

Impact of insufflator/aspirator versus exclusive insufflator during robotic radical prostatectomy: a comparative prospective cohort study

Hugo Otaola-Arca, MD, PhD^{a,c,*}, Orlando Mejías, MD^{a,c}, Juan Cristóbal Bravo, MD^c, Rodrigo Pinochet, MD^{a,c}, Pablo Bernier, MD^{a,c}, Lorena Muñoz, MD^{b,c}, Marcelo Orvieto, MD^{a,c}

Background: New generation devices that combine high-flow insufflation with smoke aspiration using continuous gas recirculation]so-called Insufflator/aspirator systems (IAS)] have recently been developed to generate pneumoperitoneum. The use of an IAS could have an impact on surgical compared to conventional insufflation systems (CIS). The present study aimed to compare the clinical effectiveness/safety, healthorganizational, and pathological/oncological outcomes of the CIS versus IAS during robot-assisted radical prostatectomy (RARP).

Methods: Comparative retrospective cohort study including patients with non-metastatic prostate cancer treated with RARP by four expert surgeons at a robotic referral centre between January 2020 and December 2021. A CIS was used until 15 March 2021, and the IAS thereafter. Data were extracted from the Institutional Review Board-approved (#1064) retro and prospective institutional database.

Results: The final analysis included 299 patients (143 CIS; 156 IAS). We found no statistically significant differences in demographic data and preoperative results, allowing adequate group comparison. The rate of complications of any degree (9.1% and 1.9%, P < 0.05) and major complications (4.2% and 0.6%, P < 0.05) were lower in the IAS group. Accordingly, the hospital stay was shorter in the IAS group (P < 0.05); however, the small size of this statistically significant difference probably lacks clinical value (1.9 ± 1.6 vs. 1.6 ± 0.8 days). There was no significant difference in surgical time, bleeding, pathological findings, or oncological results.

Conclusions: Data from this large group of patients showed that the rate of overall complications, the rate of major complications, and the length of stay were lower in the IAS group. Implementing the IAS in RARP patients increased the occurrence of SCE and affected our daily practice of transversus abdominis plane block. Interpretation of the results should be made with caution since the design of this study did not allow for the identification of a causal relationship.

Keywords: artificial pneumoperitoneum, prostate cancer, prostatectomy, robotic-assisted surgery, technology assessment

Introduction

Robot-assisted radical prostatectomy (RARP) is the most frequently performed robotic-assisted surgery in urology^[1]. Currently, most teams prefer the transperitoneal over the retroperitoneal approach because of the more extensive surgical space and the easier and faster access^[2]. Yet, like all laparoscopic

^aDeparment of Urology, Clínica Alemana de Santiago, ^bDepartment of Anesthesiology, Clínica Alemana de Santiago and ^cFaculty of Medicine, Clínica Alemana-Universidad del Desarrollo, Santiago, Chile.

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

*Corresponding author. Address: Department of Urology, Clínica Alemana, Avda. Manquehue Norte 1410, Piso 12, Vitacura, Región Metropolitana, Santiago, Chile. Tel: +56222101111. E-mail address: hugotaolarca@hotmail.com (H. Otaola-Arca).

Copyright © 2023 The Author(s). Published by Wolters Kluwer Health, Inc. This is an open access article distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as the author is credited and the new creations are licensed under the identical terms.

Annals of Medicine & Surgery (2023) 85:1480-1485

Received 29 October 2022; Accepted 18 March 2023

Published online 19 April 2023

http://dx.doi.org/10.1097/MS9.000000000000512

HIGHLIGHTS

- Laparoscopic procedures require the creation of pneumoperitoneum by gas insufflation.
- Conventional insufflation systems allow the surgeon to set a target intra-abdominal pressure.
- Insufflator/aspirator systems (IAS) allow also smoke aspiration.
- IAS may lead to a lower rate of postoperative complications in patients subject to robot-assisted radical prostatectomy (RARP).
- IAS may lead to a shorter length of stay in patients subject to RARP.

procedures, transperitoneal RARP requires the creation of pneumoperitoneum by insufflation of carbon dioxide (CO₂) that allows for the normal development of the surgical space. In addition, maintaining a steady intra-abdominal pressure is related to lower intraoperative bleeding during RARP than in open surgery, especially during transection of the dorsal venous complex (DVC)^[3]. More importantly, this is also crucial to minimize the risks of intraoperative complications related to sudden loss of pneumoperitoneum.

