

Uncertain added value of Global Trigger Tool for monitoring of patient safety in cancer care

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ABSTRACT

INTRODUCTION: Monitoring patient safety is a challenging task. The lack of a golden standard has contributed to the recommendation and introduction of several methods. In 2000 the Danish Lung Cancer Registry (DLCR) was established to monitor the clinical management of lung cancer. In 2008 the Global Trigger Tool (GTT) was recommended in Denmark as a tool for the monitoring of patient safety. Ideally, the recommendation of a new tool should be preceded by a critical assessment of its added value.

MATERIAL AND METHODS: Data on complications related to lung cancer surgery from the Department of Cardiothoracic Surgery at Odense University Hospital were collected using the DLCR and the GTT in 2008. The capacity of these two methods to identify complications is compared and discussed.

RESULTS: A total of 59 complications were registered in the DLCR, while 58 complications were registered using the GTT. The two methods were equally good at identifying complications, but the DLCR seems to be borderline significantly better at detecting arrhythmia, while the GTT was significantly better at detecting "other events".

CONCLUSION: Nearly half of the adverse events identified with the GTT were complications which were also registered by type in the DLCR. The two methods were almost equally good at identifying specific types of complications, but the GTT identified more "other events". The majority of these events were well-known to clinicians. The comparison illustrates why the implementation of new methods should be preceded by critical assessment. In this case, it is crucial to assess whether the current method should be modified by the addition of more patient safety indicators rather than by introducing a new method that partly duplicates existing data.

Monitoring patient safety is a challenging task. In Denmark, the lack of a robust standard methodology for the identification of adverse events has led to the introduction of various tools aiming at identifying hazards and at monitoring the effect of interventions. In recognizing that healthcare facilities are operating under pressure (workload, economy and performance), the introduction of new methods should be preceded by critical assessment of any added value.

Providing care to cancer patients is a process that

involves many care providers, numerous professionals in various disciplines and many health care institutions. Treatment often consists of a combination of surgery, radiotherapy and chemotherapy which in itself presents a number of hazards to the patient. Safety and complexity are correlated, and – as for most patient groups – safety is an important issue for cancer patients, as it may affect their treatment outcome.

The Danish National Lung Cancer Registry (DLCR) was established in 2000 with a view to monitoring the implementation of Danish national guidelines on the treatment of lung cancer and improving the quality of its clinical management [1]. The DLCR is a case-based quality registry which over time has developed into an established data source for quality improvement.

The Global Trigger Tool (GTT) was introduced in Denmark in 2008 as a method for identifying adverse events, measuring the rate of adverse events over time and identifying areas needing improvement [2]. The tool has been recommended nationally as a method to monitor and improve safety.

Adverse events identified with the GTT consist of harm as experienced by the patient, including complications. Since complications are routinely registered in the DLCR, it is relevant to compare the information gained from the two data sources. The aim of this paper was to describe and compare the information on safety in Danish cancer care originating from the DLCR with the newly introduced GTT and to estimate any value added by the new method.

MATERIAL AND METHODS

Danish Lung Cancer Registry

Data in the DLCR are registered nationwide by departments of cardiothoracic surgery as well as by departments of pulmonary medicine and oncology using an internet-based programme. In 2008, the Department of Cardiothoracic Surgery, Odense University Hospital registered that a total of 191 patients had cancer surgery. Data reported to the DLCR by February 2009 covering patients with a date of diagnosis in 2008 were included. Data on staging, surgical procedures, survival and complications were registered for these patients. The estimated completeness of patient registration was over 90% [3].

