



Can we sell something people don't want?

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Received: 25 January 2021; Accepted: 01 March 2021; Published: 15 September 2021.

doi: 10.21037/vats-21-8

View this article at: <http://dx.doi.org/10.21037/vats-21-8>

Performing thoracic surgery in a patient who is not intubated under general anesthesia is an exciting idea. When I first heard and saw in earlier 2000 I was genuinely excited and sanguine for its promise. Finally, there was something new in our specialty and at our international meetings. An innovation. A game changer. On paper, it looked like a “can’t miss” disruptive technological advance. A true paradigm shift. Some thought it would quickly revolutionize how thoracic surgery was performed. Think of the all of the theoretical advantages it conveys, such as: the avoidance of muscle paralysis and the incumbent hemodynamic fluctuations and post-operative muscle pain that many patients experience, the elimination of intubation and the placement of a double-lumen tube which for the uninitiated takes significant time and has risk, the mitigation of atelectasis of one lung during the operation and thus the improved PaO₂, the elimination of the need to reserve anesthetic agents and extubation that often causes large swings in intra-thoracic pressure and the propagation of air leaks, etc. Yet, despite these many theoretical advantages some of which have been shown to be true, it has not been widely accepted. Flash-forward 19 years later and how is its adoption? Non-intubated thoracic surgery or non-intubated minimally invasive pulmonary resection using video-assisted thoracoscopic techniques (VATS) or robotic techniques is rarely chosen, especially in the United States despite the fact that the concept has advantages and has been around for a long time. Why? The answer is simple. The consumers, the patients, the surgeons and the anesthesiologists do not want to do it. It is hard to sell something that the consumer does not want even if it “may be better for you.” Its marketing is poor to say the least. Before we explore the consumer part of this equation let’s see the actual data that may or may not support the purported advantages.

The data

There are three prospective randomized studies published on non-intubated thoracic surgery but despite these efforts the level of data is still poor. There exist little to no grade A evidence for us, as we see too often for surgical questions.

Prospective randomized trials

All three prospective randomized studies on this issue have problems.

The first by Pompeo a thoracic surgeon in Italy was reported in 2004 (1). He and colleagues randomized 60 patients into two arms. One arm, the control group, received a general anesthesia, double lumen endotracheal tube and a thoracic epidural and the other arm featured patients that were not intubated and received epidural anesthesia alone. The authors found that: the anesthesia time, operative time, and global operating room time were all better (less) in the awake group. Interestingly, they reported that the anesthesia satisfaction score was higher in the awake group. This latter finding if better described and validated and/or reproduced in any other future study could demonstrate the real value of non-intubated patients undergoing pulmonary resection. They also showed that there was less reduction in PaO₂ and the hospital stay was less in the awake group. The problems with this study are many. First, the N is small (only 30 patients in each arm). Second, two of the 30 patients in the awake group had to be intubated during the operations because of adhesion takedown and two others (so a total of 4 of the 30, 13%) had to be converted to the intubated group because they had lung cancer after pulmonary wedge was performed and the frozen returned. At this early (2004) time the authors were not performing lobectomy in non-intubated patients.

The second prospective study is also from the same group. Pompeo in 2007 (2) reported on 43 patients who underwent VATS but all of these patients had surgical intervention for spontaneous pneumothorax blebectomy surgery. Most of us acknowledge the feasibility and advantages of non-intubation in this group of patients. This operation is technically easier, has little to no risk of pulmonary artery injury and requires no lymph node dissection along the airway that may cause coughing. It is merely a wedge resection with or without chemical or mechanical pleurodesis. From personal experience, mechanical pleurodesis in an awake patient without an epidural is abject misery—for everyone, the patients, surgeon and anesthesiologist.

The third prospective study is from Liu and colleagues in 2015 (3). This study unfortunately has three types of pulmonary resection: blebectomy, wedge resection and lobectomy. This of course muddies the waters. These patients were divided into two groups: those that had non-intubated VATS using an epidural compared to those that had general anesthesia using a DLET. Thus, to be clear, there are clear methodological differences in these control groups. In this study, the control group did not have an epidural. Parenthetically, as a patient, I would much rather come to the operating room and be put to sleep than have someone place an epidural in my back. This declares my clear conflict of interest and bias as well as my own prejudice from seeing it done in hundreds of patients both ways. The authors found that the awake group was quicker to eat post-operatively, had a shorter duration of antibiotic use and a shorter hospital stay and less cytokines. The first three findings are mundane at best. All three are in the purview of the surgeon and have little to nothing to do with the surgical or anesthetic platform chosen but everything to do with the postoperative protocols implemented. Now there is a true bias. The last finding however is very intriguing and may also be one of the important metrics and findings that shows the true advantage of non-intubated compared to intubated. It is consistent with our belief that less is better (4). Based on these data, there is no imprimatur or solid recommendation that can be offered from these prospective randomized studies. What about other data or reports? We are left with individual reports or better a compilation of reports such as that contained in meta-analyses.

