Introduction

Quantitative and qualitative improvement of outcome after rectal cancer treatment has been documented. Replacement of conventional rectal cancer surgery (blunt pelvic dissection) by sharp total mesorectal excision (TME) with preservation of the autonomic nerve plexuses (1) and the construction of a colo-anal anastomosis (2) with a reservoir or coloplasty (3-5), has led to quantitative and qualitative improvements in outcome. Pre-operative radiotherapy or combined chemoradiation (6-8) have further reduced the local recurrence rate (LRR) in resectable, mobile rectum cancers, with an impact on APR rate (abdominoperineal resection with definitive colostomy). Thus, high quality surgery with pathologic assessment (9, 10) plays a key-role in the management of rectum cancer, but both its quality and its result also depend on pre-operative radiologic information (11, 12) and neo-adjuvant therapy in clinical stage II and III tumours, in particular when located in the middle or lower third of the rectum (7). Finally, major breakthroughs in the treatment of metastatic colorectal cancer have been reported in recent years using new drugs, combined chemotherapy and/or biologicals (13-17).
Multidisciplinary guidelines based on these achievements aim to improve the quality of care through standardisation, i.e. reduction of variability in routine practice. Variation in outcome between hospitals/teams treating rectum cancer patients has been reported (18-21). The relationship between case-load and outcome is much debated, but outcome can improve through implementation of recent knowledge in high- as well as in low-volume hospitals (20, 21).

Population-based audits reflect the overall quality of care in a region or nation. Multi-centre trials with specific protocols (guidelines) give an estimate of the optimally reachable quality of care. Implementation of guidelines on a regional or nationwide basis is challenging, but feasible (22-27). This type of quality assurance requires surveillance in a specific rectal cancer database and a profession-driven audit with feedback (28).

The aim of this population-based audit on rectal cancer treatment in Belgium was to assess overall performance and outcome variability, in an era when formal national multidisciplinary guidelines did not exist and specific workshops had not been organised. Recently, the Belgian scientific societies involved in rectal cancer treatment have reached consent concerning multidisciplinary guidelines (29). In 2006 a nationwide project on cancer of the rectum (PROCARE) will be launched. By comparing the Belgian results with those reported in large multi-centre prospective trials, performed in the same observation period, we aim to estimate the potential benefit of the PROCARE project.

Patients and methods

All 3079 patients notified to the National Cancer Registry (NCR) with a diagnosis of rectal carcinoma between January 1997 and December 1998 were included in this study. Identification was based on code C-20 of the International Classification of Diseases (ICD-10) for rectum cancer below 16 cm from the anal verge.

The Belgian NCR is a non-compulsory population-based registry initiated in 1983. The general registration form includes information on: the unique patient code, postal code of residence, date of birth, sex, date of incidence, histological diagnosis, clinical and pathological tumour TNM stage, type and sequence of treatment modalities. This dataset does not include documentation on comorbidity, identity of the surgeon, type of operation, incidence of recurrent disease (local and/or distant). Hence, APR rate, disease free or cancer specific survival could not be calculated. The quality of about 55% of patient/tumour data is improved by linkage and summarization of individual records coming from physicians, pathologists, 2 provincial cancer registries (Antwerp, Limburg), and all sickness funds (health insurers). The identity of the patient is encrypted by the data source itself. Analysis is made on anonymous data. All deaths registered by the sickness funds between 1/1997 and 12/2003 were linked to the NCR database for calculation of the observed survival. The cause of death is unknown.

Stage grouping was according to the 4th edition of the TNM classification (30) based on a combination of pathological staging (pTNM) and clinical staging (cTNM). pTNM was available in 1248 patients with stage I-III cancer. Presence of distant metastasis, as mentioned in the clinical staging, was accepted as stage IV (263 patients). Otherwise, staging was recorded as unknown for further analysis in this study.

Rectum cancer in Belgium is treated in about 113 hospitals. In view of the low number of patients per hospital entered in the 2-year observation period, inter-hospital variability of performance could not be assessed. Instead, variation per province was analysed.

