



The impact of AirSeal® on complications and pain management during robotic-assisted radical prostatectomy: a single-tertiary center study

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Abstract

Purpose We aimed to compare perioperative outcomes, post-operative complications, and opioid use between AirSeal® and non-AirSeal® robotic-assisted radical prostatectomy (RARP).

Methods We retrospectively collected data on 326 patients who underwent elective RARP at our institution either with or without AirSeal®. The first 60 cases were excluded accounting for the institutions' learning curve of RARP. Patient demographics, oncologic, pathologic, and surgical characteristics between AirSeal® and non-AirSeal® cases were compared. Furthermore, outcomes of interest including operative time, length of stay, morbidity, and opioid use for pain management were compared between the two groups. Univariate linear and logistic regression models were developed.

Results The AirSeal® group consisted of 125 (38.3%) patients while the non-AirSeal® group consisted of 201 (61.7%) patients. No statistically significant difference was seen in terms of patient demographics, oncologic characteristics, surgical characteristics, and pathologic characteristics between the two groups. In addition, univariate linear regression showed that RARP with AirSeal® displayed shorter operative times by 12.3 min and a shorter length of hospital stay by 0.5 days compared to the non-AirSeal® group ($p < 0.001$). Furthermore, the AirSeal® group witnessed lower odds of Clavien-Dindo (CVD) Class > 2 complications (OR = 0.102) and a lower need for opioid use (OR = 0.49) compared to the non-AirSeal® group ($p < 0.022$).

Conclusion RARP using AirSeal® is associated with shorter operative times, shorter length of hospital stays, lower odds of CVD > 2 complications, and lower odds of opioid use with respect to non-AirSeal® RARP. The efficacy and cost effectiveness of using the AirSeal® system during RARP should be further studied and evaluated by clinical trials.

Keywords Prostatectomy · Robotic surgical procedures · Low pressure pneumoperitoneum · Outcomes · Morbidity

Introduction

Prostate cancer (PCa) is the second most frequently diagnosed cancer worldwide and the fifth leading cause of cancer death among men [1]. Treatment strategies for clinically localized PCa include active surveillance, radiation therapy,

cryosurgery, focal therapy, and radical prostatectomy [2, 3]. Minimally invasive (MIS) radical prostatectomy, including laparoscopic and robotic approaches, has been extensively compared to open radical prostatectomy revealing comparable and, in some cases, favorable perioperative outcomes [4, 5]. Compared to open surgery, MIS prostatectomy is associated with better outcomes in terms of nerve sparing, urinary continence, blood loss, as well as lower need for blood transfusion rates and post-operative pain medications [6, 7].

During MIS, pneumoperitoneum is required to create a sufficient workspace between the abdominal wall and intrabdominal organs. AirSeal® is a valveless trocar system that has been recently implemented during MIS such as RARP. AirSeal's trocars and tube sets are made up from three lumens where the first lumen facilitates smoke evacuation

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and filtration, the second one establishes insufflation and real-time pressure control, and the third lumen creates and maintains an invisible air barrier. This system directs carbon dioxide to the abdominal cavity whilst filtering and redirecting any leaking gas back to the cavity leading to a constant intrabdominal pressure throughout the procedure. This maintains the pressure barrier and eliminates smoke. The absence of a physical valve in the AirSeal[®] system allows for easy removal of needles and specimens without obstruction or risk of intraabdominal gas loss [8]. It also prevents smudging from collected moisture and surgical debris. This valve system ensures the maintenance of pneumoperitoneum even during smoke and liquid suctioning. This entails an enhanced surgical visualization during the procedure [9]. The use of AirSeal[®] with laparoscopic and robotic surgeries provided surgeons the ability to operate at lower intra-abdominal pressures without affecting the operative efficiency; in addition, it led to a significant decline in the rates of subcutaneous emphysema and overall post-operative pain [10–12]. In comparison to non-AirSeal[®] insufflators, the use of AirSeal[®] during urological surgeries was shown to improve cardiopulmonary parameters yielding lower inspiratory plateau pressures, minute volumes, CO₂ elimination rates, and end tidal CO₂ levels. It also led to a higher static compliance [13, 14].

