



Clinical outcomes of powered and manual staplers in video-assisted thoracic surgery lobectomy for lung cancer

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Methods: This retrospective cohort study identified patients who underwent video-assisted thoracic surgery (VATS) lobectomy for lung cancer from January 2016 to December 2018 in a Chinese tertiary general hospital. The electronic hospital medical records associated with the VATS lobectomy for lung cancer were the data sources. **Results:** Based on the analysis of 433 patients with the utilization of staplers in their VATS lobectomy for lung cancer, using powered stapler was associated with significantly shorter operation time and postsurgery hospital stay length than using the manual stapler in the multivariable generalized linear regression analyses with the adjustment of patient characteristics. However, no other significant differences were observed for other clinical outcomes between the two staplers.

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Keywords: length of stay • lung cancer • operation time • powered stapler • VATS lobectomy

Surgical staplers have been used for decades for bronchial stump closure and pulmonary hilum vessel ligation in pulmonary surgery given their superior clinical outcomes (less bleeding, less pulmonary air leaking and fewer post-surgery complications), shorter operation time and faster postsurgery recovery than manual bronchial suturing [1–4]. As video-assisted thoracoscopic surgery (VATS) has become the mainstream approach for pulmonary resection [5], the limited operation space associated with VATS significantly increased the difficulty of manual suturing and made surgical stapler essential for bronchial stump closure and pulmonary hilum vessel ligation in VATS lobectomy [6].

The manual stapler was a standard tool in VATS. The powered stapler was designed for easy operation and further reducing the risks of air leak and bleeding through even nail formation force [7,8]. A recent retrospective study reported that powered stapler was associated with a significantly lower risk of bleeding-related complications, shorter postsurgery length of stay, lower blood transfusion rate and lower hospitalization costs than manual stapler in VATS lobectomy conducted in the USA [9]. The first powered stapler, Powered ECHELON FLEX, was introduced to China in 2014. A multicenter single-arm prospective study evaluated this powered stapler and reported a 5.3% postoperative air leak rate among 94 patients who underwent VATS lobectomy using powered surgical stapler in four Chinese tertiary hospitals [10]. To further clarify the real-world clinical impact associated with a powered stapler in Chinese patients with VATS lobectomy, a comparative effectiveness study was conducted with a manual stapler as the control.

Materials & methods

This study was designed as a retrospective cohort study to compare the clinical outcomes associated with the powered stapler and manual stapler in patients who underwent VATS lobectomy for lung cancer in a Chinese tertiary hospital. The study protocol was reviewed and approved by the Ethics Review Board of Xiangya Hospital (IRB approval number: 202105205), which provided the de-identified data to create the study cohort and conduct data analysis for this study. This manuscript was written by following STROBE guideline for observational studies [11].

Study cohort

This study used 'lung' as the keyword to search the surgical records in the study hospital to identify the patients who underwent VATS lobectomy for lung cancer from 1 January 2016 to 31 December 2018, when both powered staplers and manual staplers were accessible for VATS lobectomy in the hospital. The patients with a plan for VATS lobectomy were assessed for predicted postoperative forced expiratory volume in 1 s. The minimum requirement for predicted postoperative forced expiratory volume in 1 s was set as 60%, which suggested that the patients with VATS lobectomy were likely to have a normal lung function. The billing records associated with the identified VATS lobectomy hospital episodes were used to identify the stapler types, which were used to create the study groups for powered stapler and manual stapler. The medical records linked with these hospital episodes were further used to assess the enrollment eligibility through the following inclusion and exclusion criteria. The inclusion criteria included: patients were aged 18 years old or above; patients underwent VATS lobectomy for lung cancer and under general anesthesia; the brand name of utilized powered staplers was ECHELON FLEX™ ENDOPATH® and the brand name of the utilized manual staplers was Victor Medical; patients were routinely admitted and discharged for VATS lobectomy. Patients were excluded if they met any of the following criteria: the patient was deceased within the hospital episode for VATS lobectomy; patients with operation time >8 h, postsurgery hospital stay length >21 days, perioperative bleeding volume >600 ml, postsurgery drainage volume >2400 ml and postsurgery drainage tube placement duration >22 days; patients without adequate information for operation time or tumor stage; and patients with using both powered stapler and manual stapler in the same VATS lobectomy.

