Surgical Endoscopy
https://doi.org/10.1007/s00464-021-08953-6

NEW TECHNOLOGY

New 5-mm laparoscopic pneumodissector device to improve laparoscopic dissection: an experimental study of its safety in a swine model

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Received: 11 July 2021 / Accepted: 6 December 2021

Abstract

Background To improve the laparoscopic surgical dissection, the aim of the study was to assess the safety of burst of high-pressure CO_2 using a 5-mm laparoscopic pneumodissector (PD) operating at different flow rates and for different operating times regarding the risk of gas embolism (GE) in a swine model.

Methods The first step was to define the settings use of the PD device ensuring no GE. Successive procedures were conducted by laparotomy: cholecystectomy, the PD was placed 10 mm deep in the liver and the PD was directly introduced into the lumen of the inferior vena cava. Different PD flow rates of 5, 10, and 15 mL/s were used. The second step was to assess the safety of the device (PD group) during a laparoscopic dissection task (cystic and hepatic pedicles dissection, cholecystectomy and right nephrectomy) in comparison with the use of a standard laparoscopic hook device (control group). PD flow rate was 10 mL/s and consecutive burst of high-pressure CO_2 was delivered for 3–5 s.

Results In the first step ($n = 17$ swine), no GE occurred during cholecystectomy regardless of the PD flow rate used. When the PD was placed in the liver or into the inferior vena cava, no severe or fatal GE occurred when a burst of high-pressure CO_2 was applied for 3 or 5 s with PD flow rates of 5 and 10 mL/s. In the second step (PD group, $n = 10$; control group, $n = 10$), no GE occurred in the PD group. The use of the PD did not increase operative time or blood loss. The quality of the dissection was significantly improved compared to the control group.

Conclusions The 5-mm laparoscopic PD appears to be free from CO_2 GE risk when consecutive bursts of high-pressure CO_2 are delivered for 3–5 s with a flow rate of 10 mL/s.

Keywords Laparoscopic pneumodissector · Safety study · Laparoscopic innovation · Gas embolism · Swine model

The development of laparoscopic procedures has led to a reduction in abdominal wall trauma and improved postoperative outcomes [1–3]. However, these procedures continue to be hindered by cumbersome and manually demanding instrumentation (fulcrum effect, haptic feedback, grasping force control). In laparoscopic surgery, the lack of direct tissue palpation has significantly changed the haptic perception of surgeons. Thus, surgeons must plan their actions based on distorted haptic feedback perceived through instrument handles [4, 5]. Therefore, further technical advances in laparoscopy require technological developments in tissue dissection to compensate for the surgeon's distancing from the operating field. In this way, laparoscopic graspers, bipolar forceps, monopolar coagulation, and automatic and semiautomatic powered instruments have all been developed. However, when used for the dissection of anatomical planes, the physical, mechanical, and electrothermal properties of these advanced technological devices can cause plan fusion rather than division.

A few years ago, a laparoscopic instrument that delivered controlled bursts of high-pressure carbon dioxide (CO_2) was developed as a pneumodissector (PD) [6]. This instrument enabled surgeons to dissect along tissue planes without damaging the surrounding vessels or organs during laparoscopic nephrectomy [6–8]. However, laparoscopic use of the PD did

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Published online: 03 January 2022

not find widespread acceptance. One reason is the potential risk of hypercarbia and pulmonary gas embolism (GE) from CO_2. The course of this complication can vary from asymptomatic up to impairment of normal flow through the right ventricle or pulmonary artery, potentially leading to acute heart failure. CO_2 has emerged as a safe gas for insufflation to achieve pneumoperitoneum during laparoscopic surgery because it is non-flammable and extremely soluble [9]. However, the risk GE is an acknowledged complication of laparoscopic surgical procedures due to organ resections (cholecystectomy [10], liver resection [11–13]), or vascular injury (inferior vena cava [14] and hepatic vein) [11, 12] and is still of concern [15, 16].

In this study, a swine model was used to assess the safety of bursts of high-pressure CO_2 using a 5-mm laparoscopic PD operating at different flow rates and for different operating times regarding the risk of GE.

Methods

This study of instrument safety could not be ethically performed in humans, so it was carried out in a swine model. This large animal model provides sufficient quantities of tissue, and all surgical devices and techniques useful for data collection can be used in swine. In addition, the similar anatomy and physiology of swine and human organs make this model particularly beneficial for research in medical and surgical devices development [17, 18].

Concerning the aim of the present study, the swine model has already been used as an experimental model for assessing the risk of GE in laparoscopic surgery [19–22]. The study design, the care, and handling of animals were approved by the institutional review board of the Aix-Marseille University and French Authorities (*Ministère de l'Enseignement et de la Recherche*, authorization APAFIS#1502-2018052315292155 v3—2019/01/10). A written consent was not required in the present study.

