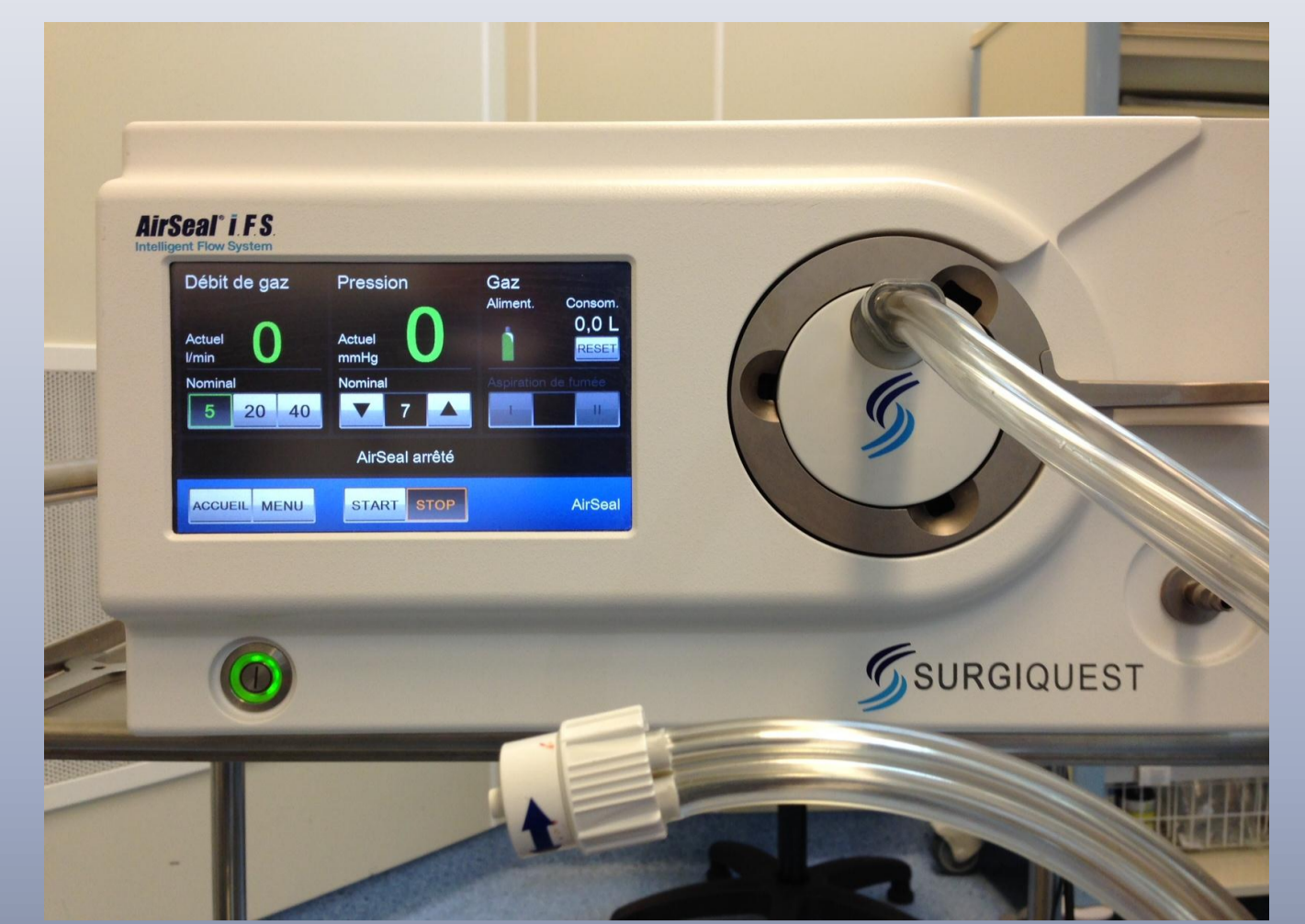


Laparoscopic surgery at low (7 mm Hg) pressure with AirSeal® system

A comparative prospective pilot study with a standard insufflation (15 mm Hg) in 60 patients

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INTRODUCTION

Pneumoperitoneum can be a purveyor of scapular post-operative pain and requires constant manipulation in intraoperative anesthesia parameters and ventilatory settings (peak airway pressure, end tidal CO₂). The purpose of this study was to evaluate the feasibility of performing benign pathology, gynecologic surgery with low pressure (7mmHg) stable pneumoperitoneum made possible by the AirSeal® System and to study potential benefits in terms of anesthesia parameters during the surgery and patient's post-operative pain when compared to the standard insufflation group (15mmHg) pressure.