The conventional Insufflation System (CIS) allows the surgeon to set a target intra-abdominal pressure (usually 12–15 mmHg),

Supplemental Digital Content is available for this article. Direct URL citations are provided in the HTML and PDF versions of this article on the journal's website, www. annalsjournal.com.

after which the system will automatically adjust the CO_2 flow to keep a stable pneumoperitoneum pressure. However, several intraoperative factors, such as the presence of a gas leak, migration of a trocar, or the use of a suction device—frequently utilized by the assistant to aspirate blood or smoke from the surgical field —, may exceed the insufflation recovery capability of CIS, leading to sudden gas loss^[4]. As a solution to this problem, new generation devices that combine high-flow insufflation with smoke aspiration through the use of continuous gas recirculation (socalled Insufflator/Aspirator Systems (IAS)^[2,4] have recently been developed.

The present study aimed to compare the clinical effectiveness/safety, health organizational, and pathological/oncological outcomes of the CIS versus IAS during RARP.

Materials and methods

Study design and patient selection

Between January 2020 and December 2021, all RARPs for nonmetastatic prostate cancer performed by four experienced surgeons at a single tertiary robotic referral centre were registered in a comparative retrospective cohort study. A CIS was utilized on all RARP cases performed through March 15, 2021. Subsequently, the Airseal system (SurgiQuest—CONMED Corporation) was used as an IAS. Only patients with a minimum follow-up of greater than or equal to 3 months were included. Patients who did not have the minimum necessary information were excluded from the study.

Surgical technique

All surgeries were performed with a da Vinci Si Surgical System (Intuitive Surgical) using a six-port configuration (four ports for the robotic arms and two as assistant's ports). A transperitoneal approach was used, with Trendelenburg angulation (23°) and the lowest intra-abdominal pressure (between 12 and 15 mmHg) offering adequate operative field exposure. Extended pelvic lymphadenectomy was performed prior to the prostatectomy in patients with a Briganti score (2018) greater than 7%^[5]. RARP continued with bladder descent, bladder neck incision, and dissection of the seminal vesicles. After opening Denonvilliers' fascia, athermal dissection of the neurovascular bundles was performed, with different degrees of preservation according to tumour stage.

Subsequently, prostatic pedicles were clipped and transected, preserving the endopelvic fascia. After transecting the DVC, the prostatic apex was dissected, and the anterior aspect of the urethra was sectioned. At this point, the DVC was controlled with a 3/0 barbed running suture, and the posterior aspect of the urethra was subsequently divided. Next, local haemostasis at the prostatic fossa was performed based on the surgeon's criteria. Finally, the urinary tract was reconstructed with a modified Rocco stitch and vesicourethral anastomosis with a modified van Velthoven technique over a 20 Ch foley catheter. We do not use routine abdominal drainage. Hospital discharge is planned 24–48 h after surgery when the patient has pain control with oral painkillers, has transit for gases, wanders around the unit, and the laboratory exams lack signs of bleeding or acute renal failure. Supplementary table 1, Supplemental Digital Content 1 http:// links.lww.com/MS9/A82 describes the postoperative management of patients.

In our centre, patients were managed according to a wellestablished Enhanced Recovery After Surgery (ERAS) protocol that included an ultrasound-guided transversus abdominis plane (TAP) block. TAP block was performed with a solution composed of 100 mg Bupivacaine 0.25% (40 ml) and one mcg/Kg dexmedetomidine (Precedex. Pfizer), injecting half on each side. As successfully reported by Sawczyn *et al.*^[6], we pretend opioidfree management after RARP.

