Quality Assurance Through Outcome Registration in Colorectal Cancer: An ECCO Initiative for Europe

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ABSTRACT

In recent years there have been significant improvements in the outcome of rectal cancer treatment. Both new surgical techniques as well as effective neoadjuvant treatment regimens have contributed to these improvements. It is key to spread these advances toward every rectal cancer patient and to make sure that not only patients who are treated within the framework of clinical trials may benefit from these advancements. Throughout Europe there have been interesting quality programs that have proved to facilitate the spread of up-to-date knowledge and skills among medical professionals, resulting in improved treatment outcome.

Nevertheless, between European countries remain differences in outcome and treatment schedules that cannot be easily explained. The European CanCer Organisation (ECCO) has recognized these importance and created the “European Registration of Cancer Care” (EURECCA) framework to develop a European colorectal audit structure. EURECCA will advance future treatment improvements and spread these to all European cancer patients. It provides opportunities to treat elderly and comorbid patients evidence based while offering a unique insight into social-economical healthcare matters. As such, ECCO has established the basis for a strong, multidisciplinary audit structure with the commitment to improve cancer care for every European cancer patient.

Keywords: colorectal cancer, rectal cancer, outcomes assessment, audit

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INTRODUCTION

Currently, quality of healthcare is a widely discussed topic and this is especially true for cancer care. Patients try to seek the best care available. As a result, several ranking lists can be found on the Internet and in popular presses around the world. Unfortunately, many of these lists do not meet the requirements needed for a fair comparison of healthcare providers and can therefore give misleading results. Nevertheless, search for quality is plausible since there seem to be substantial differences in quality of care between countries, hospitals, and doctors. Apart from patients, politicians, insurance companies, and medical professionals also strive for a higher quality of care, all with their own reasons and strategies. In many countries, governments have tightened their existing regulations and created new ones trying to improve quality of care in a “top-down” manner. Obviously, medical professionals also put great effort in improving their quality of work, but this happens in a “bottom-up” manner. All initiatives to improve quality of care can be nominated as “quality assurance”. While lacking a strict definition it can be summarized as “the complete set of systematic actions that is required to achieve a treatment result that meets a certain standard”. Quality assurance in surgical oncology is relatively new as compared with other medical fields such as chemotherapy and radiotherapy. For a long time, surgery was thought to have too much unexpected variation to be feasible for standardization and quality control. However, the conception of surgery is steadily shifting from being a non-definable craftsmanship to a transparent and well-defined skill. Nowadays many quality assurance programs have been successfully enrolled in surgical oncology with encouraging results, in particular for treatment of rectal cancer. In the early nineties, outcome after rectal cancer surgery was poor, with survival as well as recurrence rates of approximately 45%. In addition, there was a remarkable variation in outcome between hospitals and between individual surgeons. At that time the Total Mesorectal Excision (TME) technique was introduced by Heald et al. Instead of a blunt dissection, the rectum is sharply dissected within its mesorectal fascia under direct vision. Many European countries initiated quality assurance projects as an answer to these challenges. In this article, we will describe the different aspects of quality assurance and we will conclude with a framework for the future of surgical oncology in Europe.

CLINICAL TRIALS

Several European studies showed improvements in outcome after implementation of the TME technique in rectal cancer surgery. Studies showing the benefits of the TME technique contributed to the quality of rectal cancer care in two ways. On the one hand by publishing, spreading, and recommending the new technique, and on the other hand because standardized and quality-controlled surgical trials seem to have a positive effect that reaches beyond the patients and...
doctors that participated in the study. Improvements in quality of care as a direct consequence of registering surgical data, has been observed in multicenter clinical trials with mandatory criteria for surgical technique and quality of care. A good example is the Dutch TME trial, which studied the value of preoperative short-term radiotherapy in combination with standardized TME surgery in patients with rectal cancer. Standardization and quality of treatment was continuously emphasized by means of master classes, supervision, and visitation. This resulted in lasting positive effects. Rectal cancer patients in the region of the Comprehensive Cancer Centres South and West were clustered in three groups: before, during, and after the trial period of the TME study (1996–1999). Of the 3179 patients analyzed, only 421 (12%) participated in the TME trial. Survival improved for all the patients in the period during the trial and in the last period survival improved further.