This study aims at comparing outcomes including operative time, length of stay, complications severity, and opioid use between AirSeal[®] and non-AirSeal[®] robotic-assisted radical prostatectomy (RARP). To the best of our knowledge, this is the first study to investigate the impact of AirSeal[®] in radical prostatectomy.

Materials and methods

Study design and population

We retrospectively collected data from our institution's electronic health records between July 2013 and January 2022 after receiving Institutional Review Board approval. We selected all patients who underwent elective RARP using the current procedural terminology (CPT) code 55.866. Surgeries were performed by 4 experienced urologists under the supervision of a fellowship trained robotic-urologic oncologist who was present in all cases. Decision towards the use of the AirSeal[®] system was primarily based on funding coverage of the trocar system. During AirSeal[®] cases, pneumoperitoneum is set at 10 mmHg as compared to 12 mmHg for non-AirSeal[®] cases. To note, the learning curve was accounted for by excluding the first 60 cases from the analysis; therefore, data entry started from the 61st case performed at our institution.

Data collection

Patient demographics, oncologic, pathological, and surgical characteristics were collected. 30-day post-operative events were reported. Patient demographics included age, body mass index (BMI), and American Society of Anesthesiologists' (ASA) classification. Oncologic characteristics included preoperative prostate-specific antigen (PSA), clinical oncologic stage based on digital rectal exam (DRE), and pathologic WHO stage and Gleason score based on transrectal ultrasound (TRUS) core biopsies. Pathological characteristics were obtained using the institution's pathology report after prostate removal that included prostate size, tumor volume, extraprostatic extension, seminal vesicle involvement, lymphovascular invasion, perineural invasion, pathological grade and stage assigned in line with the American Joint Committee of Cancer (AJCC) and WHO grade. Surgical characteristics included AirSeal[®] port used (8 or 12 mm), operative time (minutes), length of stay (days), estimated blood loss (cc), surgical margin involvement, and the need for packed red blood cell (pRBC) transfusion. In addition, cases with pre-operative positive lymph nodes were noted. For cases that underwent lymphadenectomy, total number of lymph nodes retrieved, number of positive nodes, and percentage of positive to total lymph nodes was noted.

Post-operative events included post-operative complications categorized according to the Clavien–Dindo grading system, rates of adjuvant androgen-deprivation therapy (ADT) and external beam radiation therapy (EBRT) use either due to surgical margin involvement, PSA persistence, or PSA failure, in addition rates of post-operative administration of chemotherapy was noted. Biochemical recurrence was similarly recorded and defined as post-operative PSA level of ≥ 0.2 ng/ml, with a second confirmatory level exceeding 0.2 ng/ml.

Our institution's post-operative pain protocol includes an as needed intravenous acetaminophen administration as a first line analgesic. If pain persists, an as needed intravenous opioid administration (morphine, tramadol, or meperidine) is performed as a second line analgesic. The latter was recorded from patients' charts, and post-operative opioid use was defined as any opioid administration after discharge from the recovery room.

Statistical analysis

Patient demographics, oncological, pathological, surgical characteristics, as well as post-operative events were compared between patients who underwent RARP with or without AirSeal[®]. Categorical variables were compared

using chi-square test and presented as count and percentages while continuous variables were analyzed using the Wilcoxon rank sum test and presented as mean and standard error of the mean. The results were then reported as odd's ratios after univariate linear and logistic regression. Significance level was set at <0.05 for all analyses. Statistical analyses were performed using the IBM SPSS statistical package (version 28, IBM Corp., Armonk N.Y., USA).

