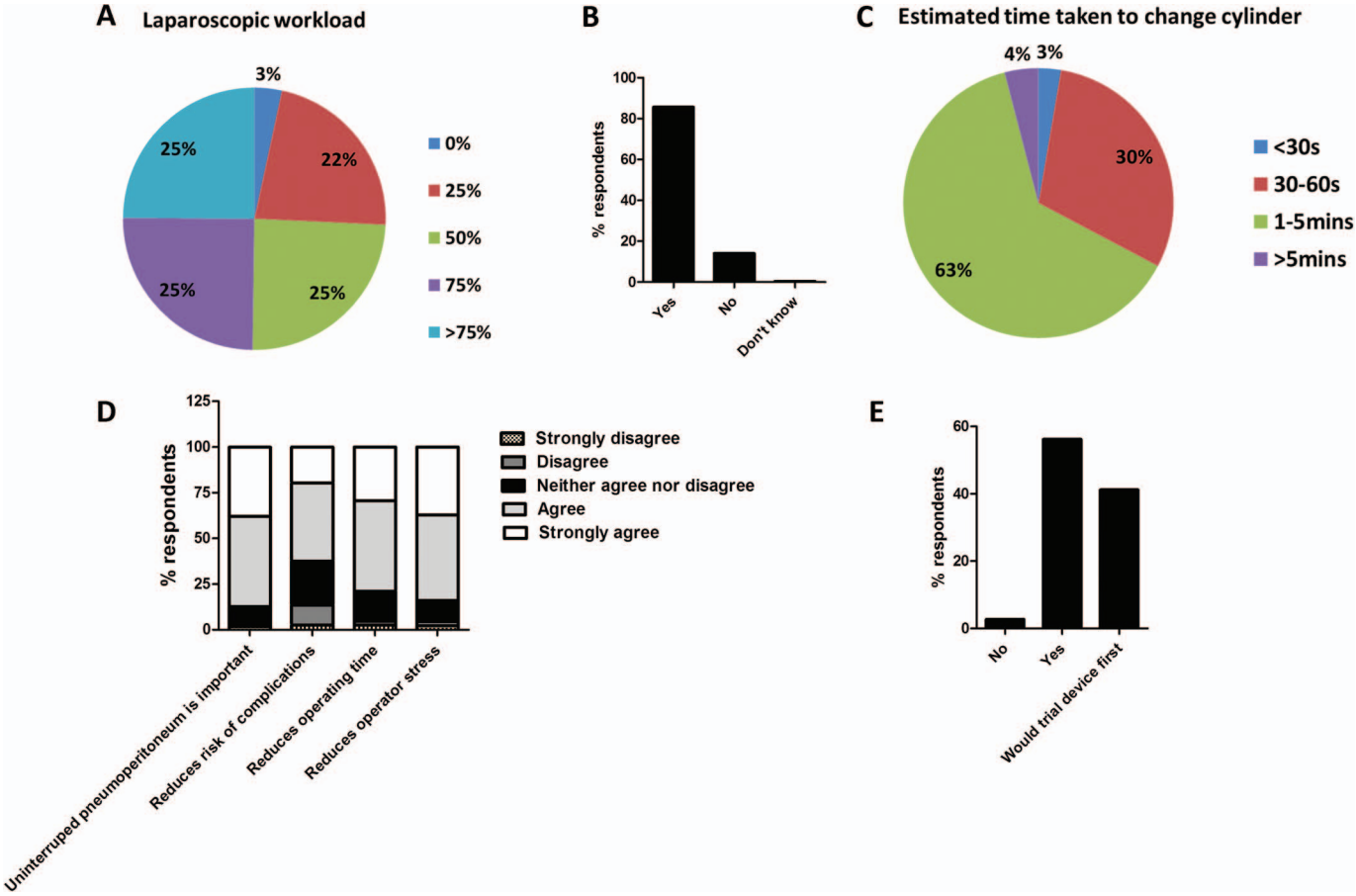

Figure 2. A, Laparoscopic surgical workload of survey respondents (N = 237). B, Proportion of respondents who have experienced loss of pneumoperitoneum. C, Estimated time to replace CO_2 cylinder. D, Likert scale on respondent's views. E, Proportion of respondents who welcome the novel device.

or strongly agreed that maintaining uninterrupted pneumoperitoneum would reduce the risk of complications; and 79% (180/228) said that it would reduce operating time. Eighty-four percent (190/226) of respondents felt that uninterrupted pneumoperitoneum would reduce operator stress and irritation during laparoscopic surgery (**Figure 2D**). Fifty-six percent (127/226) of the respondents would use a device that reduces gas cylinder exchange times to less than 30 s, and 41% (93/226) would use the device after trialing it first (**Figure 2E**).

Device Trial

Thirty-four hospital staff participated in the timed comparison between the 2 systems. The mean time taken to operate the valve on the novel system was 30.4 times less than that needed to change the cylinder in the conventional way (2.0 ± 0.2 s vs. 61.3 ± 7.3 s; **Figure 3A**).

Fourteen participants were familiar with changing the CO_2 cylinder in the conventional way and did so as a regular part of their job. Twenty participants were not familiar with cylinder exchange. This group included 5 participants who did not work in the operating room environment and who had never seen the cylinder or laparoscopy stack system. No significant difference in times was observed between these 2 groups (conventional cylinder exchange: experienced, 52.9 ± 12.3 s vs. no experience, 67.1 ± 9.0 s; prototype device: experienced, 2.2 ± 0.3 s vs. no experience, 1.9 ± 0.4 s; **Figure 3B**).

