Reasons not to perform subxiphoid video-assisted thoracic surgery

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The title of this paper can be read in two ways. Many readers will first think it is meant to say "these are the reasons that one should not perform subxiphoid VATS". Another reading is that "these should not be the reasons for one to perform subxiphoid VATS". The authors' intention is decidedly in line with the latter.

There is no doubt that video-assisted thoracic surgery (VATS) is the greatest step forwards in general thoracic surgery in the past quarter of a century (1,2). The introduction of minimally invasive surgical approaches to operations in the chest has not only reduced morbidity for each individual patient, but allowed safe, effective surgery to be offered to patients previously deemed unfit or unwilling to undergo open thoracotomy. Since the gradual establishment of VATS in the 1990s, thoracic surgeons have endeavoured to look for the next big breakthrough. First, robotic-assisted surgery gathered much interest, but rates of adoption worldwide have been limited by issues of cost (3). Subsequently, 'next generation' VATS approaches have been introduced—including needlescopic and 2-port VATS techniques (2). Uniportal VATS in particular has created much enthusiasm around the globe, with thoracic surgeons in many countries now keen to learn this approach (4). The ability to restrict surgical access trauma to just one small incision via one single intercostal space appealed to many—even if the clinical evidence supporting this as being advantageous has so far not been consistent (5).

One of the newest attempts to produce a novel technical innovation has been to perform single port VATS via a subxiphoid approach. This was first described for thymic resections (6), and has since been developed to permit anatomical and bilateral lung resections (7-9). Even though this approach may seem technically challenging to perform, its proponents claim many benefits. It allows great access to the anterior mediastinum for thymectomy, and access to both sides of the chest with only a single incision. Most importantly, it is claimed that by avoiding the intercostal space altogether, the subxiphoid approach completely negates trauma and compression to the intercostal nerves: often quoted as the major source of post-operative pain and paresthesia after thoracotomy and VATS (9,10).

Is there evidence to support the claims?

The theoretical benefits of subxiphoid VATS sound very attractive. Is this now the time to start jumping on the bandwagon? The answer to that certainly requires a look at the current evidence. As with Uniportal VATS, it is prudent to look beyond the hype and bold claims regarding any new surgical technique, and see whether boasts of clinical advantage are supported by hard clinical data (5,11).

To this end, the authors undertook a simple search of the PubMed database using the National Center for Biotechnology Information website on October 7, 2018. Searching for the word "subxiphoid" in the article title, 67 unique articles were identified that pertained to subxiphoid VATS for pulmonary and mediastinal/thymic surgery (those dealing with cardiovascular and pericardial indications were excluded). These are listed in Supplementary files. These papers included 42 papers on pulmonary surgery, and 25 on mediastinal/thymic surgery.

On closer scrutiny, the vast majority of the papers on

subxiphoid VATS for pulmonary surgery were simple case reports, commentaries, reviews, how-to-do-it technique articles, and animal studies. Such papers provide little or no original clinical data on the outcomes of the technique. There were only 8 papers reporting case series that gave clinical data on the use of this approach, and only 2 papers that compared this to conventional VATS. The latter 2 comparative studies suggested that subxiphoid VATS gave lower post-operative pain scores (10,12)—but such scores are not necessarily reliable given the small cohorts, subjectivity of pain reporting, and lack of standardized pain control protocols used in these studies (5,11). No other differences favouring the subxiphoid approach were found. Moreover, 22 (52%) of the 42 papers were produced by merely 3 centers alone. This reflects the likelihood that subxiphoid VATS is currently being practiced only by a handful of specialists, high-volume centers.

Regarding the 25 papers on subxiphoid VATS thymectomy, there were 6 papers reporting case series that gave clinical data on the use of this approach, and 3 papers that compared this to conventional VATS or open sternotomy. The latter 3 comparative papers reported results that favoured the subxiphoid approach (13-15), but all were small retrospective studies in which peri-operative management was not well standardized and bias has not been excluded. Of the 25 papers, 15 (60%) were produced by 3 centers alone.

What the above simple analysis shows is that there is currently very little hard clinical data illustrating the use of the subxiphoid VATS approach. Two issues arise from this. First, the reasonable number of case series published apparently suggests that the technique can be feasibly performed. However, with so many subxiphoid papers coming from only a few centers, it is open to question whether there was overlap of the patient numbers reported between the papers, and whether the fairly good results reported were only achievable by those few high-volume centers that particularly focused on developing this technique. Indeed, other VATS experts have already questioned the reproducibility of such results by the 'average' thoracic surgeon (16,17). Second, with only a few very limited comparative studies available, there is actually insufficient volume of evidence to convincingly support superiority (or even non-inferiority) of the subxiphoid approach over other approaches.