Despite all these improvements there remain differences between European rectal cancer studies that cannot be explained easily. For instance, the 5-year survival rate in the German CAO/ARO/AIO-94 study exceeds the 5-year survival rate of the Dutch TME trial by more than 10% (75% versus 64%). Differences in study design could play a major role in these variations in outcome, besides differences in infrastructure and patterns of care between the hospitals participating in these studies. Another downside of relying on clinical trials as a tool to judge and improve quality of care is that most patients are treated without being enrolled in clinical trials. Elderly patients or those with multiple comorbidities are often excluded from clinical trials, leaving little evidence for the treatment of these categories of patients.

MULTIDISCIPLINARY TREATMENT

The importance of multidisciplinary treatment cannot be emphasized enough. Even the best surgeon is helpless without an adequate radiologist, pathologist, medical oncologist, and radiotherapist. Much effort has been put in the multidisciplinary approach of cancer treatment for rectal cancer patients. Radiologists had to facilitate MRI diagnostics whereas pathologists had to adapt to the protocol of Quirk et al. to adequately identify lateral spread of tumor. Radiotherapists had to shift to preoperative radiation treatment schemes for a majority of patients. It is essential to include all multidisciplinary fields of cancer treatment in quality assurance programs by standardizing, training, and visitation with feedback.

CONCENTRATING TREATMENT TO HIGH-VOLUME CENTERS

A growing number of studies report variation in outcomes between institutions providing healthcare. For cancer surgery in particular, a relationship exists between hospital or surgical volume and patient outcomes, in terms of operative mortality, complications, and overall survival. In most western healthcare systems, efforts are made to reduce this variation among hospital. Most initiatives focus on selective referral, encouraging patients to seek care in high-volume hospitals. A strategy were to treat a larger proportion of patients in specialized centers, could evidently improve the overall results for complex surgical procedures, such as esophagectomies and pancreactomies. Although there are also multiple studies showing a positive volume-outcome relation for colon and rectal cancer, variation is smaller as compared with esophagectomies or pancreactomies. Besides, one must bear in mind that there are also low-volume providers who perform very well and high-volume providers with unacceptable outcomes. Moreover, the expertise for diagnosis and treatment for common types of cancer should be preferably widespread and easily accessible for all patients.

NATIONAL AUDITS

As an alternative to volume-based referral, hospitals and surgeons might improve their results by learning from their own outcome statistics and those of colleagues treating a similar patient group. Surgical audit is a quality instrument that collects detailed clinical data from different healthcare providers, which can be adjusted for baseline risk and subsequently fed back to individual hospitals or surgeons. Identifying, communicating, and adopting “best practices” might improve the quality of care nationwide. An important condition for the success of outcome registries is the quality of collected data. Data has to be prospective, complete, case-mix-adjusted, and preferably collected by independent investigators. In addition, the quality of data has to be assured by a second independent registry.

In Europe, several national rectal cancer audit registries have been established since the nineties. Themost important advantage of these audit registries compared with clinical trials is the fact that they include the entire patient population without excluding certain patient groups. After case mix adjustments a fair judgment can be made on the quality of cancer treatments, and healthcare providers can be faced with their own results compared with those of colleagues treating the same patient category. For instance, the Norwegian Rectal Cancer Project, founded in 1993, includes more than 99% of patients operated for rectal cancer. After 4 years the results of this audit were remarkable: the proportion of TME surgery rose from 78% to 92% and the local recurrence rate decreased from 28% to 7%. These results, published in 2002, are indeed spectacular. Moreover, it also showed to be very cost-effective, with the cost of every saved life being less than €700. Swedish initiatives were also successful. The Swedish Rectal Cancer Registry was started in 1995, with over 97% of patients with rectal cancer included. The postoperative mortality rate was less than 2.5%, with a local recurrence rate of less than 10%. Survival had dramatically improved: patients with rectal cancer had an even better 5-year survival rate than those with colon cancer. This is remarkable because in the same period important improvements in chemotherapy for patients with colonic cancer had been achieved. Rectal cancer patients did not benefit from these
changes as adjuvant treatment after rectal cancer surgery is still considered experimental in many European countries. Besides, rectal cancer is much more technically demanding as, in contrast to colonic cancer, the pelvic area, including the rectum, contains only a little space to perform a radical resection. Nevertheless, the fact that survival of rectal cancer patients was superior to those of colon cancer patients shows the considerable effect of surgical training and feedback. The Danish ColoRectal Cancer Database also produced satisfying results.  