Variables

Data were extracted from the IRB-approved retro and prospective institutional database. In addition, preoperative data [age, American Society of Anesthesiologists (ASA) score, comorbidities, BMI, prostate-specific antigen (PSA), the density of PSA, MRI results, clinical International Society of Urological Pathology (cISUP) grade groups, Briganti 2018 score, and clinical Tumour, Node, Metastasis (cTNM) stage], clinical effectiveness/safety outcomes [intraoperative estimated blood loss (EBL), transfusion rate, use of drainage, conversion to open surgery rate, postoperative complications according to Clavien-Dindo system^[7], and readmission and reoperation rates at 30 days], health-organizational outcomes [operative time (OT) (skin to skin) and length of stay] and pathological/oncological outcomes [pathological ISUP (pISUP), pathological TNM (pTNM) stage, number of resected and positive lymph nodes, and status of the margin in the surgical specimen] were used.

Statistical analysis

Categorical variables were described with absolute numbers and proportions; quantitative variables with mean, standard deviation (SD), and range (minimum-maximum). The normal distribution of quantitative variables was assumed due to the sample size. As appropriate, the analysis was performed using χ^2 /Fisher's exact test or Student's *t*-test.

Statistical significance was set as a two-tailored *P* less than 0.05. Statistical analysis was performed using IBM SPSS Statistics v25 (Armonk, NY: IBM Corp).

Ethical issues

The study was approved by the Clinical Research Ethics Committee (#1064) and conformed to provisions of the Declaration of Helsinki. All included patients sign the informed consent. The work has been reported in line with the STROCSS 2021 criteria^[8], Supplemental Digital Content 2, http://links. lww.com/MS9/A51.

Results

The final analysis included 299 consecutive patients undergoing RARP; 143 were performed with the CIS and 156 with IAS (Supplementary Fig 1, Supplemental Digital Content 3, http://links.lww.com/MS9/A52).

Demographic and preoperative data were summarized in Table 1. In the CIS and IAS groups, the mean age at surgery was 64.7 (SD 7.1) and 66.8 years (SD 7.1). Most patients were ASA I–II (95.8% and 96.8%), and the mean BMI was 27.3 (SD 3.2) and 27.3 kg/m² (SD 3.7) for each group, respectively. The mean

Variables		CIS (<i>n</i> =143)	IAS (<i>n</i> =156)	P
Age (years), mean \pm SD (m	in–max)	64.7 ± 7.1	66.8 ± 7.1	0.08
		(44-83)	(47–81)	
ASA score, n (%)	1	20 (14.1)	19 (12.2)	0.70
	11	116 (81.7)	132 (84.6)	0.78
Body mass index (kg/m²), m		6 (4.2) 27.3 <u>+</u> 3.2	5 (3.2)	0.83
(min-max)	10011 ± 30	(20.2–37.5)	27.3 ± 3.7 (11.4–42)	0.05
(/	ain may	(20.2-37.5) 7.4 ± 5.7	(11.4-42) 7.5 ± 6.3	0.85
PSA (ng/ml), mean \pm SD (n	nin—max)	(1.6-40.6)	(1.1–64.3)	0.00
PSA density (ng/ml ²), mear		(1.0-40.0) $0.2 \pm 0.2 (0-1.4)$		0.58
(min-max)	1±3D	0.2 ± 0.2 (0-1.4)	0.2 ± 0.1 (0-0.8)	0.00
Prostate volume on MRI (ml),		45.4 ± 17.2	47.1 ± 20.4	0.52
mean \pm SD (min–max)		(21-91)	(21-153)	
Lesion size on MRI (mm), m (min–max)	nean ± SD	12.3±6.5 (4-37)	13.6 ± 7 (4–41)	0.13
Extra prostatic involvement on MRI, <i>n</i> (%)	No	113 (85.0)	122 (82.4)	0.56
	Yes	20 (15.0)	26 (17.6)	
PI-RADS, <i>n</i> (%)	2	2 (1.5)	2 (1.3)	0.72
	3	21 (15.3)	17 (11.2)	
	4	74 (54.0)	83 (54.6)	
	5	40 (29.2)	50 (32.9)	
cISUP, <i>n</i> (%)	1	35 (24.6)	26 (16.8)	
	2	55 (38.7)	66 (42.6)	
	3	29 (20.4)	41 (26.5)	0.29
	4	6 (4.2)	9 (5.8)	
	5	17 (12.0)	13 (8.4)	
Briganti (%), mean \pm SD (min–max)		10.0 <u>+</u> 15.4	10.9 <u>+</u> 17.0	0.68
		(1.4-86.1)	(1.5–82.6)	
cT, <i>n</i> (%)	cT1	110 (76.9)	120 (76.9)	
	cT2	23 (16.1)	34 (21.8)	0.06
	cT3a	6 (4.2)	1 (0.6)	
	cT3b	4 (2.8)	1 (0.6)	
cN, <i>n</i> (%)	cN0	137 (95.8)	150 (96.2)	0.87
	~N14	0 (4 0)	C (O O)	

