Annals of Thoracic Oncology Research

Editorial
Published: 02 Jun, 2017

What is the Level of Evidence for the Effectiveness of Minimally Invasive Surgery for the Treatment of Lung Cancer?

*Alain Bernard**

Department of Thoracic Surgery, CHU Dijon, France

Editorial

Looking back, lung cancer surgery has been performed by thoracotomy for several decades with no major changes. Over the last five years, the practice has evolved enormously thanks to technological innovations. Surgeons are now able to use Video-Assisted Thoracoscopic Surgery (VATS) for lobectomies or segmentectomies. All of these minimally invasive techniques are supposed to be a medical advance for patients. We have the weakness to believe that doctors using this new technology do so in order to improve the management of patients with lung cancer. By conducting one or more studies, it would be possible to confirm the real clinical benefit of these new techniques. This issue should be tackled by the doctors who wish to develop such technologies at the moment their use is spreading. Good medical practice encourages health professionals to carry out high-quality studies to validate any new therapy for the benefit of patients. An excellent report from the WHO [1] published in 2012 highlighted the value of conducting studies to evaluate any new technology. This report emphasized that health professionals perceive technology assessment as an obstacle to the introduction of innovative technologies. It appears nonetheless that the evaluation of health technologies is very beneficial to the transfer of technologies from the laboratory to the patient's bedside. This report clearly demonstrated that such evidence-based studies not only generated information for the ministry of health but were also necessary for patients. According to the report, conducting a high-quality clinical study should be seen as an opportunity to upgrade any new technology or medical device. This is the only way to confirm that it is a true innovation by demonstrating that it significantly improves the health or quality of life of patients. The completion of the clinical study should no longer be perceived as an administrative obligation but as an opportunity to confirm the therapeutic innovation. Let us return to the many studies recently published on VATS lobectomies. Even though these techniques continue to spread to institutions around the world, no randomized controlled trials (RCT) showing a clinical benefit have been reported so far [2]. The various guidelines [3] that advocate VATS lobectomies for cancer are based on observational studies, which are potentially biased. With an observational study, we can never be certain that the differences observed are due to the treatment and not to other factors that have not been taken into account. In the absence of randomization, the two groups of patients may have different characteristics making it impossible to conclude that one of the therapies is superior to the other. Moreover, in the absence of randomization, the choice by the clinician to apply one method more than another is not random. The clinician will prefer to apply one method or the other according to the characteristics of the patient or disease, and this choice will influence the outcome of the study. Many observational studies have used the propensity score method to reduce bias [4-6]. This method is widely used but does not provide the same level of evidence as an RCT. In a study of this type, we are never certain that all of the confounding factors were collected to make the two groups of patients comparable. Randomization is the only method by which two groups of patients are comparable on average. A systematic review compared the results of observational studies and randomized trials for the same endpoint [7]. It focused on 18 types of digestive surgery and showed that RCTs were generally more conservative since only 4 were statistically significant compared with 7 for observational studies. Heterogeneity was greater between observational studies than between RCTs. This analysis showed that observational studies were on average more favorable than RCTs.

In conclusion, the use of observational studies to evaluate a new technology should be prudent because, unlike RCTs, they do not ensure that two treatment groups are sufficiently comparable. However, the reality is quite different since minimally invasive surgery techniques are disseminated in the absence of RCTs for their validation. Several reasons can be put forward to explain this

OPEN ACCESS

Correspondence:
Alain Bernard, Department of Thoracic Surgery, CHU Dijon, Bocage Central, 14 Rue Gaffarel 21079, Dijon, France, Tel: 33 380293352; E-mail: alain.bernard@chu-dijon.fr

Received Date: *12 May 2017*
Accepted Date: *25 May 2017*
Published Date: *02 Jun 2017*

Citation:
Bernard A. What is the Level of Evidence for the Effectiveness of Minimally Invasive Surgery for the Treatment of Lung Cancer?. Ann Thorac Oncol Res. 2017; 1(1): 1003.

