**Acta Medica Ruha**
*International Journal of Medicine and Health Sciences*
E-ISSN: 2980-1184

**REVIEW ARTICLE**
Volume:2 Issue:3 Year:2024 https://doi.org/10.5281/zenodo.13784407

# How Much Do Guidelines in Thoracic Surgery Influence Our Daily Practice? – A Review of the Current Routine

Göğüs Cerrahisinde Kılavuzlar Günlük Pratiğimizi Ne Kadar Etkiliyor? – Mevcut Rutinin Gözden Geçirilmesi

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**ABSTRACT**

Guidelines are formulated based on the results of randomised clinical trials, other non-randomized studies, and expert opinions (i.e., the opinions of most guideline committees). A randomised, multicenter, controlled trial is the ideal study to determine a patient population's mean values. However, some diseases and populations do not lend themselves easily to this format, and therefore, studies with less stringent design and enrollment criteria are often used. The latest guidelines have more reliable data and distinct subgroups and carry a higher risk of misinterpreting results than older models. Guidelines are part of a continuous educational program to facilitate a more homogeneous approach to all patients with the same disease, reduce inappropriate and unnecessary testing, ineffective treatments, and health costs, and ultimately improve care. As a result, guidelines are allegiant. The surgeon should question why and how this guideline was prepared, who supported its creation, who is on its organisation committee, and what it represents. Within the scope of this review, recommendations to improve the guidelines will be presented.

**Keyswords:** Thoracic Surgery, Guidelines, Randomised Controlled Trials, Clinical Practice.

**ÖZET**

Kılavuzlar, randomize klinik araştırmaların, diğer randomize olmayan çalışmaların sonuçlarına ve uzman görüşlerine (yani çoğu kılavuz komitesinin görüşlerine) dayanarak formüle edilir. Randomize, çok merkezli, kontrollü bir çalışma, hasta popülasyonunun ortalama değerlerini belirlemek için ideal çalışmadır. Ancak bazı hastalıklar ve popülasyonlar bu formata kolaylıkla uyum sağlamamaktadır ve bu nedenle daha az katı tasarım ve hasta alım kriterlerine sahip çalışmalar sıklıkla kullanılmaktadır. En yeni kılavuzlar daha güvenilir verilere ve farklı alt gruplara sahiptir ve öncekilere göre sonuçların yanlış yorumlanma riski daha yüksektir. Kılavuzların, aynı hastalığa sahip tüm hastalara daha homojen bir yaklaşımı kolaylaştırmak, uygunsuz ve gereksiz testleri, etkisiz tedavileri ve sağlık maliyetlerini azaltmak ve sonuçta bakımı iyileştirmek için sürekli bir eğitim programının bir parçasını oluşturduğu iddia edilmektedir. Sonuç olarak, yönergeler sadıktır. Cerrah bu kılavuzun neden ve nasıl hazırlandığını, oluşturulmasına kimlerin destek verdiğini, organizasyon komitesinde kimlerin bulunduğunu, neyi temsil ettiğini sorgulamalıdır. Bu inceleme kapsamında kılavuzların iyileştirilmesine yönelik öneriler sunulacaktır.

**Anahtar Kelimeler:** Göğüs Cerrahisi, Kılavuzlar, Randomize Kontrollü Çalışmalar, Klinik Uygulama.

## INTRODUCTION

The doctor's mission is to protect human health. To achieve this goal, the doctor must possess the necessary knowledge and be able to apply it to an individual patient. This process must be governed by medical ethics. Therefore, the total of a physician's training should equip him/her with everything necessary to accomplish his/her mission. Some randomised prospective studies can provide data on groups of patients with small differences between them, which clinicians cannot distinguish, no matter how careful they are, and also on patients they systematically follow. Guidelines play a crucial role in our mission, with advantages and disadvantages. The accumulation of medical knowledge on diagnosis and management in the last 5-6 years has changed the course of diseases, improved clinical outcomes and increased survival. Therefore, it has been difficult for the practising physician to assess a particular therapy's long-term effects on a patient's survival. Moreover, each physician's approach to a patient with the same disease is not always uniform. Various scientific organisations have introduced clinical practice guidelines to assist physicians in applying newly acquired knowledge to patients, underscoring the significant impact of your work. Guidelines help translate new research discoveries into clinical practice (1).

