A comparative effectiveness study of two narrow profile staplers used in VATs surgery lobectomy

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IW PAN, MPH, PhD[1], NP DESAI[2]

[1]Medtronic, plc, Boston, MA, USA, [2]Medtronic, plc, New Haven, CT, USA

INTRODUCTION

Studies showed that the narrow-profile powered vascular (PVS) had a similar effectiveness to standard-of-care staplers in video-assisted thoracoscopic surgery lobectomy.[1] Later, the other narrow-profile small-diameter reloads (SDR) were launched in 2020, the prospective non-comparative registry study demonstrated that SDR addressed the unmet need without introducing new risks or harms to the subjects[2].

OBJECTIVE

To evaluate the effectiveness of SDR versus PVS on patients treated with lobectomy VATs procedures

Type of staplers:

- SDR: Medtronic Signia ™ small-diameter reloads, either with manual or powered handlers
- PVS: Johnson and Johnson Echelon Flex™ Powered Vascular Stapler.

METHOD

Data Sources:

PINC AI™ Healthcare Data, 2021-2022

Figure 1: Cohort Selection:

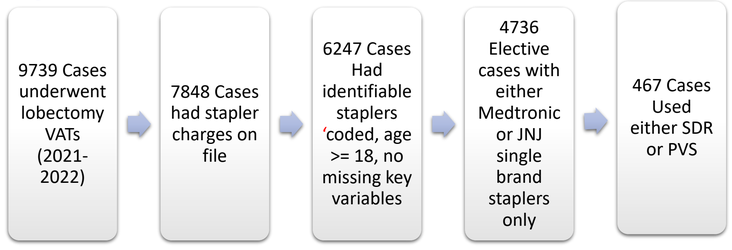
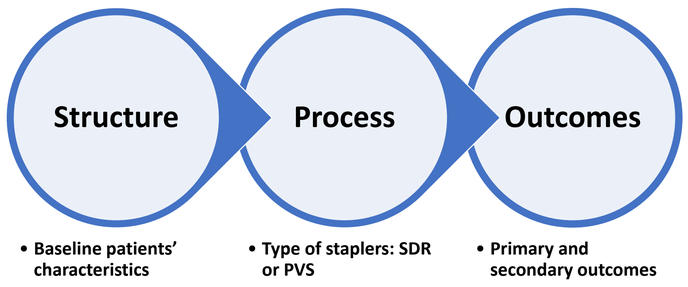


Figure 2: Study Framework: SPO Quality Framework[3]



Defined lobectomy VATs procedures:

- Patients who had inpatient claim with primary procedures codes in the following list: 0BTC4ZZ, 0BTD4ZZ, 0BTF4ZZ, 0BTG4ZZ, 0BTJ4ZZ, 0BTK4ZZ, 0BTL4ZZ

Baseline patient characteristics:[4,5]

- Patient characteristics: age, marital status, gender, race and ethnicity (White versus non-White race), Payer (Medicare versus other payers), and Charlson comorbidity index (0-2, 3 and above)

Primary and secondary outcomes:

The effectiveness of staplers was measured by (ICD 10 or CPT codes):

§ Primary outcomes: blood transfusion, bleeding
§ Secondary outcomes: conversion to open

Statistical analysis:

Bivariate analysis (Chi-square, Fisher exact test, or t-test) was used to examine baseline balance between SDR and PVS.

Propensity scores matching (PSM) methods (1:1 matched, Caliper = 2.0) based on patient characteristics were used to assess outcome variations and obtained adjusted outcomes in two groups.

Sensitivity analysis: was done by multivariate logistic regression model to test the robustness of results obtained from PSM.