Pneumodissector characteristics

The PD device is developed by Ab Medica sas, Mery-sur-Cher, France. The PD device is similar to Ab Medica's monopolar electrosurgery instruments. The PD device is a standard monopolar hook that can deliver CO2 flow on demand. This monopolar hook design is equivalent, especially in terms of material to the other manufacturer and respect the IEC 60601, which manage the safety requirements on the medical electrical equipment. It delivers pressurized CO_2 gas to achieve separation of tissue layers prior to their dissection (Fig. 1). The PD device consists of a handle and a tube, through which the CO_2 gas is delivered. The distal part of the tube is hook-shaped, and CO_2 delivery is triggered through a piston present on the handle. The shape of the PD device is similar to a standard laparoscopic hook-shaped device, allowing for easier tissues dissection and better control. The electrothermal effects (e.g., coagulation or cutting) are achieved by connecting the device to an electrosurgery generator through the jack plug connector. The shaft is a stainless steel pipe with an insulating sleeve to prevent undesired energy transmissions around the shaft. The PD hook is connected to a CO_2 gas cylinder through a pressure regulator and a hose. The outlet pressure of the pressure regulator can be set from 750 to 7500 mmHg. The maximum inlet pressure of the PD hook is 7500 mmHg. In the present study, the handle N°:SN172120-2 and the tube N°:SN172122-1 of the PD hook were used for the experiments. The inlet pressure of the PD hook was set at 750 mmHg, between 1125 and 1500 mmHg, and between 1875 and 2250 mmHg in order to obtain different PD flow rates of 5, 10, and 15 mL/s, respectively.

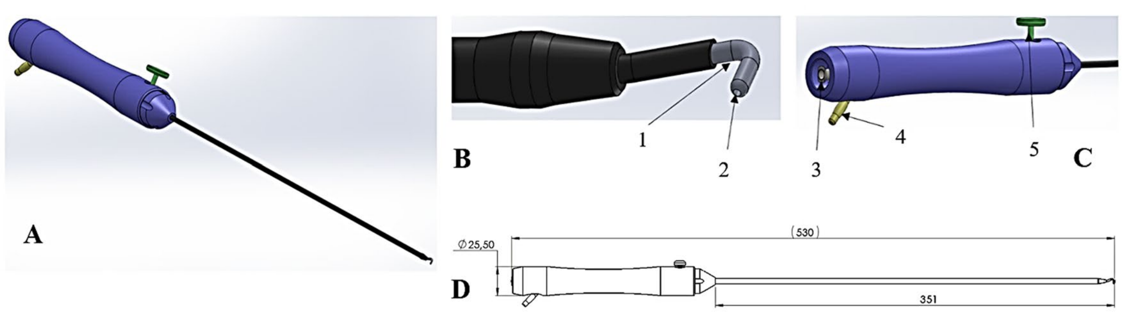

Fig. 1 5-mm Pneumodissector (PD) hook characteristics. The PD hook is a monopolar electrosurgery instrument composed of a handle and a tube, through which the CO_2 gas is delivered (**A**). The distal part of the tube has the shape of a hook (**B**). The CO_2 gas delivering is triggered by the presence of a piston on the handle (**C**). The overall dimensions (mm) are described here (**D**). [1]Hook shape, [2]CO_2 gas outlet, [3]CO_2 gas inlet, [4]jack plug, [5]piston

Animal preparation

All the procedures were conducted in accordance with the European Convention on the protection of vertebrates used for experimental or other scientific purposes. Due to the resemblance with human organs, female domestic swine aged about 3–4 months were included in the study. The animals were fasted overnight with free access to water. For induction of general anesthesia, the pigs received intramuscular injections of azaperone (2 mg/kg) and ketamine (10 mg/kg). The animals were then anesthetized with intravenous propofol (4 mg/kg) prior to orotracheal intubation and subsequent mechanical ventilation. The tidal volume was set at 20 mL/kg and the respiratory rate at 15 breaths/min. End-tidal (ET) CO_2 tension was continuously monitored with a Nellcor N-1000/N-2500 (Nellcor Inc., CA, USA) gas analyzer. A continuous intravenous infusion of propofol (0.2 mg/kg/min) and sufentanil (1 µg/kg/h) was used to maintain anesthesia. Swine were placed in a supine position at an angle of 5°. A pulmonary artery catheter (7.5 Fr) and central venous catheter (7.0 Fr) were placed in the right external jugular vein. Ringer's solution was administered to achieve a central venous pressure (CVP) of 5 mmHg prior to beginning the experiment. An arterial catheter (18 G) was inserted into the right external femoral artery for pressure monitoring. After the procedure, the animals were terminated with an intravenous infusion of pentobarbital (1 mL/kg) under general anesthesia.

Study design

First part of experimental protocol

The first experimentation part was to define the settings ensuring no CO_2 GE event when using the PD device. We assessed consecutive bursts of high-pressure CO_2 using the PD device operating at different flow rates and for different operating times.

After completing the above preparations, the animals were left for 20–30 min with no intervention to ensure hemodynamic and respiratory stability. Baseline values were obtained then a median laparotomy was performed to expose the inferior vena cava, the hepatic pedicle, and the gallbladder. This was followed by a second stabilization period before starting the procedures.

First of all, the PD was fired continuously for 3 s on the kidney surface, on the liver surface, and directly on the inferior vena cava to assess the risk of acute damage. Then, three successive procedures in 17 female domestic swine (mean weight of 34.1 (±4.9 SD) kg) were done by two experienced surgeons through an open approach.