Since 1994, 93% of all colorectal cancer patients were included. After 5 years of auditing, the 5-year survival increased from 42% to 63% for women and from 37% to 55% for men.

More recently, other European countries followed in the Scandinavian footsteps by setting up their own national (colo)rectal audit programs. In 2001, The Association of Coloproctology of Great Britain and Ireland (ACPGBI) started the National Bowel Cancer Audit Programme (NBOCAP). In 2008, 95% of trusts in England and Wales submitted data. Within 5 years, 30-day mortality dropped from 7% to 4.5%.

In 2000, the “International Quality Assurance in Colorectal Carcinoma” was initiated in Magdeburg, Germany. Between 2000 and 2008, 372 hospitals from Germany and Poland included 57,429 patients. Since 2009, patients from Naples, Italy, have been included and Lithuania is scheduled to join in 2010. The percentage of abdominoperineal excision was significantly reduced from 26.1% in 2000 to 21.3% in 2008.

In 2005, Belgian surgeons initiated the Project on Cancer of the Rectum (PROCARE). After standardization and implementation of guidelines, prospective registration started in 2006 on a voluntary basis. Until now, 50% of the Belgian hospitals have participated and around 2500 patients have been included. Besides registering crude outcome data after rectal cancer treatment, extensive efforts and resources are used to train surgeons, pathologists, and radiologists in the latest standards of rectal cancer treatment.

In 2006 Spanish the TME project was founded. This rectal cancer audit registration has a national coverage of 20%. So far, 3100 patients have been included. First reports show a 30-day mortality of 3.1% and an anastomotic leakage rate of 8.2%.

In 2009, the Dutch society of surgical oncology, the Dutch society of gastrointestinal surgery, and the Dutch colorectal cancer group started the Dutch Surgical ColoRectal Audit (DSCA). Within a year, national inclusion coverage reached 100% and more than 10,000 patients were included. Recently, the DSCA published its first annual report covering 2009. Obviously, in a first report no statements can be made about the quality-enhancing effect of the audit. However, important findings were discovered such as the percentage non-elective colon cancer operations. Twenty-one percent of all operations were acute or urgent, with a mortality rate up to 14%. Striking is the fact that 26% of the patients who underwent acute or urgent surgery, had visited a surgical outpatient clinic before their situation became urgent. Given the fact that for colon cancer, mortality after elective surgery is only 2.9% compared with 14.3% after acute surgery, it seems obvious that many lives can be saved when these “unnecessary acute” patients are reduced.

Considering the magnitude of improvements induced by the audit projects described above, the costs are futile in comparison with several adjuvant therapies. Most importantly, the benefit for individual patients of most adjuvant therapies is several orders of magnitude smaller than that of the major improvements achieved by the audits.

EURECCA: AN INTERNATIONAL, MULTIDISCIPLINARY, OUTCOME-BASED QUALITY IMPROVEMENT PROJECT OF THE ECCO

Although all national audits achieved excellent results, there remain differences in treatment outcomes between European countries. On review of the results, there appear differences in mortality, complications, recurrence, and survival. Moreover, there is a wide variation in practice and protocol. Whereas in Sweden and the Netherlands most rectal cancer patients receive preoperative radiotherapy, in Norway a minority of patients receive radiotherapy (4% between 1993 and 1997). Nevertheless, local recurrence rates in Norway equal the rates in Sweden and the Netherlands. In other countries, preoperative chemoradiation is used for patients with resectable rectal cancer instead of short-course radiotherapy.

The current differences in treatment protocols among European countries clarify in some cases a shortage of unambiguous and convincing evidence, which provokes controversies. On the other hand, it lays bare the differences in traditional practice and national progress in quality assurance programs in which Scandinavian countries clearly take the lead. For countries with a backlog in terms of state-of-the-art practice and quality assurance infrastructures, it is unnecessary and time-consuming to reinvent the wheel in order to catch up. Instead, it is much more efficient to learn from other countries by identifying and spreading best practice in an international audit structure.