ASA, American Society of Anesthesiologists; cISUP, clinical International Society Urological Pathology; CIS, conventional insufflation systems; cN, clinical stage of the regional lymph nodes; cT, clinical stage of the primary tumour; IAS, insufflator/aspirator systems; Max, maximum value; Min, minimum value; PI-RADS, prostate imaging-reporting and data system; PSA, prostate-specific antigen.

6 (4.2)

6 (3.8)

cN1

preoperative PSA was 7.4 (SD 5.7) and 7.5 ng/mL (SD 6.3), and the mean prostate volume on MRI of 45.4 (SD 17.2) and 47.1 mL (SD 20.4). Prostate Imaging Reporting & Data System (PI-RADS) 4 (54%) and cISUP 2 (38.7%) were the most frequent findings in the CIS group. In this group, the mean Briganti score was 10.2% (SD 15.4), the majority of patients were cT1 (76.9%), and six patients were cN1 (4.2%). Similarly, in the IAS group, most patients presented with PI-RADS 4 (54.6%) and ISUP 2 (42.6%) disease. Within this group, the mean Briganti score was 10.9% (SD 17), most patients were cT1 (76.9%), and six patients were cN1 (3.8%). We found no statistically significant differences in demographic data and preoperative results, allowing for adequate group comparison.

Clinical effectiveness/safety and health organizational outcomes

Effectiveness and organizational outcomes are listed in Table 2. The mean EBL [CIS: 394.8 (SD 225.0); IAS: 366.5 ml (SD 221.8)] and the blood transfusion rate (0.7% and 0.6%, respectively) were comparable between both groups.

Variables		CIS (<i>n</i> = 143)	IAS (<i>n</i> = 156)	Р
Clinical effectiveness/safety	outcomes			
Estimated blood loss (ml), r (min–max)		394.8 <u>+</u> 225.0 (100–1,500)	366.5 <u>+</u> 221.8 (50–1500)	0.274
Blood transfusion, n (%)	No Yes	142 (99.3) 1 (0.7)	155 (99.4) 1 (0.6)	1.000
Conversion to open surgery, n (%)	No	143 (100.0)	156 (100.0)	1.000
	Yes	0	0	
Use of intra-abdominal drainage, n (%)	No	143 (100.0)	156 (100.0)	1.000
	Yes	0	0	
Postoperative complications, n (%)	No	130 (90.9)	153 (98.1)	0.005
	Bleeding	1 (0.7)	2 (1.3)	
	Arrhythmia	1 (0.7)	0	
	Constipation	1 (0.7)	0	
	Incisional hernia	2 (1.4)	0	
	Hyponatremia	0	1 (0.6)	
	Small bowel perforation	1 (0.7)	0	
	Acute urinary retention	6 (4.2)	0	
	Deep venous thrombosis	1 (0.7)	0	
Postoperative complications: Clavien, n (%)	Minor (Clavien I–II)	7 (4.9)	2 (1.3)	0.021
(··)	Major (Clavien III–IV)	6 (4.2)	1 (0.6)	
Readmission \leq 30 days, <i>n</i> (%)	,	140 (97.9)	155 (99.4)	0.352
	Yes	3 (2.1)	1 (0.6)	
Reoperation \leq 30 days, <i>n</i> (%)	No	141 (98.6)	155 (99.4)	0.608
	Yes	2 (1.4)	1 (0.6)	
Health-organizational outco Operative time (min), mean		199.8 ± 52.3	191.3 ± 51.4	0.158
		(90-360)	(60-340)	
Length of stay (days), mear (min-max)	ı±SD	1.9 ± 1.6 (1–19)	· /	0.020

Clinical effectiveness/safety and health organizational outcomes.

