



PD23-07 A MULTI-CENTER, PROSPECTIVE, RANDOMIZED, CONTROLLED STUDY TO EVALUATE THE SAFETY OF A VALVE-LESS TROCAR INSUFFLATION SYSTEM (AIRSEAL) VS. CONVENTIONAL INSUFFLATION FOR THE MANAGEMENT OF PNEUMOPERITONEUM DURING ROBOTIC PARTIAL NEPHRECTOMY

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Disclosures

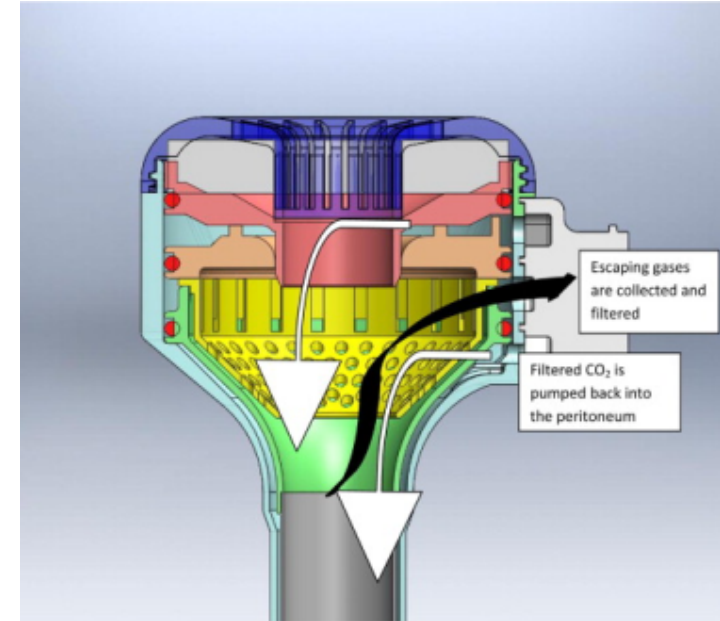
- Intuitive Surgical
- C-SATS
- Ethicon
- VTI
- ConMed





Introduction

- Airseal (Valveless Trocar Insufflation) introduced in 2007
- Air barrier, no duckbill
- .01 micron filter





- Advantages

- Stable pneumoperitoneum
- Decrease in CO₂ absorption
- Able to suction without loss of pneumoperitoneum
- Decrease in IAP -> decrease in pain

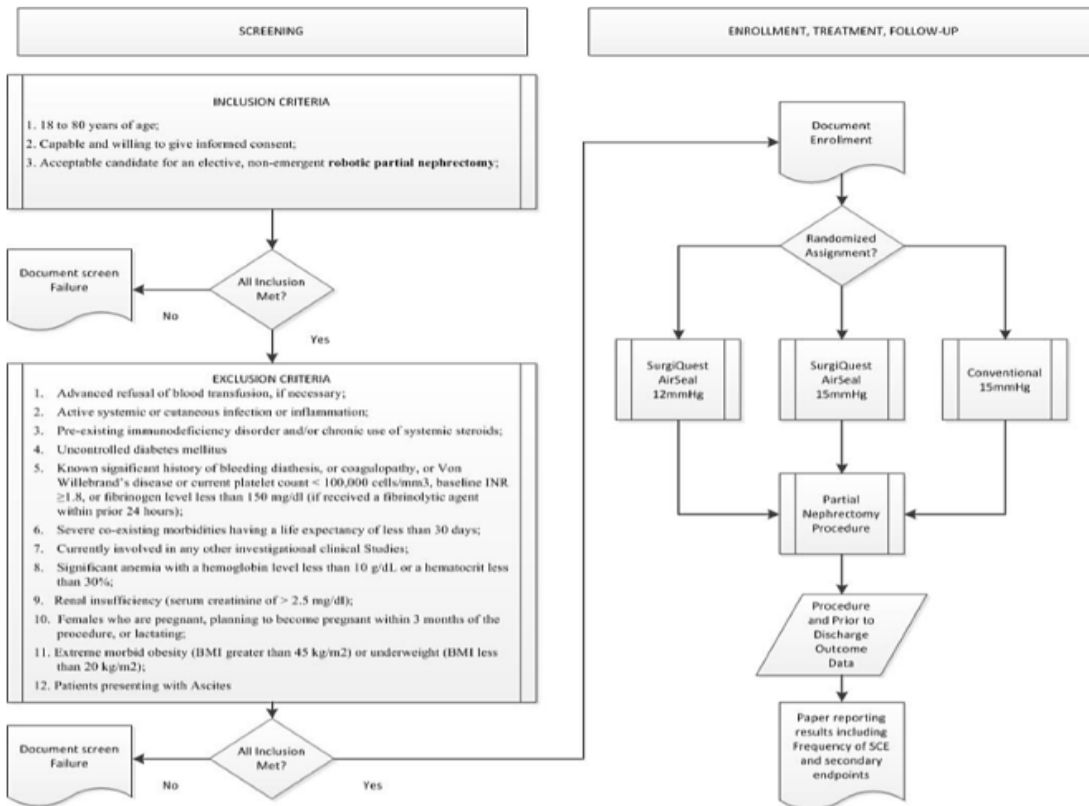
- Disadvantages

- Masked Pneumothorax
- Increase risk of SQE
- Increase risk air embolism





Material Methods





Outcome Data

- Effectiveness endpoints:
 - maintenance of stable pneumoperitoneum as measured by fluctuations in intraabdominal pressure
 - insufflation time,
 - ease of anesthesia management,
 - recovery room time,
 - hospital discharge time
- Safety endpoint:
 - Insufflation device-related subcutaneous emphysema
 - Rate of pneumothorax, pneumomediastinum
 - Post-operative pain (general/shoulder) measured with Visual Analogue Scale
 - Complications.





