



Evidence of the Impact of Stapler Choice on Clinical and Economic Outcomes in Video-Assisted Thoracoscopic Surgeries (VATS): A Perspective from Thoracic Surgeons in China

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Abstract

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Background: VATS lobectomies have been shown to offer benefits over open thoracotomies in terms of clinical and economic outcomes for patients and hospitals. New innovation in stapling technology is expected to deliver improved clinical and economic outcomes in VATS procedures. This study documents comparative evidence between major brands of staplers, and an aggregate qualitative reaction from practicing thoracic surgeons in China in terms of utility of such evidence in informing surgical choice in China.

Methods: Brief summaries of published pre-clinical and real-world database studies were presented to a group of thoracic surgeons on-site in Shanghai. The evidence focused on comparing two major stapler brands on device stability, bleeding complications, air leaks, and procedure economics. Surgeons' anonymized reactions to the presented evidence were captured through instant polls conducted using an on-line polling software. Following a simplified Delphi Consensus development methodology, absolute proportions of surgeon responses were calculated, with an a priori threshold of 80% used as a general consensus position.

Results: Based on their review of the evidence, surgeons most agreed that a stapler does have a role to play in the outcomes of VATS lobectomies. Based on multiple corroborating studies, surgeons agreed that stapler choice does influence bleeding and air leak outcomes in lung surgery. Cost of staplers was mentioned as a barrier for adoption owing to lack of understanding of downstream value of higher priced technology - and further building the economic value proposition was suggested.

Conclusion: The presented evidence was found to be informative for clinical decision making. Additional guidance was sought regarding cartridge/ reload selection, which would positively affect the quality and cost of minimally invasive thoracic surgery. Observation of similar benefits associated with latest powered and tissue-specific staplers across patients and geographies helps build further confidence in their utility in China.

Keywords: VATS, Thoracic Surgery; Stapler; Bleeding; Air Leak

Introduction

Enabled by the recent progress in surgical technologies and techniques, Video-Assisted Thoracic

Table 1: Evidence of the impact of stapler innovation in VATS thoracic surgery presented.

Publication	Type of study	Data source	Relevant sample	Outcome focus
Miller et al. 2015 [10]	Delphi consensus panel study	Global survey	11 thoracic surgeons representing 8 countries in US, EMEA, and ASPAC	Clinical impact of stapler tip stability
Miller et al. 2018 [11]	Retrospective database study	Premier Healthcare Database (USA)	3,759 VATS lobectomies	Bleeding and economic impact
Park et al. 2019 [12]	Retrospective database study	Yonsei University Severance Hospital EMR (Korea)	275 VATS lobectomies	Bleeding and economic impact
Tsunezuka et al. 2019 [13]	Case series study	Ishikawa Prefectural Central Hospital EMR (Japan)	239 VATS lobectomies	Bleeding
Eckert et al. 2019 [14]	Pre-clinical study	Physiologic Lung Model	110 porcine lung resections	Air leak
Chen et al. 2019 [15]	Decision analysis study	Clinical trial efficacy data, and hospital cost data	346 VATS lobectomies	Economic impact

Surgery (VATS) - a minimally invasive technique, has been shown to be associated with lower complication rates and morbidity to patients in comparison with open thoracotomy [1,2]. Additionally, recent studies among cancer surgery patients have also shown that VATS lobectomy was associated with less postoperative pain, improved quality of life, and similar hospital costs when compared with open thoracotomy [1-3].

With a relatively higher lung cancer mortality rate in China, expected to be growing approximately 40% in the next decade, lung cancer surgery is a critical part of available treatment pathways [4,5]. VATS procedures have gained in their prominence in the last twenty years or so in China, but the widespread adoption rate for such procedures are not well documented-especially beyond large hospitals [6]. A recently published analysis of the Chinese lung cancer national database for the years 2013 to 2016 reported that the rate of VATS procedures was about 48% nationwide and varied widely (from 14% to 75%) across geographic regions, and from 13% to 90% across hospital levels [7]. Older patients, with greater comorbidity burden, smaller tumors and detected in earlier stages of cancer had a greater chance of receiving VATS surgeries. The study also estimated nationwide mean VATS-associated total hospital cost (¥55,683 ± 17,512) to be over 6% higher than the cost associated with open thoracotomy procedures (¥52,345 ± 26,135, P<0.001) [7].

