



Nationwide Rectal Cancer Management – Strategies and Outcomes

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Abstract

Objective The aim of this nationwide project was to improve prognosis for rectal cancer in Norway.

Methods A comprehensive educational programme was launched in 1993, focussing on improved radiological work-up, a tailored strategy for neo-adjuvant radiochemotherapy, optimization of surgery, and more detailed reporting of pathological data. A national rectal cancer database was established. All hospitals were invited to take part, and none refused. Every hospital receives its own results on a regular basis. At first this project was funded by the Norwegian Cancer Society, a non-profit organization, but since 2000 it has been funded by the Ministry of Health.

Results The 5-year rate of local recurrence has been reduced from 19.3% in 1994 to 3.8%

in 2009. Distant metastases have been reduced from 27% to 20%, and overall survival has increased from 60% to 76%. The rate of anastomotic leaks was reduced from 17% to 6%, and 30-days mortality from 3% to 1%. Treatment of rectal cancer has been centralized from 55 hospitals in 1993 to 25 hospitals today. Only multidisciplinary teams of dedicated experts are now treating rectal cancer.

Conclusions A permanent quality assurance programme for cancer treatment can be implemented at a national level. Such an initiative has had a considerable impact on prognosis for rectal cancer. Thus, in 2007, colon cancer was included into the same programme.

Introduction

Management of rectal cancer is based on surgery, radiotherapy and chemotherapy. Modern surgery was developed by Heald thirty years ago, while strategies for radiotherapy +/- chemotherapy still are under discussion (1, 2). In Norway the prognosis of rectal cancer has been very poor. Although treated for cure, the rate of local recurrence was 28%, and overall survival was 55% in the period 1986-1988 (3). Following local recurrence only 8% survived five years. The Norwegian surgical community acknowledged the work of Heald, and twenty years ago a nationwide programme was launched in order to develop strategies to improve outcomes of rectal cancer treatment at a national level (4). Every hospital (n=55) was invited to take part in a national auditing initiative.

Although cancer treatment is depending on individual personal skills, from the very beginning it became clear that managing rectal

cancer should be handled in a multidisciplinary setting, and therefore a comprehensive educational programme was launched. Twenty-four workshops for surgeons, radiologists, oncologists, and pathologists have been arranged, in which modern preoperative work-up, live surgical procedures, and how to examine the specimen were demonstrated. Every hospital agreed to submit demographic, clinical and outcome data to the national database at the Norwegian Cancer Registry in Oslo (4).

Before, and also during the first years of this national project, rectal cancer was treated at every hospital in Norway, mostly by general surgeons, and often by young inexperienced doctors in training for general surgery. In the period 1986-1988, the median number of rectal cancer procedures per surgeon per year was one (3). The board members (n=18), being professors of surgery, oncology,

radiology, or pathology, did not acknowledge this practice, and it was recommended that rectal cancer should be treated by specialists

in gastrointestinal surgery only (Colorectal surgery still is not a speciality in Norway).

Methods

The population of Norway is 5 million, and there are 55 hospitals, of which there are seven university hospitals, 14 county hospitals, and 34 local hospitals. There are about 800 new cases of rectal cancer a year. Due to the compulsory reporting of all malignancies to the national cancer registry since 1951, both by pathologists and clinicians, the staff of the specific rectal cancer database easily can identify every case of rectal cancer. Thus, if any clinical or outcome data are missing, the staff of the database is able to identify which hospital and which surgeon to be responsible for submitting data, and routine reminders are sent to assure complete data collection. The submitted data include details on work-up, clinical staging, preoperative treatment, surgical data, complications, pathological staging,

postoperative treatment, date and location of local recurrences and distant metastases, including any treatment for recurrent disease (4). Date of death is collected from Statistics Norway. Regularly, each hospital receives their own results, together with national means, on the most important outcomes. The results of each hospital have been anonymous to everybody but the staff of the hospital, but from 2013 such results are public. Regular feedback of main results has been recognized as a most important tool for quality assurance, and every hospital may on request receive detailed data on their own performance in order to identify non-optimised standards of work-up or treatment. Summarized data are used by the board to revise national guidelines on rectal cancer.

Results

Implementing optimised work-up and treatment for rectal cancer has improved the prognosis considerably, reducing the 5-year rate of local recurrence from 15% in 1993-

1997 to 5% in 2007-2009, and improving 5-year overall survival from 60% to 76% in the same two periods (Figure 1-2) (5).

