Data from a national lung cancer registry contributes to improve outcome and quality of surgery: Danish results

Erik Jakobsen, Torben Palshof, Kell Østerlind, Hans Pilegaard

Abstract

Objective: In 1998 The Danish Lung Cancer Group published the first edition of guidelines for diagnosis and treatment of lung cancer. A national registry was implemented in the year 2000 with the primary objective to monitor the implementation of these guidelines and nationwide to secure and improve the quality of the clinical management of lung cancer. The results of this effort are reported with special focus on surgery.

Methods: Through systematic nationwide registration a total of 24,153 patients have been included in the period 2000—2007. Indicators describing staging, surgical procedures, complications and survival have been registered in those 5007 patients who underwent surgery. Using an Internet based closed circle with a safe program (firewall and encryption) more than 95% of this subgroup of patients have been notified. Each year the results have been audited locally, regionally and nationally and improvements have been proposed, implemented, monitored and consecutively evaluated by the audit-plenary.

Results: This strategy has been a contributory factor to significantly improve the results in mortality, survival and surgical procedures. Thus, the 30-days mortality following surgery has decreased from 5.2% to 3.6% and survival has increased from an overall 1- and 2-year survival of 69% and 50% in 2000 to 77% and 60% in 2007, respectively. A number of other key indicators were also improved: the lobectomy rate has increased from 54% to 73% and the pneumonectomy rate has decreased from 23% to 11%. The proportion of patients having surgery within 14 days from referral has increased from 69% to 87%.

Conclusions: Establishment of a national lung cancer group with the primary tasks to implement updated national guidelines and to secure valid registration of clinical baseline data and quality parameters has been a contributory factor to significantly improve the quality of lung cancer surgery.

Keywords: Lung; Cancer; Surgery; Registry; Outcome; Quality

1. Introduction

At the beginning of the 1990s there was a growing and documented concern among health professionals in Denmark caused by the continuing very poor prognosis for Danish lung cancer patients. The relative 5-year survival had shown no improvement for the past decades, and furthermore the Danish results were significantly inferior compared to survival rates observed in the other Nordic countries [1,2]. A fatalistic approach to the disease was dominant, and it was believed that the only way to reduce lung cancer overall mortality was to reduce the number of new cases through smoking cessation [3].

In 1992 representatives from the scientific societies of thoracic surgery, respiratory medicine and oncology in Denmark established The Danish Lung Cancer Group (DLCG). DLCG evaluated and concluded that the diagnostic procedures and the treatment strategy of lung cancer did not fulfil the basic requirements of good clinical practice [4]. Due to these facts DLCG decided to implement a double strategy. The first task was to publish a complete set of national guidelines, and secondly to establish a database with the primary aim to document the degree of agreement between recommendations and clinical practice. Thus, in 1998 The Danish Lung Cancer Group published the first edition of guidelines and a national registry was opened for registrations in the year 2000.

The purpose of this article is to describe the results of these organisational efforts among all involved professionals.
and to discuss how it is possible to improve the quality of care through quality measurement.

2. Materials and methods

The scientific and theoretical frameworks and methods for quality improvement have been known since the 1960s [5] and have been evolved since [6]. Indicator monitoring in outcome assessments have been established as an epidemiologic valid method [7]. There is evidence that quality measurement, monitoring and feedback, auditing, and public disclosure of results leads to improvements of the quality of care. In fact, performance and outcome measurement using indicators represent the only way to obtain quantitative data on the quality of care for quality improvement [8].

When The Danish Lung Cancer Registry (DLCR) was established the national guidelines were used to identify clinical problems of interest for registration, and these elements together with information on morbidity and prognostic factors formed the first set of data in the database. In 2002 lung cancer was included in The Danish National Indicator Project (NIP). NIP has been a project in The Danish Healthcare System since 1999, and measures the quality of care provided by the hospitals to groups of patients with specific medical conditions. It is a basic principle for the project that the development of standards and indicators follows a clear and transparent process. A standardised process of identifying evidence-based structure, process and outcome indicators accordingly was implemented [9], and DLCR and lung cancer has since been a part of this project.