The first surgical procedure was a cholecystectomy using the PD device (Fig. 2A). In the second procedure, the PD was placed 10 mm deep in the liver parenchyma in the middle part of the gallbladder bed (Fig. 2B). The third procedure involved direct introduction of the PD into the lumen of the inferior vena cava at the level of the right renal vein (Fig. 2C). In the second and third procedures, consecutive

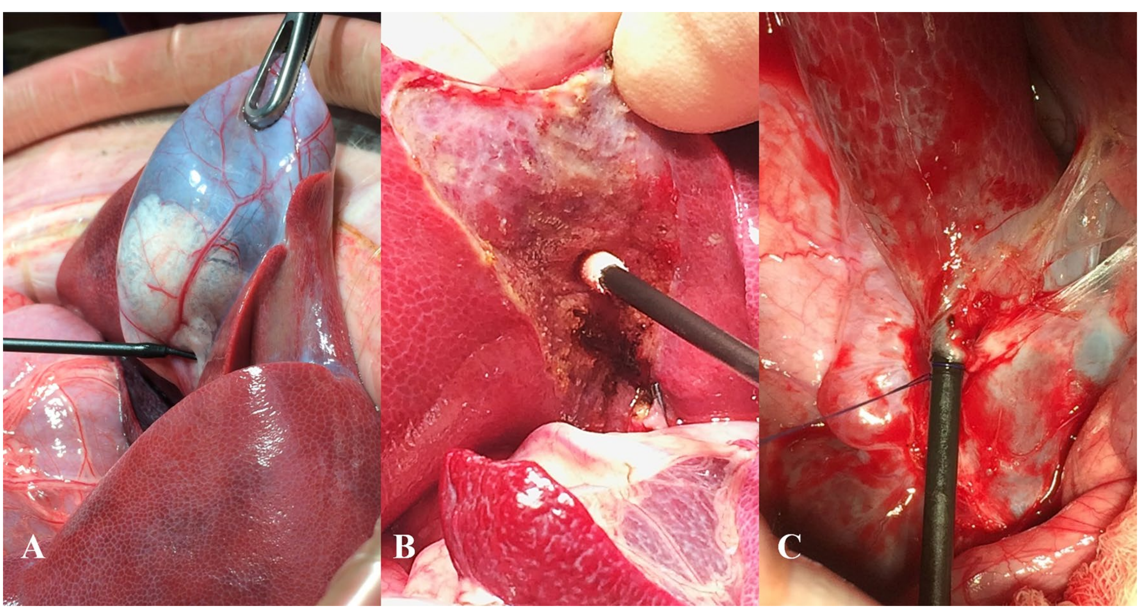

Fig. 2 Procedures assessing the safety of bursts of high-pressure CO_2 using a 5-mm pneumodissector (PD). Three successive procedures were performed: **A** a cholecystectomy was performed using the PD, **B** the PD was placed in the liver parenchyma 10 mm deep at the middle part of the gallbladder bed, **and C** the PD was introduced directly into the lumen of the inferior vena cava, at the level of the right renal vein

bursts of high-pressure CO_2 were delivered for 3, 5, 10, and 30 s. Before each new burst of high-pressure CO_2, recovery of the basal values was expected. Female domestic swine were separated in 3 groups according to the flow rate used (i.e., 5, 10, or 15 mL/s). For each group, the three procedures were analyzed according to the insufflated volume of CO_2 related to the weight of the animal and occurrence of GE.

Second part of experimental protocol

The second experimentation part was to assess the safety of the PD device to dissect tissues by laparoscopy in common and standardized procedures. Operative characteristics associated with the use of the 5-mm laparoscopic PD in domestic swine (PD group) who underwent successively a cystic pedicle dissection, a retrograde cholecystectomy, a hepatic pedicle dissection, and a right nephrectomy were compared to the use of a standard laparoscopic electrode-coated hook-shaped device (control group) (CleanCoat™ electrodes, Medtronic, Minneapolis, USA).

After completing the above preparations, the animals were left for 20–30 min with no intervention to ensure hemodynamic and respiratory stability.

The second part of experiments was conducted through a laparoscopic approach in 2 groups of 10 female domestic swine (*i.e.*, PD group, 5-mm laparoscopic PD vs. control group, standard laparoscopic electrode-coated hook-shaped device). Their mean weight was of 32.9 (± 3.0 SD) kg. The pneumoperitoneum was set at 12 mmHg.

Four successive procedures were performed: (a) a cystic pedicle dissection, (b) a retrograde cholecystectomy, (c) a hepatic pedicle dissection to identify the main biliary duct and the portal vein anterior side, and (d) a right nephrectomy. Before each procedure, recovery of the basal values was expected. According to the results of the first part of experiments, the flow rate used by the PD was 10 mL/s (considered as free from CO_2 GE risk in the first set of experiments) and consecutive burst of high-pressure CO_2 was delivered for 3–5 s.