Analysis

Age was categorised into 5 groups: < 50, 50-59, 60-69, 70-79, 80 or more years. Patients were followed-up until death or for a minimum of 5 years. The Kaplan-Meier method was used to calculate the observed survival (OS) from the date of diagnosis. Relative survival (RS), a measure for disease-specific survival, was calculated as the ratio of the OS of the patients and the expected survival of an age and sex matched sample of the general Belgian population. The expected survival was based on data from the Belgian population life tables (31).

In order to assess the performance of rectal cancer treatment in Belgium, the results of this survey were compared with those reported in other population-based observational studies/audits. The potential benefit of the PROCARE project in resectable rectal cancer (stages I-III) was estimated by comparing Belgian results with those of recent large multi-centre trials on TME with or without radio(chemo)therapy. Also, the outcome in patients with metastatic rectum cancer was compared with recently published studies. Where appropriate and possible, our patients were matched to those reported, taking into account the most important prognostic factors related to survival, i.e. tumour stage and age. Survival rates were compared using the log rank test.

Statistical analysis was performed using SAS® software version SAS 9.1.3.

Results

Demographics

The mean age of the 3079 patients registered in the NCR database was 69.5 years (median 71 years; range 18-99). About 19% (587/3079) of the patients were 80 years old or more. Fifty-eight percent were male.
The incidence of rectal cancer seems to vary widely between provinces, although a rather comparable incidence was expected. This illustrates the non-compulsory nature of cancer registration for Belgium in 1997-1998 and the fact that in some provinces cancer registration is better organised or gets a better response than in others (Table I).

Tumour stage was known in 1511 patients (49.1%); it was based on pathology reports in 1248 patients with stage I-III cancer and on cTNM in 263 patients with stage IV cancer. Stage distribution was comparable in both sexes. More advanced stages were observed in the group < 50 years and in the group > 80 years with about 55% of patients presenting node positive or metastatic disease (Fig. 1).

Use of (neo)adjuvant treatment for Stage II and III rectum cancer

At the time of the observation period, the NIH Consensus Conference guideline of postoperative combined chemoradiation therapy for patients with stage II and III rectal cancer was well known (32). Although the benefit of pre-operative, neo-adjuvant treatment for these types of tumour was not established at that time (the Swedish Rectal Cancer Trial was published in 1997), it was considered a valuable alternative.

The analysis of the therapeutic approach in stage II and III rectal cancer focused in particular on patients < 70 years old, as these are less likely to have contraindications for (chemo)radiation. Data on the therapeutic approach were available in 82% of patients with a known tumour stage. Neo-adjuvant or adjuvant radio(chemo)therapy was administered in 57.1% stage II (109/191) and in 52.6% stage III tumours (102/194), i.e. a total of only 54.8% of stages II-III patients < 70 years of age who had surgery (Table II). The application rate of radiotherapy for stage II-III tumours varied from 0% (0/6) to 67% (73/109) per province. The fact that 16% of patients with stage I tumours had radio(chemo)therapy may be related to down-staging after neo-adjuvant treatment or to adjuvant therapy after incomplete resection or intra-operative tumour break (R1 resection). Radio(chemo)therapy has been administered in 28% of patients with stage IV rectum cancer, which may be because of pre-operative under-staging or in the context of maximal treatment of the primary tumour with limited and/or resectable metastasis.

National survival results

The overall 5-year observed survival was 46.6%. It was age and stage dependent (Table III), but was not related to gender (data not shown). The 5-year relative survival rate was 58.5%. It was tumour stage dependent with an overall RS rate of less than 50% in stage III tumours and 10% in patients with metastatic disease (Table III). The cumulative 5-yr RS for all stages of rectal cancer varied between provinces from 48% to 71% (Fig. 2).

Table IV summarizes the comparison of this Belgian survey with the results of other national or regional audits for patients treated between 1987 and 1999. Although maximum effort was made to match the patient, tumour and treatment characteristics of the Belgian patients with those in the comparator groups, this could not always be achieved. TME was not implemented in the comparator surveys, except in Munich. The period of observation was much longer in Luxembourg and much earlier in the Netherlands and in Sweden than in Belgium. Outcome in Belgian patients was similar to that reported for Luxembourg (33), the Netherlands (22) and Sweden (6), but better than that observed in Denmark (34). OS and RS were slightly worse than in the Munich region (35).

