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Medico-Economic Impact of the AirSeal® Insufflator: Example of Laparoscopic Sacrocolpopexy

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Abstract

Introduction: AirSeal® is an insufflation system that enables a stable pneumoperitoneum during laparoscopic surgery, thus providing a permanent renewal of the abdominal gas in a closed system. The aim of this study was to evaluate the medical and economic impact of the AirSeal® system for laparoscopic sacrocolpopexy.

Materials and Methods: A preliminary mono-centric retrospective study has been performed during a period of 9 months between May 2019 and February 2020. Post-operative pain was evaluated by a visual analog scale on days 0, 1, and 2. Analgesic and antiemetic use was also collected. The main intraoperative anesthesiologic parameters (morphine and curare doses, peak airways pressure, end-tidal CO_2, and temperature) were also studied. The patient's outing ability was evaluated by the CHUNG score.

Results: Thirty-four consecutive patients treated by laparoscopic sacrocolpopexy have been included in the present study. The first 17 were operated using the AirSeal® system and the other half using a standard insufflating system, by the same surgeon. Mean age was 58.9 ± 12.2 years. Postoperative pain was lower in the AirSeal® system group with 40% of morphinic use *vs.* 52% in the standard system group. The length of stay was also shorter, with 65% of AirSeal® system patients able to leave on an ambulatory basis *vs.* 35% in the second group, and 95% on first day *vs.* 76% in the standard insufflation system group.

Conclusion: These preliminary results may suggest a positive medical and economic impact of the AirSeal® insufflation system by reducing length of stay, postoperative pain and analgesic use.

Keywords: Sacrocolpopexy; Low impact laparoscopy; laparoscopy; Postoperative pain

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Introduction

Laparoscopic sacrocolpopexy is the standard treatment for symptomatic genitourinary prolapse. The laparoscopic approach has revolutionized this technique, already described for many years, thanks to the insufflation of gas into the peritoneal cavity and the creation of a pneumoperitoneum providing a comfortable working space. CO_2 is the most widely used gas, because it is non-expansive, non-flammable, and eliminated by the systemic circulation. [1-3]. The insufflation of gas is usually continued until sufficient abdominal pressure is obtained and is well tolerated by the patient. In addition to creating an adequate workspace, this increase in pressure has a hemostatic role, assists in surgical dissection (pneumodissection), and determines the operating time and the safety of patients during the procedure [1].

A standard insufflator works as a unidirectional flow pump delivering a volume of CO_2 into the abdominal cavity to maintain the pre-determined pressure [4]. Insufflation is cyclical as it stops to perform the pressure sensing function, thereby during a gas leak or aspiration, the workspace collapses until additional gas insufflation restores the space created which could extend the operating time. Besides, the high pressures of the pneumoperitoneum decrease the perfusion pressure of the abdominal organs, but also ventilation and blood flow in the inferior vena cava. Therefore, there are an increased risk of thromboembolism, cardiovascular, respiratory, and metabolic disturbances [1,5].

The AirSeal® system is an intelligent insufflation system (iFS: intelligent Flow System), without a valve, ensuring automatic smoke evacuation. It filters and recycles the gas constantly to the insufflation port thus allows not only to have a stable pneumoperitoneum but also to maintain the intra-abdominal pressure at its lowest effective value throughout the operation [6].

The objective of this study was to assess the medical and economic benefits of using the AirSeal® insufflator through the example of laparoscopic promontofixation.

Materials and Methods

This is a retrospective, single-center comparative study.

Population

All the patients included underwent laparoscopic promontofixation for symptomatic genitourinary prolapse.

The patients included must be over 18 years of age and have symptomatic genitourinary prolapse of stage greater than or equal to 2 according to the international Pelvic Organ Prolapse Quantification (POP-Q) classification.

We excluded patients with a history of pelvic radiotherapy, requiring total hysterectomy at the same time of operation, and also the cases of vaginal or rectal wound occurring during surgery.