Meta-analyses

Zhang *et al.* in 2019 (5) reported a series comparing non-

intubated video-assisted thoracoscopic surgery versus intubated video-assisted thoracoscopic surgery in a meta-analysis of 1,684 patients. Like any meta-analysis, this study suffers from non-matched patients. There were different reasons to place patients into the two different groups and patients had various types of operations, surgical approaches and surgeons. After accounting for these many differences, the authors reported a shorter in-operating room time, shorter hospital stay, shorter anesthesia time, shorter chest tube time and lower perioperative mortality rates for those that had a non-intubated operation.

In 2018, Shi and colleagues (6) reported on another meta-analysis of 754 articles including 3 randomized controlled trials on 1,138 patients. This study found no difference in pulmonary complications but did show a shorter hospital length of stay. These studies included the 3 prospective randomized studies described above in detail.

In 2018, Alghamdi and colleagues (7) reported a study comparing 62 patients who underwent VATS lobectomy, 31 patients had a VATS lobectomy and were intubated and 31 had a VATS lobe and had a non-intubated approach. This is the ideal study because it is evaluating the operation we want to study, minimally invasive lobectomy not wedge resection. The authors found that the operative time was shorter in the non-intubated group (but only by 3 minutes, 121 minutes compared to 118). This difference was not statistically significant. They did show that there was a great number of lymph nodes resected in the intubated patients (13 versus 18, $P=0.003$). This may be an important problem with the non-intubated group. Was this from surgeon inpatient or from anesthesia prodding to hurry along? Was it from patient's coughing as the airway was perhaps tickled during the lymph node dissection around and/or off the airway in lymph node stations 2R, 4R, 7 and 4L? The number of lymph nodes and a complete thoracic lymphadenectomy are critical metrics that demonstrate a high quality operation. We demand them here at NYU-Langone for every operation we do. They may convey important survival advantages for patients for better as well as better staging. Other findings in this report showed no operative mortality and one patient in the non-intubated group was converted to intubated and underwent a thoracotomy for bleeding.

Final thoughts

What I love about medicine is that it is data driven. Follow the science. Numbers don't lie. Opinions do not matter. The

answer is always in the data and in the metrics if: the metrics measure what matters, if the data has high fidelity and accuracy, if the variables are properly assessed and weighted, if all of the risks can be objectively and properly quantified, and if the attribution is fair and accurate. Make the metrics right, tweak them to get them better with each iteration, make the data clean and accurate, have the contestants own their own data and create a culture of fairness and engage in a positive friendly open and fun competitive ambiance and the right answer and behavior always follows—always. We have leveraged the novel efficiency quality index, the EQI (8) to drive world-class outcomes here at NYU Langone hospital to achieve some of the highest-ranking quality metrics of any hospital or healthcare care system in the world. In highly reliable organizations that are transparent and fair but demand accountability the cultures will change to what you measure and publically report and reward. Behavior follows metrics that are posted for all to see.

Medicine is both a science and an art. The literature above suggests that not only is non-intubated VATS surgery safe but this avant-garde, the innovative technique is perhaps superior in many ways compared to the eristic dogma of yester-year. No one dislikes dogma more than me and few have challenged it in a more, public “in-your-face” manner than me. Our group has challenged and debunked: the treatment of air leaks, the optimal conduct for lobectomy and the need for no more than a one-day length of stay after lobectomy as well as the benefit of telemedicine over ten years ago long before Covid-19. We have shown the lack of need of arterial lines, epidurals, types and screen, axillary rolls, bean bags etc. in the operating room and the need for an intensive care unit post-operatively. And more recently the advantages of a robotic platform. But importantly, if others do not see value in your new ideas and adapt them into their practices then your pioneering efforts return little to no value besides your own institution. If you can't sell it to others who do you help? So why has non-intubated VATS lobectomy not taken off? The reason is that it does not resonate with the customers. Patients do not want it and neither do most surgeons or anesthesiologists.

The customers

Patients are already nervous about having “their chest entered and part of their lung removed.” They are afraid and entitled to be and these attributes have and will only continue to increase in most all of our cultures. Patients demand and expect a perfect experience and outcome every

time, all the time. And we should deliver one, they deserve it. There is nothing better from the patients' perspective than coming to the operating room and “just going to sleep” and waking up in the recovering room. No one wants to have a needle placed in their back as they bend over a cold metal tray (that offers risk and a failure rate) or be told to relax and “take deep slow breathes” as surgeons place sharp instruments inside their chest cavity. They do not want to be aware of anything during the procedure: smells, sounds, sights—nothing just pleasant dreams. This fact is especially true in the United States. When you start to explain to a patient that they will be awake for the lung resection their eyes balls begin to bulge and their blood pressure rises. Now those of us who practice clinical medicine recognize that we can describe and convince our patients to do almost anything. They trust us and should, and most follow our recommendations. There are many ways to better explain it to patients. “You are not really awake, you are sort of asleep in La-La land, you are often snoring and very comfortable and safe and the anesthesiologist is right next to you the whole time.” We can comfort them and explain the advantages of non-intubated awake lobectomy, but at the end of the day, this adds times to their clinic visit. Time, that few of us have in a busy day jammed with many patients and other responsibilities. Is this a common excuse to avoid change, and get better? Yes. Is it like the safety-card that many doctors and nurses overplay to avoid changing and getting better? Yes. However, is it true? Yes. Innovations should reduce risk and time, not add them.