Results

Our cohort consisted of 326 patients who underwent RARP. The AirSeal[®] insufflator was used in 125 (38.3%) RARP cases while 201 (61.7%) RARP cases did not use the AirSeal[®] system. Patients who underwent RARP with or without AirSeal[®] were statistically insignificant in terms of difference in demographics, oncologic characteristics, and pathologic characteristics. In regard to surgical characteristics, both groups revealed similar estimated blood loss, transfusion rates, surgical margin involvement, and lymph node involvement (Table 1).

Additionally, patients who underwent RARP with AirSeal[®] had shorter operative times (304 min) and shorter length of stay (1.51 days) in comparison to RARP without AirSeal[®] (317 min and 2 days, respectively) ($p < 0.024$). The two groups showed similar complication rates; however, RARP with AirSeal[®] was associated with a decreased severity of complications indicated by a lower rate of CVD > II ($p < 0.001$). Furthermore, patients who underwent RARP with AirSeal[®] showed decreased rates of opioid use as compared to non-AirSeal[®] RARP (12 vs 21.9%) ($p = 0.024$) (Table 2).

To note, there was no need to control for confounders since the two groups were similar in terms of pre-operative variables assessed. Moreover, a univariate analysis similarly revealed the advantage of RARP with AirSeal[®] revealing shorter operative times (by 12.3 min), shorter length of stay (by 0.5 days), decreased odds of CVD > II complications (OR = 0.102), and decreased odds of opioid use (OR = 0.49) as compared to non-AirSeal[®] RARP ($p < 0.038$) (Table 3).

Discussion

Current literature on the use of AirSeal[®] is inconclusive in terms of outcomes of robotic radical prostatectomy and a knowledge gap exists in regard to the advantage of its use in this procedure. Despite the lack of evidence related to its advantages, it has been increasingly used by surgeons regardless of the additional cost per procedure [15]. The reason being the ability to operate at lower abdominal pressures and the better visualization provided by the smoke

evacuation. Through highlighting our institution's experience, this study aims to address the use of AirSeal[®] insufflation and its impact on the outcomes of RARP. Our results reveal that the use of AirSeal[®] during RARP is associated with shorter operative times, length of stay, opioid use, and severity of complications.

Laparoscopic and later robotic surgery revolutionized surgical approaches during radical prostatectomy. The prostate is a highly vascular organ situated deep in the pelvis [16]. Control of bleed and a clear visual field are of utmost importance throughout the different steps of the procedure in order to maximize outcomes. As such, the introduction of robot-assisted radical prostatectomy offered significant advantages in terms of precision, maneuverability, and vision [17, 18]. An essential adjunct to RARP is a balanced pneumoperitoneum that decreases blood loss and optimizes visibility without compromising on the intraoperative hemodynamics. The excess use of CO₂ pneumoperitoneum leads to long-term deleterious changes in respiratory and cardiovascular functions especially in comorbid patients [19]. Higher insufflation pressures and prolonged insufflation times lead to increased CO₂ absorption [20]. Such an increase was shown to be directly correlated to an increased incidence of respiratory acidosis, gas embolism, and post-operative pain, [21, 22]. Therefore, low-pressure insufflation using valved trocar systems has been adopted to limit the aforementioned side effects [19]. AirSeal[®] maintains an intraoperative stable pneumoperitoneum through continuous smoke evacuation, and CO₂ extraction followed by recirculation leading to a low pressure intracorporeal cavity throughout the procedure [23]. In addition, RARP can be safely performed at pneumoperitoneum pressures as low as 8mmHg and in steep Trendelenburg position [24, 25]. In theory, a low-pressure stable pneumoperitoneum enhances vision and facilitates bedside assistance potentially resulting in improved perioperative outcomes such as operative time, blood loss, and post-operative complications.