Data collection

The data were collected retrospectively on the computerized intra-operative and post-operative data collection software of our center. Intraoperatively, the systematic anesthetic report allows us to exploit data at induction, at the first hour, and then at exsufflation; it concerned the total dose of curare and morphine, arterial pressure, heart rate, peak pressure, $ETCO_2$ (End Tidal CO_2 or CO_2 at the end of expiration), that reflects the absorption of CO_2 by the body, and the temperature. Postoperative pain was assessed by the Visual Analog Scale (VAS) in the hospital ward on day 0, day 1, and day 2, as reported systematically by the service nurse team. Data relating to the administration of analgesics were also collected at the various stages of the hospital stay. The ability to hospital discharge was assessed by Chung's score on day 0, day 1, and day 2. A score greater than or equal to 9 validated this aptitude. This score is based on five parameters: vital constants (temperature, pulse, and breathing), ambulation, nausea, and/or vomiting, pain, intraoperative bleeding.

Ethics

All patients signed a written consent to participate, and the study was approved by the ethics committee and registered under number No. 20.09.03.

Statistical analysis

Qualitative data are expressed as numbers and percentages, and quantitative data as mean and standard deviation or median. Statistical analyzes were performed using BiostaTGV software. Univariate analysis was performed. The Student's t-test was used to compare quantitative variables. A p-value <0.05 was considered statistically significant.

Result

Population

Thirty-four consecutive patients treated with laparoscopic promontofixation were included. The patients were operated on consecutively by the same surgeon over nine months (May 2019 to February 2020). The overall cohort was divided into two subgroups. The first 17 patients were operated on using the AirSeal® system and the next 17 using a standard insufflator.

Two patients from each group underwent laparoscopic promontofixation for recurrent genitourinary prolapse after vaginal surgery.

The characteristics of the population included are shown in Table 1. The mean age at inclusion was 58.9 ± 12.2 years. Twenty-three patients (67.6%) underwent sacrocolpopexy with a single anterior sling, including twelve using the AirSeal® insufflator. Eleven patients (32.3%) received two slings (anterior and posterior); five of them were from the AirSeal® group. Eleven patients (32.3%) underwent associated procedures, including eight sub urethral tension-free vaginal tapes, two subtotal hysterectomies, and one salpingectomy. Twenty-five patients were operated on by conventional laparoscopy and nine by robot-assisted approach.

Intraoperative data

The mean pressure of the intraoperative pneumoperitoneum was 12 mmHg for the patients operated on using a standard insufflator and 7 mmHg (pre-determinate by the surgeon) for the AirSeal® group. The evaluation of the anesthetic parameters objectified a lower mean peak pressure at the first hour for the AirSeal® group (21.5 *vs.* 19.6 CmH_2O) and also at exsufflation (18.5 *vs.* 16.18 Cm H_2O, $p<0.05$). The mean tele-expiratory CO_2 concentration at the first hour was 33 mmHg for the AirSeal® *vs.* 39.5 mmHg group ($p>0.05$). The intraoperative temperature difference between induction and exsufflation was lower for the AirSeal® group (0.3 *vs.* 0.5; $p>0.05$) (Table 2).

Analysis of the surgical parameters revealed a statistically significant, but not clinically consistent difference in the mean operating time, which was less for the AirSeal® group (121 *vs.* 110 min; $p<0.05$). This difference is noticed especially in patients who have benefited from laparoscopic promontofixation by a single anterior strip without associated procedure and this despite the more frequent use of robot-assisted laparoscopic surgery in the standard insufflator group where 8 patients (47%) benefited from robot assistance *vs.* 1 patient (5.8%) for the AirSeal® group. The mean intraoperative blood loss was nearly the same in the two subgroups; 41.5 ml for the AirSeal® group *vs.* 44.7 ml for the standard insufflator group, $p>0.05$ (Table 2).

Medico-economic analysis

The mean duration of hospitalization reported in the aftermath of laparoscopic promontofixation is 2.37 days. The overall average cost of a laparoscopic sacrocolpopexy is estimated by the HGP (Homogeneous Group of Patients) 13C041 at €2,867.05. The pricing of one night of hospitalization is 1350€.

Table 1: Characteristics of patients.

Parameters	Standard insufflator	AirSeal® insufflator
Number of patients	17 (50%)	17 (50%)
Mean age (years)	58 ± 13.6	56 ± 10.16
Mean BMI (Kg/m²)	25.18	24.13
Single Anterior sling	11 (64.7%)	12 (70.5%)
Double slings (Anterior and posterior)	6 (35.2%)	5 (29.4%)
Associated procedures	6 (35.2%)	5 (29.4%)
Sub-urethral sling (TVT)	3	5
Sub total hysterectomy	2	0
Salpingectomy	0	1
Tubal ligature	1	0
Conventional laparoscopy	9 (52.9%)	16 (94.1%)
Robot assisted laparoscopy	8 (47.05%)	1 (5.8%)

Table 2: Intra-operativeresults.