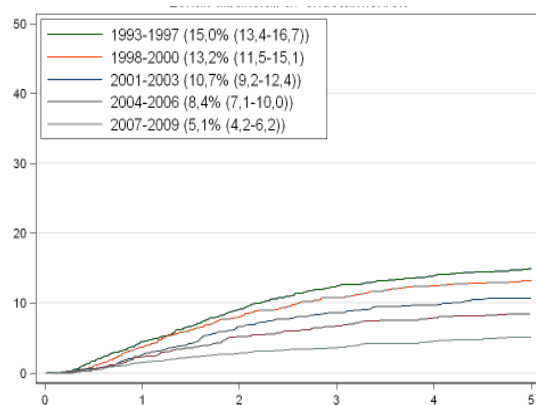


Figure 1. Local recurrence for rectal cancer patients treated for cure according to period

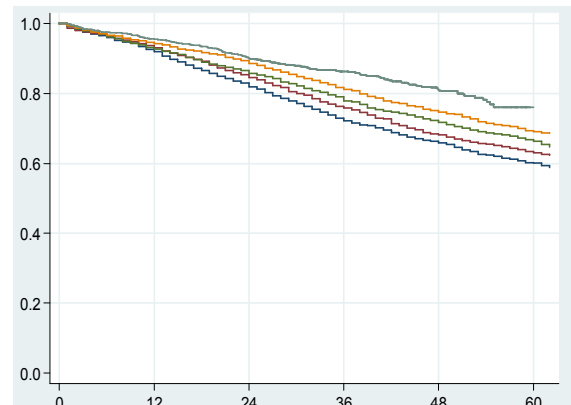


Figure 2. Overall survival for rectal cancer patients treated for cure according to period



Most improvement was seen in stage III in which overall survival increased from 43% to 57%, compared to 62% to 73% and 78% to 82% for stage II and stage I, respectively (Table 1).

| | 1993-1997 | 1998-2000 | 2001-2003 | 2004-2006 |
|-----------|-----------|-----------|-----------|-----------|
| Stage I | 78% | 81% | 79% | 82% |
| Stage II | 62% | 64% | 66% | 73% |
| Stage III | 43% | 47% | 57% | 57% |

Table 1. Overall survival by stage and period for rectal cancer patients treated for cure

The improved treatment of the primary tumour also seems to reduce the risk of distant metastases, as the 5-year rate has been reduced from 27% to 20% (5).

As the oncological results became public, although anonymously, showing significant worse prognosis for patients treated at local hospitals, general surgeons at most local hospitals decided to stop treating rectal cancer (Table 2) (6).

| Annual caseload | 2001 - 2003 | 2004 - 2006 | 2007 - 2009 |
|-----------------|-------------|-------------|-------------|
| >25 | 67% | 69% | 78% |
| 16-25 | 66% | 69% | 78% |
| 6-15 | 67% | 69% | 72% |
| ≤5 | 59% | 59% | 69% |

Table 2. Overall survival for rectal cancer patients treated for cure according to annual hospital caseload and period

Also because the regional medical directors require dedicated multidisciplinary teams to treat rectal cancer, this treatment has been centralized from 55 hospitals to 25 hospitals.

The involved circumferential resection margin has become the most important prognostic factor for local recurrence, distant metastases, and for survival (7-9). Because of that, and in order to decide on any preoperative treatment, MRI is now the gold standard for pelvic work-

up of rectal cancer (10-13). Most likely, the improved techniques for preoperative staging by MRI, and the following increased use of radiochemotherapy in Norway, from 4% to 35%, have been important to further improve outcomes also after optimizing surgery (Table 3) (4, 5).

| | 1993 - 1997 | 2004 - 2006 | 2009 |
|-------------------|-------------|-------------|-------|
| MRI | 0% | 80% | > 95% |
| Radiochemotherapy | 4% | 25% | 35% |

Table 3. MRI and radiochemotherapy for rectal cancer patients according to period

After implementation of total mesorectal excision and centralized surgery the quality of surgical treatment has improved. The rate of peroperative perforation of the tumour, or the bowel wall close to the tumour, has been reduced from 10% in 2001-2003 to 4% in 2007-2009 (5, 14). Similarly, in spite of more use of preoperative radiochemotherapy in recent years, the rate of anastomotic leaks has been reduced from 17% in 1994 to 6% in 2007-2009 (5, 14).

| 1994 | 1999 | 2007 - 2009 |
|------|------|-------------|
| 17% | 8% | 6% |

Table 4. Anastomotic leaks by period

During the same period the 30-days mortality was reduced from 3% to 1% for patients treated for cure. Interestingly, hospitals having most local recurrences also had the highest rate of anastomotic leaks and the highest 30-days mortality (6).