Stapling is a critical step during VATS lobectomy procedures for the transection of pulmonary veins and arteries, bronchi, and lung parenchyma - and may have material impact on overall outcomes and costs of the procedure. New innovation in stapling technology has introduced powered devices, as well as, reloads with design features such as a narrow anvil, two-row design etc. for specific tissue effects in pulmonary vasculature—all aimed at improving precision and integrity of the staple line upon transection.

Clinical studies have established the safety, efficacy and satisfactory performance of latest innovations in powered and tissue-specific stapling technology in China [8,9]. However, an overall assessment of available comparative evidence of the relative

benefits of latest competing stapling technologies from major global manufacturers, has not been documented yet. As such, it is unclear how, if at all, the available evidence is informing clinical decision-making among thoracic surgeons in China, and what gaps in the evidence may potentially exist.

Objective

This study documents qualitative reaction from the perspective of a select group of practicing thoracic surgeons in China to currently available literature assessing impact of stapler innovation—with a goal of assessing their potential utility in informing and shaping choice of stapling technology in regular surgical practice in China.

Methods

Brief summaries of published pre-clinical and real-world database studies were presented to a group of eight thoracic surgeons on-site in Shanghai, China. Participating surgeons were high-volume operators, performing mostly traditional VATS or single-port lung surgeries at major hospitals in several provinces in and around Shanghai.

Evidence presented by lead researchers were focused on impact of stapler innovation on (Table 1):

- Overall benefit of stability
- Bleeding complications
- Air leaks, and
- Procedure economics

Participating surgeons’ reactions to the presented evidence were captured through instant polls conducted using an online polling software where respondents could anonymously input their responses using their mobile phones to questions presented to them on-site.

Following a simplified Delphi consensus development methodology, absolute proportions of surgeon responses were calculated—with an a priori threshold of 80% used as general consensus position of the participating surgeons.

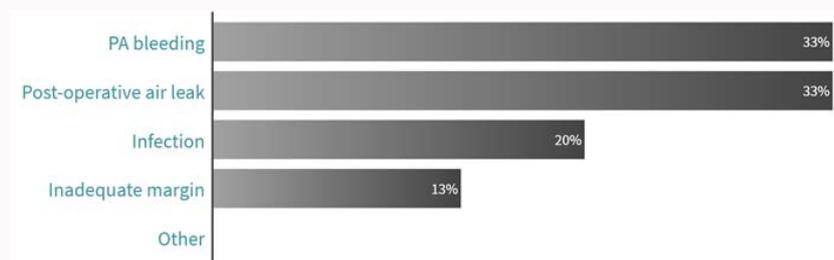


Figure 1: Most concerning complications in VATS lobectomy and segmentectomy.

Table 2: Participating thoracic surgeons in China.