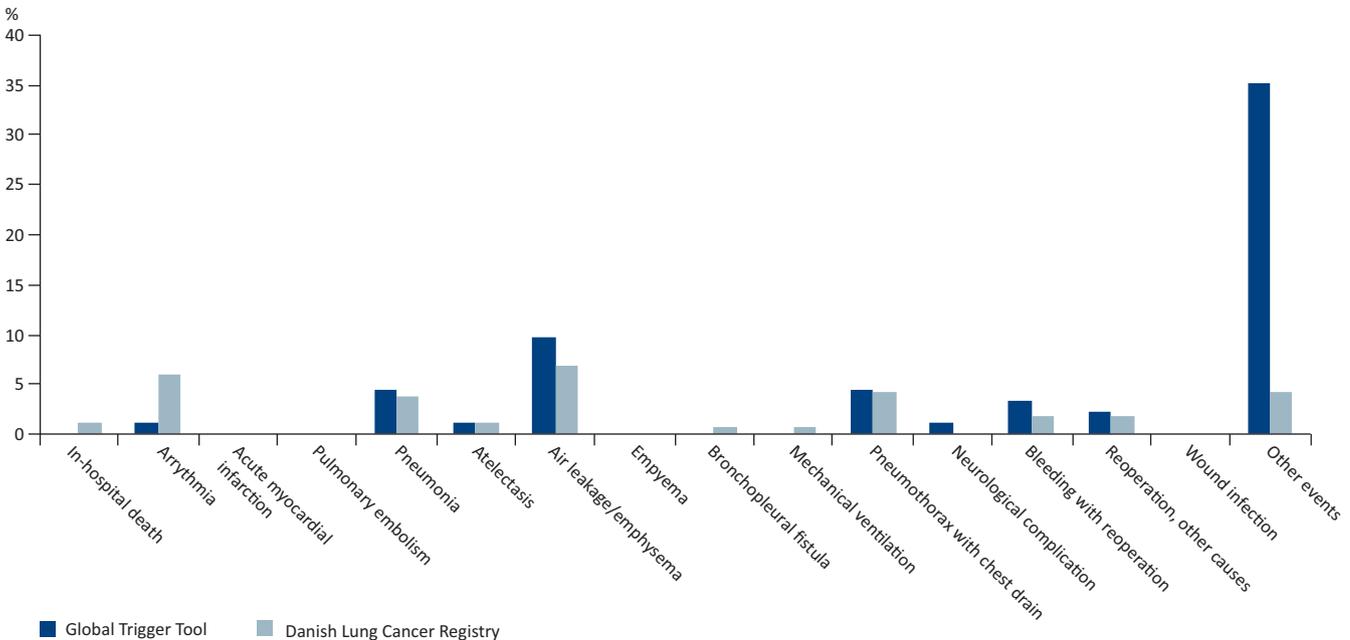
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FIGURE 1

Complications identified with Global Trigger Tool and Danish Lung Cancer Registry.



Frequencies of complications related to the surgical cancer procedures were recorded in 16 DLCR categories (**Figure 1**). Results from the Department of Cardiothoracic surgery in Odense as well as from the three remaining surgical facilities treating lung cancer in Denmark were published in an annual report and fed back to the wards. Results were audited at the local, regional and national level and improvement activities have been described and will be implemented, i.e. selection of patients with preoperative co-morbidity for certain kinds of surgical procedures will be much more sophisticated [4].

Global Trigger Tool

Various trigger tools exist, but no cancer-specific trigger tool was identified prior to this study. The GTT was chosen with a view to achieving an overall impression of harm in cancer care.

Trigger tool methodology is based on a retrospective review of a random sample of records. The reviewer looks for “triggers” – predefined criteria that indicate adverse events (harm) – facilitating the identification of events that require further investigation to determine if an adverse event has occurred (**Figure 2**) [2, 5].

A random sample of 94 records from the population of lung cancer patients discharged from the Department of Cardiothoracic Surgery, Odense University Hospital from May to October 2008 were reviewed as part of a

larger study [6]. The records represent a subset of all cancer patients treated in this department in 2008 and thus a subset of the total of 191 patients who were registered in the DLCR as described above.

It was planned that 120 records should be reviewed (ten records per 12 sampling periods), but in nine periods fewer than ten patients were discharged, which left 107 cases from which sampling could be performed. Among the 107 records, 11 did not fulfill the inclusion criteria (patient age 18 and older, minimum length of stay 24 hours, closed and completed record, cancer diagnosis) and two were unavailable at the time of review. In periods with more than ten cases, records were selected randomly using a random number generator tool [7].

A review team from the Danish Cancer Society (one pharmacist, one medical consultant) carried out the review under the supervision of a senior hospital physician from the ward (thoracic surgeon), who also validated the finding of adverse events.

Records were reviewed according to the protocol of the Institute for Health Care Improvement [2, 5]. Identified triggers were recorded and adverse events that had harmed the patient were briefly described.