In the second part of experiments, the median flow rate used by the PD, the number of consecutive burst of high-pressure CO_2, and the intra-abdominal pressure variation were recorded. Laparoscopic operative data included the following: operative time, blood loss, occurrence of GE, and adverse event due to burst of high-pressure CO_2 and/or due to monopolar electrocoagulation and quality of the surgical dissection during the four successive procedures performed. The quality of the surgical dissection was assessed by two experienced surgeons in hepatobiliary and laparoscopic surgery (DJB and TG). Evidence-based intraoperative data were used to define the quality of the surgical dissection as follows: very high, fast, and easy dissection without bleeding or adjacent organ injury and no requirement of additional trocar for operative field exposure; high, good dissection with minor bleeding easily controlled, no adjacent organ injury, and no requirement of additional trocar for operative field exposure; moderate, minor adjacent organ injury (i.e., gallbladder perforation, hepatic or renal minor injury), requirement of additional trocar for operative field exposure in order to control bleeding or to avoid major adjacent organ injury; low, major adjacent organ injury, uncontrolled major bleeding, need for open conversion.

Measurements and criteria for gas embolism

The mean arterial pressure, pulmonary artery pressure, right atrial pressure, standard electrocardiogram (EGG), temperature, and end-tidal (ET) CO_2 were continuously monitored and recorded on a computer at 10-s intervals following the start of the high-pressure CO_2 bursts using the PD.

A physiological response to CO_2 embolism was defined as a decrease in ET CO_2 of > 10% of the baseline value or an increase in mean pulmonary arterial pressure of > 10% of the baseline value. Severe GE was defined as a decrease in mean arterial pressure of ≥ 40% and/or a decrease in cardiac output of ≥ 50% and/or an increase in mean pulmonary arterial pressure of ≥ 40% of the baseline value and/or the occurrence of heart rhythm disorders on the ECG (i.e., ventricular tachycardia, atrial fibrillation, asystole). All fatal GEs were recovered.

Results

First part of experimental protocol

Macroscopic examination did not reveal acute damage when the PD was fired continuously for 3 s on the kidney surface, on the liver surface, and directly on the inferior vena cava.

Three groups of swine were created according to the flow rate used with the PD: 5 mL/s group ($n = 5$), 10 mL/s group ($n = 6$), or 15 mL/s group ($n = 6$).

In the first procedure, 17 cholecystectomies were performed with the PD. The mean operative time was 7.35 (± 1.8) min, and the mean blood loss was 3.25 (± 3.5) mL. The median number of consecutive bursts of high-pressure CO_2 was 3 (range 1–4), and the mean duration of each burst was 5.6 (± 3.7) s. Liver and gallbladder injuries occurred in 5.8% ($n = 1$) and 11.7% ($n = 2$) of cases. No GE occurred during the cholecystectomy procedure.

Results for the occurrence and severity of GE during the second procedure are presented in Table 1. No GE occurred in the 5 mL/s group when consecutive bursts of high-pressure CO_2 were applied for 3, 5, 10, and 30 s. In the 10 mL/s group, a GE occurred in half of the swine, but only when a burst of high-pressure CO_2 was applied for 30 s. Among these GEs, one severe and one fatal GE were reported,

Table 1 Occurrence and severity of gas embolism when consecutive bursts of high-pressure CO_2 were performed for 3, 5, 10, and 30 s in the liver parenchyma according to the flow rate used by the pneumodissector

Burst of high-pressure CO_2	Groups (flow rate)		
Insufflated volume	(mL/kg)		
	5 mL/sec	10 mL/sec	15 mL/sec
	$n=5$	$n=6$	$n=6$
3 s	0,3	0,3	1,0
	0,1	0,3	2,1
	0,6	0,5	1,5
	0,3	0,7	1,6
	0,4	0,6	1,2
		0,8	1,2
5 s	0,9	0,7	2,1
	0,5	0,4	2,7
	0,8	0,9	2,1
	0,3	1,0	2,4
	0,7	1,1	1,0
		1,2	2,3
10 s	2,1	2,2	1,6
	0,2	2,1	5,2
	1,2	1,9	5,5**
	0,6	1,6*	5
	0,4	2,7	2,1
		2,7	5,1
30 s	5,7	7,6*	10,3**
	1,7	6,7	17,1*
	2,1	4,9	15,7***
	1,8	5,7***	10,4
	4,1	5,5**	9,2*
		7,9	13,4

*indicates gas embolism

**indicates severe gas embolism

***indicates fatal gas embolism

Table 2 Occurrence and severity of gas embolism when consecutive bursts of high-pressure CO_2 were performed for 3, 5, 10, and 30 s in the inferior vena cava according to the flow rate used by the pneumodissector

Burst of high-pressure CO_2	Groups (flow rate)		
Insufflated volume	(mL/kg)		
	5 mL/sec	10 mL/sec	15 mL/sec
	$n=5$	$n=5$	$n=5$
3 s	0,5*	0,8*	0,8*
	0,5*	0,5*	1,4*
	0,5*	0,7*	1,9**
	0,5*	0,6*	1,8**
	0,4*	0,7*	1,4*
5 s	1,0*	1,4*	1,2*
	0,8*	0,9*	2,7*
	0,8*	1,3*	2,1*
	0,9*	1,2*	2,7**
	0,6*	1,4*	1,9**
10 s	2,1*	3,0**	3,2**
	1,5*	1,6*	4,6**
	1,9*	2,7**	4,2**
	1,4*	2,5*	5,6***
	1,1*	3,3**	3,9**
30 s	5,3**	8,8**	10,4***
	4,0*	6,9***	13,3***
	4,7*	8,5***	13,3***
	3,9*	7,2**	
	2,7*	9,2**	11,0***