A wide range of indicators have been identified, documented and monitored in this process and through careful nationwide registration of all lung cancer patients since the year 2000 a total of 24,153 patients have been included in the database. Indicators describing staging, surgical procedures, complications and survival have been registered in 5007 patients who have received surgical treatments, which mean that more than 95% of this therapeutic subgroup of patients, have been included in the database.

Reporting to the database is processed by an Internet based closed network with a secured program. The name of the computer program is TOPICA and it has been developed in co-operation between CSC Scandihealth A/S and DLCR. All clinical data come from the nearly 50 participating departments involved in the treatment of lung cancer. Data is reported to the database when the diagnostic procedures have been completed, or when a specific treatment has been finished. This material is then complemented with data from three national databases including data regarding the patient’s personal and demographic status, which are retrieved from the Centralised Civil Registry, pathology information from The National Pathology Registry and to ensure a high level of data completeness DLCR is compared to The National Cancer Registry. Fig. 1 illustrates the structure of DLCR.

Results are reported in three different ways. (1) The departments have the opportunity to see their own data in TOPICA on a day-to-day basis, where a number of online reports are at their disposition. Waiting time, type of operation, 30-day mortality and several other topics are presented in online reports showing the current status of their work, and they have the opportunity to identify individual patients of interest. Two different national reports are published once a year. (2) The National Indicator Project publishes an annual report with focus on a limited number of well-defined evidence-based indicators. National and regional results are published comparing regions and departments. These data are followed by comments and recommendations from a steering committee. A process of local, regional and national audits is performed in order to identify problems and barriers and to propose specific strategies in order to improve specific results. Implementation of these proposals is then the next, but difficult step, followed by a process of monitoring and consecutively evaluating the progress. (3) The Danish Lung Cancer Group also publishes an annual report. This report includes data from NIP but is extended by supplementary indicators and information on comorbidity and details on treatment.

In total 5007 patients with lung cancer operations are recorded in DLCR. A total of 5063 operations were performed in seven hospitals in the period 2000–2007. Since 2004 the surgical procedures have been centralised to five university hospitals. The material is given in Table 1. Statistics used in the next chapter are unadjusted χ² tests for trend in proportions with a significance level of 0.05. All patients in the survival analysis were followed for 1, 2 or 5 years and the follow-up was 100% completed at the end of 2007.

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Included total number of patients in The Danish Lung Cancer Registry and number of these who had an operation.
3. Results

Overall survival after surgery is of course the central and most important indicator when striving to increase quality of lung cancer surgery. Data shows an improvement in survival from an overall 1- and 2-year survival of 69% and 50% in year 2000 to 77% and 60% in 2005, respectively (Fig. 2). These improvements are statistically significant ($p = 0.001$ and 0.004, respectively), while the observed increase in 5-year survival from 32% in 2000 to 35% in 2002 is not significant ($p = 0.448$).

There have been significant changes in central indicators. Thus, the 30-day mortality after surgery defined as the percentage of all lung cancer patients receiving surgery, who die within 30 days after surgery, has decreased from 5.2% to 3.6% (Table 2).

Furthermore, there have been improvements in various other indicators in the same period. Overall survival and 30-day mortality are typical examples of outcome indicators, but a number of process and structure indicators are also monitored and reported. Process indicators assess what the provider did for the patient and how well he or she did it. Structure indicators assess the characteristics of the health care system that affect the system’s ability to meet the health care needs of individual patients or a community.

Three examples of this type of indicator include agreement between clinical TNM stage (cTNM) and pathological TNM stage (pTNM), operation types (lobectomy vs pneumonectomy) and waiting times.

Agreement between cTNM and pTNM in the period 2003—2007 is an indicator describing the quality of the diagnostic procedures prior to surgery. The only incongruity that could have had a relevance to the treatment strategy is taken into account. Changes in T status from T1—2 to T3—4, changes in N status from N0—1 to N2—3 or changes in M status from M0 to M1 are all included in the calculations. Fig. 3 shows the improvement in this indicator in the period from 2003 to 2007. Stage distribution for the overall population and for the surgical patients is given in Table 3.

There is international consensus and good scientific evidence to support that lobectomy is the type of operation associated with the highest level of survival and lowest level of morbidity, and lobectomy is in our national guidelines and recommended as the operation of choice. In the observed period the lobectomy rate rose from 54% to 73%; pneumonectomy rate has decreased from 23% to 11% (Fig. 4).