The collected data were presented in run charts as “adverse events per 1,000 patient days” and “percentage of admissions with an adverse event” and at table with a short description of each event. Results were fed

back to clinicians, which gave rise to no corrective actions.

Harm was subsequently categorized according to type using the DLCR classification of complications (Figure 1). The type group of "other events" was further analyzed to highlight any additional safety information.

Comparison

Complications in the DLCR and harm in the GTT study were all categorized by type using the 16 item DLCR classification (15 specific types of complications and a type called "other events"). Comparison was made at two levels: Comparison of the distribution of complications for GTT versus DLCR, and if the overall comparison showed significance, a comparison of specific complications for each method was made.

Statistics

Individual comparison of each type of complication was made using the chi-square test when the expected number of complications in both DLCR and GTT was at least five. When less than five, Fisher's exact test was used. For complication categories with no cases identified with neither GTT nor DLCR, statistical testing is not possible (acute myocardial infarction, pulmonary embolism, empyema and wound infections).

For the multiple comparisons of the two methods, the significance level was adjusted according to the Bonferroni correction. In our case, the Bonferroni-corrected significance level is 0.005 including the "other" category and 0.004 excluding this category, at a 5% significance level within the categories.

RESULTS

Danish Lung Cancer Registry

In 2008 a total of 59 complications were registered in the DLCR in connection with the 191 surgical procedures carried out at the Department of Cardiothoracic Surgery, Odense University Hospital (31%). The distribution of complications on the 16 harm categories is illustrated in Figure 1.

Global Trigger Tool

A total of 58 adverse events (harm) were identified in 94 records from May to October 2008. Identified harm was classified into the 16 DLCR complication categories (Figure 1). Of the 58 adverse events, 25 were categorized as distinct types of complications (27%), whereas 33 were categorized as "other events" (57%). The latter primarily consisted of infections (fungal infections and urinary tract infections), insufficient epidural pain treatment (malfunctioning catheter or accidental displacement), intraoperative bleedings and intubation problems (dental injury, vocal cord paralysis). Single cases of

fall, allergic reaction to band-aid, contrast extravasation, ulcer, postoperative organ failure and postoperative delirium were also identified.

Comparison

Individual comparison of complication categories showed significant difference in the ability of the two methods to identify "other events" (p value < 0.001) and a borderline significant difference for "arrhythmia" ($p = 0.045$). No significant differences were found between the remaining complication categories.

In the multiple comparisons of the two methods, the only category that yielded a statistical difference between the methods was "other events" (p value < 0.001).

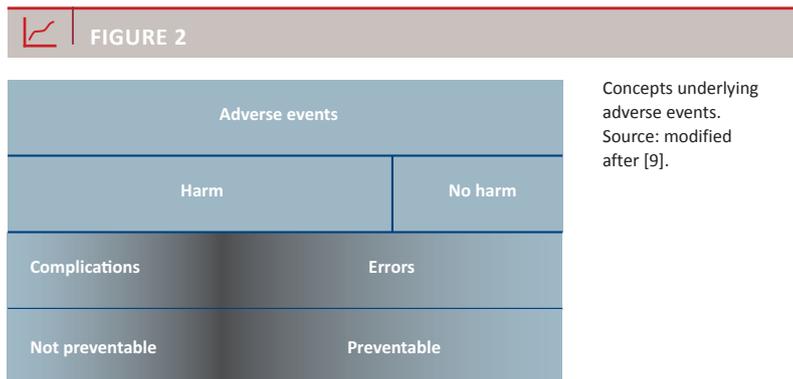
DISCUSSION

The size of the two datasets does not allow for a robust comparison of events identified with GTT and DLCR, but the results suggest that the two methods are equally good at identifying specific surgical complications. The trigger tool used is "global" and covers a broader spectrum of safety issues than the DLCR. It is suggested that this difference is compensated by registration of additional safety information in the DLCR.