Table 2

CIS, conventional insufflation systems; IAS, Insufflator/Aspirator Systems; Max, maximum value; Min, minimum value.

In the CIS group, 13 patients (9.1%) had postoperative complications, six of them (4.2%) majors: three (2.1%) Clavien III (deep venous thrombosis treated with anticoagulants in one patient; two patients required reintervention because of incisional hernia) and three (2.1%) Clavien IV (one bleeding treated with blood transfusion, arterial embolization, and exploratory laparoscopy; one paroxysmal supraventricular tachycardia due to unknown preexisting intranodal reentry treated with cardioversion; and one small bowel perforation secondary to intense adhesiolysis prior to prostatectomy, treated conservatively in an intensive care unit). Conversely, in the IAS group, only three patients (1.9%) had postoperative complications, and only one (0.6%) of them was major: one patient developed a pelvic haematoma treated with laparoscopic drainage (Clavien III). No Clavien IV complications were registered in the IAS group. Thus, the proportion of patients with complications of any degree and

Variables		CIS (<i>n</i> = 143)	IAS (<i>n</i> = 156)	Р
Tumour volume (ml) (min–max)	$\text{mean} \pm \text{SD}$	4.0±5.0 (0.1-44.5)	4.6±5.4 (0.2–43.1)	0.381
pISUP, <i>n</i> (%)	1	4 (2.8)	4 (2.6)	
	2	73 (51.0)	75 (48.1)	
	3	46 (32.2)	54 (34.6)	0.953
	4	6 (4.2)	5 (3.2)	
	5	14 (9.8)	18 (11.5)	
pT, <i>n</i> (%)	pT2	107 (74.8)	107 (68.6)	
	pT3a	24 (16.8)	28 (17.9)	0.333
	pT3b	12 (8.4)	21 (13.5)	
pN, <i>n</i> (%)	pNx	85 (59.4)	94 (60.3)	
	pN0	43 (30.1)	45 (28.8)	0.971
	pN1	15 (10.5)	17 (10.9)	
Resected nodes (numeration mean ± SD (min-		24.5 ± 9.3 (11–45)	21.7 ± 9.2 (9–54)	0.107
Positive nodes (num mean ± SD (min-	ber),	1.1 ± 2.7 (0–13)	0.7 ± 2 (0-14)	0.348
Margin status, n (%)		86 (60.1) 21 (14.6)	95 (60.9) 23 (14.7)	0.893

CIS, conventional insufflation systems; IAS, insufflator/aspirator systems; Max, maximum value; Min, minimum value; pISUP, pathological International Society Urological Pathology; pN, pathological stage of the regional lymph nodes; pT, pathological stage of the primary tumour.

major complications was statistically higher in the CIS group (P = 0.005 and P = 0.021).

Readmission and reoperation rates were 2.1% and 1.4% for the CIS group and 0.6% and 0.6% for the IAS group; we found no statistically significant differences between groups.

The mean operative time was 199.8 (SD 52.3) in the CIS and 191.3 min (SD 51.4) in the IAS group, with no statistically significant differences between the two groups. However, the mean length of stay was, on average, 0.3 days longer in the CIS group [1.9 (SD 1.6) in the CIS and 1.6 d (SD 0.8) in the IAS group], being this difference statistically significant (P = 0.020).

Pathological/oncological outcomes

Pathological data are registered in Table 3. Final pathology revealed acinar adenocarcinoma of the prostate in all patients. In the CIS and IAS groups, most tumours were classified as pT2 (74.8% and 68.6.3%, respectively). The most common pISUP grade group found in both groups on the prostatectomy specimen was pISUP 2 (51% and 48.1%, respectively). In the CIS and IAS group, 58 (40.6%) and 62 patients (39.7%) were subjected to extended pelvic lymphadenectomy, with a positive lymph node rate of 25.9% and 27.4%, respectively. Furthermore, 21 and 23 patients had a PSM (14.6% and 14.7%, respectively). Regarding pathology findings, we found no statistically significant differences between groups.

