Quality assurance through outcome registration in colorectal cancer: An ECCO initiative for Europe

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In recent years there have been significant improvements in 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 towards 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 recognised these importances's 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 it offers an unique insight in 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.

Key words: Colorectal cancer, Rectal cancer, Outcomes assessment, Audit

INTRODUCTION

Currently, quality of healthcare is a hot topic and this 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 press around the world. Unfortunately, many of those 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 relative new compared to 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 programmes have been successfully enrolled in surgical oncology with encouraging results, in particular for the 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. In 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 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 standardised and quality controlled surgical trials seem to have a positive effect that reaches further then 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. Standardisation and quality of treatment was continuously emphasised 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 analysed only 421 (12%) participated in the TME trial. Survival improved for all patients in the period during the trial and in the last period survival improved even more. Despite all these improvements there remain differences between European rectal cancer studies that can not 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 with more than 10 percent (75% versus 64%). Differences in study design could play a major role in these variations in outcome, besi-des differences in infrastructure and patterns of care between the hospitals participating in these studies. Ano-ther 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 evi-dence for the treatment of these categories of patients.

**MULTIDISCIPLINARY TREATMENT**

The importance of multidisciplinary treatment can’t be emphasised 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 while pathologists had to adapt to according to the protocol of Quirke et al to adequately identify lateral spread of tumour. 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 centres A growing number of studies report variation in outcomes between institutions providing health care. 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 health care systems efforts are made to reduce this hospital variation. Most initiatives focus on selective referral, encouraging patients to seek care in high-volume hospitals. A strategy were a larger proportion of patients is treated in specialised centres, could evidently improve overall results for complex surgical procedures, such as esophagectomies and pancreatectomies. Although there are also multiple studies showing a positive volume-outcome relation for colon and rectal cancer, variation is smaller compared to esophagectomies or pancreatectomies. Besides, one must keep in mind that there are also low volume providers who perform very well and high volume pro-viders 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 health care 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 the collected data. Data has to be prospective, complete, case-mix adjusted and preferably collected by independent investigators. In addition, the quality of the data has to be assured by a second independent registry. In Europe, several national rectal cancer audit registries have been established since the nineties. The most important advantage of these audit registries compared with clinical trials is the fact that they include the entire patient population without excluding certain pati-ent groups. After case mix adjustments a fair judgement 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, in the Norwegian Rectal Cancer Project, founded in 1993, includes more than 99% of patients operated for rectal cancer. After four years the results of this audit were remarkable: the proportion of TME surgery rose from 78 to 92% and the local recurrence rate dropped from 28 to 7%. These results, published in 2002, are indeed spectacular. Moreover, it also showed to be very cost effective with the costs of every saved life being less then 700. Also Swedish initiatives were successful. The Swedish Rectal Cancer Registry was started in 1995, with over 97% of
patients with rectal cancer included\textsuperscript{22}. 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\textsuperscript{22}.

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 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 impact of surgical training and feedback.

The Danish Colorectal Cancer Database also produced satisfying results\textsuperscript{24}. 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%\textsuperscript{25}. 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 are included and Lithuania is scheduled to join 2010.

The percentage of abdominoperineal excision was significantly reduced from 26.1% in 2000 to 21.3% in 2008\textsuperscript{26}. In 2005, Belgian surgeons initiated the Project on Cancer of the Rectum (PROCARE)\textsuperscript{27}. After standardisation and implementation of guidelines, prospective registration started in 2006 on a voluntary basis. Until now, 50% of the Belgian hospitals participate and around 2500 patients are included\textsuperscript{27}.

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 TME project was founded. This rectal cancer audit registration has a national coverage of 20%. So far, 3100 patients are included. First reports show a 30 day mortality of 3.1% and an anastomotic leakage rate of 8.2%\textsuperscript{28}. 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\textsuperscript{29}.\textsuperscript{18} 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. 21% of all operations were acute or urgent, with a mortality rate up to 14%. Striking is the fact that 26% of the patients that underwent acute 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 to 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 to 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.