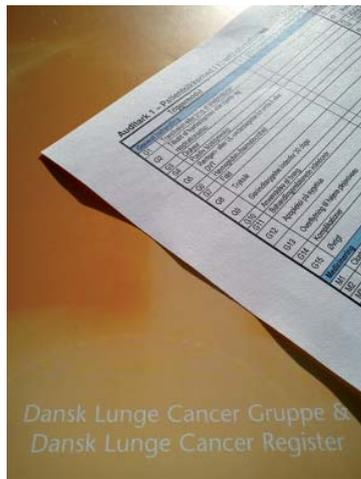
The methods used do not allow for comparison of cases identified with the GTT and the DLCR, respectively. This methodological weakness should be taken into consideration in the interpretation of the results.

Both DLCR and GTT data in this study come from the Department of Cardiothoracic Surgery at Odense University Hospital. It is estimated that 90% of the patients treated for lung cancer are registered in the DLCR. Charts reviewed in the GTT study were randomly sampled from all patients treated for lung cancer at this department. It is therefore most likely that the majority of the patients in the GTT study are also part of the DLCR material.

The findings raise awareness of factors that should be taken into consideration when deciding how patient



Record review using Global Trigger Tool and registration of complications in the Danish Lung Cancer Registry – the two methods seem to be equally good at identifying surgical complications.



safety in Danish lung cancer care is most efficiently monitored. In addition to the ability of the method to identify complications, several other parameters should be considered, i.e.:

- The GTT relies on a repeated small, random sample of records – the DLCR has longitudinal data registration and covers more than 90% of all surgical lung cancer procedures performed in Denmark.
- The GTT measures harm and severity of harm – in the DLCR, complications are registered along with information on other quality and (proxy) patient safety aspects like mortality, waiting times, length of stay, risk factors and a variety of clinical parameters. This allows clinicians to monitor diagnosis and treatment in relation to clinical guidelines and nationally integrated lung cancer pathways.
- GTT data can be obtained and updated every two weeks – the DLCR is impaired by latency in data reporting.
- Resources used for GTT reviews are considerable and requires the participation of selected clinicians as well as administrative staff – registration in the DLCR is electronic and involves both administrative staff and clinicians. Clinicians enter data on their own patients in a procedure that is less time-consuming than chart review.
- The use of GTT information to enhance safety calls for an organization to support further analysis of the results, decision and implementation of corrective actions and evaluation hereof – the DLCR is rooted in the clinical environment, has well-established improvement strategies and has proven to be a contributory factor to significantly improve mortality, survival and surgical procedure results [2].

The DLCR is a case-based database and it is well-established as a tool for monitoring quality, whereas the GTT is a relatively new tool designed to monitor patient safety. In line herewith, the DLCR monitors complications recorded by the surgeon, whereas the GTT is used to monitor adverse events that harm the patient. The definition of an adverse event in this context implies that complications are a subset of adverse events. This is reflected in the fact that the group of “other events” identified with the GTT constitutes more than half of the GTT material. Looking further at this group, some would argue that the majority of information concerns “known complications” including infections, insufficient pain relief due to displacement of the epidural catheter, intraoperative bleedings and intubation problems which are all known risks accompanying cancer surgery. From this point of view, the amount of new safety information generated with the GTT is limited, but this does not mean that these kinds of problems should not be monitored and acted upon.

Complications can result from recognized risky but correctly administered therapies [8]. In order to use complications to improve patient safety, focus should be on learning potential and preventable harm, but estimation of preventability is not an exact science. The ability to prevent complications is seldom a matter of all or nothing, but rather a matter of degree (gray zone, Figure 2), and learning may be influenced by problems in linking exposure and outcomes as well as by patient factors [9]. Since preventability has not been assessed with either method, the exact potential for safety improvement remains unknown and needs further analyses.

The fact that the GTT identifies complications not identified in the DLCR could justify the use of a supplemental method for monitoring safety in cancer. The consequence would be a partial duplication of registrations and findings. Another possibility would be to further improve the DLCR and incorporate registration of e.g.:

- infections (other than pneumonia and wound infection)
- epidural pain treatment
- intra operative bleedings.

International experience on the use of patient safety indicators exists and could be used in the further development of the DLCR [10, 11].

This study provides input to a discussion of the monitoring of patient safety in Danish lung cancer care and underlines the importance of ensuring that the implementation of new methods is preceded by a critical evaluation of the pros and cons of both the existing and the new methods.

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CONFLICTS OF INTEREST: none

LITERATURE

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