As a retrospective cohort study, this study did not perform sample size calculation but included the patients who met the inclusion and exclusion criteria during the defined period for patient identification.

Data sources

The study data were acquired from the hospital information system (HIS) of Xiangya Hospital. The electronic medical and billing records for the hospital episode of the included VATS lobectomy were exported from HIS to obtain the information for patient baseline characteristics, surgery process, stapler types, perioperative outcomes and postsurgery outcomes. More specifically, the hospital admission summary sheet was used to extract patient demographics (age, gender), patient social economics (residence, education, employment and insurance plan), admission diagnosis, histology of lung cancer and comorbidities; the blood laboratory tests before surgery were used to extract the test results indicating bone marrow function and coagulation function; the anesthesia records were used to extract operation time and intraoperative blood transfusion volume; the surgery notes were used to extract the operation site, surgery process and tumor stage; the postsurgery medical notes were used to extract data for the postsurgery occurrence of pulmonary air leakage, drainage volume, duration of drainage tube placement, postsurgery length of stay and postsurgery complications.

Outcome measures

The outcome measures included intraoperative blood transfusion rate, intraoperative blood transfusion volume, operation time, postsurgery air leak, extended drainage tube placement duration (defined as postsurgery drainage tube placement duration longer than 7 days) and postsurgery length of stay.

Statistical data analysis

This study conducted descriptive statistical analyses to summarize the patient baseline characteristics, numbers of utilized staplers and cartridges and measured outcomes associated with the two created patient groups by the stapler type (powered stapler vs manual stapler). The continuous variables for patient characteristics, utilized number of staplers and cartridges and measured outcomes were summarized using mean and standard deviation. The categorical variables for patient characteristics and measured outcomes were summarized using percentages. Additionally, the patient characteristics, utilized number of staplers and cartridges and measured outcomes associated with the two stapler groups were compared using student t-test (for continuous variables) and chi-square test (for categorical variables). This study conducted several regression analyses for adjusted comparisons of the measured outcomes associated with two stapler types according to the plotted distributions of the measured outcomes in the included patients. The conducted regression analyses included linear regression analyses for intraoperative blood transfusion volume, logistic regression analyses for intraoperative blood transfusion, postsurgery air leak and extended drainage tube placement duration, Poisson regression analyses for the utilized number of staplers and cartridges and generalized linear regression analyses (distribution assumption: inverse Gaussian) for operation time in