DISCUSSION

The importance of incorporating incremental changes into routine operating room practice to improve patient safety and outcomes is increasingly evident.[8] Although 1 study

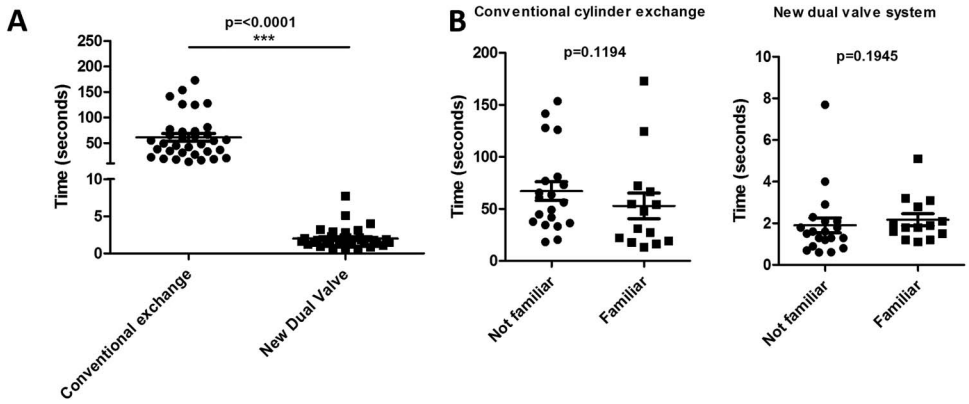

Figure 3. A, A novel connecting device significantly reduced the time taken to exchange cylinders during laparoscopic surgery. B, There was no significant difference in the time taken to change cylinders between staff familiar or unfamiliar with performing cylinder exchange.

examined the impact of losing visualization of the surgical field due to laparoscopic camera lens fogging,[9] we found no data on the effect of losing pneumoperitoneum as a result of intraoperative CO_2 cylinder exchange.

This survey of laparoscopic surgeons in the United Kingdom has shown that most of them have experienced this problem at crucial moments during laparoscopic procedures and that a large majority (87%) thought the maintenance of uninterrupted pneumoperitoneum to be important. Most surgeons believed that this improvement would reduce operating times and complications and, in particular, would avoid unnecessary stress among the surgical staff. We are of the opinion that as laparoscopic procedures become increasingly complex, maintaining pneumoperitoneum to avoid interruption of the surgeon's concentration becomes increasingly important for safe surgery.

Few operating rooms in the United Kingdom supply piped CO_2 for laparoscopy, and most have the standard laparoscopy stack systems that are equipped with space for a spare CO_2 cylinder. To replace an empty cylinder, the empty one must be unscrewed from the connector to the insufflator and its replacement aligned with a set of connecting prongs (pin indexes) before being screwed into place. In the United Kingdom, each type of gas cylinder has a unique pattern of pin indexes to prevent the wrong gas from being connected. We observed that the alignment of the pin indexes was by far the principal limiting factor in prolonging the time taken to connect a replacement cylinder to the insufflator. Furthermore, if the pin indexes are not aligned perfectly, the result is an audible environmental gas leak necessitating repositioning of the cylinder and causing further delay in reestablishing pneumoperitoneum.

The device presented herein allows simultaneous attachment of 2 CO_2 cylinders to the insufflator. The central switch is turned 180° to turn off flow from the first cylinder and turn on flow from the second. The mean time taken to operate this switch in our trial was 2.0 s. The time did not vary, even if the operator was completely unfamiliar with the equipment. This device should enable any person present in the operating room to provide an uninterrupted supply of CO_2, regardless of experience. The empty cylinder can then be replaced in an unhurried manner. Although not practical for simulation in this study, further time is added to conventional cylinder exchange by the need to remove the plastic seal from the replacement gas cylinder. The proposed design eliminates this further delay, as both cylinders are attached to the insufflator before the surgery begins.

During the course of this study, 2 participants, both of whom are surgical staff who change cylinders regularly, sustained skin abrasions while changing the cylinder using the conventional system. Although an element of pressure is naturally introduced by timing the subjects against the clock, it can equally be argued that this, to some extent, replicates the scenario that occurs when cylinders become empty during the procedure, potentially at crucial moments of the operation, when staff are under pressure to reestablish pneumoperitoneum as quickly as possible.

A potential pitfall is to neglect changing the empty cylinder once the control switch has been turned. Once the plastic seal has been broken and the cylinder attached,

there is no way of knowing whether the cylinder is empty or full without turning the switch to connect to the patient circuit. If empty, the laparoscopic stack will sound an alarm, and the cylinder will have to be changed in the conventional way. This delay can be eliminated by providing responsibility awareness to surgical personnel operating the switch and including cylinder checks in the preoperative checklists. The prototype device cost approximately £450 (~US $650) to develop, but we anticipate that the amount will be lower if the system is produced commercially or is incorporated into existing stacker systems.

CONCLUSION

This study has demonstrated that most of the laparoscopic surgeons surveyed in the United Kingdom have experienced loss of the surgical field of view at critical moments during laparoscopic surgery as a result of the exhaustion of CO_2 cylinders during surgery. Most surgeons would be interested in a solution to this problem. We have trialed a simple, safe, and cost-efficient device that can be easily fitted to existing laparoscopy stack systems, with positive results in a nonclinical setting. When developed and approved for use in a clinical setting, we are certain that this device will reduce operator stress and have a beneficial impact on patient safety.

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