European Registration of Cancer Care "EURECCA": an International, Multidisciplinary, Outcome-based Quality Improvement Project of the European CanCer Organisation.

Although all national audits achieved excellent results, differences remain between European countries that cannot be easily explained. On review of the results, there are differences in mortality, complications, recurrence and survival. Moreover, there are substantial differences in (neo)adjuvant treatment regimens. While 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\textsuperscript{21}. Nevertheless, local recurrence rates in Norway equal the rates in Sweden and the Netherlands\textsuperscript{20}.

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 in treatment outcomes is needed union wide. A European audit registration will provide transparency, benchmarking and feedback across nation’s borders. This can rapidly lead to treatment improvements and a decrease variation in the quality of care around 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, tumour 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. Key partners in realizing the vision are the European CanCer Organisation, the European Society of Surgical Oncology, 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:

• To perform research on the currently available population-based registries of patients with colorectal cancer in order to identify communalities 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 impact on survival than any of the adjuvant therapies currently under study. Moreover, they offer the possibility to perform research on patient groups that are usually excluded from clinical trials such as elderly. The ECCO has recognised these importance’s 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 evidence based while it offers an unique insight in social-economical healthcare matters such as the consequences of commercialisation, treatment availability and screening initiatives. Although EURRECCA 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 concerning health care providers, compared with an international case-mix adjusted mean outcome. While to a large extent, the EURRECCA framework is still under construction, 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 "surgical outcome: can we do better" in September 2010 in Bordeaux. At this conferen-ce, a pre-negotiated call of agreement will be signed by all participants. In 2011, a multidisciplinary consensus meeting will be organised in Perugia, Italy. The objecti-ve is to present extensive results at the 2013 ECCO-17 conference in Amsterdam. As such, ECCO has establi shed the basis for a strong, multidisciplinary audit structure with the commitment to improve cancer care for every European cancer patient. All information about EURRECCA can be found on the webpage: www.canceraudit.eu

SUMMARY

UNIVERSE O KVALITETU KROZ REGISTRACIJU REZULTATA KOD KOLOREKTNOG KARCINOMA: ECCO INICIATIVA ZA EVROPU

Poslednjih godina postignut je značajan pomak u lečenju karcinoma rektuma. Nove hirurške tehnike, kao i efektivni neoadjuvantni režimi tretmana doveli su do ovog poboljšanja. Ključno je širenje ovih prednosti ka svakom pacijentu obolelom od karcinoma rektuma, kao i da pacienti koji nisu uključeni u kliničke studije mogu imati koristi od ovih pomak. U većem delu Evrope postoje interesantni kvalitetni programi koji podržavaju širenje najnovijih saznanja i veština medicinskim profesionalcima vodeći poboljšanja rezultata lečenja. Ipak, medju evropskim zemljama postoje razlike u rezultatima i șemama tretmana koje se ne mogu lako objasniti. European CanCer Organisation (ECCO) prepoznal je značaj ovih razlika i kreirala "European Registration of Cancer Care" (EURECCA) - "Evropski registar brige o kanceru" u cilju razvoja evropske kolorektna auditarne strukture. EURRECCA će poboljšati buduće pomake u tretmanu i podeliti ih sa svim evropskim pacijentima obolelim od karcinoma. To nam daje šansu da tretiramo starije pacijente i one sa komorbiditetima zasnovano na činjenicama, dok nam istovremenom pruža jedinstveni uvid u socio-economsko zdravstvena pitanja. Kao takav, ECCO je formirao bazu za jaku, multidisciplinarnu auditornu strukturu posvećenu poboljšanju brige o kanceru za svakog pacijenta Evrope sa karcinomom.

Ključne reči: kolorektni karcinom, rektalni karcinom,

REFERENCES