Discussion

The AirSeal system is an "intelligent" flow system that supplies high-flow insufflation, stable pneumoperitoneum, valveless trocar access, constant smoke evacuation, and a clear operating field. A three-component integrated system (a console, the access port, and the tri-filtered tube set) grants these features through high-flow and pressure-sensing capabilities.

A series of high-pressure nozzles placed within the trocar direct a downward pressure of CO2 equal to the intra-abdominal pressure set by the surgeon. This technology creates an invisible and horizontal barrier inside the trocar that instantly responds to changes in the intra-abdominal pressure, either by allowing more CO_2 inflow when the pressure drops or by serving as a pressure relief valve during pressure spikes. Hence, it provides at the same time to evacuate the intra-abdominal gas (CO2 and smoke), filter (0.01-micron pore), and recirculate it. In addition, this valve-free design provides smudge-free scope insertion (when used as the scope port), intact specimen removal, and unimpeded introduction of sutures, needles, or clips. Colorectal, gallbladder, hernia repair, and kidney surgery have reported these benefits^[5,9]. Finally, it should be noted that the trocar utilized for insufflation has small lateral holes near the tip through which the air is expelled; to guarantee the correct function of the trocar, the black dotted line located just above the holes must always be visible from the intra-abdominal cavity (Fig. 1 A).

The present study assessed the CIS versus IAS during RARP regarding clinical effectiveness/safety, health organizational, and pathological/oncological outcomes. Data from our large study found a statistically significant difference in clinical effectiveness/safety, specifically in the rate of complications of any

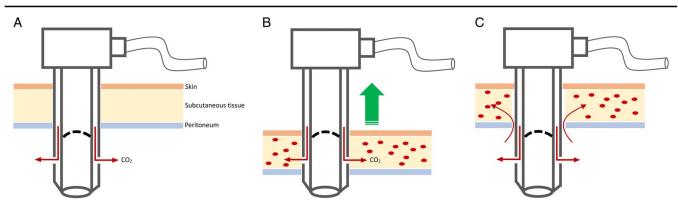


Figure 1. Access port. (A) The access port was correctly positioned, allowing the AirSeal system normal function. (B) The access port was accidentally externalized beyond the black line, which would produce the injection of CO_2 directly into the subcutaneous cellular tissue. (C) The access port was correctly positioned, but the high flow and pressure generated by the AirSeal system would facilitate the diffusion of CO_2 around all the abdominal trocars because of too large orifices in the abdominal wall or by the fulcrum exerted on the abdominal wall.

 Table 4

 Advantages and disadvantages of insufflation-aspiration system.

Advantages	Disadvantages	
Lower rate of complications	Takes up more space in the operating room	
Lower hospital stays	Decreases the duration of TAP block in the postoperative period	
Lower indirect costs	Higher direct costs	
Lower contagion of health personnel	Higher rate and severity of subcutaneous emphysema	
Greater safety in an academic environment		

TAP, transversus abdominis plane.

degree and major complications that were seven times lower in the IAS (AirSeal) group. According to the theoretical benefits of IAS, the lower rate of complications could be due to less bleeding leading to better surgical field visualization. However, the EBL and the transfusion rate in our sample were comparable. Thus, we could not explain the higher incidence of arrhythmias, constipation, incisional hernia, deep venous thrombosis, and acute urinary retention found in the CIS group.

Due to the higher occurrence of postoperative complications in the CIS group, the hospital stay was also longer; however, the small size of this statistically significant difference probably lacks clinical value. Concerning histological findings and oncological outcomes, no differences were found.

Luketina *et al*^[10]. showed in an randomized clinical trial (RCT) that the use of the AirSeal® system in cholecystectomy, colorectal surgery, and hernia repair did not reduce operative time and was associated with higher postoperative shoulder pain compared to standard CO₂ insufflator. Annino *et al*^[11]. showed preliminary outcomes of an RCT where using AirSeal® during robot-assisted partial nephrectomies improved overall operative time and decreased warm ischaemia time.