RESULTS

- ❑ 467 (9.9%) of 4736 lobectomy VATs cases used narrow profile reloads/staplers. (Figure 1)
- ❑ After propensity scores are matched, all patient's characteristics are balanced in two groups (Table 1 and Figure 3)
- ❑ Patients who used SDR had less blood transfusion compared to PVS. (SDR vs PVS: before PSM: 0.6% vs 5.0%; after PSM 0.6% vs 4.8%; both p-values < 0.05) (Table 2 & 3)

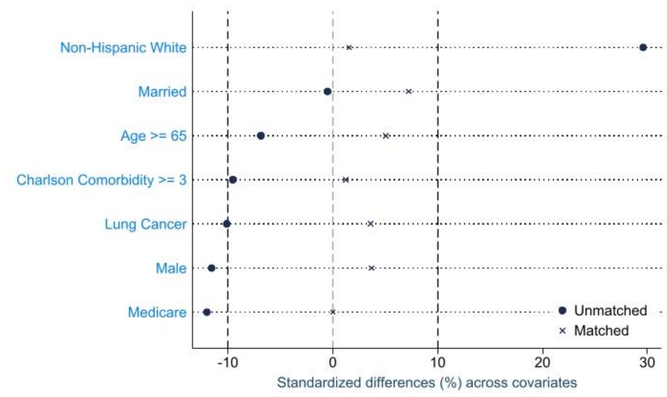
Table 1: Patient characteristics before and after PSM in two groups

Before PSM	Full cohort (N=467)		
	SDR %	PVS %	p-value
Description	N=167, 35.8%	N=300, 64.2%	
Age >= 65	64.07	67.33	0.476
Male	34.73	40.33	0.231
Married	58.08	58.33	0.958
Non-Hispanic White	86.83	75.33	0.003
Medicare	62.28	68.00	0.211
Lung Cancer	85.63	89.00	0.291
Charlson Comorbidity (3+)	63.47	68.00	0.32

After PSM	Matched sample (167 pairs)		
Description	SDR %	PVS %	p-value
Age >= 65	64.07	61.68	0.520
Male	34.73	32.93	0.730
Married	58.08	54.49	0.510
Non-Hispanic White	86.83	86.23	0.873
Medicare	62.28	62.28	1.000
Lung Cancer	85.63	84.43	0.760
Charlson Comorbidity (3+)	63.47	62.87	0.910

Abbreviation: PSM: propensity scores matching; SDR: Small diameter reload; PVS: powered vascular stapler;

Figure 3: Standard difference of patients characteristics in two groups before and PSM



Abbreviation: PSM: propensity scores matching

Table 2 : Unadjusted outcomes before propensity scores matched

Unadjusted incidence rates	SDR (N= 167) N (%)	PVS (N=300) N (%)	P-value
Blood transfusion	1(0.6)	15(5.0)	**0.014[1]**
Bleeding	5(3.0)	18(6.0)	0.15
Conversion to open[2]	1(0.6)	0(0.0)	0.36[1]

[1]Fisher exact test; [2]Due to small or zero events, propensity scores matching analysis did not include conversion to open.

Table 3: Adjusted outcomes after PSM and sensitivity analysis done by multivariable logistic regression

	Post PSM – Main model (164 pairs)				Multivariable logistic regression - Sensitivity			
Primary outcomes	SDR	PVS	DIFF	P-value	SDR	PVS	DIFF	P-value
	%	%	%		%	%	%	
Blood Transfusion	0.6	4.8	-4.2	**0.037[1]**	0.6	5.1	-4.5	**0.031[2]**
Bleeding	3.0	5.4	-2.4	0.28	2.9	6.1	-3.2	0.14

Abbreviations: PSM: propensity scores matching; SDR: small-diameter reload; PVS: powered vascular stapler; DIFF: differences;
[1]Two side Fisher exact test p= 0.037; one side Fisher exact test p = 0.018; [2]p= 0.031; SDR is significantly less blood transfusion than PVS)
PSM covariates for the main model: age, male, marital status, white, Medicare, lung cancer, and comorbidity
Covariates for sensitivity analysis: age, male, marital status, white, Medicare, lung cancer, and comorbidity

DISSCUSIONS

- ❑ SDR results in less blood transfusion than PVS in lobectomy VATs.
- ❑ Patient characteristics were applied to the propensity scores matched model based on existing literature, though providers' characteristics may play a role in outcomes.
- ❑ The sample size is small. More data, more robust. Obtaining multiple years of data will help to improve the robustness of the study.

CONCLUSIONS

The study demonstrated that staplers with small diameter reloads (SDR) outperformed powered vascular staplers (PVS) in reducing the need for blood transfusions. This superior performance can be attributed to their effective division of the pulmonary vasculature and their narrow profile, which enhances access.

REFERENCES

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CONTACT INFORMATION

I-Wen Elaine Pan: elaine.pan@medtronic.com