Estimation of the potential benefits of the PROCARE project

TME may have been performed in some of the patients included in our survey, but no data are available for
analysis. (Neo)adjuvant radio(chemo)therapy certainly was not performed in all those who would benefit from it (cf. supra). Neo-adjuvant radio(chemo)therapy is recommended in the PROCARE guidelines for patients with cStages II and III rectal cancer (29). Consequently, the potential benefit of the PROCARE project was estimated by comparison of the results of this Belgian survey with those reported in national audits or multi-centre trials in which TME with/without neo-adjuvant radiotherapy or radiochemotherapy was performed as a routine (Table V).

In the TME alone arm of the Dutch trial, the 5-yr OS was 63.5% (36). The Norwegian audit found a 61% 5-yr OS during a national TME project, postoperative
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mortality (3%) included (27, 37). The effect of pre-operative $5 \times 5$ Gy radiation therapy followed by TME surgery has been documented in the Dutch trial with a 64.0% 5-yr OS (36). For comparison, the 5-yr OS in patients of any age with stage I-III rectal cancer was 57% in this Belgian survey. A 76% 5-yr OS was observed after neo-adjuvant 50.4 Gy radio chemotherapy followed by TME surgery in the German multi-centre trial randomising patients up to 75 years of age with cStage II-III between pre- and postoperative radio chemotherapy (8). After exclusion of patients with stage IV disease and R1 resection, the 5-yr OS after neo-adjuvant radio chemotherapy and TME surgery was 83% (38). The abstracts from the French FFCD 9203 trial (39) and of the multinational EORTC 22921 trial (40) report a 5-year OS of 65-66% for cStage II-III tumours after neo-adjuvant radiotherapy with or without chemotherapy; TME was recommended but the quality

### Table IV

<table>
<thead>
<tr>
<th>Reference</th>
<th>Region or country</th>
<th>Period of observation</th>
<th>Patients, tumour and treatment characteristics in comparator group</th>
<th>Outcome criterion</th>
<th>Comparator Belgium 1997-1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>33</td>
<td>Luxembourg</td>
<td>1988-1999</td>
<td>St I-IV ; resection Ranys</td>
<td>5-yr OS</td>
<td>46%</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>St I ; resection Ranys</td>
<td></td>
<td>81%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>St II ; resection Ranys</td>
<td></td>
<td>55%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>St III ; resection Ranys</td>
<td></td>
<td>34%</td>
</tr>
<tr>
<td>34</td>
<td>Denmark</td>
<td>1995-1996</td>
<td>all St ; no TME</td>
<td>5-yr OS</td>
<td>46.6%</td>
</tr>
<tr>
<td>35</td>
<td>Munich</td>
<td>1996-98</td>
<td>all St ; 20.8% TME ; 9% ne-oadj. RT ; 40% adj. ther.</td>
<td>5-yr RS</td>
<td>96.9%</td>
</tr>
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<td></td>
<td></td>
<td>St I ; patients with neo-adj. ther. excluded</td>
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<td>75.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>St II ; patients with neo-adj. ther. excluded</td>
<td></td>
<td>58%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>St III ; patients with neo-adj. ther. excluded</td>
<td></td>
<td>61.0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&lt; 65 yr</td>
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<td></td>
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<td>65+ yr</td>
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<td>64%</td>
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<td></td>
<td>men</td>
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<td>62.8%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>women</td>
<td></td>
<td>61.5%</td>
</tr>
<tr>
<td>22</td>
<td>Netherlands</td>
<td>1987-1990</td>
<td>St I-III ; no TME ; 38% adj. RT ; no neo-adj. RT</td>
<td>2- yr RS</td>
<td>77%</td>
</tr>
<tr>
<td>6</td>
<td>Sweden</td>
<td>1987-1990</td>
<td>&lt; 80 yrs ; St I-III ; no TME ; S only</td>
<td>5-yr OS</td>
<td>48%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&lt; 80 yrs ; St I ; no TME S only</td>
<td>5- yr OS</td>
<td>78%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&lt; 80 yrs ; St II ; no TME S only</td>
<td>5- yr RS</td>
<td>64%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&lt; 80 yrs ; St III ; no TME S only</td>
<td>5- yr RS</td>
<td>37%</td>
</tr>
</tbody>
</table>

St stage ; R type of resection ; TME total mesorectal excision ; neoadj. ther. neoadjuvant therapy ; adj. adjuvant ; RT radiotherapy ; S surgery.

