

The standardised mortality ratio is unreliable for assessing quality of care in rectal cancer

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ABSTRACT

Background: The standardised mortality ratio (SMR) for rectal or anal cancer was above average in a large tertiary referral centre for locally advanced rectal cancer in the Netherlands. The aim of this study was to investigate whether the increased SMR was indeed related to poor quality of care or whether it could be explained by inadequate adjustment for case-mix factors.

Methods: Between 2006 and 2008, 381 patients were admitted for rectal or anal cancer. The SMR score of this diagnostic group was 230 (95% CI 140 to 355), corresponding with 20 in-hospital deaths. The hospital dataset was merged with data from the Eindhoven Cancer Registry to obtain more detailed information.

Results: Patients admitted for palliative care only accounted for 45% (9/20) of the in-hospital mortality. In contrast to the high SMR, postoperative mortality was low, i.e. 2.6%. The majority of the rectal or anal cancer patients were diagnosed in and referred from another hospital. Referred patients more often had an advanced tumour stage, more often underwent resection and were more frequently treated with chemotherapy and/or radiotherapy than non-referred patients ($p < 0.01$). Postoperative mortality rates for referred and non-referred patients were 2.9% and 1.9%, respectively.

Conclusions: The increased SMR appeared to be caused by the admission of patients who received palliative care only. Consequently, the SMR is unreliable for the assessment of quality of care in patients with rectal or anal cancer.

KEYWORDS

Quality of care, rectal cancer, standardised mortality ratio

INTRODUCTION

Quality of care has become increasingly important in the last decades. Nowadays, in the Netherlands, quality of care of colorectal cancer is measured by a number of indicators. These include hospital participation in the Dutch Surgical Clinical Audit (DSCA) (which registers outcome of colorectal surgery), data on the number of examined lymph nodes after resection, and whether a patient is discussed during a preoperative multidisciplinary team meeting.

However, also other quality of care indicators are currently used, such as the hospital standardised mortality ratio (HSMR).¹ This measure is calculated by dividing the number of observed deaths in a given hospital by the number of patients that would be expected to die there. The national HSMR reference value is 100, hospitals with a higher score are supposed to have performed worse while the reverse would be true below 100. The HSMR is a hospital-wide measurement including several diagnostic groups (50 for the Dutch model) which are responsible for 80% of the in-hospital mortality. One of the 50 diagnostic groups comprises patients admitted for rectal or anal cancer. For each diagnostic group, a separate standardised mortality ratio (SMR) is calculated. The different SMR results could be interpreted and used separately or aggregated to create the overall hospital HSMR.

For each Dutch hospital, the HSMR is published by the Dutch Health Care Inspectorate (IGZ) in December 2011. However, the validity of HSMRs and their accuracy to reflect quality of care is heavily contested. Some have suggested that the HSMR is an appropriate measure to monitor hospital quality of care,^{1,3} while others stated that it should not be used as a performance and/or quality indicator.⁴⁻⁹ The consequences of making invalid measures

public could provoke an unjustified good or bad hospital reputation, groundless sanctions or rewards, disturbed collaborations between health care providers as well as damage to the public confidence. The HSMR calculation should be valid and accurate before making results public or incorporating in policy decision making.

In the last years, the SMR for rectal or anal cancer appeared to be increased in the Catharina Hospital. For a specialised centre for patients with locally advanced rectal cancer¹⁰ this is very concerning. The aim of the present study was to investigate whether the increased SMR for rectal or anal cancer was indeed related to poor quality of care or whether it could be explained by inadequate adjustment for case-mix factors.

MATERIALS AND METHODS

Patients and data

Between 2006 and 2008, there were 484 admissions (381 patients) for rectal or anal cancer in the Catharina Hospital Eindhoven in the Netherlands. Of this diagnostic group about 20 patients died while a maximum of nine patients were expected to die based on the national average. The 11 excess deaths resulted in a significantly increased SMR of 230 (95% CI 140 to 355). The national SMR reference value is 100, scores above this value indicate that more patients died than expected while scores below 100 indicate that less patients died than expected. In the Dutch HSMR model (calculated over the period 2006-2008), expected mortality was calculated adjusted for age, sex, primary diagnosis, urgency of admission, Charlson comorbidity index, month of admission, year of discharge, social deprivation and source of referral. However, continuous refinements are made yearly to the included variables in the HSMR model.² The SMR calculations are based on data from the National Medical Registration (LMR) which are provided by hospitals and gathered by the Dutch Hospital Data (DHD). The diagnosis of rectal or anal cancer is classified according to the International Classification of Disease, Tenth Revision (ICD-10) and included the following codes: C154.0, C154.1, C154.2, C154.3, C154.8, C230.4, C230.5, C340.6 and V10.06. Consequently, these codes comprise one of the 50 Clinical Classification System (CCS) groups for which SMRs are calculated, i.e. rectal and anal cancer.