*indicates gas embolism

**indicates severe gas embolism

***indicates fatal gas embolism

with a total insufflated CO_2 volume of 5.5 and 5.7 mL/kg, respectively. In the 15 mL/s group, no GEs were reported when a burst of high-pressure CO_2 was applied for 3 or 5 s. However, one severe GE occurred (16.7%) when a burst of high-pressure CO_2 was applied for 10 s. During this burst of high-pressure CO_2, the total insufflated volume of CO_2 was 5.5 mL/kg. When a burst of high-pressure CO_2 was delivered for 30 s, 66.6% ($n=4$) of cases presented a GE. Among these GEs, one severe and one fatal GE occurred in this group. In both cases, the total insufflated volume of CO_2 was 5.5 mL/kg or higher.

In the final procedure, each of the three groups (i.e., 5, 10, and 15 mL/s) included five domestic swine. Regardless of the duration of the high-pressure CO_2 burst and the group, a GE was documented (Table 2). In the 5 mL/s group, only one severe GE occurred when a burst of high-pressure CO_2 was delivered for 30 s, together with a total insufflated volume of CO_2 greater than 5.0 mL/kg. In the 10 and 15 mL/s groups, the occurrence of severe and fatal GEs tended to increase along with a stepwise decrease in the total insufflated volume of CO_2. In the 10 mL/s group, a severe GE occurred when the total insufflated volume of CO_2 was greater than 2.5 mL/kg, while in the 15 mL/s group, a severe GE occurred when it was higher than 1.5 mL/kg. Thus, severe GE did not occur in the 10 mL/s group when consecutive bursts of high-pressure CO_2 were delivered for 3 and 5 s, whereas severe GE was observed in 40% ($n=2$) of cases when a burst of high-pressure CO_2 was delivered for 3 or 5 s at a flow rate of 15 mL/s.

During this part of experimentation, seven fatal GEs occurred: two swine died when a burst of high-pressure CO_2 was delivered for 30 s at a flow rate of 10 mL/s; one swine died when a burst of high-pressure CO_2 was delivered for 10 s at a flow rate of 15 mL/s; and the other four died when a burst of high-pressure CO_2 was delivered for 30 s at a flow rate of 15 mL/s. In all cases of death due to GE, the total insufflated volume of CO_2 exceeded 5.5 mL/kg.

Second part of experimental protocol (supplementary data, video)

Domestic swine were separated in two groups: PD group ($n=10$) and control group ($n=10$) (Table 3). Regardless of each procedure, no GEs and no adverse event due to burst of high-pressure CO_2 were recorded in the PD group. The flow rate used by the PD device did not excide 10 mL/s.

For cystic pedicle dissection, the median number of consecutive burst of high-pressure CO_2 was 3 (range 2–5). In one case, a minor bleeding occurred and was easily controlled. During retrograde cholecystectomy, the median number of consecutive burst of high-pressure CO_2 was 4 (range 3–5). In one case, a gallbladder perforation was recorded secondary to the electrothermal effect of the PD.

For hepatic pedicle dissection, the median number of consecutive burst of high-pressure CO_2 was 3 (range 2–6) and allowed a smooth dissection to identify the main biliary duct and the portal vein anterior side in all cases.

During the right nephrectomy, the median number of consecutive burst of high-pressure CO_2 was 4 (range 2–7). In two cases, a venous injury of the inferior polar renal vein and the right adrenal vein was recorded during vascular control before ligation of the right renal vein. Bleeding control was achieved with one additional trocar allowing the use of a laparoscopic vascular clamp.

Regarding each procedure, operative time was not increased in the PD group compared to the control group (Table 3). Similarly, intraoperative blood loss and adverse event rate due to the use of monopolar electrocoagulation did not differed between groups. The quality of the dissection was significantly improved by the use of the PD during cystic pedicle dissection ($p=0.001$), retrograde cholecystectomy ($p=0.003$), and hepatic pedicle dissection ($p=0.002$) and tended to improve during right nephrectomy ($p=0.068$). Regarding each procedure, a fast and easy dissection without bleeding or adjacent organ injury and no requirement of additional trocar for operative field exposure was recorded in 70% of cases or higher. In only two cases, one additional trocar for operative field exposure was required.

Discussion

In laparoscopic surgery, the ability to perform a procedure depends on the availability of appropriate instrumentation for the safe and rapid dissection of tissue. In this way, advanced laparoscopic devices have been developed. However, the natural tissue planes are not always recognized, increasing both the difficulty of surgery and the potential for bleeding or visceral injury. In the present report, a new laparoscopic 5-mm PD hook was developed and its safety was assessed in terms of GE risk.

The objective of the present study was to evaluate the device's safety under laparoscopic conditions and during complete surgical procedures. This evaluation was achieved during the second experimental phase of our study. Indeed, concerning the risk of GE, our scientific decision was to assess the specific risk for GE, ruling out any evaluation bias linked to the presence of pneumoperitoneum. For this reason, our study was divided into two parts.