OS observed survival ; RS relative survival.

### Table V

Comparison of 5-year observed survival in Belgium 1997-1998 with results of national projects or multicentre randomised trials

<table>
<thead>
<tr>
<th>Reference</th>
<th>Region or country</th>
<th>Period of observation</th>
<th>Patients, tumour and treatment characteristics in comparator group</th>
<th>Comparator Belgium 1997-1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>27, 37</td>
<td>Norway</td>
<td>1993-1999</td>
<td>&lt; 75 yrs ; pSt I-III ; TME ; 9% adjuvant RT</td>
<td>61%</td>
</tr>
<tr>
<td>36</td>
<td>Netherlands</td>
<td>1996-1999</td>
<td>all ages ; cSt I-III (% St IV incl.) ; TME</td>
<td>63.5%</td>
</tr>
<tr>
<td>25</td>
<td>Stockholm</td>
<td>1995-96</td>
<td>all ages ; cSt I-III ; TME or 25 Gy RT + TME ; R0 only</td>
<td>58.2%</td>
</tr>
<tr>
<td>8</td>
<td>Germany</td>
<td>1995-2002</td>
<td>&lt; 76 yrs ; cSt II-III (6% St IV incl.) ; 50.4 Gy RCT + TME</td>
<td>76%</td>
</tr>
<tr>
<td>38</td>
<td></td>
<td></td>
<td>&lt; 76 yrs ; cSt II-III (7% St IV incl.) ; TME + 50.4 Gy RCT</td>
<td>74%</td>
</tr>
<tr>
<td>38</td>
<td></td>
<td></td>
<td>&lt; 76 yrs ; cSt II-III (St IV and R1 excl.) ; 50.4 Gy RCT + TME</td>
<td>83%</td>
</tr>
<tr>
<td>38</td>
<td></td>
<td></td>
<td>&lt; 76 yrs ; cSt II-III (St IV and R1 excl.) ; TME + TME</td>
<td>77%</td>
</tr>
<tr>
<td>39</td>
<td>France</td>
<td>1993-2001</td>
<td>&lt; 75 yrs ; cSt II-II up to 10 cm ; TME ? ; 45 Gy RT</td>
<td>66%</td>
</tr>
<tr>
<td>39</td>
<td></td>
<td></td>
<td>&lt; 75 yrs ; cSt II-II up to 10 cm ; TME ? ; 45 Gy RCT</td>
<td>66%</td>
</tr>
<tr>
<td>40</td>
<td>EORTC</td>
<td>1993-2001</td>
<td>&lt; 80 yrs ; cSt II-III ; TME recommended ; 45 Gy RT</td>
<td>64.8%</td>
</tr>
<tr>
<td>40</td>
<td></td>
<td></td>
<td>&lt; 80 yrs ; cSt II-III ; TME recommended ; 45 Gy RCT</td>
<td>65.6%</td>
</tr>
</tbody>
</table>

St stage ; TME total mesorectal excision ; RT radiotherapy ; RCT radiochemotherapy.
of its performance is not yet reported. For comparison, the 5-yr OS in patients up to 75 years old with stage II-III cancer was 58% in this Belgian survey. These data indicate that the OS in patients with resectable rectal cancer could optimally be improved by more than an absolute 20%, i.e. a relative improvement of about 40%.