It is appropriate at this time to mention the work of Dr. João Carlos Das-Neves-Pereira's team. Using a bespoke peri-operative regime that includes a novel topical analgesic solution, dietary control, massage, aromatherapy, and other simple techniques, this team was able to achieve oral feeding and full ambulation within the first hour in over 90% of patients (18). Remarkably, these results were attained in patients who received lobectomy exclusively via an open incision and with full general anesthesia. Such recovery is at least as good as anything reported after any minimally invasive approach. This would cast doubt on whether it is reasonable to attribute any 'advantages' solely to the use of subxiphoid VATS—or any other approach for that matter.

The news is not all bad for proponents of subxiphoid VATS. There is similarly little evidence to support the criticisms of opponents of the technique (16). Their concerns about safety and of inadequacy of resection (including lymph node dissection) have thus far not been confirmed. It is also too early to tell if this is a result of most of the data coming from leading specialist centers only, too little overall data accumulated thus far, or bias against submitting/publishing negative results.

It is customary in such situations to suggest that "future randomized studies are needed". However, what would this really achieve? In the history of VATS itself, only a few such randomized trials have ever been completed (19,20), and their impact has been limited due to misjudged inferences being drawn or their confirming only what surgeons already knew. That has not stopped VATS becoming established in clinical practice today. It has been argued that randomized trials to compare minimally invasive thoracic surgical approaches are not feasible, expensive, and have little to no impact on actual clinical practices (21). Clearly, more clinical evidence on subxiphoid VATS is required to define its place in thoracic surgery—although randomized trials may not be the panacea many think they are.

Are we forgetting to care about the evidence?

However, it is perhaps of even greater importance to appreciate another more worrying trend. That is that clinical evidence itself seems to be increasingly ignored by many thoracic surgeons today. The fever-pitch fervour for Uniportal and now perhaps subxiphoid VATS appears to continue in spite of the lack of good clinical evidence supporting claims of advantage (5,11).

Conventional VATS lobectomy was first described in the early 1990s, and yet it was not until the last 10 years or so that it became established as the preferred approach for early stage lung cancer management (2,5). Along the way, the pioneers of VATS overcame widespread initial

scepticism by producing ever better quality of clinical evidence to validate their approach (5). Regrettably, it appears that this lesson is becoming forgotten. Many are rushing to embrace the 'next generation' VATS approaches today without responding to constructive criticism with good clinical research. Worryingly, proponents of the latest techniques have a tendency to portray potential advantages as actual advantages (22). Many unsuspecting followers then mistakenly believe them to be proven advantages despite the lack of good comparative studies to show this. In this way, 'fake news' is born about how 'good' a new technique is.

The dangers of falling for such news that is 'too good to be true' have been witnessed in cardiothoracic surgery before. In the 1990s, reduction left ventriculoplasty (the 'Batista operation') received international attention as an exciting new 'cure' for end-stage dilated cardiomyopathy (23). Many around the world (including this author as a young surgeon) were caught up by the hype and rushed to learn about this fantastic new technique that promised to offer so much to patients (24), until later studies confirmed that the procedure was associated with high early and late failure rates (25). In more recent times, reports of using a patients' own stem cells to grow trachea transplants on biological and synthetic scaffolds received global attention (26). This 'breakthrough' was feted and widely hailed when reported at surgical meetings around the world. The hype reached a crescendo amongst 'fans' of the approach, before the scandalous—and sadly terrible—truth was finally revealed (27). The authors by no means suggest that subxiphoid VATS would lead to such unpleasant outcomes! However, the message is that surgeons can easily get caught up by the latest 'fashionable' techniques, and sometimes become too mesmerized to evaluate them objectively.

Part of the reason that surgeons fall for the alluring siren call of a new surgical technique is that its advocates are often very prolific in their speech-giving and article-writing (28). The exposure that a new technique receives at international meetings and in the pages of journals often misleads surgeons into thinking that 'everyone else is doing it' and hence 'so should I'. In reality, as shown above, many if not most of the reports come from just a few specialist centers. The average surgeon may not appreciate that a technique is 'safe and feasible' only in the expert hands at such centers, and may mistake potential benefits for proven ones as said above. If the average surgeon then proceeds to try such a technique because of an "if they can do it, why can't I" attitude, it is the patient who may be put at risk. This is when hype can lead to harm.

The authors wish to emphasize that the intent of this article is not to discourage all surgeons from exploring new surgical techniques—including subxiphoid VATS. On the contrary, the need for more clinical evidence requires that pioneers must first boldly innovate with their operations (28). The authors suggest that perhaps 5% of the surgical community are true pioneers, with innovative ideas and the proven operative and research skills needed to explore new ways to advance patient care. We believe such pioneers with good track records should be applauded for their pathfinding efforts and amply supported with research funding. But we also appreciate another 5% of the surgical community who are inevitably conservative sceptics, whose voices of caution should be duly respected and not casually dismissed by the pioneers. Our concern is rather with the remaining 90% of surgeons. This majority of surgeons need to remember that the surgeon's first obligation is to offer the safest, evidence-proven practices for their patients at all times. Recognizing whether you yourself are a true pioneer or a lemming-like follower of fashions is a keen test of insight versus ego, but nonetheless a vital step whenever a surgeon contemplates pursuing any new surgical technique.