The work at each hospital, in order to improve standards of treatment in their daily practice, is the cornerstone for managing rectal cancer nationwide. Due to the feedback of results to each hospital, together with regional and national means, the staff at each hospital regularly is able to check their own performance. One large central hospital (Haugesund Hospital) had 31% local recurrence and 48% overall survival for patients treated for cure in the period 1993-1997. During the following years overall survival increased to 70%, and there was no local recurrence in the period 2005-2008 (15). Similarly, another central hospital (Levanger



Hospital) had 19% local recurrence and 58% overall survival in the period 1990-1999, compared to 2% local recurrence and 71% survival in 2000-2004 (16).

Although adjuvant or neoadjuvant radiochemotherapy has been used in most developed countries for stage II and III disease since the recommendation by the US National Institute of Health conference in 1990, some countries chose another strategy. Short course radiotherapy, given as 5 x 5 Gy during one week and surgery the next week, was developed in Sweden and later also implemented in the Netherlands. In Norway it was decided to stick to a more tailored strategy, as the TNM system alone was not considered as an optimal guide for decision making. In cases where the T3 tumours are not threatening (>3 mm) the mesorectal fascia on MRI, and neither there are any malignant nodes close to the fascia, neoadjuvant therapy is not recommended in Norway. Thus, nowadays 65% of Norwegian rectal cancer patients treated for cure will have no other treatment than surgery. As reported by four recent Norwegian and Swedish studies, a lot of long-term side effects are doubled or tripled

by adding radiotherapy to surgery for rectal cancer. Incontinence for solid stools is increased from 5% to 15%, for loose stools from 15% to 49%, and urinary incontinence from 2% to 9% by adding radiotherapy (17-20). Similarly, sexual disorders are much more common after radiotherapy. Vaginal dryness is reported by 50%, dyspareunia by 35% and the erectile function score is reduced from 14 to 7. A restricted social life is reported by 7% after surgery alone compared to 35% for patients also treated with radiotherapy. The risk of a hip fracture increases from 1% to 5%, and a second cancer is developed by 4.3% after surgery alone compared to 9.5% for patients also having radiotherapy (17-20).

Ever since The Cancer Registry of Norway was established in 1951 patients with colon cancer have had better survival compared to patients with rectal cancer. During the period 2007-2009 the 3-year overall survival of rectal cancer had surpassed that for colon cancer, 78% vs. 66%, which supported the decision not only to include colon cancer, but all gastrointestinal cancer into nationwide quality assurance programmes in Norway (5).

Discussion

A national strategic change of treatment for rectal cancer was implemented in Norway 20 years ago. The main objectives were to increase overall survival by reducing the rate of local recurrence, and to tailor treatment in order to reduce the amount of long-term side effects. The nationwide agreement to start and to continue this educational initiative was imperative for the success of this project, which during the first years was supposed to be stopped in 1999. However, due to the considerable differences of oncological outcomes between hospitals, also between university hospitals, we made the decision to proceed this work into a continuous quality assurance system for cancer treatment. Quality of medical treatment in general, and especially for cancer, became a political issue, also reflected by the change of funding source. During the first six years the project was funded by The Norwegian Cancer Society, a non-profit organization, but from 2000 The Ministry of Health has been the only funding source.

A lot of small hospitals have lost rectal cancer treatment. Most often that was their own

decision, but in some cases the regional medical director has been involved in the process of reorganizing cancer care in general, as today cancer patients should be treated by dedicated experts working in teams. Most likely, this strategy has been an important success factor of the present project. Some of the local hospitals have established "production lines" for less advanced surgery, like hernia repairs and cholecystectomies etc., receiving such cases from larger hospitals.

The reduced rates of local recurrence, of peroperative perforations, and of anastomotic leaks most certainly are due to better surgical treatment. Interestingly, also the lower incidence of distant metastases may be due to better surgery, as the use of neo-adjuvant therapy is low in Norway compared to other countries, and no adjuvant chemotherapy has been used.

Altogether, such improvement in cancer therapy which we have experienced in this project never would happen without the genuine interest, focus and dedication of specialized surgeons, radiologists,



pathologists and oncologists throughout the country. Similar initiatives have been launched in several countries in Europe, and we are

confident that similar progress is to be awaited in those countries.

Conclusion

By optimizing surgical technique, by centralizing treatment, by using better imaging methods, by decision making in multidisciplinary teams, by tailoring neo-adjuvant treatment, and by establishing a

permanent quality assurance system with regular feedback of results to every hospital, rectal cancer patients have got less treatment complications and a longer life.

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