Despite the numerous national projects, international initiatives are limited. To generate the best care for colorectal cancer in the whole of Europe and to meet political and public demands for transparency, a deep and broad insight into treatment outcomes is needed union-wide. A European audit registration will provide transparency, benchmarking, and feedback across nations’ borders. This can rapidly lead to treatment improvements and decreased variation in the quality of care across the continent.

Urged by these arguments, the European CanCer Organisation (ECCO) initiated an international, multidisciplinary, outcome-based quality improvement program, European Registration of Cancer Care (EURECCA). The goal is to create a multidisciplinary European registration structure for patient, tumor, and treatment characteristics linked to outcome registration (morbidity, mortality, loco-regional control, and survival). The registration will be used for benchmarking and
internal feedback among participants, and enhance further improvements in quality and efficiency of cancer care. All eight audit registries described in this article have given their full commitment to participate in the EURECCA framework.

Considering the multidisciplinary aspect of cancer treatment, collaboration between the European cancer organizations is pivotal for the success of EURECCA. The key partners in realizing the vision are the ECCO, the European Society of Surgical Oncology (ESSO), the European Society for Therapeutic Radiology and Oncologists, the European Organisation of Research and Treatment of Cancer, and the national audit structures.

The EURECCA project has a strong clinical research component complemented by the provision of practical tools for care providers all aiming at the optimization of the delivery of surgery, radiotherapy, and chemotherapy in colorectal cancer. Among the main scopes of the research is the definition of the “core quality treatment standards,” which, by way of recommendations, will be systematically disseminated in order to optimize current treatment patterns and offer patients the maximum quality treatment locally available, with strategies to limit undesirable effects. The main objectives of the project are as follows:

- To perform research on the currently available population-based registries of patients with colorectal cancer in order to identify commensurality and differences of surgery, radiotherapy, and chemotherapy modalities of treatment in the European regions covered by these registries.
- Research to derive treatment outcomes from population-based registries in order to optimize current treatment approaches by defining “core quality treatment strategies” as well as treatment recommendations.
- To integrate “core treatment quality strategies” in clinical practice data collection, develop validation methods, and facilitate outcome monitoring with feedback.
- To optimize the level of knowledge and experience in the treatment of colorectal cancer through professional education and dissemination programs.

CONCLUSION AND FUTURE PERSPECTIVES

National audit registries in surgical oncology have led to improvements with a greater effect on survival than any of the adjuvant therapies currently under study. Moreover, they offer the possibility to perform research on patient groups who are usually excluded from clinical trials, such as elderly patients. The ECCO has recognized these importance and created the EURECCA framework to develop a European colorectal audit structure. EURECCA will advance future treatment improvements and spread these to every cancer patient in Europe. It provides opportunities to treat elderly and comorbid patients on the basis of evidence while offering a unique insight into social-economical healthcare matters such as consequences of commercialization, treatment availability, and screening initiatives. Although EURECCA definitely contributes to transparency in healthcare, there is emphatically no intention to create an environment, which is dominated by a “naming, shaming, and blaming culture”. Therefore, individual surgeon or hospital data will only be accessible for the concerned healthcare providers, compared with an international case-mix-adjusted mean outcome.

To a large extent, the EURECCA framework is still under construction and probably some roadblocks have to be conquered before the structure is fully functional. However, there is a strong commitment among the national participants and first orientations are already made for future intercontinental comparisons. Momentarily, final preparations are made for pooled analyses on the effects of neoadjuvant radiotherapy on long-term outcomes. Simultaneously, datasets are being harmonized to facilitate future analyses with respect to national privacy legislations. Early summarily results, will be presented at the ESSO conference in September 2010 in Bordeaux. At this conference, a pre-negotiated call of agreement will be signed by all the participants. In 2011, a multidisciplinary consensus meeting will be organized in Perugia, Italy. The objective is to present extensive results at the 2013 Ecco-17 conference in Amsterdam. As such, ECCO has established the basis for a strong, multidisciplinary audit structure with the commitment to improve cancer care for every European cancer patient.

All information about EURECCA can be found on the website www.canceraudit.eu

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