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Original Article

Low pressure gynecological laparoscopy (7 mmHg) with AirSeal® System versus a standard insufflation (15 mmHg): A pilot study in 60 patients

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ABSTRACT

Objectives. – To evaluate feasibility of performing benign gynecologic pathology low pressure (7 mmHg) laparoscopy (LPL) with AirSeal® system and to study benefits in terms of postoperative pain, when compared to a standard insufflation group (15 mmHg).
Materials and methods. – In this prospective randomized pilot study, 60 patients had laparoscopy for gynecologic benign pathology: 30 with 7 mmHg and AirSeal system, and 30 with 15 mmHg standard insufflator. The primary endpoint was incidence of shoulder pain. A postoperative questionnaire was completed by each patient to assess shoulder pain (Numeric Rating Scale [NRS], from 0 to 10) at H4, H8, H24, and consumption of morphinics was notified. During each procedure, anesthesia parameters were collected (peak airway pressure, systolic blood pressure, end tidal CO_2).
Results. – Laparoscopy was performed on 30 patients in AirSeal®-LP group without need to increase pressure above 7 mmHg, and no complication was reported. Incidence of shoulder pain was significantly lower in the AirSeal®-LP group (23.3% vs. 73.3%, $P < 0.001$). NRS shoulder pain was significantly lower in AirSeal® LP group at hour 4, 8 and 24. Maximal values of $ETCO_2$, systolic blood pressure, and peak airway pressure were significantly lower in AirSeal®-LP group.
Conclusion. – LP (7 mmHg) laparoscopy with AirSeal® platform allows laparoscopic surgery with less postoperative shoulder pain. These results could facilitate the development of ambulatory laparoscopy.

Introduction

Determination of intra-abdominal pressure in laparoscopic surgery is challenging. Pneumoperitoneum ranging from 12 to 15 mmHg is advantageous to secure sufficient working space and to enable free use of suction devices [1,2]. However, several complications related to insufflation of carbon dioxide (CO_2) have been reported including hypercapnia, subcutaneous emphysema, pneumothorax, and pneumomediastinum [3–5]. Moreover, several physiological cardiopulmonary changes occur during insufflation of abdomen, that may be tolerated by normal individuals, but not by patients with poor heart or lung function [6]. In addition, shoulder pain is a common complaint following laparoscopic surgery [7–9] and several randomized clinical trials showed that lower than 10 mmHg pressure pneumoperitoneum is effective in decreasing shoulder pain after laparoscopic cholecystectomy when compared to standard pressure [6,7,10,11]. Moreover, a recent study has showed that low intraperitoneal pressure (8 mmHg) minimizes the adverse impacts on surgical peritoneal environment during a CO_2 pneumoperitoneum in comparison with a standard pressure (12 mmHg) [12]. For all these reasons, lowering the pressure while keeping satisfactory intra peritoneal visibility seems to be an objective and a challenge.

Recently, a new AirSeal® insufflation management platform with a valve-free trocar that provides stable pneumoperitoneum even under constant suction [13] has been made available to market. Thanks to this new insufflation platform and stable pneumoperitoneum, we noticed that laparoscopy was feasible at 7 mmHg with satisfactory visualization.

Therefore, the aim of this prospective comparative pilot study was to evaluate feasibility of low pressure pneumoperitoneum (7 mmHg) with the AirSeal® System in gynecological benign pathology, and to study benefits in terms of postoperative shoulder pain, compared to a standard pressure group (15 mmHg). Standard

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pressure may be 12 mmHg for some surgeons, but we have chosen 15 mmHg because many laparoscopists still operate at 15 mmHg, and in our guidelines, there is neither clear indication of the pressure to insufflate, nor recommendation about benefit of low pressure [14]. We have elected shoulder pain as primary endpoint like most of the authors who published about low pressure in general surgery. In a meta-analysis about low pressure, Hua et al. reported eight randomized clinical trials with shoulder pain as an endpoint [15]. We also analyzed and compared the intraoperative anesthesia parameters (systolic blood pressure, end tidal CO_2, peak airway pressure).

Materials and methods

Patients

All surgeries were performed in our gynecological endoscopy unit at Hospital Trousseau, by two surgeons. We included, in a six months period, 60 patients aged from 18 to 50 years old, French speaking, operated by laparoscopy, for a gynecological benign pathology. Indications for laparoscopy procedures are presented in Table 1. For this pilot study, we planned different type of surgeries, but we have considered that they were quite similar in terms of operative time, complexity and patient recovery.