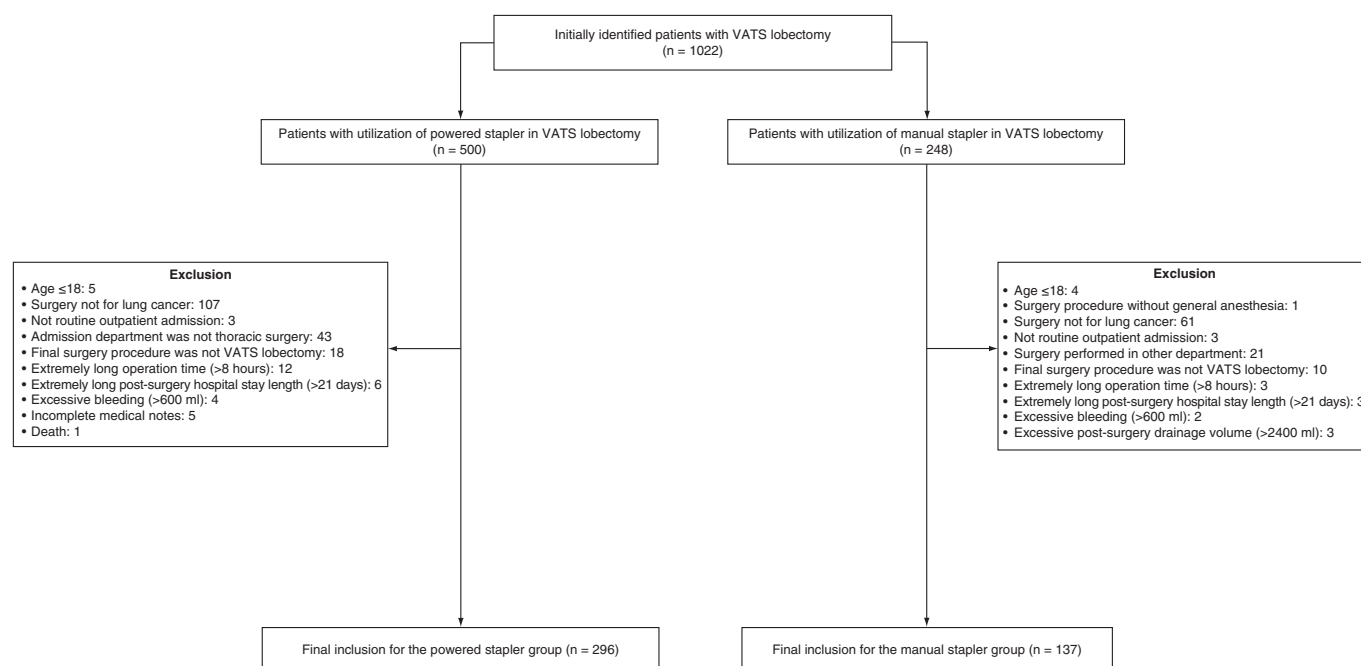


Figure 1. Patient identification flow chart to create powered stapler group and manual stapler group.
VATS: Video-assisted thoracic surgery.

h and postsurgery length of stay in days. This study first conducted univariable regression analyses to identify patient characteristics that could significantly be associated with the dependent variables in the regression analyses. The multivariable regression analyses were further conducted with the adjustment of the identified patient characteristics with the significant association in the univariable regression analysis and the stapler type. These regression analyses did not include the patients if their variable information was missing. To facilitate the interpretation of the performed multivariable regression analyses, this study used the recycled prediction method [12] to predict the measured outcomes associated with the powered stapler and manual stapler using the equations derived from the multivariable regression analyses and the individual level patient characteristics of the included patients. The developed equations are summarized in [Supplementary Table 1](#). All data analyses were conducted using statistical software R (4.0) [13] and the statistical significance was defined as a p-value less than 0.05 in the results.

Results

The initial search of the hospital surgery records identified 1022 patients who underwent VATS lobectomy for lung cancer in the period from 1 January 2016 to 31 December 2018. The final analysis included 433 eligible patients, including 296 patients who underwent VATS lobectomy using the powered stapler and 137 patients who underwent VATS lobectomy using the manual stapler. The patient identification flowchart is illustrated in [Figure 1](#).

Patient baseline characteristics & stapler utilization

The patient baseline characteristics in the two stapler groups were highly comparable except for significant differences that were identified for BMI distribution, lobectomy site and comorbidity distribution. The powered stapler group had a higher BMI than the manual stapler group (23.8 $\pm$ 3.1 vs 22.1 $\pm$ 2.8; $p = 0.08$). The comparisons of BMI distribution in the two stapler groups observed significantly higher proportions of normal bodyweight (BMI from 18.5 to 24: 50.3 vs 75.0%; $p < 0.001$) and overweight (BMI from 24 to 28: 37.0 vs 17.9%; $p < 0.001$) in the powered stapler group. Additionally, the powered stapler group had a significantly lower proportion of lobectomy at the bottom of the right lung (14.3 vs 22.6%; $p = 0.024$). The comparisons of the distributions of comorbidities in the two stapler groups detected significant differences in the proportions of bronchus related diseases (13.5 vs 6.6%; $p = 0.034$), coronary heart disease (2.7 vs 8.8%; $p = 0.004$) and digestive diseases (43.9 vs 32.1%; $p = 0.020$).

