

Role and utility of the national registers of VATS major procedures

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Contributions: (I) Conception and design: D Divisi; (II) Administrative support: D Divisi, G Zaccagna; (III) Provision of study materials or patients: D Divisi; (IV) Collection and assembly of data: D Divisi, F Gabriele; (V) Data analysis and interpretation: D Divisi, R Crisci; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

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Abstract: The national registers arise from the need to collect data in order to improve the known techniques and to direct towards new treatment strategies. In this study we tried to emphasize the importance of the sampling of information taking into account two aspects: (I) analysis of learning curves; (II) the choice of surgical strategies, by which to set a standardization of techniques designed to establish future treatment guidelines. Data collection and medical practice will influence each other. In fact, we find in literature several studies conducted on very large series which provide valuable support to the therapeutic choices. The goal is to reach new standards of treatment, through the consent of the national and international scientific community.

Keywords: National register; video-assisted thoracic surgery; non-small cell lung cancer; database

Received: 19 December 2016; Accepted: 30 December 2016; Published: 10 February 2017. doi: 10.21037/vats.2017.01.01 View this article at: http://dx.doi.org/10.21037/vats.2017.01.01

Introduction

The scientific value of medical practice is based on the collection of data on patient characteristics, the disease and the different methods of treatment as well as on the comparison of centers that carry out similar activities. The idea of a database shared on a national or international basis, which all study groups can access, allows for the opportunity to provide information from a practical point of view in order to improve statistical results. This new scientific approach based on log analysis is widely reflected in literature through a large number of studies with different purposes, arising from the study of the impressive amount of data extrapolated. The purpose is to determine which is the best strategy in planning a treatment, also counting on the support of the extrapolated assessments. Desai et al. (1), using the database of the United States Healthcare Cost and Utilization Project Nationwide Inpatient Sample (HCUP-NIS), compared the video-assisted thoracic surgery (VATS) lobectomy and classical thoracotomy lobectomy taking into account mortality rate, length of stay, complication rate and morbidity. Twenty seven thousand-four hundred

fifty one [27,451] patients were operated on for lung cancer between 2009 and 2012, of whom 9,495 (35%) underwent VATS lobectomy and 17,956 (65%) lobectomy using the classic approach. The mortality rate (1.3% vs. 2.5%), the length of stay (6.21 vs. 8.75 days), the rate of complications (24.31% vs. 32.06%) were significantly lower in the VATS Group compared to Thoracotomy Group as well as the indexes of morbidity (infections, blood clots, cardiovascular and kidney problems). The Society of Thoracic Surgery (STS) has analyzed its database in which, accumulated data on more than 5 million patients in 26 years, was divided into three main areas (2). The information is recorded in the STS General Thoracic Database (STS-GTDB) counts 231 study groups and a number of cases included more than 312,000. This database allows to evaluate the clinical condition of patients during hospitalization and the mortality rate at 30 days. Furthermore, it provides for the integration of their data with those of the Registers of other clinical specialties in order to perform a careful followup of patients treated for lung cancer. This has allowed us to define and update guidelines as well as new therapeutic

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standards by analyzing complications and mortality rates, length of stay, risks associated with different procedures and levels of effectiveness of various techniques. The aim of the study is the evaluation of different purposes, the potential of national registers and the impact of the results on daily clinical and surgical practice.

Learning curve

The collection and evaluation of register information allow the evaluation of the learning process of the technique and to quantify the number of procedures to be carried out to consider them consolidated. Sihag et al. (3), analyzing the data of the Register of STS related to 3,780 esophagectomy, have noted that the success rate as well as the mortality rate was consistent with minimally invasive approach and the "open" technique. Furthermore, considering the duration of the procedures and the rate of re-operation they were able to trace the learning curve on the method. In Italy the input given by video surgery and in particular by VATS lobectomies led to the establishment in 2013 of the VATS Group (4), which collects data from 62 accredited centers (87.5% of the centers throughout the country) and currently has 3,680 patients enrolled. The Register collects the following data: (I) patient characteristics (personal data and medical history, comorbidity indexes, risk stratification, functional tests, radiological and preoperative procedures); (II) surgical procedure (approach, access, tools, duration of surgery, type of surgery, methods and materials, blood loss, need for conversion); (III) detailed reports of individual cases (pathology and its staging, complications, length of hospital stay and drainage times with relative air leaks, intensity of postoperative pain, EuroQol questionnaire). In accordance with the literature (5,6) we believe that a center can be considered qualified if it performs an annual minimum of 50 procedures (number which is also referred to as minimal learning threshold for surgeons in training). In addition, a surgeon should perform a minimum of 20 specific interventions every year to keep in training (6). However, different parameters may be used as a reference for a learning curve on VATS lobectomies: the index of complications, the mortality rate, length of stay, the rate of conversion to open thoracotomy. The latter seems reduce significantly once exceeded the threshold of 50 procedures, although this parameter is cause for debate as it is not closely related to the number of interventions (6-8). In fact, we must consider two factors: (I) the existence of a physiological conversion rate, which is independent from