Parameters		Standard insufflator	AirSeal® insufflator	P Value
Operating time (min)		121	110	<0.05
(For a single anterior sling procedure)				
Mean pneumoperitoneum (mmHg)		12	7 (pre-determinated)	1
Intraoperative complications		0	0	
Blood loss (ml)		44.7	41.5	0.7
Anesthetic parameters				
At the induction	Peak pressure (CmH_2O)	17	15.4	0.9
	$ETCO_2$ (mmHg)	34.5	34.02	0.92
	Temperature (C)	35.3	35.7	1
A the first hour	Peak pressure (CmH_2O)	21.5	19.6	0.15
	$ETCO_2$ (mmHg)	39.5	33	0.65
	Temperature (C)	35.35	35.55	<0.05
	Arterial pressure (CmHg) (systolic/diastolic)	112.5/63.58	113.94/64.41	0.82
	Heart rate (bats/min)	66.05	61.11	0.18
At the exsufflation	Peak pressure (CmH_2O)	18.5	16.18	<0.05
	$ETCO_2$ (mmHg)	37.75	37.5	0.87
	Temperature©	34.7	35.25	0.32
	Arterial pressure (CmHg) (systolic/diastolic)	104.52/60.47	103.52/61.11	0.79
	Heart rate (bats/min)	67.5	66	<0.05

Table 3: Evaluation of postoperative parameters.

Postoperative parameters		Standard insufflator	AirSeal® insufflator	p value
Results in day 0	Mean VAS	4.7	3.58	0.23
	Use of morphinics	6 (35.2%)	4 (23.5%)	0.45
	Use of level II analgesics	4 (23.5%)	4 (23.5%)	-
	Use of level I analgesics	8 (47.05%)	4 (23.5%)	0.1
	Nausea - Vomiting	4 (23.5%)	2 (11.7%)	0.2
	Chung score	7	8.5	0.07
	Ability to exit at day 0	7 (41.1%)	12 (70.58%)	0.07
Results in day 1	Mean VAS (MD=4)	1.41 (MD=2)	0.94 (MD=2)	0.5
	MD (Missing Data)			
	Use of morphinics	0	0	-
	Use of level II analgesics	2 (11.7%)	0	-
	Use of level I analgesics	4 (23.5%)	6 (35.2%)	0.2
	Nausea - Vomiting	0	0	-
	Chung score	9.41	9.76	0.11
	Ability to exit at day 1	15 (88.2%)	16 (94.11%)	0.11

Among the seventeen patients in the AirSeal® group, twelve patients could have been discharged on day 0, four on day 1, and only one on day 2. Using the AirSeal® insufflation system could save 46,291€.

The cost of the AirSeal® trocar is 183€ and the filtered tube with 3 lumens at 192€, for a total of 375€ tax included per patient. The price of a standard trocar is 43.20€ and the insufflation tubing at 3.3€ tax included. The additional cost caused by the use of the AirSeal® system is therefore estimated at 328.50€ per intervention.

In the standard non-AirSeal® group, seven patients could have been discharged on day 0 *vs.* twelve patients in the AirSeal® group, which means that 70.58% of outpatient discharges facilitated by the use of the AirSeal® system (Table 3).

The reduction in the hospital length of stay could allow to save 1,350€ per patient and per night of hospitalization, which offsets the additional cost of 328.50€ for the consumable products of the AirSeal® insufflator.

The difference in the use of analgesics and antiemetics was not included in this analysis.

Discussion

To our knowledge, this is the first study comparing the impact of

the AirSeal® insufflation system during laparoscopic sacrocolpopexy.

Two prospective randomized studies conducted by Topcu et al. [7] and by Sroussi et al. [8] including 150 and 60 patients respectively, compared laparoscopy with low-pressure insufflator (8 mmHg) and standard (12 mmHg to 15 mmHg), in gynecological surgery [7,8]. However, the authors did not include any patients who had undergone promontofixation. These studies demonstrated a statistically significant difference in terms of postoperative pain in favor of the Airseal® system. Besides, Sroussi et al. [8] have also demonstrated a significant gain in terms of opioid consumption.