Name	Academic Title	Highest Academic qualification	Number of Years in Practice	Technique Specialty	Number of surgical cases per year
Fei Cui	Associate Chief Physician	Ph.D. from Nanjing Medical University	22	Uni-portal VATS lobectomy and segmentectomy	800
Xiaoyong Shen	Chief Physician	Master of Cardio Thoracic Surgery from Fudan University	22	Uni-portal VATS lobectomy	800
Yang Xue	Deputy Chief Physician, Thoracic Surgery Department	Ph.D. from West China School of Medicine, Sichuan University	17	VATs segmentectomy and minimally invasive esophagectomy	280
Minwei Bao	Attending Surgeon, Department of Thoracic Surgery	Doctor of Thoracic Surgery, Shanghai Pulmonary Hospital Tongji University School of Medicine	13	Uni-portal VATS lobectomy, segmentectomy, and pneumonectomy	1,000
Wenshu Chen	Associate Chief Physician	Ph.D. from Thoracic Surgery of Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology	15	VATS lobectomy and segmentectomy	410
Qu Qi	Deputy Director, Department of Thoracic Surgery	Doctor Degree in Surgery, Zhengzhou University	16	Robotic and VATS segmentectomy	900
Zheng Ma	Associate Chief Physician, Director of Thoracic surgery Deputy Director, Division of Esophageal Cancer Center, and Research Professor, Department of Thoracic Surgery	Doctor Degree, from the Third Military Medical University	24	Uni-portal VATS lobectomy and segmentectomy	300
Jun Yin		Ph.D. from Charité Medical University, Humboldt University Berlin, Germany, and postdoc from University of Toronto, Canada	17	Uni-portal VATS lobectomy and segmentectomy	300

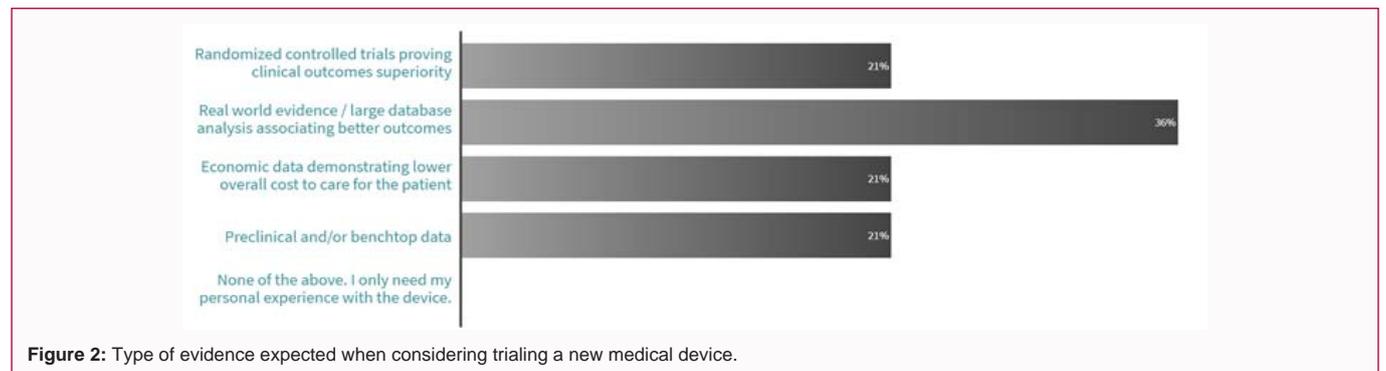


Figure 2: Type of evidence expected when considering trialing a new medical device.

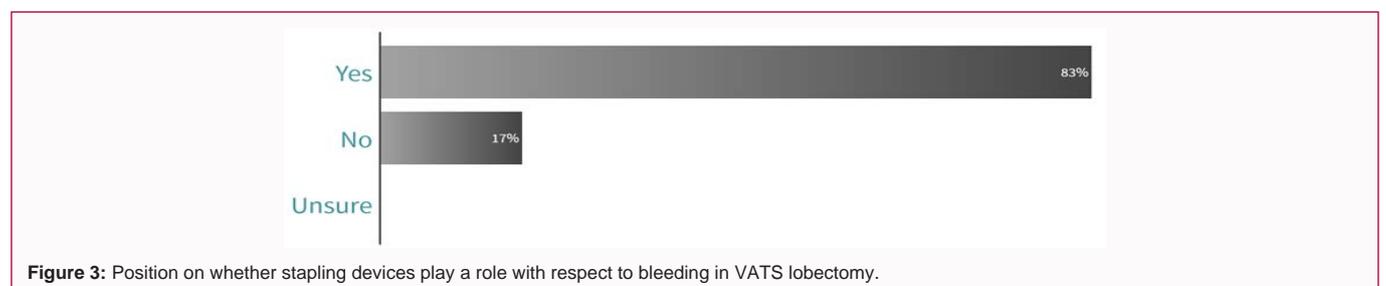


Figure 3: Position on whether stapling devices play a role with respect to bleeding in VATS lobectomy.