The first part of the experimentation was performed by laparotomy, evaluating the specific risk of GE with different parameters of use of the device (i.e., flow rates of 5, 10, and 15 mL/s, and consecutive bursts of high-pressure CO_2 delivered for 3, 5, 10, and 30 s). During this phase, we aimed at determining the parameters of use for the device allowing a reasonable use and ruling out any risk of clinically significant GE (i.e., severe or fatal GE) in case of occurrence of an undesirable intraoperative event such as the traumatic insertion of the device in the hepatic parenchyma or a blood vessel. During this part of the experimentation, no clinically significant GEs were recorded when consecutive bursts of high-pressure CO_2 were delivered by the 5-mm PD hook for 3 or 5 s with a flow rate of 5 or 10 mL/s.

Based on the results of the first part of the experimentation, the second part was undertaken: we performed 40 surgical procedures under laparoscopic conditions (i.e., cystic pedicle dissection, retrograde cholecystectomy, hepatic pedicle dissection, right nephrectomy) on 10 swine. The following parameters were used: flow rate of 10 mL/s and consecutive burst of high-pressure CO2 delivered for 3–5 s. No GE occurred during the second part of the experimentation when using the device.

The insufflation gas of choice, CO_2, is rapidly absorbed into the circulatory system, while nitrogen and oxygen gases are slowly absorbed from the bloodstream, compounding the effects of GE when it occurs [23]. While CO_2 GE may be as high as 17% in certain laparoscopic procedures [24], clinically significant intraoperative GE is rare, occurring in only 0.06–0.15% of procedures [15, 25], due to the rapid absorption of CO_2 in the body. GE, however, has a reported mortality rate of up to 30% [26, 27]. Therefore, the main focus of the present study was to identify the operating parameters of the 5-mm PD hook that are free from CO_2 GE risk. In two previous series, fatal GE was reported to occur with intravenous volumes of 200–300 mL or with volumes ranging from 2 to 5 mL/kg [25, 27]. The present study showed that the risk of severe or fatal GE increased when the intravenous insufflated volume of CO_2 was higher than 1.7 mL/kg. When consecutive bursts of high-pressure CO_2 were delivered by the 5-mm PD hook for 3 or 5 s with a flow rate of 5 or 10 mL/s, insufflated volumes ranged from 0.1 to 1.4 mL/kg,

Table 3 Operative characteristics associated with the use of the 5-mm laparoscopic PD compared with the use of a standard laparoscopic electrode-coated hook-shaped device in domestic swine who underwent successively a cystic pedicle dissection, a retrograde cholecystectomy, a hepatic pedicle dissection, and a right nephrectomy

	Cystic pedicle dissection				*p* value	Retrograde cholecystectomy				*p* value
	PD group (*n* = 10)		Control group (*n* = 10)			PD group (*n* = 10)		Control group (*n* = 10)		
Flow rate used by the PD (mL/s), median (range)	9.42	(8.95–9.80)	–			9.39	(8.80–9.71)	–		
Number of consecutive burst of high-pressure CO_2, median (range)	3	(2–5)	–			4	(3–5)	–		
Intra-abdominal pressure increase	0		0			0		0		
Operative time (min), median (range)	1.95	(1.00–4.15)	1.84	(1.00–3.83)	0.140	3.75	(1.85–6.50)	4.00	(1.67–5.83)	0.191
Blood loss (mL), median (range)	0	(0–5)	0	(0–10)	0.967	0	(0–10)	0	(0–10)	0.056
Adverse event due to burst of high-pressure CO_2	0		–			0		–		
Adverse event due to monopolar electrocoagulation	1	(10)	4	(40)	0.303	3	(30)	5	(50)	0.650
Quality of the dissection					0.001					0.003
Very high	9	(90)	1	(10)		7	(70)	0		
High	1	(10)	6	(60)		2	(20)	6	(60)	
Moderate	0		3	(30)		1	(10)	4	(40)	
Low	0		0			0		0		
GE	0		–			0		–		
	Hepatic pedicle dissection				***p* value**	**Right nephrectomy**				***p* value**
	PD group (*n* = 10)		**Control group (*n* = 10)**			**PD group (*n* = 10)**		**Control group (*n* = 10)**		
Inlet pressure of the PD (bar), median (range)	9.39	(8.95–9.71)	–			9.39	(8.95–9.71)	–		
Number of consecutive burst of high-pressure CO_2, median (range)	3	(2–6)	–			4	(2–7)	–		
Intra-abdominal pressure increase	0		0			0		0		
Operative time (min), median (range)	4.33	(2.33–5.15)	6.58	(4.00–8.67)	0.274	9.59	(3.83–20.50)	11.43	(8.33–24.75)	0.777
Blood loss (mL), median (range)	0	(0–10)	1	(0–10)	0.815	0	(0–25)	0	(0–55)	0.075
Adverse event due to burst of high-pressure CO_2	0		–			0		–		
Adverse event due to monopolar electrocoagulation	0		3	(30)	0.211	1	(10)	3	(30)	0.582
Quality of the dissection					0.002					0.068
Very high	7	(70)	0			7	(70)	2	(20)	
High	3	(30)	7	(70)		1	(10)	5	(50)	
Moderate	0		3	(30)		2	(20)	3	(30)	
Low	0		0			0		0		
GE	0		–			0		–		