Shorter operative times is a key prognostic indicator of lower complication rates and shorter hospital stays after urological procedures [26]. The effect of AirSeal[®] use on operative duration is yet to be determined with several studies demonstrating a categorical advantage in terms of shorter operative times with the use of AirSeal[®] [12, 27, 28]. Nevertheless, Bucur et al. showed no significant difference in operative times with or without the use of AirSeal[®] [29]. Operative time is influenced by multiple factors that mainly relate to surgeon's experience, surgical complexity, surgical approach [30]. Even though surgeons involved in this study were experienced in radical prostatectomy, we accounted for the learning curve for RARP excluding the first 60 cases. Furthermore, surgical complexity was similar between the two groups evidenced by tumor and pathological similarities between the two arms. In addition, a trans-peritoneal anterior

Table 1 Demographics, oncologic, pathological, and surgical characteristics in AirSeal® and non-AirSeal® RARP

	N=326	AirSeal®		P-Value
		No AirSeal® (N=201)	Yes AirSeal® (N=125)	
		N (%)	N (%)	
Demographics				
Age		63.7 ± 7.3	65.1 ± 6.6	0.067 ^a
Body mass index		28.4 ± 5	28.8 ± 4.2	0.407
ASA class				
1		8 (4)	3 (2.4)	0.776
2		153 (77)	95 (76)	
3		37 (18.6)	27 (21.6)	
4		1 (0.5)	0 (0)	
Oncologic characteristics				
Clinical stage				
< T3a		179 (89.1)	116 (92.8)	0.262
T3a, T3b, T3c		22 (10.9)	9 (7.2)	
Pathological grade on TRUS				
≤ 2		108 (53.7)	58 (46.4)	0.198
≥ 3		93 (46.3)	67 (53.6)	
Gleason score				
6		6 (3)	9 (7.2)	0.125
7		155 (77.1)	100 (80)	
8		25 (12.4)	7 (5.6)	
9		13 (6.5)	8 (6.4)	
10		2 (1)	1 (0.8)	
Preoperative PSA		9 ± 7.2	8.76 ± 6	0.323
Pathological characteristics				
Extraprostatic extension		56 (27.9)	47 (37.6)	0.066
Seminal vesicle involvement		25 (12.4)	22 (17.6)	0.197
Lymphovascular invasion		18 (9)	13 (10.4)	0.665
Perineural invasion		148 (73.6)	99 (79.2)	0.254
Pathologic grade				
≤ 2		84 (42.9)	55 (44.7)	0.745
≥ 3		112 (57.1)	68 (55.3)	
Pathological stage (AJCC)				
≤ 2		125 (62.2)	78 (62.3)	0.977
≥ 3		76 (37.8)	47 (37.6)	
Prostate size		53.6 ± 18.2	57.5 ± 21	0.093
Tumor volume		22 ± 17.4	21.6 ± 18.6	0.422
Surgical characteristics				
AirSeal port (mm)				
8		–	29	–
12		–	96	
Operative time (mins)		317 ± 54	304 ± 45	0.024 ^a
Length of stay (days)		2 ± 0.06	1.51 ± 0.062	< 0.001 ^a
Estimated blood Loss (cc)		235.5 ± 120	270 ± 156	0.083
Transfusion		3 (1.5)	1 (0.8)	0.99
Surgical margin involvement		57 (28.4)	46 (36.8)	0.111
Lymphadenectomy		149 (75.3)	102 (82.9)	0.126
Positive nodes		24 (16.2)	9 (7.4)	0.039 ^a
Total lymph nodes removed		14.9 ± 6	11.7 ± 7.9	< 0.001 ^a
Number of positive lymph nodes removed		0.52 ± 1.7	0.11 ± 0.42	0.019 ^a
Percentage of positive to total lymph nodes		2.4 ± 10	0.8 ± 2.7	0.105

ASA American Society of Anesthesiologists, TRUS Transrectal ultrasound, AJCC American Joint Committee of Cancer, Transfusion indicates receiving pRBC transfusion intra or post-op