The utilized number of staplers and cartridges associated with the two stapler groups were comparable without any significant differences. However, the powered stapler group has a higher proportion of utilizing one stapler

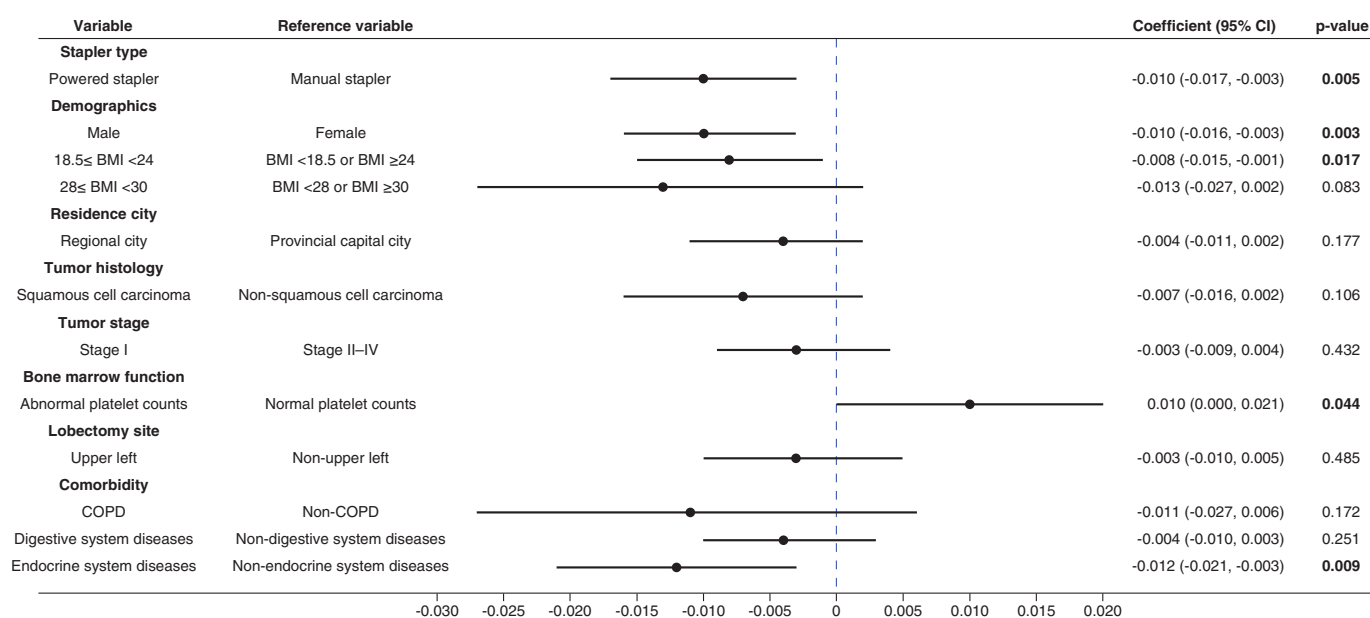


Figure 2. Multiple generalized linear regression analysis (inverse gaussian distribution) assessing the impact of powered stapler relative to manual stapler on operation time after the adjustment of patient baseline characteristics.

Bold terms indicate statistical significance.

COPD: Chronic obstructive pulmonary disease.

(82.4 vs 76.6%; $p = 0.098$). The patient baseline characteristics and utilized number of staplers and cartridges associated with the two stapler groups are summarized in [Table 1](#).

Adjusted comparisons of clinical outcomes

Multivariable generalized linear regression analyses with adjustment of patient baseline characteristics indicated that the use of the powered stapler was associated with significantly shorter operation time (co-efficient -0.010; $p = 0.005$) and shorter postsurgery hospital stay days (co-efficient -0.003; $p = 0.002$) than the manual stapler. The results of multivariable generalized linear regression analyses for operation time and postsurgery hospital stay days are illustrated in [Figures 2](#) and [3](#), respectively. The comparisons of the predicted outcomes for the two stapler types in the included patients confirmed the shorter operation time (3.62 vs 3.89 h, change: -6.9%) and shorter postsurgery length of stay (7.70 vs 8.49 days, change: -9.3%) in powered stapler group. The conducted multivariable regression analyses did not identify any significant differences in other measured outcomes, which included the intraoperative blood transfusion risk, postsurgery air leak risk, total blood transfusion volume and extended drainage tube placement duration. This study did not conduct logistic regression analysis for the adjusted comparisons of postsurgery complications due to their low occurrences in the two stapler groups (infection: 1.0 vs 1.5%; $p = 0.686$; pneumothorax: 0.3 vs 0%; $p = 0.496$; poor healing of surgical wounds: 0 vs 0.7%; $p = 0.141$; surgical fistula: 0 vs 0.7%; $p = 0.141$). The comparisons of the predicted outcomes for other outcome measures indicated that the powered stapler was associated with lower total blood transfusion volume (33.93 vs 95.61 ml, change: -64.5%), lower intraoperative blood transfusion rate (2.65 vs 3.89%; change: -31.9%), lower postsurgery air leak rate (44.54 vs 49.62%, change: -10.2%) and extended postsurgery drainage tube placement duration rate (13.69 vs 14.23%, change: -3.8%) than manual stapler group. The predictions on the clinical outcomes associated with the powered stapler and manual stapler in the included patients are summarized in [Table 2](#).