The Eindhoven Cancer Registry collects data on all patients with newly diagnosed cancer in a large part of the southern Netherlands. The area comprises approximately 2.3 million inhabitants, six pathology departments, ten community hospitals (including the Catharina Hospital) and two radiotherapy institutions. Besides patient characteristics, tumour data such as site, differentiation grade and depth of penetration are recorded as well. Tumour differentiation

grade is classified as: well differentiated, moderately differentiated, poorly differentiated and unknown differentiation grade. Both clinical (cT) and pathological (pT) tumour penetration depth are recorded. For patients who did not meet the minimum requirements for classification (such as physical examination for cT or surgery/biopsy for pT) the tumour stage was classified as N/A. Due to neoadjuvant chemotherapy and radiotherapy, a less advanced tumour stage or even the absence of a tumour might occur during pathological examination resulting in a pT0 classification. In addition, data on hospital of diagnosis and treatment are recorded as well so referral patterns could be investigated. Patients admitted directly to the Catharina Hospital (non-referred) were distinguished from those diagnosed in another hospital and subsequently referred to the Catharina Hospital (referred).

To investigate patient and tumour characteristics of the 381 patients diagnosed at the Catharina Hospital with rectal or anal cancer, data of the Eindhoven Cancer Registry were merged with the hospital dataset on the basis of gender and date of birth. Patients with multiple matches were checked manually and those with corresponding zip codes were included. Patients with more than one tumour who had multiple matches were manually checked as well to select the correct tumour. From the hospital dataset 363 patients could be matched and were included in the new database. The other 18 patients were admitted to the Catharina Hospital for a recurrent rectal or anal tumour of which the primary tumour was diagnosed outside the Eindhoven Cancer Registry. Data of these patients were obtained from the Netherlands Cancer Registry which contains all newly diagnosed cancer patients in the Netherlands. Moreover, medical records of patients whose tumours were diagnosed more than one year before the hospital admission date were manually checked to rule out that they had presented with a recurrent instead of a primary tumour. As all registered data on patient and tumour characteristics of the Cancer Registries include information on time of primary tumour diagnosis and not regarding local recurrence, some analyses did not comprise patients admitted for a recurrent cancer (n=50). If this was the case, results were based on analyses of 331 (87%) patients.

Data on in-hospital mortality were obtained from the hospital database including 381 patients with rectal or anal cancer. In addition, the hospital medical records of the 20 patients who died during the hospital stay were reviewed for additional information including the reason of the admission (diagnostics, treatment, or palliative care).

Statistical analysis

Differences between referred and non-referred patients were compared using a Student's t-test for continuous variables and using chi²-test for categorical variables

and reported as percentages. Statistical analyses were performed using SAS/STAT® statistical software (SAS system 9.3, SAS Institute, Cary, North Carolina, USA). A p-value <0.05 was considered to be significant.

RESULTS

Patient and tumour characteristics

Fifty patients (13%) had a locally recurrent tumour. As mentioned previously, no data were available for these patients with respect to their recurrent cancer and were therefore not included in *table 1*. The mean age of the remaining 331 patients was 65 (±11) years and 61% were men. The majority of the patients (97%) were diagnosed with rectal cancer, whereas only 3% were admitted for anal cancer. More than half of the patients had a tumour stage T₃ or T₄ (both cT and pT) and approximately half of the patients had a moderately differentiated tumour.