Surgery as a drug

Perhaps the problem with new operative techniques exposes an inherent flaw in how surgery is governed.

In medicine, when a new pharmaceutical drug is developed, it must first undergo three phases of clinical trials to determine: the safety and dose-ranging; the biological activity versus side-effects profile; and the clinical effectiveness compared to current 'gold standard' therapy, respectively (29). At every step, the trials are governed by Institutional Review Boards (IRB) to ensure safety and ethical practice at the centers where they are conducted. Following trials, governmental regulatory bodies scrutinize all aspects of the evidence before allowing the drug to be made available for public consumption. A classic example is the cancer immunotherapy drug pembrolizumab (30). This was invented in 2006. Phase I trials were conducted in 2011. Results were first published in the *New England Journal of Medicine* in 2013 (28). It was only after that that the US Food and Drug Administration (FDA) provisionally approved pembrolizumab under the FDA Fast Track Development Program. In 2015, the FDA approved pembrolizumab for treating metastatic lung cancer patients in whom other chemotherapeutic agents have failed (30). Finally, in 2017, it was approved for use

in any unresectable tumor with DNA mismatch repair deficiencies or a microsatellite instability-high state, with no limitation on the site of the cancer or the kind of tissue in which it originated. This entire process took over 10 years to progress from bench to bedside, reflecting the care with which a new therapy was handled to ensure patient safety and well-being.

In contrast, any new surgical approach receives no such rigorous oversight. The first operations using the approach and any prospective study may undergo IRB assessment, but generally any new idea can be tried by a surgeon almost immediately. There is today little to stop a surgeon watching a video of a subxiphoid VATS operation on the Internet, and then deciding to try it out the next day. If a surgeon decides to learn a new technique, there is often no certified course to teach it, no defined benchmarks to demonstrate he/she has attained a 'required level of competence', no process of accreditation to show that the institute's program has reached recognized safety standards, and very little government regulatory oversight in most countries. In other words, there is relatively little to protect the patient from a surgeon's personal belief that a new-fangled technique is 'safe' and 'has advantages'. In the UK, the British National Formulary (BNF) operates a central body to which all adverse reactions from pharmaceutical drugs in the country must be reported. There is no equivalent national agency to which adverse events from surgery need to be similarly reported.

As surgeons, we must ask ourselves why each new surgical technique in this day and age is not subject to the same scrutiny as each new drug. The potential for harm with a major thoracic procedure is certainly no less than with a pharmaceutical agent, and yet the difference in terms of governance can be very great. What harm could be caused—and what harm may be avoided—if the subxiphoid (or any other) approach was required to undergo thorough trials before being made generally available to the public?

Conclusions

In conclusion, the authors reiterate that it is not our intent to dissuade readers from practicing the subxiphoid VATS approach. Indeed, it is important for pioneer surgeons to constantly seek ways to improve their practice, and each new idea has the potential to bring great rewards for patients. Both authors themselves are also exploring the subxiphoid approach.

The key message is rather that if any surgeons do decide to explore subxiphoid VATS, they must be under no illusions about what that decision is based on. It is not a decision based on the subxiphoid approach being irrefutably 'safe and feasible', because most case series data come from only a handful of very specialized centers. It is not a decision based on the so-called 'advantages' of the approach, because any such 'advantages' are—at the time of this writing—only theoretical ones, and have not yet been validated by a body of robust clinical evidence. Whether such potential advantages may outweigh the potential disadvantages remains to be determined by future studies. Until then, surgeons should be careful not to tell patients that a subxiphoid strategy is being used because it is necessarily 'better' surgery.

If a surgeon proceeds with subxiphoid VATS in the spirit of a pioneer, it is still prudent to view it as a new technique that requires more clinical data to define its proper place in thoracic practice. With this exploratory mindset, it is advisable to consider framing one's early experience as a clinical trial with IRB oversight. This would provide some degree of regulatory protection for surgeon and patient, reduce the chance of the surgeon 'over promising, under delivering', and increase the likelihood that the experience may get properly collected and shared with the thoracic surgical community. That experience may (or may not) one day provide the reasons for why one should perform subxiphoid VATS.

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Footnote

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Supplementary

A crude literature search for articles related to "subxiphoid VATS"

- Date of search: 7 Oct 2018
- Search database: Medline (accessed via Ovid SP search engine)
- Search terms: "subxiphoid" in Title
- Selection: inclusion—all articles relevant to pulmonary, mediastinal surgery; exclusion—articles related to cardiac, pericardial, chest wall, non-thoracic surgery

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