DLCR have reported waiting times from the beginning and it is now possible to show an effect since the proportion of patients having surgery within 14 days from referral has increased from 69% to 83% (Fig. 5).

4. Discussion

The Danish Lung Cancer Registry is a practical example proving that surveillance of clinical performance and treatment outcome based on specific quality indicators and national guidelines can lead to improvements in the quality of care. The success depends, however, on good feedback of results to responsible clinicians and hospital staffs, systematic auditing, public disclosure of results and actions to improve treatment and care [10,11]. Quality indicators describing performance and outcome are necessary to document the quality of care, benchmarking, quality

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Table 2

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Percentage of dead patients within 30 days after lung cancer surgery in Denmark 2000—2007, total and according to type of operation.
improvement, accreditation and giving preferences. The indicators are, however, no better than the data on which they are based, and the scientific evidence is crucial for consensus among and impact on the involved health professionals [12].

It is the experience of DLCG and DLCR that support from the clinicians is an indispensable requirement for successful implementation of a quality securing system. High data completeness and a high level of data quality are very important to ensure valid results from the database and are only possible with support from clinicians and hospital staff. Registration of clinical data is a time-consuming process, and professional understanding and backup is obviously necessary. A relationship between the indicator, measurement and clinical outcome based on scientific literature must have been demonstrated to secure this support.

Structure and process indicators as used in DLCR are useful when quality improvement is the goal, and since comparisons based on process data are easier to interpret and sensitive to small differences they are good tools in the process of quality improvement. Outcome data on the other hand are useful when the outcome is affected by health care, and the performance of a whole system is studied. Implementation of new processes of care can be monitored through outcome measurement [13].

The process of developing quality indicators in specific diseases is a relatively new way of clinical work, and there are very few examples in the literature in particular in relation to lung cancer. The work of Hermens et al. [14] is one of the few examples, and even though the methods they used to select the indicators are slightly different from the methods used by DLCR, there is a good agreement and consensus on the conclusion, that only through the use of evidence-based clinical indicators is it possible to predict patient outcomes and measure quality.

The most important indicator in DLCR is survival after 1, 2 and 5 years. The standards defining this indicator are very well documented [15,16], but interpretation of results is likewise difficult. It is a typical outcome indicator, where the results are influenced by multiple factors. Characteristics of the patient (age, sex, smoking, social status), the disease (stage, comorbidity), the treatment (competence, equipment, practice) and the organisation (guidelines) are all determinants of the outcome, which makes risk adjustment and control of these confounding factors important for assessing quality.

Our results show significant improvements in 1- and 2-year survival rates, but it is difficult precisely to point out how the work of DLCG and DLCR contributes to this improvement. Development of new and advanced methods in diagnostics procedures and in particularly new treatments in oncology contributes more accurate staging and better short-term survival, but it still remains to be seen if these improvements are persistent in the long-term survival too. Table 1 shows difference in accrual rates over time as an expression of progressive compliance adjustment between departments, which could be a bias that should be taken into account when explaining part of the observed differences in survival. There is, however, no doubt that implementation of national guidelines and the work of DLCR should be ascribed a good share of the honour for this improvement.

It is easier to argue that the work of DLCR has improved the 30-day mortality. This indicator is in general accepted with a high level of evidence directly to indicate the quality of patient selection and of surgery [17–19]. The results from Denmark are satisfactory compared with these standards. The improvement is a result of the work with national annual audits, where all perioperative deaths are analysed and discussed. This work has identified and increased clinicians awareness towards a number of risk factors, i.e. alcohol abuse, pneumonectomy and COPB, which have changed the professional behaviour without leading to ‘defensive medicine’ because the resection rate has risen. Currently, therefore, patients with relevant risk factors will receive an individualised treatment reducing the risk of postoperative death.

It is evident that unnecessary operations should be avoided because it affects the patient quality of life. A correct preoperative staging is therefore important as reflected by the agreement between cTNM and pTNM [20,21]. During the observed period uniformity in the methods used in preoperative staging has been obtained, as documented by DLCR. Furthermore a process of centralisation of departments performing the procedures has been completed, and it is likely that this has resulted in a higher quality of the preoperative staging. The Danish results are significant better now than 4 years ago, and this indicator is a good example of how it is possible to improve results of a process indicator in the short-term, and thus affecting the quality of care. The same is the case with the process indicator concerning types of operation. This indicator is also based on good evidence supporting that lobectomy should be
the recommended type of operation, since it is associated with the lowest mortality and the highest survival [22].