Results

Participating surgeons

Perceptions of participating surgeons and their reaction to the presented evidence was the key focus of this study. Details about the practice and experience of participating surgeons are provided in Table 2.

Participating surgeons shared their primary concerns related to complications in VATS surgery. As shown in Figure 1, bleeding at the pulmonary artery was the number one concern in thoracic surgery. Air leaks also were of high concern, especially as they tend to keep the patients in hospital longer.

Surgeon participants in the panel also expressed a strong preference for real-world evidence to inform their surgical practice

(Figure 2). While they also appreciate the availability of randomized controlled trial evidence, benchtop or preclinical data, as well as, evidence of pure economic impact—not having any evidence at all was not considered an acceptable option to generate trial for new medical devices [10-13].

Presented evidence

Key findings from studies related to the outcomes of interest (Table 3), were presented to the participating surgeons as stimuli to generate and capture their reaction to such evidence—in perspective of their own surgical experiences. Surgeons had the ability to express their opinions and to discuss the findings among themselves prior to and after responding to polling questions meant to assess the level of simplified position consensus. Prior to reviewing the evidence, a majority (83%) of the participating surgeons expressed their belief

Table 3: Key study findings presented.

Publication	Key findings	Outcome category
Miller et al. 2015 [10]	<ul style="list-style-type: none"> 88% surgeons considered staple line oozing or bleeding controllable with clips, suture or fibrin glue as a potential hazard of (mechanical) stapler tip instability. 50% panelists reported observing staple line oozing that required additional OR time. – owing to excessive tip movement 	Stapler stability
	<ul style="list-style-type: none"> Tip stability imparted by powered cutting/stapling would reduce staple line oozing/bleeding in: <ul style="list-style-type: none"> Thin critical structures (88%) Thick, less critical structures (88%) Lung tissue of poor quality (88%), and Tight spaces (75%) 	Stapler stability
Miller et al. 2018 [11]	<ul style="list-style-type: none"> Compared to manual staplers, the use of newer powered staplers resulted in: <ul style="list-style-type: none"> 47% lower adjusted composite hemostasis complication outcome (bleeding and/or transfusion) (8.5% vs. 16.0%, P<0.001); and 51% lower adjusted transfusion rates (5.4% vs. 10.9%, P=0.002) 	Bleeding
	<ul style="list-style-type: none"> Compared to MDT manual group, the use of ETH powered stapler group resulted in: <ul style="list-style-type: none"> 41% lower adjusted rates of the composite hemostasis complication outcome (bleeding and/or transfusion) (8.2% vs. 13.9%, P=0.022), 47% lower transfusion (4.7% vs. 9.3%, P=0.018) 14% shorter adjusted hospital LOS (4.89 vs. 5.66, P<0.037) 	Bleeding
	<ul style="list-style-type: none"> Compared to manual staplers, the use of newer powered staplers resulted in: <ul style="list-style-type: none"> 47% lower adjusted composite hemostasis complication outcome (bleeding and/or transfusion) (8.5% vs. 16.0%, P<0.001); and 51% lower adjusted transfusion rates (5.4% vs. 10.9%, P=0.002) 	Bleeding
	<ul style="list-style-type: none"> Compared to MDT manual group, the use of ETH powered staplers resulted in: <ul style="list-style-type: none"> 9% lower adjusted total hospital costs (\$23,785 vs. \$26,180, P=0.008), 16% lower adjusted supply costs (\$5,021 vs. \$5,989, P=0.016), and 15% lower adjusted room and board costs (\$6,792 vs. \$7,984, P=0.039); 	Economics