Finally, the outcome in stage IV patients can be improved. The median survival in patients with unresectable metastatic colorectal cancer has increased to more than 20 months since the introduction of combinations of irinotecan or oxaliplatin with continuous FA/5-FU (FOLFIRI or FOLFOX) (14). In second-line therapy, patients should receive oxaliplatin after irinotecan, or vice versa (13), resulting in a median OS of 20.2-21.5 months and a 2-yr survival of 41-45%. For comparison, in this Belgian survey, a median OS of 13 months and a 2-yr OS of 28% were observed in stage IV patients up to 75 years, indicating a potential for significant improvement.

Discussion

Population-based audits of the treatment and outcome in patients with rectal cancer have been shown to contribute to the improvement of the quality of care (24-27). The retrospective analysis that we have performed can be criticised because of several shortcomings of the available database. The incompleteness of data is related to the non-compulsory and non-specific character of rectal cancer documentation. The fact that the database is not profession-driven could contribute to the lack of registration compliance by the physicians. The absence of precise data on the type of surgery does not permit evaluation of the APR rate nor of the incidence of temporary derivative stoma construction in cases of sphincter preservation. In this study, it has not been feasible to link the NCR data with information on the comorbidity or ASA-status of the patient, postoperative morbidity or inhospital mortality. Histopathological evaluation of the quality of surgery is also missing (no data on the circumferential margin). LRR and disease-free survival can not be calculated, as non-lethal events occurring during follow-up are not registered. Cancer-specific survival can not be calculated if the cause of death during follow-up is unknown. It can, however, be substituted by relative survival calculations, as was done in this report. Finally, no feedback could be given in the current situation as the team or the hospital where the patient was treated was not included in the NCR data. Hence, prospective registration of all patients presenting rectal cancer in a specific, detailed database, with quality control of the data entered, is a condition sine qua non for a credible audit with feedback to the individual health-providing teams in order to improve overall and individual performances. In Sweden, improved outcome after rectal cancer treatment has been attributed to better surgery and a more selective use of radiotherapy, but most of all to an increased awareness of the treatment results and a focus on good, credible auditing (28). In spite of incomplete registration and the obviously very limited dataset in this audit, we feel that the results of this study permit some other important conclusions and indicate areas for significant potential improvement.

Many patients still present with advanced disease: 32.4% with node positive stage III and 17.4% with distant metastasis. We observed that node positive or metastatic rectum cancer was more frequent in patients < 50 and > 80 years old. This may indicate insufficient screening and poor public awareness of alarming symptoms in the younger age group, but it might also be partially related to sub-optimal management in the elderly.

The data available at the NCR mainly allowed survival to be assessed. The 5-year OS and RS were 46.6% and 58.5%, respectively. Survival was stage dependent, but comparable in both sexes. This outcome of patients treated in Belgium in 1997-1998 was not significantly different from that reported in national observational studies performed before the introduction of TME surgery in Sweden (6), the Netherlands (22) and Luxembourg (33). It should be noted that in these reports most patients were recruited in a period prior to this Belgian observation. Outcome in Belgian patients was better that that reported from Denmark (34), but slightly worse than in the Munich study (35). The latter may be related to the fact that TME resection was performed in 20.8% of their cases; moreover, (neo)adjuvant treatment was also more frequent in Munich (49%) than in Belgium (36%).