^aSignificant $p < 0.05$

Table 2 Post-operative events in AirSeal® and non-AirSeal® RARP

	N = 326	AirSeal®		P-value
		No AirSeal® (N = 201)	Yes AirSeal® (N = 125)	
		N (%)	N (%)	
Post-operative events				
Complications		28 (13.9)	17 (13.6)	0.933
Clavien-Dindo Grade I		3 (10.7)	0 (0)	0.02 ^a
Penile hematoma		1 (0.5)	0 (0)	
Scrotal edema		1 (0.5)	0 (0)	
Transient anastomosis leak		1 (0.5)	0 (0)	
Clavien-Dindo Grade II		15 (53.6)	16 (94.1)	
UTI		12 (6)	13 (10.4)	
Flank hematoma		1 (0.5)	2 (1.6)	
Leg lymphedema		1 (0.5)	0 (0)	
SSSI		1 (0.5)	0 (0)	
Ileus		0 (0)	1 (0.8)	
Clavien-Dindo Grade III		7 (25)	0 (0)	
Incisional hernia requiring repair		7 (3.5)	0 (0)	
Clavien-Dindo Grade IV		3 (10.7)	1 (5.9)	
Intraabdominal abscess & sepsis		1 (0.5)	0 (0)	
Sepsis & diverticulitis with perforation requiring ICU		1 (0.5)	0 (0)	
Sepsis, acute kidney injury, pneumonia, partial bowel obstruction requiring ICU		1 (0.4)	0 (0)	
Urosepsis		0 (0)	1 (0.8)	
Received Adjuvant (ADT + EBRT)		28 (14.7)	13 (23.6)	0.149
Chemotherapy		5 (2.6)	1 (1.9)	0.99
Biochemical recurrence		24 (12.6)	11 (16.7)	0.411
Opioid Use		44 (21.9)	15 (12)	0.024 ^a

ICU Intensive Care Unit, SSSI Superficial surgical site infection, UTI Urinary Tract Infection, ADT Androgen deprivation therapy, EBRT External Beam Radiation Therapy, Biochemical recurrence is defined as a post-operative PSA level of ≥ 0.2 ng/ml, with a second confirmatory level exceeding 0.2 ng/ml

^aSignificant $p < 0.05$

Table 3 Univariate linear and regression models on operative time, length of stay, Clavien-Dindo grade, and opioid use in AirSeal® and non-AirSeal® RARP

Variable	No AirSeal®	Yes AirSeal®	95% Confidence Interval	P-Value
Univariate linear regression				
Operative time (mins)	Ref	-12.3	-23.6, -1.0	<0.001 ^a
Length of stay (days)	Ref	-0.5	-0.68, -0.32	<0.001 ^a
Univariate logistic regression				
Clavien-Dindo > II	Ref	0.102	0.012, 0.88	0.038 ^a
Opioid use	Ref	0.49	0.26, 0.92	0.026 ^a

^aSignificant $p < 0.05$

approach was used for all cases. Therefore, significant clinical relevance can be attributed to a shorter operation time of just 12 min, especially in procedures like robotic-assisted radical prostatectomy (RARP), as even minor reductions in time can yield numerous benefits. These benefits include minimizing patient exposure to anesthesia, reducing surgical site infections, reducing economic burden on patient, and

improving patient outcomes through decreased blood loss, fluid shifts, and surgical stress-related complications.

To the best of our knowledge, the cost effectiveness of using an AirSeal® system is yet to be established [15]. Length of hospital stay plays a major role in the overall financial burden of any surgical procedure [31]. Consequently, several studies compared the length of hospital

stay between low pressure AirSeal[®] systems and standard pressure pneumoperitoneum revealing no difference [14, 27, 29]. However, a meta-analysis by El-Taji et al. showed that patients undergoing RARP with low pressure had a shorter length of stay [32]. Similarly, our study demonstrated a significant shorter length of hospital stay for patients who underwent RARP with AirSeal[®] as compared to non-AirSeal[®] RARP (2 vs 1.51 days, respectively). A reduction in hospital length of stay even by half a day after major surgeries such as RARP, which necessitate significant post-operative care, offers numerous advantages. These include cost savings, decreased infection risk, reduced medication dependency, and a lower occurrence of hospital-related complications. Patients benefit from faster recovery, increased satisfaction, and an overall positive experience. Furthermore, shorter hospital stays optimize resource allocation, enhancing efficiency and potentially improving access to care for other patients. Further studies on the effect of using AirSeal[®] during RARP are still needed to determine its implications on length of hospital stay and overall financial consequences.