	<ul style="list-style-type: none"> No costs (total, supply, room & board etc.) were statistically different between the MDT manual and the ETH PVS stapler group – in spite of the use of two powered staplers in the ETH group. 	Economics
Park et al. 2019 [12]	<ul style="list-style-type: none"> Compared to using Ethicon’s manual staplers, the use of Ethicon’s powered staplers (GST+PVS) resulted in: <ul style="list-style-type: none"> 56% lower intraoperative blood loss (182.4 mL vs. 79.8, p=0.0004), and 32% lower related usage of hemostatic material per case (1.34 vs. 0.91, p<0.0001) 	Bleeding
	<ul style="list-style-type: none"> Compared to using ETH manual staplers, the use of ETH powered staplers (GST+PVS) resulted in: <ul style="list-style-type: none"> 12% lower adjusted hospital costs (KRW 14,610,162 vs. KRW 12,876,111, p<0.0001) 12% lower adjusted hemostasis related costs (KRW 198,996 vs. KRW 175,291, p=0.0101) 24% lower cartridge related adjusted costs (KRW 1,105,091 vs. KRW 839,011, p<0.0001). 	Economics
Tsunezuka et al. 2020 [13]	<ul style="list-style-type: none"> Overall, bleeding after stapling occurred in 24/239 (10.0%) VATS lobectomy cases – for both manual and powered stapling device groups 	Bleeding
	<ul style="list-style-type: none"> Group using manual staplers (ETH or MDT) experienced greater percentage (29.2%) of bleeding cases – compared to powered staplers for either ETH or MDT. 	Bleeding
	<ul style="list-style-type: none"> Most bleeding occurred in the MDT group (Endo-GIATM iDriveTM; 70.8%): <ul style="list-style-type: none"> 24.6% with gray cartridges, 50% with white cartridges, respectively. No incidences of bleeding were observed in the ETH (PVS) group. 	Bleeding
Eckert et al. 2018 [14]	<ul style="list-style-type: none"> The impact of stapler design (uniform [UNI] vs. graduated [GRD] staple heights) and ventilation modality (positive [PPV] vs. negative [NPV] pressure) on air leaks were evaluated Under negative pressure, graduated height staplers had a 2.2x increase in incidence of air leaks (p=0.004, GRD=44%, UNI=20%) Under negative pressure, GRD staplers had greater magnitude air leaks than UNI staplers (p=0.003, GRD=15.8 ml/min, UNI = 1.87 ml/min) Negative pressure increased the incidence and severity of air leaks in both stapler groups. Compared to conventional staplers, unit cost for ETH PVS was 1,750 CNY greater per case. 	Air Leaks
Chen et al. 2019 [15]	<ul style="list-style-type: none"> However, reduction in bleeding (8.5%), could be associated with the reduction of: <ul style="list-style-type: none"> 133.39 CNY in bleeding treatment cost, and 1,455.13 CNY in other hospitalization cost. Hence, PVS could improve bleeding outcomes without significantly increasing hospital costs. 	Economics



Figure 4: Position on whether stapling devices may have a positive impact on bleeding outcomes in VATS lobectomy, based on the reviewed evidence.

that stapling devices do play a role in bleeding in VATS lobectomy (Figure 3). Their position did not move significantly after reviewing the evidence, as a similarly high percentage (83%) of surgeons continued to believe that stapling devices may have a positive impact

on VATS thoracic procedures (Figure 4). However, the remaining 17% surgeons moved from disagreeing with the potential role of a stapler to being unsure.

In addition, the fact that there were multiple corroborating



Figure 5: Position on whether the Physiologic Lung Model is a valid and relevant model in which to test air leaks.



Figure 6: Position on whether negative pressure ventilation could result in higher leak rates than positive pressure ventilation.

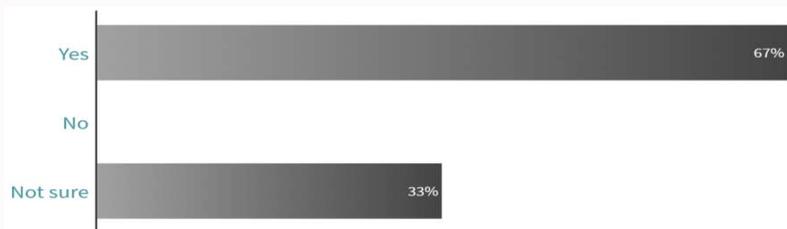


Figure 7A: Position on whether the choice of a stapler may influence air leak development – before exposure to presented evidence.