Three non-RCT investigated the impact of the use of AirSeal in RARP. Horstmann *et al*^[4]. found a more stable pneumoperitoneum during surgery than Versaport Plus V2. George *et al*^[12]. and Shahait *et al*^[13]. found that the use of AirSeal® was associated with shortened operative times. The latter also found minor postoperative pain scores and fewer nausea episodes without increasing the 30-day complication rate.

A stable pneumoperitoneum is essential because a sudden loss in intra-abdominal pressure can negatively impact surgical performance by disrupting surgical exposure, increasing the risk of intraoperative complications, and prolonging surgical and anaesthetic time^[14]. Additionally, since the da Vinci system uses trocars fixed to the robotic arms and not the abdominal wall (i.e. they do not have an intra-abdominal balloon), a sudden loss of pneumoperitoneum could unintentionally disengaging the trocars from the abdominal wall while keeping the robotic instruments inside the abdomen, putting the patient's safety at risk. This harmful situation could be triggered by excessive suction by an inexperienced assistant during the procedure. Thus, using an IAS may be especially beneficial in academic centres where surgical residents initiate their training in assisting cases.

Additional benefits of using a closed insufflation system like AirSeal would be to reduce CO_2 leakage to the environment and, indeed, to protect healthcare workers in the operating room from air contamination, especially during the COVID-19 pandemic, as recommended by international societies^[15].

The development of subcutaneous emphysema (SCE) is intrinsically related to pneumoperitoneal pressure, which can appear in different degrees. In our series, SCE after RARP with CIS was usually minimal. However, after the implementation of the AirSeal system, the severity of the SCE in our patients increased, including a rare case of massive upper body and cervicofacial SCE with no clinical repercussions.

As mentioned above, we routinely performed a TAP block after completion of the RARP as part of a well-established ERAS protocol. However, since the introduction of the AirSeal system, we had to switch and perform the blockage before RARP because the increased incidence of SCE led to considerably worsened ultrasound visualization of the anatomical landmarks necessary to perform the TAP block. Hence, we had to relinquish some hours of postoperative TAP analgesia since a portion of the medication used was consumed during the surgical act. We believe that the increased severity of SCE in our patients undergoing RARP with the AirSeal® system was attributable to two factors. On the one hand, the insufflation port could be accidentally externalized beyond the black line, which would produce the injection of CO₂ directly into the subcutaneous cellular tissue (Fig. 1 B). On the other hand, the high-flow and high pressure generated by the AirSeal system would facilitate the diffusion of CO₂ around all the abdominal trocars because of too large orifices in the abdominal wall or by the fulcrum exerted on the abdominal wall (Fig. 1 C).

Although we did not conduct a formal economic analysis, we found a higher direct cost of using AirSeal®. The estimated cost of the tube plus the access port used with the CIS was 67,000 CLP (80 US\$ approx.). Within the IAS, instead, the set of Tri-Lumen filter (ASM-EVAC) and the ad hoc access port (iAS12-100LPi) increased the total costs to 200,000 CLP (240 US\$ approx.), which stands for an additional expense of US\$ 160 approximately for the patient. Nevertheless, this study did not evaluate the overall indirect savings due to a lower complication rate in the IAS group.

Table 4 summarizes the main advantages and disadvantages of using AirSeal as an IAS during RARP found in our study.

This work represents one of the most extensive series assessing the impact of an IAS, like the AirSeal system, and corresponds to a prospective cohort with a standardized technique. However, our study has limitations inherent to non-randomized research. Additionally, the alleged benefits of the IAS, such as better visualization, less need for smoke aspiration, or cleaning of the chamber, could not be objectified in our study through quantitative variables. The study does not include analgesic scales or intestinal motility records. Moreover, as the AirSeal® was introduced later in the series, cumulative experience may account for some differences between the groups. However, when the study was conducted, all participating surgeons had extensive experience performing RARP.

Conclusion

Data from this large group of patients showed that the rate of overall complications, the rate of major complications, and the length of stay were lower in the IAS group. Interpretation of the results should be made with caution since the design of this study did not allow for the identification of a causal relationship. The results must be contrasted in randomized clinical trials. Additional benefits such as lower indirect costs, lower contagion of health personnel, and superior safety in an academic environment could position IAS systems as a better tool during RARP but could not be objectively analyzed in this study. Implementing the IAS in RARP patients increased the occurrence of SCE and affected our daily practice of TAP block.