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Received: 06.06.2024, Accepted: 16.08.2024, Published Online: 20.09.2024
Cited: Derdiyok O. How Much Do Guidelines in Thoracic Surgery Influence Our Daily Practice? – A Review of the Current Routine. Acta Medica Ruha. 2024;2(3):216-220. https://doi.org/10.5281/zenodo.13784407

## Randomised Clinical Trials

Evidence-based practice is the process of using the best available evidence to support clinical decisions. Guidelines are not mandatory protocols. The role of guidelines is clear in the presence of two factors. The first factor is the diversity of practices that affect patient outcomes, and the second is a strong evidence-based research base for effective therapeutic intervention. There are several limitations to the preparation of guidelines, such as the quantity and consistency of resources and the generalizability and applicability of study findings. Dr Barry Greenberg, former associate editor of the Journal of the American College of Cardiology, compares trials to music (i.e., monotonous background music, usually played in elevators or on-hold telephones). However, it is like Mozart's music, with various musical notes. The patients in daily clinical practice represent various conditions, from mild to severe, acute to chronic, and simple to very complex, with multiple medical problems. In the same way that Mozart's music cannot be made muzak, applying the results from a selected homogeneous population to complex patients with complex diseases is difficult (2).

A randomised, multicenter, controlled trial is the ideal study to determine a patient population's mean values. However, some diseases and populations do not lend themselves easily to this format, and therefore, studies with less stringent design and enrollment criteria are often used. The latest guidelines have more reliable data and distinct subgroups and carry a higher risk of misinterpreting results than older models (3).

Guidelines are often presented analytically and in detail, with the result that a person reviewing this information may not be able to determine its ultimate or core message, which extremely complicates its use by clinicians. Summary guidelines or "pocket rules" become helpful to some extent but do not solve the problem. Furthermore, guidelines in their current form are designed more often for memorisation rather than stimulating the critical ability and curiosity of the thoughtful physician. In the final analysis, guidelines are difficult to read and assimilate. Because of the procedures required to produce guidelines, they tend to be published years after the end of the clinical trial, which is a serious disadvantage (4).

## DISCUSSION

Scientific societies introduced practice guidelines as a means of 'standardisation' to help physicians implement more uniform health care and bring new knowledge to each patient's care, thereby improving clinical outcomes. In 1984, the American College of Cardiology (ACC) / American Heart Association (AHA) published clinical practice guidelines for the first time. This document responded to a request from the United States Government to review the evidence on the use of cardiac pacemakers. For over 30 years, the ACC/AHA has developed more than 30 clinical practice guidelines for various conditions and procedures, with 'updates' and additional changes at intervals (5). Thus, it has become quite difficult for a single physician to assess the long-term effects of a particular treatment or intervention on 'hard' endpoints such as death, myocardial infarction, stroke, and others. Not surprisingly, each doctor's approach to an individual with the same disease is often similar but not uniform. Guidelines help translate new research discoveries into clinical practice; however, despite improvements over the years, guidelines remain controversial (6).

The concept of clinical research dates back to antiquity. In short, in randomised clinical trials, a hypothesis is formulated and based on this hypothesis- usually a null hypothesis- the study protocol is designed by a committee of experts in the field under investigation. For the conduction of a trial, overall organization and financial support are needed, and for large-scale clinical trials, the financial requirement is quite high (7). The greatest support comes from the industry in terms of limitations and costs of medical products; support should be provided by industrial firms because there are many difficulties in conducting very important studies without their support. However, companies are driven to prove that their product is better than an approved agent or placebo, and thus, they want to present 'favourable' outcomes. It is known that the way a protocol is designed can influence the results. For example, using the wrong dosage of an active control drug with unfavourable outcomes suggests the relative superiority of the study drug. Thus, industry involvement in clinical trials is associated with a risk of bias (8).

The place of these guidelines in daily use for thoracic surgery is controversial. In 2011, as a result of a meta-analysis of studies on hyperhidrosis, Cerfolio et al. revealed no standardised therapeutic approach and reported that different surgical approaches yielded nearly similar results (9). In 2014, Tschopp et al. reviewed studies on pneumothorax. They found that the rate of chemical pleurodesis, which was not included in the first options according to the 2010 pneumothorax treatment guidelines, was higher than that of mechanical abrasion and pleurectomy. However, it has been shown that chemical pleurodesis, which is not included in the first-line treatment approaches for pneumothorax in current guidelines, may come to the forefront with time in the future (10).