We randomly assigned 60 patients before surgery in two groups: 30 patients in a "low pressure" group, with 7 mmHg pneumoperitoneum, and the AirSeal® System; and 30 patients in a "standard pressure" group, with 15 mmHg pneumoperitoneum and conventional insufflation system. The study was single-blinded; hence, the patients did not know with what kind of insufflation system they had been operated. Information form was given to the patients the day before surgery, and their consent was required. The primary endpoint of the study was the incidence of postoperative shoulder pain. This pilot study received favourable opinion from our hospital ethics committee.

Surgical protocol

Open laparoscopy with trans-umbilical incision was performed. In standard group, we insufflated a 15 mmHg pneumoperitoneum with a conventional insufflator system, whereas in low pressure, a 7 mmHg pneumoperitoneum was achieved with the specialized AirSeal® System. Surgeons had to perform the entire surgical procedure with planned pressure.

Anesthetic protocol

General anesthesia included induction with propofol as a hypnotic, sufentanil as an analgesic, and vecuronium as a muscle relaxant, followed by intubation, and maintenance with desflurane and sufentanil. Prevention of nausea and vomiting was assured by dexamethasone 4 milligrams. Ropivacain 2.5 mg/mL was injected by surgeons in cutaneous incisions at the end of the intervention. Postoperative pain was managed with systematic administration of paracetamol and ketoprofen, if no contraindication existed. If despite this, Numeric Rating Scale of pain was higher than 3, nefopam (Acupan®) was given, and finally morphine (Actiskenan®) if NRS was still higher than 3 after nefopam.

Table 1
Indications for surgery.

	AirSeal® 7 mmHg	Standard 15 mmHg	Total
Tubal patency test	11	8	19
Ovarian cystectomy	3	6	9
Salpingectomy for hydrosalpinx	4	5	9
Ovarian drilling	2	3	5
Tubal plasty	2	2	4
Adhesiolysis	0	3	3
Ectopic pregnancy, salpingectomy	2	1	3
Tubal sterilization	3	0	3
Ectopic pregnancy, salpingotomy	2	0	2
Tubal cystectomy	1	1	2
Myomectomy	0	1	1
Total	30	30	60

Data collection

Before surgery

We collected for each patient: age, body mass index, and history of previous abdominal or pelvic surgery.

During surgery

The anesthesia team recorded every five minutes: systolic and diastolic blood pressure, peak airway pressure, and end tidal CO_2. Operative time (from the beginning of pneumoperitoneum insufflation to exsufflation) was documented.

After surgery

Thanks to a standardized questionnaire, we asked patients about:

- shoulder pain at hour 4, 8 and 24 after surgery;
- global pain at hour 4, 8 and 24.

Pain was evaluated with the Numeric Rating Scale (NRS, from 0 to 10) to assess the necessity of morphine medication.

Statistical analysis

Statistical analysis was performed using XL Stat software (Addinsoft, New York, NY, USA). We used Chi^2 test to compare categorical variables and Mann–Whitney U test to compare continuous variables. $P < 0.05$ was considered statistically significant.

Results

Sixty patients were included in our study. All 60 patients accepted to participate in this pilot study, and there was no missing data. Preoperative patient data is presented in Table 2. The two groups (AirSeal®, 7 mmHg and Standard, 15 mmHg) of 30 patients were comparable.

Surgery was possible with allowed pressure without need to increase or decrease it in both groups. No complication was reported.

Incidence of shoulder pain was significantly lower in the AirSeal® group than in the standard group, 7 (23.3%) versus 22 (73.3%); $P < 0.001$. Hence, 76.7% of patients had no shoulder pain at

Table 2
Preoperative patient data.

	AirSeal® 7 mmHg	Standard 15 mmHg	*P*
n	30	30	
Age			
Median (range)	33 (19–45)	35 (25–58)	0.14
Body mass index			
Median (range)	22.1 (19–29.4)	22.6 (19.3–31.2)	0.20
Previous abdominal surgeries			
n (%)	11 (36.7%)	14 (46.7%)	0.43
Operative time (minutes)			
Median (range)	26 (9–83)	30 (10–85)	0.55

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