the skill of the surgeon; (II) the tendency of some surgeons to proceed with early conversion, in case of difficulties or adverse events. Vallance et al. (9) published data on their experience of 684 VATS lobectomies in 5 years. In the first period the conversion rate was 38.8% while, in subsequent periods, the rate was reduced gradually until it stabilized at values of around 10% without any further decline. Ra et al. (10), starting from personal experience, have published guidelines for surgeons in training in VATS lobectomies. Examining 38 procedures performed in the 1st year, they noted the conversion of 10 VATS thoracotomy. The conversion rate, however, had a different frequency; significantly reduced in the second half of the training period from 7 in the first half to only 3 in the next 6 months. The figure was all the more significant considering that in the first 6 months 16 procedures were performed in total while in the second half of the reporting period 22 were carried out. Lee et al. (11) evaluated 500 patients who underwent VATS lobectomy for non-small cell lung cancer (NSCLC) between 2002 and 2012. For comparative purposes, the cohort was divided into 2 groups: the first 250 cases [2002-2010] and the second 250 cases (from 2010 to 2012). In the second group patients were older (mean age 72 vs. 69 years), had poorer lung function (FEV1: 83% vs. 91%; DLCO: 76% vs. 85%) and the tumor size was on average higher (2.0 vs. 1.8 cm). Nevertheless, the disease free survival rate at 3 years in the first and in the second group was comparable (82% vs. 85%). From analyzed studies it is clear that the completion of learning curves play a key role in the oncological radicality of VATS lobectomy.

Surgical strategies

The analysis of data collected in the national registers allows to evaluate the best surgical approaches to be used depending on the pathology and the clinical condition of the individual patient, in order to standardize the techniques to improve the outcome. In VATS lobectomies, the choice of access is still debated. Shen *et al.* (12) conducted a retrospective study of 411 patients with NSCLC (T1-3N0M0) underwent VATS lobectomy between 2013 and 2014. In 115 patients we used a "single port" approach (SP), with access by an average of 3.5 cm while in the 296 "multi port" (MP), with "utility incision" averaged 3–4 cm and 1 cm service accesses. The data showed that: (I) the SP allows shorter surgical time than the MP (65.7±14.8 *vs.* 81.3 ± 15.6 minutes); (II) the timing of lymphadenectomy were higher (29.6±16.7 *vs.* 17.4±13.3 minutes) in the SP than the MP; (III) the total duration of intervention appears comparable with the two techniques (95.3±16.9 vs. 98.8±15.3 minutes); (IV) blood loss, length of stay and the number of lymph nodes that can be removed were not significantly different in the two approaches. Gonzalez-Rivas et al. (13) have considered the role of access uniportal in the treatment of advanced NSCLC (>5 cm, T3 or T4). The 130 patients who underwent surgery were divided into two groups, Group A (87 patients with NSCLC in early stage) and Group B (47 patients with advanced NSCLC), all with similar preoperative characteristics (age, sex, smoking status, comorbidities and pre-existing conditions). In 67.4% of patients in Group B it was, however, necessary to neoadjuvant chemotherapy treatment. Intraoperatively, the conversion rate was higher in Group B (6.5% vs. 1.1%), as well as the operative time $(183.2\pm48.9 vs.)$ 144.9±41.3 minutes) and the mean number of resected lymph nodes (16 vs. 14). In the postoperative instead, there were no significant differences and, in most patients, there were no complications. Only one patient (Group A) died on 58th day to respiratory failure. The survival rate at 30 months was 90.4% in group A and 73.7% in group B. Liu et al. (14) studied the results obtained by lung resections by VATS "Single Direction" (SD-VATS) of 3,743 cancer patients, in a period from 2006 to 2013. Seven hundred eighty three [783] patients with stage I underwent lobectomy [740] or segmentectomy [43]. The mean operative time was equal to 145±54 minutes, with an average blood loss of 50 mL; the morbidity and postoperative mortality was equal to 13.3% and 1.0%. Overall survival, disease-free survival and cancer specific survival were dell'83.8%, 74.4% and 86.6% respectively. Techniques disputes related to the ease, safety and efficacy of an approach or a methodology cannot be resolved by single-center studies, often difficult to compare. The possibility of data convergence on a register allows planning and uniformity of indications and surgical strategies, resulting from careful and impartial evaluation by individual centers contributing to the data collection. The existence of a national register can statistically support the performances of the various procedures, offering the shortmedium-long term possibility of comparing results and making possible the drawing up future guidelines. Zhang et al. (15) compared the results of 2,380 VATS lobectomies and 3,009 open lobectomies on patients with early-stage NSCLC. The systemic recurrence rates (RR=0.61; 95%) CI: 48-78; P<0.01) and locoregional (RR=0.66; 95% CI: 0.46 per -0.95; P=0.03) were lower in the VATS Group, also characterized by a higher survival rate (RR=1.9; 95%