Decreased post-operative pain and lower post-operative complications are other additional advantages of low-pressure pneumoperitoneum. A moderate level of evidence showed that low-pressure pneumoperitoneum is associated with lower post-operative pain scores [33]. Additionally, Hua et al. revealed that lower pressure pneumoperitoneum was associated with a significant lower incidence of post-operative shoulder pain [34]. Our study determined post-operative pain based on patient's need for opioid administration [15]. We found that opioid use was lower after RARP with AirSeal[®] (21.9% vs 12%) which was in line with previously existing studies [11]. In regard to post-operative complications, several studies showed no statistically significant difference in the rates of complications between RARP with or without AirSeal[®] [12, 20, 27]. Nevertheless, our study revealed that RARP with AirSeal[®] had less severe complications rates indicated by lower rates of CVD > II complications [27, 29]. This is probably driven by the constellation of the aforementioned advantages of lower blood loss, improved visibility, and easier bedside assistance.

The evidence on AirSeal[®] use has been controversial and at times contradictory in the existing literature. The AirSeal[®] system's ability to maintain a low intra-abdominal pressure is the key factor contributing to its observed benefits in surgeries. Unlike standard insufflation devices, which struggle to maintain a stable pressure at a minimum of 10mmHg, the AirSeal[®] system can achieve and sustain a low pressure even in the presence of leaks and aggressive suctioning [35]. Studies have shown that using the AirSeal[®] system at low pressure results in decreased intraoperative blood loss and reduced post-operative pain, suggesting that its advantages stem from its unique ability to achieve and maintain

a low peritoneal pressure, a capability unmatched by other devices [10]. Our study revealed benefit for AirSeal[®] use during RARP in regards to a decreased use of opioids, severity of complications, length of stay, and operative time. The additional cost of using an AirSeal[®] insufflator is potentially offset by the aforementioned perioperative advantages. The generalizability of our findings and financial implications of using the system are yet to be determined and should be the focus of future research revolving around their use [15].

Limitations

This study is not without limitations. It is retrospective in nature, thus fails to account for several confounding variables that were not recorded such as the threshold of pain prior to administration of opioids. In addition, several factors were not reported including average intraabdominal pressure throughout the case, objective standardized post-operative pain scores, tidal volumes, and CO₂ parameters. Patients were followed up only for 30 days post-operation; however, we believe that complications primarily related to the insufflator or the surgical procedure tend to occur within this period. Lastly, the results are based on a single tertiary referral center's experience, hence limiting its generalizability.

Conclusion

In our single center experience, RARP with AirSeal[®] was associated with shorter hospital stay, shorter operative times, lower complications, and decreased opioid use. These findings have encouraged us to shift our practice to almost exclusively use the AirSeal. Although the added cost of using the system is possibly balanced by perioperative advantages that ultimately decrease the overall financial burden. Further studies are needed to clearly delineate the benefits of using AirSeal[®] and categorically validate their overall cost effectiveness.

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Declarations

Conflict of interest The authors have no competing interests to declare that are relevant to the content of this article.

Ethics approval and consent to participate Consent to allow data use was acquired after patients read and approved the IRB approved consent form. The data was retrospectively collected. Ethics approval and Institutional Review Board approval was received before conducting this study under IRB ID SUR.AE.03. The American University of Beirut and its Institutional Review Board, under the Institution's Federal Wide Assurance with OHRP, comply with the Department of Health and Human Services (DHHS) Code of Federal Regulations for the Protection of Human Subjects ("The Common Rule") 45CFR46, subparts A, B, C, and D, with 21CFR56; and operate in a manner consistent with the Belmont report, FDA guidance, Good Clinical Practices under the ICH guidelines, and applicable national/local regulations.

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