Consent

All patients signed informed consent.

Sources of funding

NA.

Author contributions

H.O.-A.: conceptualization; data curation acquisition and analysis; writing the original draft; reviewing and editing. O.M.: Data curation acquisition and analysis. J.C.B.: data curation acquisition and analysis. R.P.: reviewing and editing. P.B.: reviewing and editing. L.M.: reviewing and editing. M.O.: reviewing and editing.

Conflicts of interest disclosure

The authors have nothing to disclose.

Research registration unique identifying number (UIN)

- 1. Name of the registry: Research Registry.
- 2. Unique Identifying number or registration ID: researchregistry8210.
- 3. Hyperlink to your specific registration: https://www.resear chregistry.com/browse-the-registry#home/registrationde tails/62fd6fdefbfe600023b5c7c0/.

Provenance and peer review

Not commissioned, externally peer-reviewed.

References

- Mikhail D, Sarcona J, Mekhail M, et al. Urologic robotic surgery. Surg Clin North Am 2020;100:361–78.
- [2] Jones R, Dobbs RW, Halgrimson WR, et al. Single port robotic radical prostatectomy with the da Vinci SP platform: a step by step approach. Can J Urol 2020;27:10263–9.
- [3] Kim J, Garcia-Aguilar J. Minimally invasive surgical techniques for cancers of the gastrointestinal tract: a step-by-step approach. Springer Nat; 2019..
- [4] Horstmann M, Horton K, Kurz M, et al. Prospective comparison between the AirSeal® System valve-less Trocar and a standard VersaportTM Plus V2 Trocar in robotic-assisted radical prostatectomy. J Endourol 2013;27: 579–82.
- [5] Luketina RR, Knauer M, Köhler G, et al. Comparison of a standard CO₂ pressure pneumoperitoneum insufflator versus AirSeal: study protocol of a randomized controlled trial. Trials 2014;15:239.
- [6] Sawczyn G, Lenfant L, Aminsharifi A, et al. Predictive factors for opioid-free management after robotic radical prostatectomy: the value of the SP® robotic platform. Minerva Urol Nephrol 2021;73: 591–9.
- [7] Dindo D, Demartines N, Clavien P-A. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg 2004;240:205–13.
- [8] Mathew G, Agha R. STROCSS Group. STROCSS 2021: strengthening the reporting of cohort, cross-sectional and case-control studies in surgery. Int J Surg Lond Engl 2021;96:106165.
- [9] Paull JO, Parsacandola SA, Graham A, et al. The impact of the AirSeal® valve-less trocar system in robotic colorectal surgery: a single-surgeon retrospective review. J Robot Surg 2021;15:87–92.
- [10] Luketina R, Luketina TLH, Antoniou SA, et al. Prospective randomized controlled trial on comparison of standard CO₂ pressure pneumoperitoneum insufflator versus AirSeal®. Surg Endosc 2021;35:3670–8.
- [11] Annino F, Topazio L, Autieri D, et al. Robotic partial nephrectomy performed with Airseal versus a standard CO₂ pressure pneumoperitoneum insufflator: a prospective comparative study. Surg Endosc 2017;31:1583–90.
- [12] George AK, Wimhofer R, Viola KV, et al. Utilization of a novel valveless trocar system during robotic-assisted laparoscopic prostatectomy. World J Urol 2015;33:1695–9.
- [13] Shahait M, Cockrell R, Yezdani M, et al. Improved outcomes utilizing a valveless-trocar system during robot-assisted radical prostatectomy (RARP). JSLS 2019;23:e2018.00085.
- [14] Bucur P, Hofmann M, Menhadji A, et al. Comparison of Pneumoperitoneum Stability Between a Valveless Trocar System and Conventional Insufflation: a Prospective Randomized Trial. Urology 2016;94:274–80.
- [15] Porter J, Blau E, Gharagozloo F, et al. Society of Robotic Surgery review: recommendations regarding the risk of COVID-19 transmission during minimally invasive surgery. BJU Int 2020;126:225–34.