CI: 1:03–1:15; P<0.01). These data suggest that VATS may be the method of choice in the treatment of NSCLC in early stage, if that address is confirmed by several experiences related to a single collection database. A similar methodological rigor may clarify the role of VATS in patients with respiratory failure. Oparka et al. (16), analyzing the STS register approximately 4,531 patients who underwent VATS and 8,431 patients who underwent thoracotomy, have shown that: (I) patients with an FEV1 <60% showed an index of major complications if they undergo surgery thoracotomy (P=0.023); (II) patients with an FEV1 <40% had a lower incidence of pneumonia (4.3% vs. 21.7%), a shorter hospital stay (7 vs. 10 days) and a better 5-year survival (42% vs. 18%) when subjected to VATS compared to thoracotomy. Burt et al. (17) believe that an FEV1 and a DLCO <40% no longer represent a limit. Analyzing 13,376 patients underwent lung lobectomy, of which 49.1% in the VATS and 50.9% in the open, they found: (I) in patients with FEV1 <40%, reduced mortality (0.7% vs. 4.8%) and a lower rate of complications (12.8% vs. 21.9%) in the VATS Group compared with the open Group; (II) in patients with DLCO <40%, the mortality and complication rate between the two Groups were 2.0% vs. 5.2% and 10.4% vs. 14.9% respectively. The presence of a national register could avoid errors in the staging of lung cancer, from which the different assessments on survival. Licht et al. (18) having noticed a discrepancy in the postoperative lymph node staging between VATS lobectomy and those open, analyzed the Danish Lung Cancer Registry data concerning 1,513 patients with NSCLC clinical stage I undergoing lung VATS lobectomy (717 patients) and thoracotomy (796 patients). In 281 patients (18.6%) have encountered an "upstaging" lymph node, significantly higher in patients undergoing thoracotomy: 13.1% vs. 8.1% in N1 and 11.5% vs. 3.8% in N2. Whereas overall survival appears comparable between the two methods, the authors conclude that the difference seems to depend on the parameters that do not exist in the Registry. Finally, the presence of a national register allows the examination of new technological perspectives consciously orientating towards a two-dimensional videoassisted thoracic surgery (2D-VATS), three-dimensional (3D-VATS) or robotic surgery (RATS). Swanson et al. (19), using the Premier Hospital database, examined 15.502 of which 665 patients undergoing robotic surgery (RATS). The authors have shown greater uptime than VATS (on average 4.49 vs. 4.23 hours) and the costs are still too high to justify the systematic use of this technique (an average

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of \$ 25,000 vs. \$ 20,000 for single procedure).

Conclusions

The need for a national register is the need to irrefutably validate the most effective and secure strategies depending on the patient, helping surgeons to define the modalities for more effective treatment. This evidence, heard by the national and international scientific community, cannot ignore the collection, sharing and analysis of data relating to individual centers placed on a single platform for dialogue. The aim is to standardize thought and action in facing a common enemy, as clinical-scientific progress arises from the confrontation and not isolation or self-reference.

Acknowledgments

Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned by the Guest Editors (Luca Bertolaccini and Piergiorgio Solli) for the series "VATS: the age of maturity" published in *Video-Assisted Thoracic Surgery*. The article has undergone external peer review.

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at http://dx.doi. org/10.21037/vats.2017.01.01). The series "VATS: the age of maturity" was commissioned by the editorial office without any funding or sponsorship. The authors have no other conflicts of interest to declare.

Ethical Statement: The authors are 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/hbsn.2017.01.01

Cite this article as: Divisi D, Zaccagna G, Gabriele F, Crisci R. Role and utility of the national registers of VATS major procedures. Video-assist Thorac Surg 2017;2:3.

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