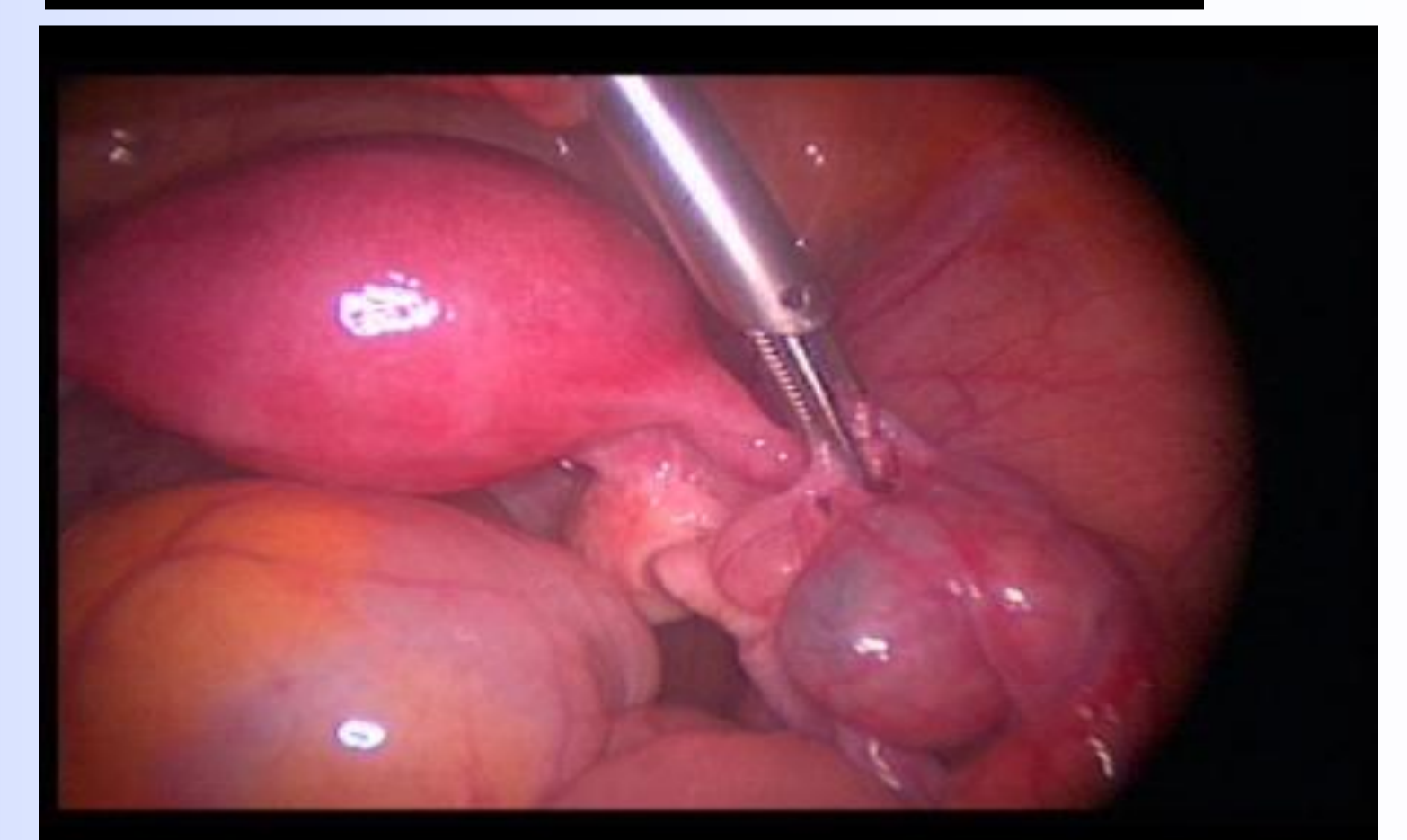
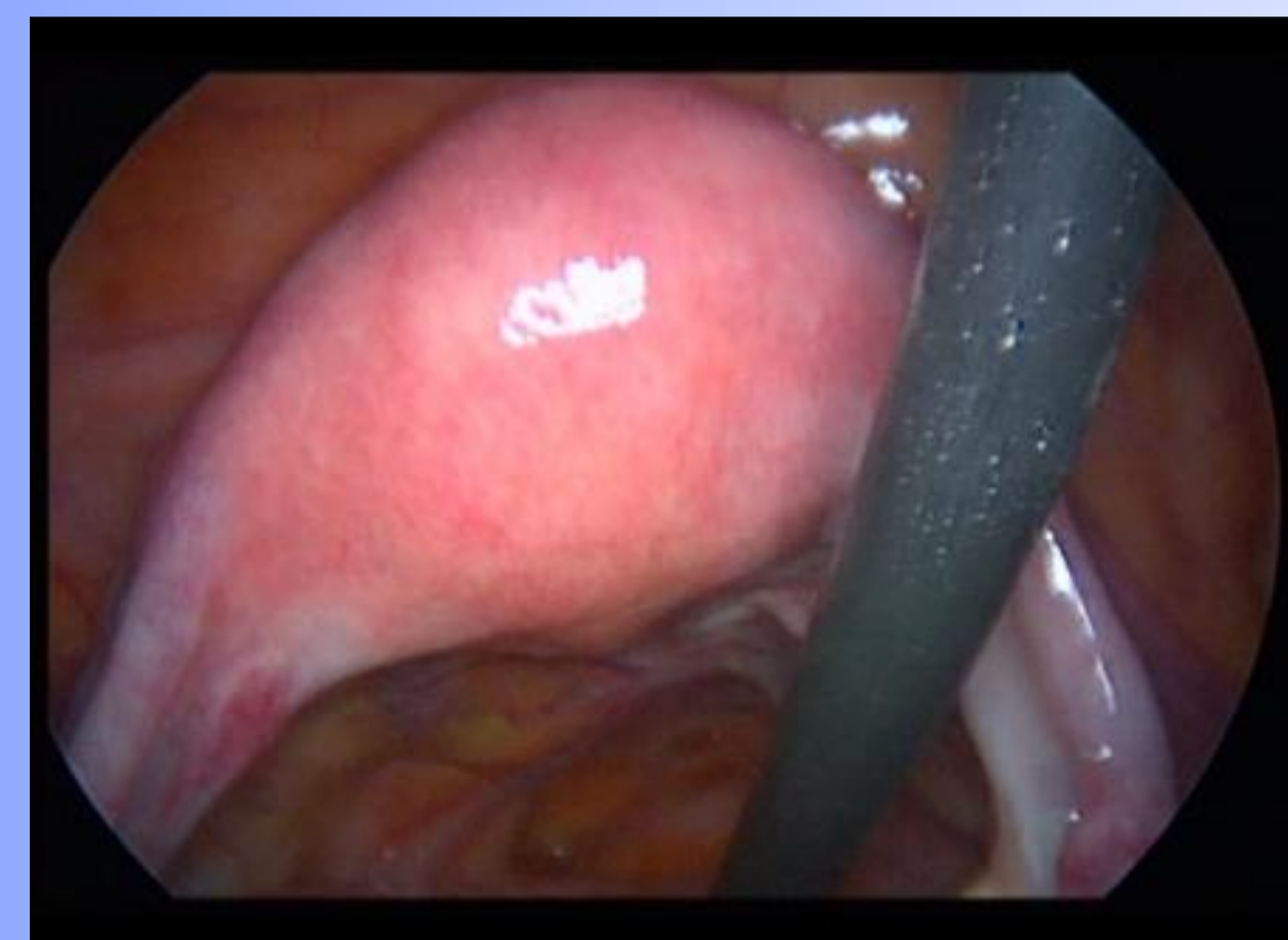