Demographics

- 202 patients randomized 1:1:1
- No difference
 - Gender
 - Age
 - BMI

Variable		AIS 12 mmHg	AIS 15 mmHg	CIS 15 mmHg	
Demographics	Enrollment (n)	67	67	68	
	Gender	Female	24 (36%)	25 (37%)	24 (35%)
		Male	43 (64%)	42 (63%)	44 (65%)
	Mean age, y (± SD) [range]	60 (13.2)[18-86]	60 (11.9)[19-80]	60.1 (12.4)[23-80]	
	Mean BMI (± SD) [range]	29.1 (6.0)[29-46]	31.3 (5.6)[22-44]	28.8 (5.6)[19-46]	
Table 1: Demographics Data					



Effectiveness AIS vs. CIS

- Decrease Airway pressure
- Decrease end tidal CO₂
- Maintain DBP

	AIS 12 mmHg	AIS 15 mmHg	CIS 15 mmHg	
Peak Airway Pressure (PAP)	Mean PAP, mmHg (± SD)	22.1 (4.0)	24.4 (3.3)	25.5 (3.7)
	Statistical Analysis			P Value
	AIS 12 vs CIS			0.000001
	AIS 15 vs CIS			0.07
	AIS 12 vs AIS 15			0.001
End-Tidal CO ₂ (ETCO ₂)	Mean ETCO ₂ , mmHg (± SD)	33.9 (3.4)	35.0 (3.1)	36.1 (4.1)
	Statistical Analysis			P Value
	AIS 12 vs CIS			0.001
	AIS 15 vs CIS			0.09
	AIS 12 vs AIS 15			0.05
Systolic Blood Pressure (SBP)	SBP, mmHg (± SD)	109.7 (13.4)	109.4 (10.4)	111.8 (11.5)
	Statistical Analysis			P Value
	AIS 12 vs CIS			0.33
	AIS 15 vs CIS			0.2
	AIS 12 vs AIS 15			0.89
Diastolic Blood Pressure (DBP)	DBP, mmHg (± SD)	64.3 (10.9)	65.0 (8.3)	69.0 (9.7)
	Statistical Analysis			P Value
	AIS 12 vs CIS			0.01
	AIS 15 vs CIS			0.01
	AIS 12 vs AIS 15			0.64
Table 2: Intraoperative Data				



Safety AIS vs CIS

- AIS 12 – Shorter RRT
- AIS 12 – Decrease SQE
- No difference in PTX
- No difference in PMS
- 2 Retro RPN need to convert CIS ->AIS

		AIS 12 mmHg	AIS 15 mmHg	CIS 15 mmHg	
Recovery Room Time (RRT)	Mean RRT, h (± SD)	2.6 (1.3)	2.2 (0.8)	2.37 (1.13)	
	Statistical Analysis				
				P Value	
		AIS 12 vs CIS		0.2	
		AIS 15 vs CIS		0.31	
	AIS 12 vs AIS 15		0.02		
Subcutaneous Emphysema (SCE)	SCE Rate (%)	15.2	30.4	38.5	
	Statistical Analysis				
		Difference (%)	Confidence	P Value	
		AIS 12 vs CIS	-23.3	-27.2 - -8.2	0.003
		AIS 15 vs CIS	-8	-23.5 - 7.9	0.37
	AIS 12 vs AIS 15			0.04	
Pneumothorax (PTX)	PTX Rate (%)	0	5	5	
	Statistical Analysis				
				P Value	
		AIS 12 vs CIS		0.24	
		AIS 15 vs CIS		1	
	AIS 12 vs AIS 15		0.24		
Pneumo-mediastinum (PMS)	PMS Rate (%)	6	12	11	
	Statistical Analysis				
				P Value	
		AIS 12 vs CIS		0.53	
		AIS 15 vs CIS		1	
	AIS 12 vs AIS 15		0.36		
Table 3: Postoperative Data					

Effect of Retro vs Trans Approach

- Higher rate of SQE
- No difference in PTX
- No difference in PMS

Approach		N	SCE	Rate	p-value*
AIS 12 mmHg	Trans	35	1	3%	0.01
	Retro	28	8	29%	
AIS 15 mmHg	Trans	38	6	16%	0.004
	Retro	30	15	50%	
CIS	Trans	44	12	27%	0.004
	Retro	19	13	68%	

Post-op Pain

- Using MMRM Analysis
 - Less shoulder pain with AIS
 - No difference in AIS 12 vs AIS 15

Combining over all time points by Mixed Model Repeated Measures (MMRM) Analysis

	Original Data		Using Ranks	
	Effect Estimate*	p-value**	p-value**	
AIS 12 mmHg vs CIS	-0.28	0.16	0.07	
AIS 15 mmHg vs CIS	-0.40	0.03	0.02	



Summary

- Largest RCT comparing AIS vs CIS for RPN
- Airseal distinct efficacy advantages
 - Stable pneumoperitoneum
 - Decrease Airway pressure
 - Decrease end tidal CO₂
 - Maintain DBP





Summary

- Distinct Safety Advantages
 - Shorter RRT
 - Decrease SQE
 - No difference in PTX or PSM
- Retro Approach higher rate SQE only
- Decrease in shoulder pain based on VAS
- No air embolism symptoms noted in any group