Table 1. Patient and tumour characteristics	
	Total (n=331)
<i>Patient characteristics (%)</i>	
Age	65±11
Male gender	61
<i>Tumour characteristics (%)</i>	
Tumour site	
- Rectal cancer	97
- Anal cancer	3
Depth of penetration	
- Pathological	
--- To/in situ	8
--- T ₁	6
--- T ₂	25
--- T ₃	42
--- T ₄	7
--- Unknown	2
--- NA*	10
- Clinical	
--- To/in situ	0
--- T ₁	4
--- T ₂	5
--- T ₃	27
--- T ₄	31
--- Unknown	31
--- NA*	2
Tumour differentiation grade	
- Well differentiated	7
- Moderately differentiated	51
- Poorly differentiated	7
- Unknown	35
Patients with recurrent disease not included. *Patients did not meet minimum requirements for classification.	

Referred and non-referred patients

Of all 381 patients, 235 (62%) were diagnosed with cancer in another hospital and subsequently referred to the Catharina Hospital. Forty-six different medical centres referred patients to this hospital. Excluding patients with a recurrent tumour, 192 of 331 (58%) were referred. Of these 331 patients diagnosed with a primary rectal or anal tumour, referred patients were younger (64 vs 67 years, respectively) and had a more advanced tumour stage (pT₃ + pT₄; 57 vs 39%, respectively) compared with non-referred patients (p<0.01).

In-hospital mortality

During the study period, 20 (5.2%) patients died in the Catharina Hospital. *Figure 1* demonstrates in detail the in-hospital mortality (including patients with a recurrent tumour). Of these 20 patients, nine were referred from another hospital and 11 were primarily diagnosed in the Catharina Hospital. Two patients had a recurrent tumour, one referred and one non-referred patient. Nine patients were admitted to receive palliative care only: eight non-referred patients and one referred patient. So only 11 of the 20 deceased patients were admitted and treated with curative intent.

Table 2 presents the percentages of in-hospital mortality for the referred and non-referred patients who underwent resection and those who did not (recurrences not included). As no treatment data were available for recurrent tumours (n=50), the results are based on analyses without these recurrences (n=331). In total 192 (58%) of the 331 patients were referred, of whom 3.7% died within the hospital whereas 7.2% of the patients who were diagnosed in the Catharina Hospital died (p=0.15). Total postoperative mortality after surgical resection was low at 2.6% and did not differ between referred and non-referred patients, 2.9% and 1.9%, respectively (p=0.61). In contrast, in-hospital mortality of the non-resected patients was 17.9%. The

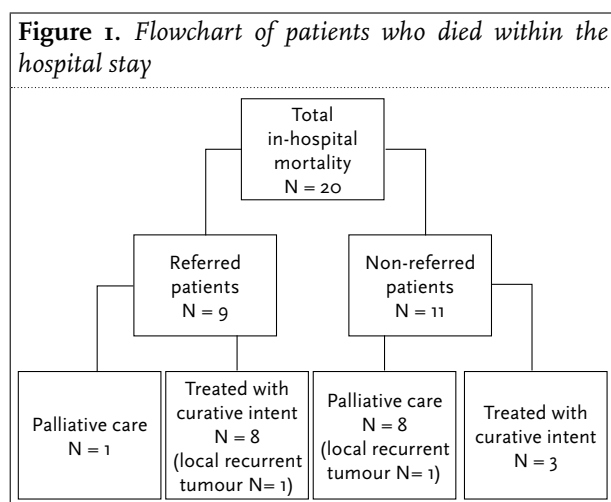


Table 2. Percentage in-hospital mortality

	Total (n=331)	Referred (n=192)	Non-referred (n=139)
	n (%)	n (%)	n (%)
Total (n=331)	17 (5.1)	7 (3.7)	10 (7.2)
Resected (n=275)	7 (2.6)	5 (2.9)	2 (1.9)
Non-resected (n=56)	10 (17.9)	2 (9.5)	8 (22.9)

majority (60%) of this group were terminally ill and admitted for palliative care only.

In total, nine of the 20 patients (45%) died within the postoperative period due to surgical complications. Two patients (10%) were admitted due to acute need for gastrointestinal surgery and died as a result of a cardiovascular cause. The remaining nine patients (45%) were all admitted with end-stage disease and severe symptoms to receive palliative care only (described above).

Therapy

Of the 331 patients of whom treatment data were available, 275 patients (83%) underwent resection for the tumour. Of these surgically treated patients, 92% received radiotherapy, 50% chemotherapy and 48% of the patients both radiotherapy and chemotherapy (figure 2). Referred

patients more often underwent surgical resection than non-referred patients (89 vs 75%, respectively; $p < 0.001$) and more often received chemotherapy, radiotherapy or chemoradiotherapy ($p < 0.01$ for all). Of the non-resected patients (n=56) two-thirds (68%) received chemotherapy or radiotherapy or both.