If we had more studies such as the one described above that showed that patient experience is better being awake than going to sleep the current sentiment might change. But convincing objective data that is critically and thoughtfully measures patients' experience and satisfaction has not been presented. I do not believe that the time to eat post-operatively, or the length of the antibiotics has anything to do with whether you had your lobectomy performed intubated or not, asleep or not, or with VATS or a robot. It has everything to do with the surgical teams' s post-operative protocols. Our post-lobectomy patients are all scheduled to eat a fatty meal 3–6 hours post-operatively, in order for us to rule out a chylothorax and remove their chest tube within 6–8 hours of surgery. Essentially no-one gets any post-operative antibiotics. Why should they? Show me the data. In these studies, described above, patients have chest tubes for 2–3 days and hospital length of stays of 3–6 days. We put everyone to sleep and they most all go home in under a day and have a chest tube for 8 hours. We

expect all patients to go home within 23 hours after surgery, early in the morning of post-operative day 1 by 8 or 9 AM. Protocols and efficient, error-free operations drive these outcomes not surgical or anesthetic platforms. Culture and leadership and expectations drive it, not awake or asleep, intubated or not intubated. Efficient, not fast, and high-quality operations that keep total operative time to 2 hours or less (skin to skin time of 1.5 hours for lobectomy and all done minimally invasively drive outcomes). A total blood loss of 20 cc or less (warning, my opinions) is also critical for these outcomes to be delivered consistently. The data on cytokines are important and speak to the fact that less is better, as we always preach. Since awake is less than asleep it probably causes a less inflammatory reaction and we postulate this may even affect long-term cancer results. But we need data.

As a surgeon, an awake patient adds complexity to my operation. For anesthesiologists the same is true. Does it add risk? Yes. Does that risk outweigh the benefits? Unknown. Is there value? Maybe. From a pure transactional vantage point of the doctors and the hospital, there is no added value for the increased work or risk. Neither the surgeon nor the anesthesiologists receive greater remuneration. We are not paid more but have to work harder. Of course, because we are doctors, we are all willing to do it, if it conveys value to our patients. But this must be shown first prior to accepting the increased risk. If major pulmonary artery bleeding occurs is the non-intubated platform safe? Conversion to an open thoracotomy (we believe and have shown this is exceedingly rare) may be needed, but we must all be prepared every time. Although rare, this fear will and has slowed adoption, same as we saw with VATS 30 years ago and the robot 10 years ago. A special skill set is required. The surgeons must compress the artery and remain calm and offer level-headed communication to the anesthesiologists. The anesthesiologist must convert to a general anesthetic with the patient in the lateral decubitus position and intubate and place a double lumen endotracheal tube while the surgeon continues to compresses the artery. Can this be done safely? Yes. Most of us have these skills but it clearly adds risk and angst. Doctors too often use the excuse of safety to resist change. We have played the “safety card” too many times. We all must be willing to accept some risk to get better and offer a better product for our patients. But we must assess these risks in a thoughtful way.

A final consideration concerns the ever-growing use of the surgical robot. It is more commonly used than VATS in the United States for pulmonary lobectomy. Does a

robot over the patient's head (or as we place it, over the patient's side) add to this risk of intubating a patient on their side? We do not think so but carefully designed studies are needed to answer these and other important clinical questions that cut to the objective assessment of the value of non-intubated minimally invasive lobectomy. For now, it remains an interesting idea with great promise that currently plays little to no role in the repertoire of the vast majority of thoracic surgeons reading this editorial.

Acknowledgments

Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned by the Guest Editors (Francesco Guerrera, Paolo Albino Ferrari and Roberto Crisci) for the series “Non-Intubated Thoracic Surgery. A Global Perspective” published in *Video-Assisted Thoracic Surgery*. The article did not undergo external peer review.

Conflicts of Interest: The author has completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/vats-21-8>). The series “Non-Intubated Thoracic Surgery. A Global Perspective” was commissioned by the editorial office without any funding or sponsorship. Consulting and education—Intuitive Surgical, Medtronic, Verb Surgical; Consulting—AstraZeneca, BARD Medical, ConMed, Covidien, C-SATS, TransEnterix, Myramid; Business (ownership interest)—Fruit Street, Tego, Inc.; Board Member (Consulting)—Bovie Medical Corporation; Private Consulting Firm—ROLO-7. No new disclosure since July 2018. The author has no other conflicts of interest to declare.

Ethical Statement: The author is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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doi: 10.21037/vats-21-8

Cite this article as: Cerfolio RJ. Can we sell something people don't want? Video-assist Thorac Surg 2021;6:23.