Values in parentheses are percentages or range. *PD* 5-mm laparoscopic pneumodissector; *GE* gas embolism no GE or clinically significant GE occurred when the PD was placed 10 mm deep in the liver parenchyma or directly into the lumen of the inferior vena cava, respectively. Our recommendation was to use the 5-mm PD hook with consecutive bursts of high-pressure CO_2 delivered for 3 or 5 s with a flow rate of 10 mL/s because these parameters appear to be free from CO_2 GE risk.

In the second part of the experimentation, no GEs were recorded in the PD group and no additional constraint or risk was observed. The present study showed that the 5-mm PD hook allowed a fast and easy tissue dissection under laparoscopic conditions in more than 70% of cases. No increase in intra-abdominal pressure was recorded, highlighting that the total volume of CO_2 insufflated by the 5-mm PD hook is negligible. To our knowledge, there is no standardized scale in the literature to assess the quality of the surgical dissection during a laparoscopic surgical procedure. In this study, we evaluated the quality of surgical dissection using evidence-based intraoperative data (i.e., bleeding, adjacent organ injury, requirement of additional trocar for operative field exposure, need for open conversion) in order to be as objective as possible. The differences between the quality of the surgical dissection during the cystic pedicle dissection, the retrograde cholecystectomy, and the hepatic pedicle dissection were due to a higher rate of moderate quality in the control group. Effectively, in this group, an additional trocar for operative field exposure was more frequently required in order to control bleeding. These findings can be explained by the fast plane division due to burst of high-pressure CO_2 with the use of the PD device. This division allowed easy dissection and control of the vascular structures. Moreover, the resultant plane division seemed to endure over time, as shown in the supplementary video. Our initial impression is that despite a short technical learning curve, this new device is relatively simple to use.

The main advantage of the 5-mm PD hook developed in the current study is that it has the physical and mechanical characteristics of a 5-mm laparoscopic electrosurgery instrument. In addition to the dissection and coagulation abilities of the device in laparoscopic surgery, the 5-mm PD hook can also deliver consecutive bursts of high-pressure CO_2, allowing atraumatic and rapid separation of tissue layers prior to their dissection. These two functions can be used independently of each other.

Nevertheless, our study had certain limitations. First, it was a preclinical study of safety performed in a swine model. Second, the objective of the study was not to determine the superiority of the PD over a standard laparoscopic hook. In addition, the number of animals included in the second part of the experimentation was too small to identify a significant difference in the intraoperative data and adverse events. Third, the present study constituted the first overview of the surgical interest of this device during procedures performed by two surgeons.

A prospective randomized multicenter study is now needed to evaluate the surgical interest of this device for targeted procedures, such as the laparoscopic cholecystectomy. Such a study would allow the determination of the possible benefit of this device for intraoperative data (i.e., intraoperative blood loss, gallbladder perforation, operative time).

Conclusion

The 5-mm PD hook appears to be free from CO_2 GE risk when consecutive bursts of high-pressure CO_2 are delivered for 3–5 s with a flow rate 10 mL/s in laparoscopic surgery. However, in case of vascular injury, we believe these situations represent a direct risk for CO_2 GE if the consecutive bursts of high-pressure CO_2 are delivered during active bleeding. Hemostasis should be achieved before the PD is reused during the procedure.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00464-021-08953-6.

Acknowledgements The authors wish to thank Marie-Ange Becaris for her assistance with this project.

Funding This work was supported by a Grant form Ab Medica sas, Mery-sur-Cher, France.

Declarations

Disclosures Drs Théophile Guilbaud, Alexia Cermolacchi, Stéphane Berdah, and David Jérémie Birnbaum have no conflict of interest or financial ties to disclose.

References

1. Bonjer HJ, Deijen CL, Abis GA, Cuesta MA, van der Pas MH, de Lange-de Klerk ES, Lacy AM, Bemelman WA, Andersson J, Angenete E, Rosenberg J, Fuerst A, Haglind E, COLOR II Study Group (2015) A randomized trial of laparoscopic versus open surgery for rectal cancer. N Engl J Med 372:1324–1332
2. Kasai M, Cipriani F, Gayet B, Aldrighetti L, Ratti F, Sarmiento JM, Scatton O, Kim KH, Dagher I, Topal B, Primrose J, Nomi T, Fuks D, Abu Hilal M (2018) Laparoscopic versus open major hepatectomy: a systematic review and meta-analysis of individual patient data. Surgery 163:985–995
3. Dagher I, Di Giuro G, Dubrez J, Lainas P, Smadja C, Franco D (2009) Laparoscopic versus open right hepatectomy: a comparative study. Am J Surg 198:173–177
4. Picod G, Jambon AC, Vinatier D, Dubois P (2005) What can the operator actually feel when performing a laparoscopy? Surg Endosc 19:95–100