situation. Insufficient knowledge of surgeons on evaluation methods could be one reason. As evidence, some authors confuse randomized controlled and double-blind trials [8]. A high-quality RCT can be conducted without double blinding, especially when two technologies or surgical procedures are compared. The other point concerns balance, which would be deemed to be in default according to the same author's [8]. This lack of balance would make it impossible to carry out an RCT. This remark reflects a lack of knowledge of the different experimental designs adapted to the problem of minimally invasive surgery [9]. To take into account the acceptability of surgeons according to their expertise and patients, several types of experimental designs exist, such as cluster randomized trials; expert-based randomized controlled trials and Zelen's design [9]. Another complaint is made about the benefit of performing a non-inferiority trial for this surgery. For the treatment of patients with severe disease, it seems necessary to show that VATS lobectomies offer patients the same chances of cure as interventions carried out by thoracotomy. All these reasons show that RCTs are essential for the valorization of new technologies in the interests of patients. Clinical studies protect patients by explicitly informing them of the goals of the study and possible complications. This is not the case when new technologies are used outside any study. Finally, concerning databases, which have been the subject of several publications [4,10,11], they are supposed to play a role following the RCT, when the technology is widely used in the different thoracic surgery centers. Their objectives are to confirm efficacy and assess safety.

One justified criticism of RCTs concerns the cost of conducting this type of study. At the time the trial is being designed, it is imperative to find funding to carry it out. This search for funding adds to the process and may discourage teams from conducting a trial. Other constraints in organizing an RCT are the regulatory and administrative procedures, which may deter teams from initiating such trials. Because of these constraints, the new technology or intervention is used by the surgical team outside any study or regulatory framework. After several months of practice, the team will carry out a retrospective study with its inherent biases, thus ruling out any possibility of demonstrating its effectiveness. In conclusion, conducting an RCT is the only way to demonstrate that minimally invasive surgery brings health benefits to patients. Conducting a high-quality, probative study will not only bring value to any new technology in the interests of patients but also help the decision-maker. To change behavior with regard to RCTs requires support and assistance from surgical teams. This support concerns the funding, the drafting of protocols and the implementation of the study. Ultimately, a clinical study should no longer be regarded as a regulatory constraint, but as an opportunity to take advantage of a new technology.

References

1. Evaluation of health technologies: Medical devices. Geneva: WHO; 2012.
2. Zhang R, Ferguson MK. Video-Assisted versus open lobectomy in patients with compromised lung function: A literature review and meta-analysis. PLoS One. 2015;10(7):e0124512.
3. Howington JA, Blum MG, Chang AC, Balekian AA, Murthy SC. Treatment of stage I and II non-small cell lung cancer: diagnosis and management of lung cancer, 3rd ed : American College of Chest Physicians evidencebased clinical pratice guidelines. Chest. 2013;143(5):e278S-313S.
4. Paul S, Altorki NK, Sheng S, Lee PC, Harpole DH, Onaitis MW, et al. Thoracoscopic lobectomy is associated with lower morbidity than open lobectomy : a propensity-matched analysis from the STS database. J Thorac Cardiovasc Surg. 2010;139(2):366-78.
5. Stephens N, Rice D, Correa A, Hoffstetter W, Mehran R, Roth J, et al. Thoracoscopic lobectomy is associated with improved short-term and equivalent oncological outcomes compared with open lobectomy for clinical stage I non-small-cell lung cancer : a propensitymatched analysis of 963 cases. Eur J Cardiothorac Surg. 2014;46(4):607-13.
6. Murakawa T, Ichinose J, Hino H, Kitano K, Konoeda C, Nakajima J. Long-term outcomes of open and video-assisted thoracoscopic lung lobectomy for the treatment of early stage non-small cell lung cancer are similar: a propensity-matched study. World J Surg. 2015;39(5):1084-91.
7. Shikata S, Nakayama T, Noguchi Y, Taji Y, Yamagishi H. Comparison of effects in randomized controlled trials with observational studies in digestive surgery. Ann Surg. 2006;244(5):668-76.
8. Korst RJ, Lee BE. Robotic assisted thoracic surgery lobectomy versus video assisted thoracic surgery lobectomy: is a randomized trial really necessary? Semin Thoracic Surg. 2016;28(1):193-4.
9. Bernard A, Vaneau M, Fournel I, Galmiche H, Nony P, Dubernard JM. Methodological choices for the clinical development of medical devices. Med Devices. 2014;7:325-34.
10. Paul S, Isaacs AJ, Treasure T, Altorki NK, Sedrakyan A. A long term survival with thoracoscopic versus open lobectomy: propensity matched comparative analysis using SEER-Medicare database. BMJ. 2014;349:g5575.
11. Falcoz PE, Puyraveau M, Thomas PA, Decaluwe H, Hürtgen M, Petersen RH, et al. Video-assisted thoracoscopic surgery versus open lobectomy for primary non-small-cell lung cancer: a propensity-matched analysis of outcome from the European society of thoracic surgeon database. Eur J Cardiothorac Surg. 2016;49(2):602-9.