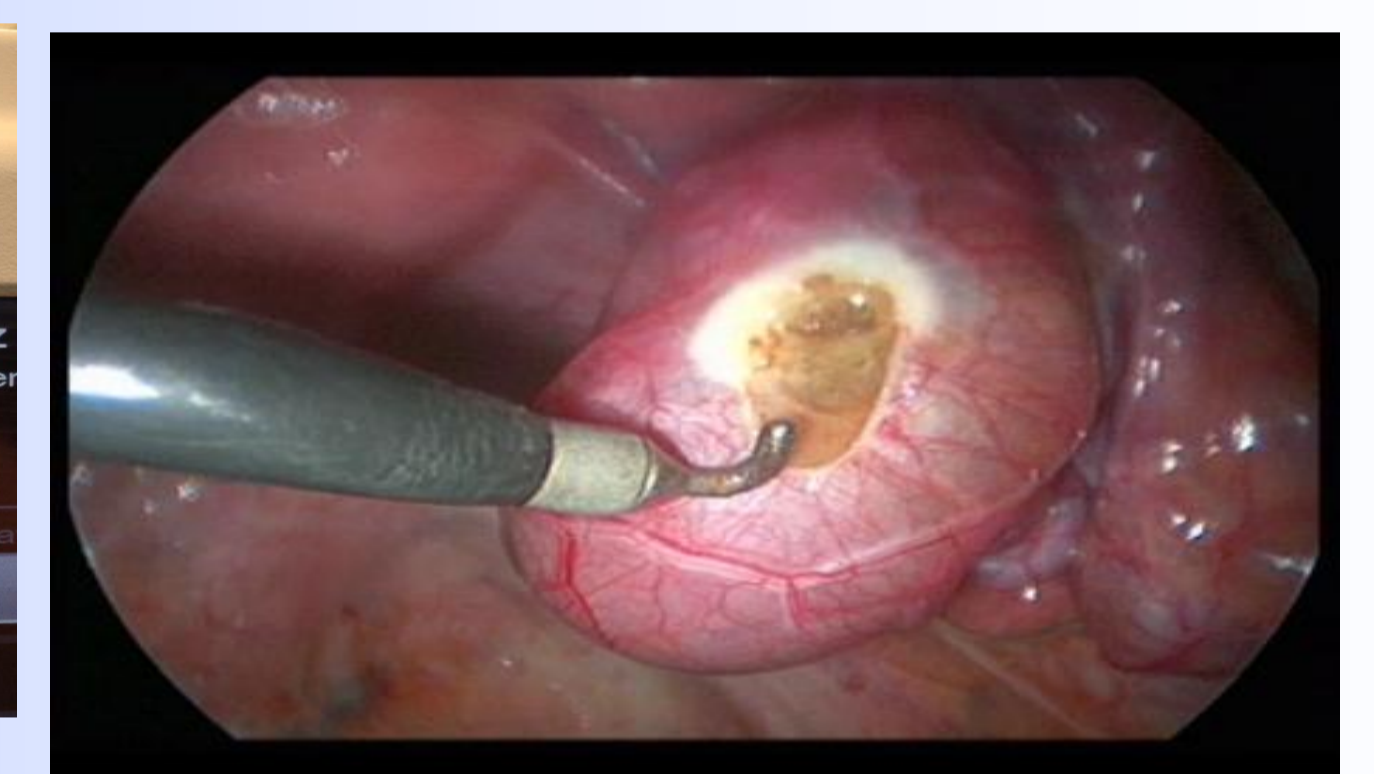
MEANS AND METHODS