Figure 7B: Position on whether the choice of a stapler may influence air leak development – after exposure to presented evidence.

studies presented suggesting clinical and economic benefits associated with the use of Ethicon’s staplers, made the overall message more convincing to 100% of the participating surgeons (Figure not presented).

The Physiologic Lung Model (PLM) [16] was lauded by the surgeon panel as a relevant and reliable pre-clinical model to test air leaks (Figure 5). This model was considered to be able to limit several of the confounding factors and was thus helpful in generating insights regarding the physiological basis of air leaks in both positive and negative pressure breathing scenarios. The finding of a higher leak rate prevalent in negative pressure ventilation scenarios, compared to positive pressure ventilation, was met with mixed skepticism by the surgeon panel (Figure 6). 40% of the thoracic surgeons did not think that such a finding aligned with their clinical perception, and the remaining 60% were not sure. 67% of the surgeons believed that choice of a stapler may influence development of air leaks, prior to being exposed to related stapler-specific evidence (Figure 7A).

However, 33% surgeons were not sure that stapler choice mattered in this regard.

Upon reviewing findings of the study [14] that suggested superior leak rates and leak volume outcomes associated with the use of Ethicon staplers in the PLM, all 100% surgeons agreed that stapler choice does seem to have an influence on leak outcomes in lung surgery (Figure 7B).

Discussion

This was the first Chinese surgeon panel review focused on currently available evidence on the clinical and economic impact of endoscopic stapler use in thoracic surgery. The simplified Delphi consensus panel approach enabled eliciting of a more structured assessment and clinical opinion in reaction to the evidence, from practicing high-volume thoracic surgeons in China.

Based on the fact that this approach involved qualified individuals (thoracic surgeons) with relevant knowledge and experience of a

particular topic (thoracic surgery), this simplified Delphi panel is of significant use in informing situations where no other definite evidence has been reported in the literature [17]. The design also followed similar approach used by the RAND Corporation, who were the originators of this methodology, in their recent work on establishing reactions from stakeholders to evidence on access management strategies in primary care [18]. While there are no hard and fast rules about the number of participants for the consensus to be meaningful, our work certainly meets the standards set by Linstone [19] for seven as a suitable minimum panel size-especially in view of the importance of the surgeons' time away from patient care.

In discussing most important concerns related to thoracic surgery, participating surgeons believe that bleeding at the pulmonary artery is the number one concern. In their opinion, major causes of bleeding in thoracic procedures include vessel dissection, and incomplete fissure typical to the Chinese patient anatomy. However, they also believe that bleeding events may be minimized or avoided altogether by exercising extra caution during dissection. Pre-operative planning is important to locate critical structures and can help avoid accidental maneuvers that cause bleeding during minimally invasive lung surgery.

Air leaks also were of high concern, especially as they tend to keep the patients in hospital longer. Surgeons believe that while bleeding may be managed with adequate caution, the unpredictable nature of air leaks makes this complication challenging.

Evidence appears to be driving surgeons' clinical decisions in big measure, with a strong preference for real-world evidence derived in regular care settings outside of a rigid clinical trial protocol. While they also appreciate the availability of randomized controlled trial evidence, bench top or preclinical data, as well as, evidence of pure economic impact, not having any evidence at all was not considered an acceptable option to generate trial for new medical devices. In fact, consensus regarding the journey to clinical adoption of new technology was described to follow the path of:

- a) Getting convinced about worthiness of new technology by reviewing population level evidence of clinical benefit;
- b) Getting convinced to try new technology based on experience shared by senior local and international colleagues through videos, conference talks etc., and
- c) Getting hands-on personal experience which validates the role of new technology in potentially benefiting patient outcomes in the surgeon's clinical practice.