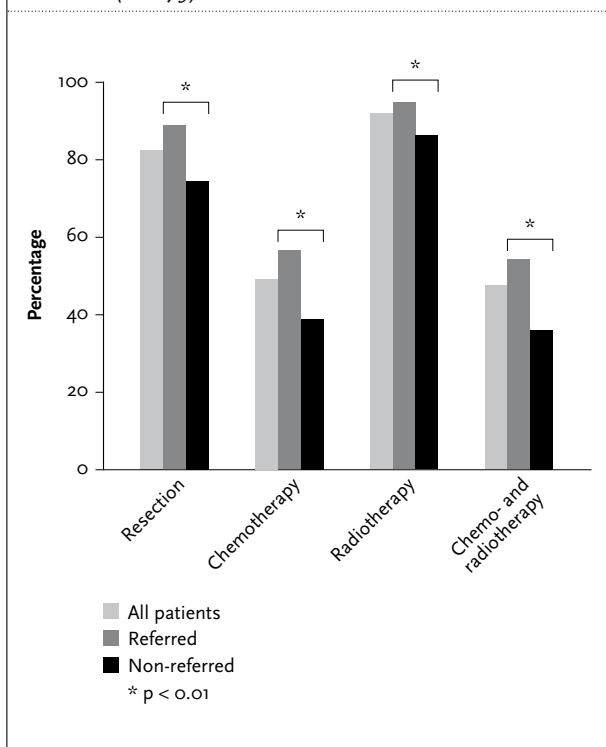
DISCUSSION

Centralisation of complex, low-volume surgery in specialised centres to improve quality of care is an important issue in the current health care system. As a result, the Catharina Hospital has successfully provided specialised care for patients with locally advanced and locally recurrent rectal cancer for several years.¹¹⁻¹⁴ However, this seems to be in contrast with the SMR for this diagnosis group which appeared to be significantly increased for the period 2006-2008 in this hospital. The results of the present study demonstrated that patients admitted for palliative care accounted for approximately 50% of the in-hospital mortality for patients with rectal or anal cancer resulting in an increased SMR. Moreover, insufficient case-mix adjustment for the reason of admission and referral patterns is likely to negatively affect the SMR for this diagnostic group.

For a significant part, the increased SMR for rectal and anal cancer is explained by the admission of terminally ill patients who require or opt for end-of-life care in the hospital, since almost half (45%) of the deceased patients were admitted to receive such palliative care only. While these patients were all expected to die during the hospital stay, the predicted chance to die, based on the SMR adjustment model, is not calculated as (nearly) 100% for these patients. This leads to an underestimation of the in-hospital mortality and consequently to an increased SMR. Moreover, comparison of in-hospital mortality rates of resected (2.6%) and non-resected (17.9%) patients confirms the suggestion that the admission of patients who could not be cured increases the in-hospital death rate. Consequently, the reason of admission should be incorporated in the HSMR adjustment model or, even better, patients admitted for palliative care should be excluded when HSMRs or SMRs are calculated.

In addition to the hospitalisation of terminally ill patients, those with recurrent rectal or anal cancer might considerably affect the SMR as well. The Catharina Hospital is a specialised centre for the treatment of patients with local recurrence;¹⁰ however, the extended anatomical resections cannot be compared with primary cases. Certain subsites of the recurrent tumour are a major problem in rectal cancer surgery such as a postero-lateral recurrence which is associated with 20% mortality within three months after surgery.¹⁵ Irradical

Figure 2. Treatment of patients with rectal or anal cancer according to referral status. Percentage chemotherapy, radiotherapy, and chemo- and radiotherapy of patients who underwent surgical resection (n=275)



resection rates and consequent cancer-related deaths are considerable among patients with recurrent rectal cancer. Furthermore, treatment of these locally recurrent cases is limited to very few centres in the Netherlands, of which the Catharina Hospital is by far the largest. This condition cannot be assessed within the framework of the SMR for rectal or anal cancer. We identified 13% of the rectal cancer patients included in our study as admitted for a recurrent tumour and patients with a recurrent tumour accounted for 10% of the in-hospital mortality.