This impact on postoperative pain and the consumption of analgesics has also been evaluated in digestive surgery in various studies [9-11], as well as in a Cochrane meta-analysis dating from 2009 [12].

The results of all of these studies are consistent with ours, reporting a 12% decrease in opioid consumption on day 0 compared to the standard insufflator and a lower visual analogical scale for pain on day 0 and day 1 for the AirSeal® group (3.5 *vs.* 4.7 at day 0 and 0.94 *vs.* 1.4 at day 1).

The physiological changes and the pathophysiological phenomena accompanying the creation and maintenance of pneumoperitoneum during laparoscopic procedures depend essentially on the intra-abdominal pressure used and the duration of the operation [13]. Different factors can be implicated in the pathophysiology of postoperative pain; in gynecological surgery, the explanation of shoulder pain is complex. It may be due not only to the operating position but also to stretching or even to diaphragmatic muscle lesions related to CO_2 pressure and compounded by the Trendelenburg position [11,14-16]. This difference in terms of postoperative pain and analgesic consumption between the two modes of insufflation could be explained by the decrease in insufflation pressure.

Eligibility for discharge was assessed by the Chung score. Our results show a higher exit aptitude for patients in the AirSeal® group on day 0 and day 1. This not statistically significant difference is possibly related to a lack of statistical power in our study. The literature comparing Chung scores in the two groups is very limited, however, some parameters of this eligibility score for hospital discharge have been compared, in particular the variations in vital, hemodynamic, and respiratory constants.

Sroussi et al. [8] observed a lower variation in systolic blood pressure for the AirSeal® group (115 mmHg *vs.* 129 mmHg; p=0.002), as well as for peak pressure and ETCO2. This is due to lower CO_2 consumption and absorption in the AirSeal® system [17,18]. In addition to the decrease in ETCO2, this low absorption would also reduce the risk of subcutaneous emphysema [19]. La Falce et al. [4] also demonstrated the safety of the AirSeal® system, responsible for a lesser magnitude of cardiovascular changes. This difference could have a limited clinical impact, but it has more interest in patients with cardiovascular and respiratory comorbidities.

There is no study evaluating the economic impact of the AirSeal® insufflation system. The results of our economic analysis objectify an additional cost of 328.5€ tax included offset by the reduction in the length of stay; however, this analysis did not include the difference in the consumption of analgesics and antiemetics and must be balanced with patient comfort.

The evaluation of the impact of the AirSeal® system on the operating time is very controversial in the literature. Our results showed a slightly shorter operating time for the AirSeal® group (12 min difference on average for the patients who received a single anterior sling, not clinically significant). These results are in agreement with several studies, particularly in gynecological surgery for benign pathology, in renal surgery, or even in colorectal surgery [18-21]. Most of these studies have linked this advantage to less handling of the AirSeal® trocars during surgery and also to more efficient smoke evacuation [17]. Nevertheless, other authors have not objectified an impact on the operating time [6,7]. Horstmann et al. [6] conducted a prospective study including thirty-six patients who underwent radical prostatectomy for cancer by robot-assisted laparoscopy and did not find a significant difference in the duration of the operation.

In addition to its medical and economic impact, the AirSeal® system could also have an interesting health impact given the current context of the coronavirus pandemic. The use of low pneumoperitoneum pressure and the Intelligent Access System (iFS) is recommended by many learned societies during a COVID-19 pandemic. Indeed, there is a risk of aerosolization of the virus which imposes the limitation of gas leaks, the use of a fume suction system and a filter system preventing the passage of the virus and limiting the risk of contamination for nursing and medical staff [22-24].

Our study, the first to evaluate the AirSeal® system in laparoscopic promontofixation, has some limitations; the small number of patients included makes it a low-power study and could not allow us to make conclusions. Its retrospective and non-randomized methods are methodological weaknesses requiring confirmation of these preliminary results in larger studies with a better level of proof. The non-inclusion of the consumption rate of CO_2, analgesics, and antiemetics in the economic analysis requires a dedicated study with a more precise calculation.

Conclusion

These preliminary results seem to suggest a favorable medico-economic impact of the AirSeal® insufflation system, with a reduction in the length of stay, and a reduction in postoperative pain, and the consumption of analgesics and antiemetic drugs. They need to be confirmed by more powerful studies with a better level of evidence. Following recommendations during the COVID-19 epidemic, AirSeal® also protects nursing and medical staff through continuous filtration of fumes during laparoscopic procedures.

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