This is a prospective monocentric comparative study. From January to August 2013, 60 patients underwent laparoscopic benign pathology, gynecologic surgery (diagnostic laparoscopy, extra-uterine pregnancy, tubal surgery, cystectomy, salpingectomy, etc.). During surgery, 30 patients were insufflated with pneumoperitoneum set to 7mm Hg, and 30 patients were insufflated with pneumoperitoneum set to standard 15mm Hg. During each operating procedure, anesthesia parameters were collected for both groups (peak airway pressure, systolic blood pressure, End tidal CO₂). A post-operative questionnaire was completed by each patient to assess shoulder pain (Numeric Rating Scale, from 0 to 10) at H4, H8 and H24, consumption of morphine and whether the patient felt they could be discharged on the same day of surgery.

RESULTS

Diagnostic and therapeutic laparoscopy was performed on 30 patients in the low pressure group with stable pneumoperitoneum without need to increase of pressure above 7mm Hg. The maximum value of EtCO₂ was significantly lower for the 7mm Hg low pressure group (36mmHg versus 40mmHg, p < 0.0001). The NRS average postoperative shoulder pain at H4, H8, and H24 were also significantly lower in the 7mm Hg group. Almost half of the patients operated on at low pressure (46.7 per cent) considered that discharge on the same day of surgery was possible, compared to 23% in patients operated at standard pressure (p = 0.058).

	AirSeal® 7mmHg	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)	0.2
Operative time (in minutes)			
Median (range)	26 (9-83)	30 (10-85)	0.55
Operative versus only diagnosis laparoscopy	19/30 (76.2%)	22/30 (66.6%)	0.48



	AirSeal® 7mmHg	Standard 15 mmHg	p
Max Peak Airway Pressure			
Median (range)	18 (14-35)	24 (17-31)	< 0.0001
End tidal CO₂ max			
Median (range)	36 (31-41)	40 (33-46)	<0.0001
Max Systolic Blood Pressure			
Median (range)	115 (96-138)	129 (105-160)	0.002

	AirSeal® 7mmHg	Standard 15 mmHg	p
NRS shoulder pain at H4			
Médiane (Min-Max)	0.8 (0-7)	2.1 (0-8)	0.004
NRS shoulder pain at H8			
Médiane (Min-Max)	0.7 (0-7)	2.6 (0-10)	0.002
NRS shoulder pain at H24			
Médiane (Min-Max)	0.5 (0-6)	1.5 (0-6)	0.004
Consumption of morphin (%)	3/30 (10 %)	10/30 (33.3%)	0.028
Feel to be discharged ?	14/30 (46.7%)	7/30 (23.3%)	0.058

CONCLUSION

The creation of pneumoperitoneum at low pressure (7mm Hg) during laparoscopy allows a diagnostic and therapeutic laparoscopic surgery to be satisfactory performed with a decrease in post-operative shoulder pain and a significant decrease in end tidal CO₂ and peak airway pressure. These results could facilitate the further development of ambulatory laparoscopy.