Discussion

This study evaluated the real-world clinical impact of powered stapler used in VATS lobectomy through comparisons with the manual stapler in a Chinese tertiary hospital. Similar to previous studies [7–9], this study observed significantly shorter operation time and significantly shorter postsurgery length of stay associated with powered stapler utilized in VATS lobectomy for lung cancer in a Chinese tertiary general hospital. However, this study did not observe any significant reduction of intraoperative blood transfusion risk, blood transfusion volume,

Table 1. The patient baseline characteristics and utilization of staplers and cartridges associated with the powered stapler group and the manual stapler group.

Variables	Powered stapler group		Manual stapler group		p-value
	(n = 296)		(n = 137)		
	n	mean +/- SD/%	n	mean +/- SD/%	
Demographics					
Age (years)	296	57.9 +/- 8.9	137	57.7 +/- 9.2	0.746
Male	157	53.0%	71	51.8%	0.814
BMI (kg/m ²)	189	23.8 +/- 3.1	28	22.1 +/- 2.8	0.008
BMI <18.5	7	3.7%	1	3.6%	0.240
18.5 ≤ BMI <24	95	50.3%	21	75.0%	<0.001
24 ≤ BMI <28	70	37.0%	5	17.9%	<0.001
28 ≤ BMI <30	12	6.3%	1	3.6%	0.059
30 ≤ BMI <40	5	2.6%	0	0.0%	0.126
Insurance plan					
Urban worker insurance plan	64	27.1%	22	20.8%	0.177
Urban resident insurance plan	52	22.0%	25	23.6%	0.863
Rural resident insurance plan	64	27.1%	38	35.8%	0.163
Other insurance plans	56	23.7%	21	19.8%	0.363
Tumor stage					
Carcinoma <i>in situ</i>	3	1.0%	3	2.2%	0.330
I	167	56.4%	78	56.9%	0.920
II	35	11.8%	18	13.1%	0.698
III	88	29.7%	37	27.0%	0.561
IV	3	1.0%	1	0.7%	0.774
Lobectomy site					
Upper right	96	38.1%	44	35.5%	0.948
Right middle	19	7.5%	7	5.6%	0.594
Lower right	36	14.3%	28	22.6%	0.024
Upper middle right	2	0.8%	1	0.8%	0.950
Lower middle right	4	1.6%	1	0.8%	0.574
Left lung	1	0.4%	0	0.0%	0.496
Upper left	65	25.8%	24	19.4%	0.288
Bottom left	29	11.5%	19	15.3%	0.209
Common comorbidity					
Digestive system diseases	130	43.9%	44	32.1%	0.020
Hypertension	60	20.3%	28	20.4%	0.968
Urinary system diseases	68	23.0%	27	19.7%	0.445
Reproductive system diseases	51	17.2%	14	10.2%	0.058
Cerebrovascular/cerebrovascular diseases	47	15.9%	21	15.3%	0.884
Bronchial diseases	40	13.5%	9	6.6%	0.034
Endocrine system diseases	33	11.1%	16	11.7%	0.871
Diabetes	27	9.1%	7	5.1%	0.149
Bone marrow function					
Abnormal INR	11	3.9%	4	3.1%	0.673
Abnormal hemoglobin	47	15.9%	26	19.0%	0.423
Abnormal erythrocyte count	72	24.4%	36	26.3%	0.662
Abnormal leukocyte count	25	8.5%	15	10.9%	0.403
Abnormal platelet count	22	7.5%	12	8.8%	0.633
Utilized number of staplers and cartridges					
Staplers	296	1.2 +/- 0.6	137	1.3 +/- 0.6	0.172
Cartridges	296	7.0 +/- 3.9	137	7.0 +/- 3.9	0.697
Bold terms indicate statistical significance. INR: International normalization ratio; SD: Standard deviation					