5. Heijnsdijk EAM, Pasdeloup A, Dankelman J, Gouma DJ (2004) The optimal mechanical efficiency of laparoscopic forceps. Surg Endosc 18:1766–1770
6. Gardner SM, Clayman RV, McDougall EM, Moon YT, Fadden P, Anderson KR, Pearle MS, Royal H, Humphrey PA, Pingleton E, Roemer FD (1995) Laparoscopic pneumodissection: a unique means of tissue dissection. J Urol 154:591–594
7. Pearle MS, Nakada SY, McDougall EM, Monk TG, Clayman RV, Pingleton E, Roemer FD (1995) Laparoscopic pneumodissection: initial clinical experience. Urology 45:882–885
8. Pearle MS, Nakada SY, McDougall EM, Monk TG, Pingleton E, Roemer FD, Clayman RV (1997) Laparoscopic pneumodissection: results in initial 20 patients. J Am Coll Surg 184:579–583
9. Graff TD, Arbegast NR, Phillips OC, Harris LC, Frazier TM (1959) Gas embolism: a comparative study of air and carbon dioxide as embolie agents in the systemic venous system. Am J Obstet Gynecol 78:259–265
10. de Jong KIF, de Leeuw PW, PW, (2019) Venous carbon dioxide embolism during laparoscopic cholecystectomy a literature review. Eur J Intern Med 60:9–12
11. Eiriksson K, Fors D, Rubertsson S, Arvidsson D (2011) High intra-abdominal pressure during experimental laparoscopic liver resection reduces bleeding but increases the risk of gas embolism. Br J Surg 98:845–852
12. Otsuka Y, Katagiri T, Ishii J, Maeda T, Kubota Y, Tamura A, Tsuchiya M, Kaneko H (2013) Gas embolism in laparoscopic hepatectomy: what is the optimal pneumoperitoneal pressure for laparoscopic major hepatectomy? J Hepatobiliary Pancreat Sci 20:137–140
13. Schmandra TC, Mierdl S, Bauer H, Gutt C, Hanisch E (2002) Transoesophageal echocardiography shows high risk of gas embolism during laparoscopic hepatic resection under carbon dioxide pneumoperitoneum. Br J Surg 89:870–876
14. O'Sullivan DC, Micali S, Averch TD, Buffer S, Reyerson T, Schulam P, Kavoussi LR (1998) Factors involved in gas embolism after laparoscopic injury to inferior vena cava. J Endourol 12:149–154
15. Sharma KC, Kabinoff G, Ducheine Y, Tierney J, Brandstetter RD (1997) Laparoscopic surgery and its potential for medical complications. Heart Lung J Acute Crit Care 26:52–67
16. Mintz M (1977) Risk and prophylaxis in laparoscopy: a survey of 100,000 cases. J Reprod Med 18:269–272
17. Judge EP, Hughes JML, Egan JJ, Maguire M, Molloy EL, O'Dea S (2014) Anatomy and bronchoscopy of the porcine lung. A model for translational respiratory medicine. Am J Respir Cell Mol Biol 51:334–343
18. Court FG, Wemyss-Holden SA, Morrison CP, Teague BD, Laws PE, Kew J, Dennison AR, Maddern GJ (2003) Segmental nature of the porcine liver and its potential as a model for experimental partial hepatectomy. Br J Surg 90:440–444
19. Nagao K, Reichert J, Beebe DS, Fowler JM, Belani KG (1999) Carbon dioxide embolism during laparoscopy: effect of insufflation pressure in pigs. JSLS 3:91–96
20. Mann C, Boccara G, Fabre JM, Grevy V, Colson P (1997) The detection of carbon dioxide embolism during laparoscopy in pigs: a comparison of transesophageal doppler and end-tidal carbon dioxide monitoring. Acta Anaesthesiol Scand 41:281–286
21. Beebe DS, Zhu S, Kumar MVS, Komanduri V, Reichert JA, Belani KG (2002) The effect of insufflation pressure on CO_2 pneumoperitoneum and embolism in piglets. Anesth Analg 94:1182–1187
22. Fors D, Eriksson K, Arvidsson D, Rubertsson S (2010) Gas embolism during laparoscopic liver resection in a pig model: frequency and severity. Br J Anaesth 105:282–288
23. Menes T, Spivak H (2000) Laparoscopy: searching for the proper insufflation gas. Surg Endosc 14:1050–1056
24. Hong J, Kim W, Kil H (2010) Detection of subclinical CO2 embolism by transesophageal echocardiography during laparoscopic radical prostatectomy. Urology 75:581–584
25. Toung TJK, Rossberg M, Hutchins G (2016) Volume of air in a lethal venous air embolism. Anesthesiology 94:360–361
26. Burcharth J, Burgdorf S, Lolle I, Rosenberg J (2012) Successful resuscitation after carbon dioxide embolism during laparoscopy. Surg Laparosc Endosc Percutan Tech 22:164–167
27. Richter S, Matthes C, Ploenes T, Aksakal D, Wowra T, Hückstädt T, Schier F, Kampmann C (2013) Air in the insufflation tube may cause fatal embolizations in laparoscopic surgery: an animal study. Surg Endosc Other Interv Tech 27:1791–1797