The association between waiting times and the results of surgery is weak even though recent publications indicate a more significant importance of this indicator [23]. Among cancer professionals there is an ongoing debate on the significance of waiting times when discussing survival, but from the patient’s point of view long waiting times for diagnosis and treatment are unacceptable [24,25]. In Denmark waiting times have been in focus for some years and a number of governmental, national and local initiatives have tried to reduce the waiting times. The positive results of this work can now be demonstrated by DLCR regarding patients receiving surgery.

In conclusion, a large scale (national) co-operation between multidisciplinary specialities and the health authorities, as managed by The Danish Lung Cancer Group, including updated national guidelines, a database, annual public reports, systematic audits and organisational commitment is worthwhile and probably the best and only way to significant improvements in treatment of lung cancer.

References


Appendix A. Conference discussion

Dr A. Bruneill (Ancona, Italy): You demonstrated that a well-designed national total quality management program can improve practice. My first comment is an invitation on behalf of our committee to co-operate with our database, and this is an invitation I extend also to any national data manager across Europe. Without losing national identities, we can build a strong registry, which can be our most powerful resource to maintain the integrity of our speciality and of our society. As we intend to implement a similar strategy in Europe in the long run, my first question is whether you think your TQM methodology can be replicated at a wider level and in a context of much greater heterogeneity? You have observed better results in the last period of your registry, but these may also have been the consequence of a selection bias or risk-averse behaviour. One way to minimise this problem and to clarify the issue is to use risk-adjusted outcomes. Have you ever considered using risk adjustment to anchor national performance to a benchmark and verify variation in practice by comparing observed versus predicted outcomes? You also demonstrated that a higher percentage of referrals have been operated within 14 days in the last period as a consequence of revised pathways of care. Have you verified if this practice led to a prolonged survival or to an increased rate of operability? You have selected a percentage of lobectomies as a process indicator of performance. However, it will remain unclear from your data whether the increased percentage of lobectomies in the entire population was due to selection bias or to an actual improvement in practice, unless you limit the analysis to a strictly defined eligible population, for example, stage I patients.

Dr Jakobsen: First of all, I, of course, would thank you for your invitation to join the European database. We believe very strongly in Denmark that this kind of database should be regarded as a multidisciplinary effort, and I think that is one of the problems with the European database at this point. Of course, we would like to co-operate with you in an effort to widen the database so that we could manage all the parts of the lung cancer course. We do perform risk adjustments in our database, and since we have all the background data to do that, we perform analysis of heterogeneity between departments and regions and have actually shown some heterogeneity. Of course, this is very important, and you have to have the data in your database to support this.

Concerning 30-day mortality, there is, of course, a risk of selection bias, but we believe that since this is a national database, and we have more than 95% of all data in our database, this perhaps would minimise this bias. But this public showing of a resource, of course, could have the impact of defensive medicine. I don’t know, actually. We discuss that a lot in Denmark actually now. And the same, I couldn’t say use the same arguments concerning lobectomy. We haven’t observed any change in the cTNM and pTNM stages over the years. And the same, I couldn’t say use the same arguments concerning lobectomy. Concerning 30-day mortality, there is, of course, a risk of selection bias, but we believe that since this is a national database, and we have more than 95% of all data in our database, this perhaps would minimise this bias. But this public showing of a resource, of course, could have the impact of defensive medicine. I don’t know, actually. We discuss that a lot in Denmark actually now. And the same, I couldn’t say use the same arguments concerning lobectomy. We haven’t observed any change in the cTNM and pTNM stages over the years. And the same, I couldn’t say use the same arguments concerning lobectomy.

Dr A. Turna (Istanbul, Turkey): I wonder what is the reason of decreasing waiting time? Is it because of governmental judgment or is it based on the hospital administration?

Dr Jakobsen: Well, actually both. There has been a lot of discussion in Denmark over the last few years about this problem. But this really changed a couple of years ago when the national authorities very heavily pointed out that these recommendations should be followed, and afterwards the organisational commitment was very clear.

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