In the 2017 National Comprehensive Cancer Network (NCCN) mesothelioma guidelines, the survival rate of previously often preferred extrapleural pneumonectomy (EPP) was found to be lower than the other surgical treatment options, i.e. pleurectomy/decortication (P / D). Indeed, patients who underwent P/D responded better to chemotherapy and survived better. P/D is one of the first treatment options for mesothelioma (11). In the non-small cell lung cancer (NSCLC) 2017 guidelines, biopsy is recommended before surgery in stage 1 and stage 2 NSCLC. However, in the treatment stages indicated in the same guideline, it is stated that high PET uptake is sufficient to establish diagnosis in stage 1 and stage 2 NSCLC. This approach can make a serious difference in treatment options (12). Currently, the NCCN guidelines recommend "consideration of " invasive mediastinal staging for clinical stage IB-IIIA non-small cell lung cancer and invasive mediastinal staging for clinical stage IA disease. However, a recent multi-institutional prospective trial questions this approach. Of 90 patients with clinical stage I NSCLC considered at risk for occult N2 disease (T2N0 or T1N0 based on positron emission tomography with a standardised uptake value >10), mediastinoscopy detected occult N2 disease in only 1.1% of patients. The mean tumour size of 4.3 cm in diameter was considered significant and ranged from 1.3 to 12 cm. Taken together, it can be expected that in the coming years, national guidelines on invasive mediastinal staging recommendations may also consider histological subtype of the tumour, will be improved (13). Currently, the NCCN guidelines recommend sub-lobar resection as an alternative treatment for patients with peripheral nodules with an adenocarcinoma in situ pattern or glass-like appearance that is larger than 2 cm in size (12).

Although bias exists in some study designs, other studies yield negative or controversial results. Patients with stage IIIA NSCLC at diagnosis represent a very heterogeneous group, including those with limited microscopic ipsilateral mediastinal lymph node involvement discovered after surgical resection and those with radiologically evident subcarinal lymph node involvement at presentation. Different treatment options for stage IIIA disease include neoadjuvant therapy followed by surgery, primary surgery, adjuvant chemotherapy with or without sequential adjuvant radiotherapy, or definitive chemoradiotherapy without surgery. When surgery is not considered an option, a combination of chemotherapy and radiotherapy may be offered for curative purposes. For stage III NSCLC, survival after surgery alone is generally poor, between 5-10% at five years, due to the higher frequency of local and distant failure to eradicate tumour foci. Randomised trials and meta-analyses have shown a modest improvement in survival with neoadjuvant chemotherapy, but local and distant failure rates remain high. Neoadjuvant or adjuvant chemotherapy is part of multimodality treatment for stage IB-IIIB, as the risk of distant metastases after surgery alone is at a higher rate (14).

Andre et al. analysed a cohort of 702 patients with N2 NSCLC. This study identified four risk factors for clinical manifestations of N2 before surgery: multistation mediastinal lymph node involvement and T3 or T4 stage disease (15). Choi et al. found that among 19 clinical pathologic prognostic factors examined in patients with pathologic manifestations of N2 NSCLC, incomplete resection detected in CT after induction chemotherapy and persistent N2 disease were negative prognostic factors in univariate analysis. The presence of clinical manifestations of N2 disease, multistation mediastinal lymph node involvement and adenocarcinoma histology indicated poor prognosis without any statistically significant prognostic significance. Moreover, the administration of adjuvant chemotherapy did not significantly improve the prognosis (16). The results of two small, randomised trials published in early 1994 have important implications for treating patients with stage IIIA. These studies confirmed the superiority of surgery followed by induction chemotherapy after surgery for patients with stage IIIA disease (17, 18). Subsequent randomised trials and two meta-analyses compared surgery alone with surgery in patients with stage IIIA NSCLC following neoadjuvant chemotherapy and demonstrated a

significant benefit in favour of neoadjuvant chemotherapy. Data from both systematic reviews show a 6-7% absolute benefit in five-year survival in IIIA patients, improving their results from 15-35% to 21-42% (19, 20).

Thoracic surgeons are generally not inclined to use medical evidence. Guidelines are seen as accepted taboos for various reasons (being unaware of relevant medical evidence, distrust in the formulation of medical evidence, refraining from being "stigmatised" in the profession, and not being sued for malpractice, etc.). Medical oncologists may also be responsible for thoracic surgeons not being inclined to use guidelines. Indeed, medical oncologists have more say in the preparation of guidelines than the main discipline of thoracic surgery because they are more investigative and financially supported. Besides they are overprotective against their discipline and essentially keep the control of the patient flow.

## CONCLUSION

As a result, guidelines are allegiant. The surgeon should question why and how this guideline was prepared, who supported its creation, who is on its organization committee, and what it represents.

## DESCRIPTIONS

**No financial support.**

**No conflict of interest.**

**Acknowledgments: The editorial support has been given by Ozan BATIGÜN MD, MBA**

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