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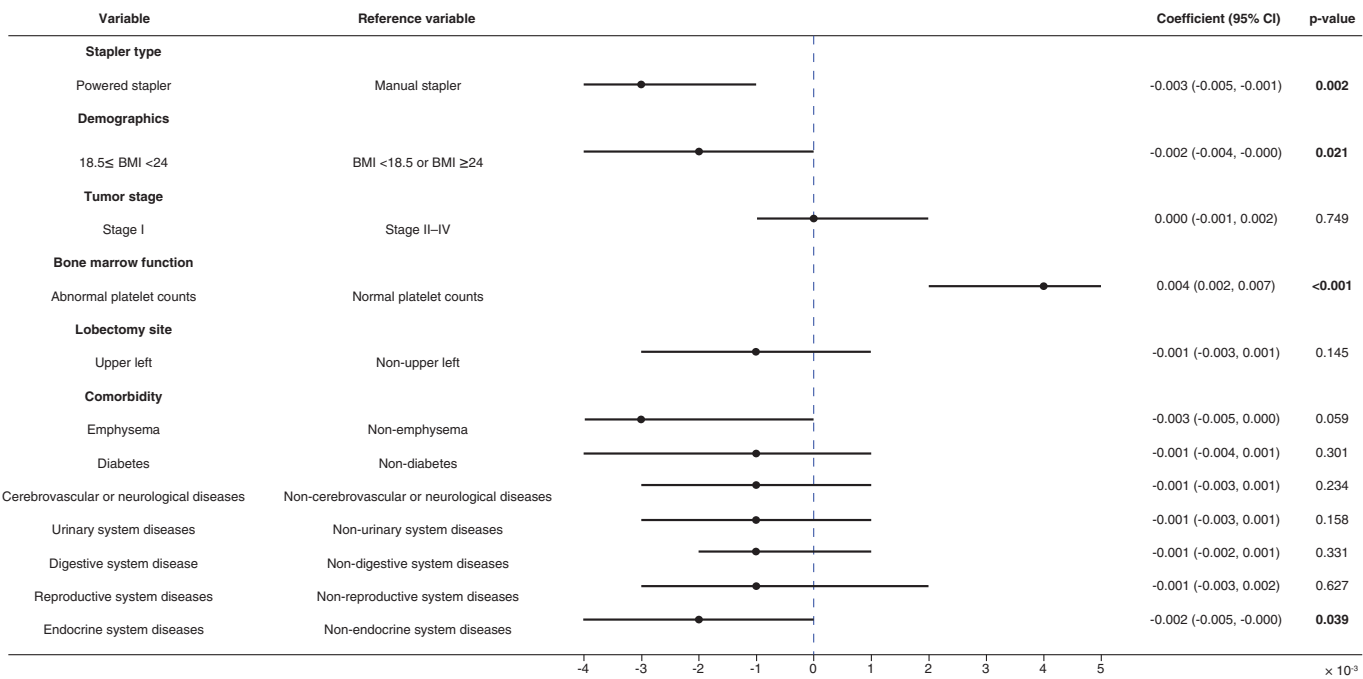


Figure 3. Multiple generalized linear regression analysis (inverse gaussian distribution) assessing the impact of powered stapler relative to manual stapler on postsurgery hospital stay length after the adjustment of patient baseline characteristics. Bold terms indicate statistical significance.