Bleeding

A significant majority of the thoracic surgeons participating in this panel in China believe in the role a stapler plays with respect to bleeding in VATS lobectomy surgeries. They demonstrated high level of confidence both before and after being exposed to the targeted evidence on the topic. Interestingly, however, a cohort of 17% surgeons who initially fully disagreed with the potential role of a stapler in this regard modified their view to being unsure-thus opening up to the utility of evidence in further informing their perception. Such overall positive impression about the role of staplers was similar to the findings of an earlier Delphi Panel study by Miller et al. [9], where 88% of a global panel of thoracic surgeons considered staple line oozing or bleeding as a potential hazard of the instability of the distal tip of a mechanically actuated stapler.

Most of the participating surgeons were familiar with Ethicon's staplers - ECHELON Flex™ GST System and ECHELON Flex™ Powered Vascular Stapler (PVS), which were featured in several real-world evidence pieces, and demonstrated potential clinical and economic benefits with their use in thoracic surgery. They considered PVS to be especially helpful in single port VATS surgeries owing to the angle at the tip of the stapler, which makes access around critical structures meaningfully easier and safer.

Air leaks

Thoracic surgeons in the panel found management of air leaks to be rather challenging owing to their unpredictability. There are many confounding factors that influence development of air leaks in the clinical setting and controlling for such factors in a laboratory model makes studying air leaks extremely difficult. That is also borne out by the unavailability of a reliable model for testing air leaks.

Surgeons agree that the Physiologic Lung Model (PLM) is a relevant and reliable pre-clinical model to test air leaks. It is able to limit critical confounding factors and is thus helpful in generating insights regarding the physiological basis of air leaks in both positive and negative pressure breathing scenarios. They suggest that this model would be even more relevant if it could incorporate simulated blood supply and utilize COPD/emphysematous lung rather than healthy lung, as was the case in the presented study. In addition, keeping the lungs alive in the PLM system to test air leaks over a longer period was suggested - to mimic the trend of air leaks evolving over time.

The possibility of a higher leak rate under negative pressure ventilation compared to positive pressure was not obvious to the surgeons and perhaps did not align with their clinical experience. Apart from considering this an unusual finding, surgeons also hypothesized that it could be of clinical advantage owing to the unpredictability in apposition of the lung tissue to the chest wall to stop air leaks.

The shift in surgeons' perception of the involvement of a stapler in reducing air leaks, before and after their being exposed to the relevant evidence, was remarkable. Upon reviewing findings of the study [14] that suggested superior leak rates and leak volume outcomes associated with the use of Ethicon staplers in the PLM, all surgeons-including the one-third of the group that was not sure earlier, agreed that stapler choice does likely have an influence on leak outcomes in lung surgery.

Cost of staplers

Cost of stapling devices was mentioned as a barrier for adoption in many provinces owing to lack of understanding and desire to assess the overall (downstream) value of using higher priced technology with potentially superior outcomes. In addition to, and utilizing the presented evidence, surgeons suggested focusing on further building the economic value proposition of the staplers. Such integrated evidence would help inform and shape government policy towards appropriate hospital reimbursement in the public sector healthcare system in China. Results of such initiatives, coupled with relevant ongoing evidence generation in local Chinese settings, could also elevate the overall quality and cost of healthcare in the country.

Conclusion

Overall, Chinese thoracic surgeons found the presented evidence to be meaningful and informative for their clinical decision making.

They further suggested that, while the evidence is informative in assessing worthiness of the technology, guidance on what cartridge/reload to use in what situation (by tissue type, thickness, presence of disease, etc.), would be highly beneficial for furthering appropriate use in China - which would in turn affect the quality and cost of minimally invasive thoracic surgery.

The observation of similar trends in clinical and economic benefits associated with latest powered and tissue-specific staplers across patients and geographies helps build confidence in their utility as part of thoracic surgeons' preferred toolkit in China.

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