The majority of the rectal or anal cancer patients were referred from other hospitals to the Catharina Hospital which serves as a tertiary centre for patients with a locally advanced and locally recurrent rectal carcinoma. The latter was confirmed by our results which demonstrated that the referred patients more often had an advanced tumour stage (T₃ and T₄) and a recurrent tumour compared with the patients who were primarily diagnosed in the Catharina Hospital. Referred patients living outside the local community usually have a different risk profile than patients who are admitted directly; they are more ill, have a longer length of hospital stay and have greater mortality rates.¹⁶⁻¹⁹

The Dutch adjustment model which was used to calculate the SMR for rectal cancer for the period 2006-2008 only included the Charlson comorbidity index to adjust for disease severity. A specific variable for disease severity was lacking. Recently, the model has been expanded by the addition of a detailed variable for disease severity. However, despite these changes to the model, the adjustment for severity of disease is still insufficient.²⁰ Moreover, transfer of severely ill patients is likely to reduce the HSMR or SMR for the referring hospital²¹ while accepting these patients may lead to increased mortality rates.^{16,22} Consequently, a tertiary referral centre will be 'punished' twice when a referred patient dies during the hospital stay; the referring hospital will be given a positive score for the high-risk patient who is leaving the hospital alive while the accepting hospital will be given a negative score when this patient dies. So large variation between hospitals in the admission of patients with advanced disease could result in diverse and conflicting in-hospital mortality rates. Consequently, publication of incorrect SMRs will cause more harm than good for hospitals as well as for patients as they could be denied admission to medical centres supplying the specialised care they require.

In contrast to the significantly increased SMR for rectal and anal cancer, the in-hospital mortality rate among patients who underwent surgical resection in the Catharina Hospital was low (2.6%) and in accordance with the national²³ and international^{24,25} literature. Our results are also confirmed by recent mortality data which were established by the Dutch Surgical Colorectal Audit, DSCA.

For the period 2009-2011, the hospital volume for rectal cancer surgery was more than 250 for the Catharina Hospital and the in-hospital mortality of 2% was below the average.²⁶ These data clearly demonstrate and confirm that our hospital serves as a centre of excellence for rectal cancer patients and provides good quality of care. The results of our study demonstrated that even for referred patients who often suffer from advanced disease, low mortality rates were accomplished. However, given the different risk profile between referred and non-referred patients and the fact that these patients affect in-hospital mortality of both the referring and accepting hospital, it is crucial that referral patterns are taken into account when SMRs are calculated. For example, intention-to-treat analysis may be considered in which mortality will count for the first hospital the patient was admitted to. Given the referral patterns due to concentration of specialised care, quality of care should be investigated at a regional level instead of a hospital level.

Quality of care is currently an important topic in health care; however, there remains considerable debate about which measures should be used to reflect quality of care.²⁷ The most common framework is that of Donabedian who conceptualised three quality of care dimensions, i.e. structure, process and outcome.²⁸ Direct outcome measures such as morbidity and mortality are most appealing to use for the evaluation of quality of care as they are relatively easy to use and usually widely available. However, as the results of our study confirm as well, the focus should not be solely on outcome measures such as in-hospital mortality. Structural elements such as hospital type, the availability of specific technologies/treatment options and the presence of health facilities such as hospices in the hospital area may have a significant impact on in-hospital outcome as this results in the admission or discharge of specific patients. In addition, outcome measures other than mortality should be considered as well. For rectal or anal cancer patients undergoing surgery, complication rates, reoperation rates, cancer recurrences, length of hospital stay and guideline-recommended treatment are related with quality of care and may also be considered.²³

The additional information obtained from the cancer registry made it possible to explore potential patient and tumour characteristics of rectal and anal cancer patients which could affect in-hospital mortality. However, less detailed data were available for patients admitted for a recurrent cancer. Moreover, the exact method of SMR calculation was unfortunately confidential, so we were not able to re-calculate the SMR for rectal and anal cancer. Additional analyses should be performed with and without the aforementioned variables (i.e. tumour recurrence, palliative care, and referral patterns) to investigate the actual effects of these factors on SMRs.

In conclusion, the SMR for rectal and anal cancer was significantly increased which is in contrast with the low postoperative mortality rates for the patients who underwent surgical resection. Patients admitted for palliative care accounted for almost half of the in-hospital mortality. Given the inadequacies, the SMR for rectal and anal cancer is unreliable and should not be used to assess quality of care.

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