In Belgium, over 100 hospitals treat patients with rectal cancer. In the absence of guidelines and audit of their implementation, diagnostic and therapeutic variability is most likely. Because of the shortness of the observational period, therapeutic variability and differences in relative survival were assessed per province. This analysis indicates that (neo)adjuvant radiotherapy was only used in about 55% of stage II-III rectal cancer patients, supporting the suggestion from an earlier questionnaire based report (41) that a substantial number of these patients are under-treated. Relative survival also showed high variability between provinces, ranging from 48% to 71%. These data should be interpreted with caution because of the low number of registered patients in some provinces. It is evident that credible audit of inter-hospital variation and stimulating feedback can only be achieved by more complete registration, so that the results of individual teams/hospitals can be appropriately compared with national or international benchmarks after risk adjustments. This requires adequate tools as well as the effective collaboration of all professionals involved in the care of rectal cancer. The PROCARE
working group has produced multidisciplinary guidelines (29) and several of the scientific organisations, including local groups of specialists, have organised postgraduate courses, seminars and workshops in 2005. The Belgian Professional Surgical Association supports the project (42). A specific database has been set up at the National Cancer Registry for prospective registration on a voluntary basis, starting in 2006. The anonymous data will be audited by delegates from the PROCARE工作组. Also, instruction/training has been organised by the respective scientific and professional organisations. The aim of the project is to improve outcome and reduce variability in quality of care. Several other national audits/projects have shown the feasibility of a major and complex undertaking like this (22, 24-27). Inter-hospital/team variation and differences in outcome is, of course, a delicate matter. The actual organisation of health care delivery and the willingness and dedication of teams and individual professionals to collaborate in a national project like PROCARE, are key factors. In contrast to other projects, PROCARE has preferred decentralised instruction/training and treatment of patients. Thus, no single team has been excluded from taking part in the PROCARE project. In Denmark, no hospital volume effects on 30-day mortality and 5-year survival were observed when data were adjusted for age, gender and tumour stage (20). These findings were explained by the fact that the excellent performance of some well trained surgeons working in medium- or lower-volume hospitals outweigh the overall influence of hospital type and volume. Major inter-hospital variation was observed in small as well as in medium and large sized Norwegian hospitals (21), and in non-academic as well as in academic German or Swedish hospitals (18, 43). Centralisation of RC treatment into large, specialised units therefore seems to be no guarantee of optimal care per se. These findings support the decentralised character of the PROCARE project. It is assumed that feedback on the performance of individual hospitals and teams will allow them to react whenever they would not perform according to the national standards or below the targets set up in national guidelines.

Survival is the single most important endpoint in the treatment of cancer patients. Comparison of the results of this Belgian audit with those of recent nationwide or multicentre prospective studies indicates a significant potential benefit of the PROCARE project. It might be argued that comparison with multi-centre trials is not completely correct because of biases in patient selection. Nonetheless, their results indicate the optimally reachable outcome. The 5-yr OS in patients of any age with stage I-III rectal cancer was 57% in this Belgian survey, and that of patients up to 75 years old with stage II-III rectal cancer was 58%. The recent trial of the German Rectal Cancer Study Group randomised patients with stage II-III rectal cancer between pre- and postoperative chemo radiotherapy. TME resection was standard. They observed a 5-yr survival of 76 and 74%, respectively, with significantly reduced LRR, acute and long-term toxicity after neo-adjuvant treatment (8). Their survival rate increases to 83% in the neo-adjuvant arm and 77% in the postoperative arm, when patients with stage IV disease and R1 resection are excluded (38). The PROCARE multidisciplinary guidelines recommend neo-adjuvant treatment for comparable tumour stages. Consequently, the current 5-yr OS of 58% for stage II and III patients in Belgium could potentially increase to an optimum of about 80% in patients up to 75 years of age. Admittedly, the PROCARE project cannot reach this optimum outcome, because no patient will be excluded from registration. The implementation of TME with pathological quality control could improve, though to a more limited extent, the 5-yr OS of 86% in stage I rectal cancer in Belgium. Indeed, the 5-yr RS in these patients is currently 94%. The potential impact of routine and adequate TME on the LRR could not be assessed.

Another potential area for significant progress is patients with stage IV disease. Implementation of combined chemotherapy could result in almost doubling their median and 2-year survival.

Conclusion

The outcome of rectal cancer treatment in Belgium in 1997-1998 was comparable with that reported in other countries before wide implementation of TME surgery and neo-adjuvant treatment. This retrospective study provides benchmark data to which the outcome of patients treated according to the multidisciplinary guidelines of the PROCARE project will have to be compared. Implementation of guidelines with quality assurance through registration in a specific database and feedback to individual teams has the potential for significant improvement, as indicated by the comparison of the results of this audit with those of recent prospective multi-centre studies on multimodality treatment of patients with resectable rectum cancer or combined chemotherapy for metastatic disease. The PROCARE project offers all Belgian professionals, involved in rectal cancer treatment, the opportunity to show their commitment to the improvement of the quality of health care delivered in rectal cancer patients.

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