Table 2. Predicted clinical outcomes associated with the powered stapler and manual stapler in the included patients.							
Outcome measures	Utilization of powered stapler			Utilization of manual stapler			Changes [†]
	Mean / %	95% CI		Mean / %	95% CI		
		Lower	Upper		Lower	Upper	
Clinical outcomes							
Operation time (h)	3.62	3.60	3.64	3.89	3.86	3.91	-6.94%
Postsurgery length of stay (days)	7.70	7.64	7.76	8.49	8.42	8.57	-9.31%
Intraoperative blood transfusion rate	2.65%	2.10%	3.20%	3.89%	3.16%	4.62%	-31.88%
Total blood transfusion volume (ml)	33.93	20.21	47.64	95.61	81.90	109.32	-64.51%
Postsurgery air leak rate	44.54%	43.18%	45.89%	49.62%	48.24%	51.00%	-10.24%
Extended postsurgery drainage tube placement duration	13.69%	12.67%	14.72%	14.23%	13.18%	15.28%	-3.80%
† Changes were calculated for the predicted outcomes of powered stapler relative to manual stapler.							

postsurgery air leak, drainage tube placement duration and postsurgery complications risk. As a retrospective study, the measurement bias and unknown confounding effects in this study could substantially confound the data analysis. Thus, the generated evidence in this study should be interpreted with caution.

This study observed significantly shorter operation time and significantly shorter postsurgery hospital stay length associated with the powered stapler. However, the observed intraoperative blood transfusion rate, total blood transfusion volume and postsurgery air leak rate associated with powered stapler did not have significant differences. We reviewed the study design and data sources of previous studies reporting significant improvement of clinical outcomes associated with powered staplers [14–16]. The discrepancies associated with our study and previous studies in study design and data sources could explain why this study did not observe the expected outcomes associated with the powered stapler. As a retrospective cohort study, this study extracted outcomes from the existing medical records that were created for clinical care but not for research purposes. The measurement bias could be widely existing in the extracted outcomes and substantially confound the comparisons of these outcomes between the powered stapler and manual stapler [17]. For example, this study extracted postsurgery air leak information from

the nursing records which did not describe the patient conditions associated with reported air bubbles [18]. Thus, the extracted air bubble information did not allow this study to further clarify the nature of the air bubble and confirm postsurgery air leaks. Additionally, the study setting could discount the clinical benefits associated with the powered stapler as well. As one of the leading tertiary hospitals in China, the study hospital has conducted VATS lobectomy since the 1990s and the surgeons in this study hospital were highly experienced in the procedure. The surgeons were highly skilled with manual staplers and switched to use the powered stapler mainly for easier operation and reduce operation time. Since all the included patients were operated by the same VATS team for lobectomy, the confounding effects associated with surgery skills in this study should be minimum but this study was unable to demonstrate the differences in the measured outcomes across the surgeons with different levels of surgery skills and experiences like other studies [19,20]. Additionally, the prophylactic use of antibiotics before surgery has been a standard practice to reduce postsurgery infection risk in Chinese tertiary hospitals [21]. Thus, postsurgery complications had been minimized in our study cohort and the clinical benefits associated with the utilization of powered stapler for postsurgery complications were unlikely to be observed. It is possible that, due to similar reasons, the reduced blood transfusion rate and blood transfusion volume associated with the powered stapler did not reach statistical significance.

The collected patient baseline characteristics were highly comparable in both groups, except that the powered stapler group had a higher BMI and a higher proportion of overweight than the manual stapler group. This finding could be a strong indicator of the surgeon's preference of using powered staplers for VATS lobectomy in an overweighted patient as the operation space of VATS in these patients might be further limited and it is more difficult to operate the manual stapler. One large observational study including 19,337 patients with lobectomy in the USA identified that the mean operation time increased by 7.2 min every 10-unit increase in BMI [22]. Thus, the higher proportion of the overweighted patients in the powered stapler group suggested that bodyweight is an important consideration for using powered stapler for VATS lobectomy in Chinese tertiary hospitals as well. This finding also indicated the need to adjust the potential confounding effects associated with BMI in assessing the clinical impact of staplers in VATS lobectomy.

The identified clinical benefits associated with powered stapler might impact the hospital costs associated with VATS. First, this study found slightly less utilization of powered stapler (mean: 1.2 vs 1.3), which was usually more expensive than the manual stapler. Thus, the less utilization of powered stapler could reduce its acquisition costs. Additionally, the shorter postsurgery hospital stay length associated with powered stapler can reduce the utilization of health resources and further offset the hospital costs. Another potential economic benefit associated with powered stapler is the reduced operation time, which could lead to reduced postsurgery complications [18] and shorten postsurgery hospital stay length [23]. Because the reduced operation time and postsurgery hospital stay length can impact the hospital care capacity, the utilization of a powered stapler might improve hospital operation efficiency as well.

As a typical retrospective cohort study evaluating medical devices for surgery, our study should be interpreted with caution for the following limitations. First, the powered stapler was a relatively new medical device when compared with the manual stapler, which had been practiced for over 10 years in our hospital. Thus, the learning curve associated with the new medical devices might discount the treatment effects associated with powered stapler [24]. Second, the measured outcomes in our study could be heavily biased due to the lack of a standard approach to assess intraoperative bleeding, postsurgery drainage volume and postsurgery air leak in the real-world hospital setting. Third, the uncertainty associated with the procedure for VATS lobectomy could substantially confound the measured outcomes. Even though this study had controlled this type of confounding effects by excluding the patients with extreme values of measured outcomes, the procedures associated with the included patients were varied and not measurable. Thus, the confounding effects associated with procedures were unlikely to be fully controlled. Additionally, the reduced sample size could further reduce the power to detect the significance for the measured outcomes between the two staplers. Prospective cohort study design with standard outcome measurement approaches could be a better study design to assess the clinical benefits associated with the powered stapler in VATS lobectomy for lung cancer. Finally, this study was conducted in a single tertiary care hospital and the included patients were operated on by the same VATS team for lobectomy. Thus, the generalizability of the generated evidence in this study is limited.

Conclusion

Even with the general limitations associated with the retrospective study design, this study has confirmed that using the powered stapler in VATS lobectomy for lung cancer was associated with significant reductions of operation time and postsurgery hospital length of stay, which indicate hospital operation efficiency, in a Chinese tertiary general hospital. Future prospective studies are still needed to further clarify the clinical benefits associated with the powered stapler in Chinese patients with VATS lobectomy for lung cancer.

Future perspective

Even though this retrospective cohort study was unable to observe previously reported clinical benefits associated with the powered stapler in VATS lobectomy for lung cancer, the significantly shorter operation time and postsurgery stay length of hospital associated with powered stapler might suggest that the lack of standardized measurement of the clinical outcomes in the real-world setting could substantially bias the study results. Future real-world studies should bear in mind this potential bias by selecting appropriate outcomes with established measurement standards.

Summary points

- The powered stapler was taken quickly in Chinese tertiary care hospitals to meet the operation needs of VATS lobectomy for lung cancer.
- Even though the clinical outcomes associated with the powered stapler and manual stapler were comparable in a Chinese tertiary care hospital, the significantly shorter operation time and postsurgery stay length of hospital associated with powered stapler suggested that the selected clinical outcome measures might not fully demonstrate the clinical benefits associated with powered stapler due to measurement bias.
- The shorter operation time associated with powered stapler confirmed that powered stapler could improve convenience of VATS lobectomy for lung cancer.
- The shorter postsurgery length of hospital stay associated with powered stapler indicated the quick recovery that could impact the long-term outcomes and hospital costs in the patients receiving VATS lobectomy for lung cancer.

Supplementary data

To view the supplementary data that accompany this paper please visit the journal website at: www.futuremedicine.com/doi/suppl/10.2217/ce-2021-0060

Author contributions

Z Qian and W Chen formulated the research idea and developed the study protocol. F Xiong, X Xia, P Gu, Q Wang and A Wu developed data extraction strategies, coordinate the data access and conducted data extraction from the HIS. H Zhan followed the study protocol to clean the extracted data and perform the data analysis. Z Qian and W Chen drafted the manuscript. All authors have critically reviewed the manuscript and approved this manuscript submission.

Financial & competing interests disclosure

This study was funded by Johnson and Johnson China, Shanghai, China. H Zhan and W Chen are employed in a consulting firm which receives industry research funds for real-world studies and health economics research. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

No writing assistance was utilized in the production of this manuscript.

Ethical conduct of research

This study was approved by the ethics review board of Xiangya Hospital.

Data sharing statement

Permission of data owner, Xiangya Hospital, is required.

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