Towards patient-centered colorectal cancer surgery : focus on risks, decisions and clinical auditing

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GENERAL DISCUSSION AND FUTURE PERSPECTIVES

General discussion and future perspectives

The health care industry is undergoing tremendous transformations. The extent of needed care is rapidly growing due to the aging of the population, and to an increase in patients with chronic diseases and multi-morbidity. As a consequence of rising health costs, health care insurers request a greater effectiveness and efficiency in health care organization. Methods are being sought to ensure sustainability of health systems, to promote quality improvement and to shorten waiting times. Subsequently, the Ministry of Health and the Health Inspectorate place high demands on quality and safety of care provided. They request an increased transparency of quality of healthcare, with the ultimate goal to improve patient outcomes. Simultaneously, patients are becoming more and more empowered and knowledgeable. Internationally, initiatives have been taken to extend patients' ability to choose their health care provider, to encourage them to make an active choice in treatment decisions, and to support them in the process of making these choices.[1-4-30]

These ongoing developments inevitably affect daily surgical practice. Surgeons are increasingly accountable for their postoperative complication rates, since quality of care has become a major topic. Quality enhancement programs, like nation-wide clinical audits, have been initiated internationally. The clinical audit contains information of different phases of treatment, such as diagnostics, treatment and outcomes. Auditing has shown to provide meaningful information to healthcare providers, who can actually for improve their quality of care with the feedback on their performance compared to other hospitals. Frequent feedback of this information can diminish the risks for postoperative complications, and subsequently reduce significant morbidity, mortality and costs.[5-7]
Simultaneously, from various angles there has been an increased demand for valid and reliable information on performance and outcomes of

care. The public reporting of outcomes may however influence surgical decision-making, since it may lead to a more risk-averse treatment strategy - with the objective to lower postoperative complication rates. Also, surgeons need reliable and accurate information on the risks and benefits of surgical treatment options to inform their patients and involve them in the treatment decision.

Colorectal cancer surgery is considered high-risk, since it brings along a relatively high number of postoperative complications. Choosing the ideal surgical treatment consists of a trade-off between benefits and risks of different surgical treatment options, which subsequently calls for preoperative information provision and the incorporation of patient preferences. Further, its high-risk nature has led to being the focus of several quality improvement initiatives, including the Dutch Surgical Colorectal Audit in the Netherlands. Therefore, colorectal cancer surgery is an exemplary setting to investigate postoperative risks, clinical decision-making and clinical auditing.

Risks and Benefits

The results in this thesis, together with existing evidence, emphasize that both doctors and patients should be aware that the surgical options for colorectal cancer have different risks and benefits to consider. It is commonly known that creating an anastomosis bears the risk of anastomotic leakage, a serious complication contributing to one third of all postoperative deaths after rectal cancer surgery (*chapter 1*). Obviously, patients with an end-colostomy have no risk of anastomotic leakage. Although these patients run risks of stoma problems, or abscess complications (*chapter 2*), these may be less consequential than immediate postoperative anastomotic leakage. An end-colostomy may therefore be a safe short-term solution, specifically in frail patients.

A defunctioning stoma seems beneficial, since earlier randomized studies have proven that a defunctioning stoma diminishes the clinical consequences of anastomotic leakage [8-10], but there are drawbacks that argue against its use. First, a residual risk of clinically relevant anastomotic leakage of 7% in these patients should not be ignored (*chapter 2*). Furthermore, a defunctioning stoma reduces the consequences of short-term generalized anastomotic leakage, but does not protect from the risk for late anastomotic leakage (*chapter 2*); if anastomotic leakage is present for more than one year, secondary complications may occur including fistula formation, peri-ureteric fibrosis and infection of adjacent tissues.[11,12] Moreover, a second surgery in which bowel continuity is restored causes an additional risk of complications including anastomotic leakage (*chapter 2*), which is confirmed by findings in previous research.[13,14] As ongoing changes in outcome occur during the first year after surgery, it is essential to include long-term complications in the initial decision making process.

Informing and involving the patient

The outcomes of the different treatment of reconstructive options in colorectal cancer surgery mentioned previously may vary in their impact on a patient's physical and psychological well being. Therefore, involving a patient in the decision seems essential, since preferences towards the different options may also vary between patients. Involving a patient, or performing Shared Decision Making (SDM), starts with thorough preoperative information provision on all relevant options, their consequent benefits and risks.[15] Although informing a patient preoperatively seems self-evident in the decision making process for colorectal cancer surgery, at present, patients are sub optimally informed about risks and alternative treatment options (*chapter 3*). Previous studies have also underlined the need for improvement of the process of

informed consent in other domains of care.[16,16,17]

Benefit

Providing risk information has additional valuable consequences; it encourages patients to be more aware of the limits of medical treatment in general; it enables the doctor to educate the patient or to discourage possible medical consumerism, and it may be easier for a doctor to maintain a constructive relationship with the patient in case a complication arises. Patients generally seem to appreciate to be informed on the risks of interventions.18 In two studies, the majority of patients expected to be informed of all known complications, even if the rates were smaller than 1%.[19,20,20]

Improving patient information

An often raised argument for withholding information on surgical risks, is doctors' perception that patients do not understand the concept of risks, and have a poor memory of the disclosed information.21 Possibly, the great number of issues to be addressed in colorectal cancer surgery acts as a complicating factor. In today's multi-disciplinary, rapid-throughput ambulatory care, in which patients may not even meet their operating surgeon until the day of the operation, such detailed information with comprehensive discussion of risks may be difficult to realize. A systematic review by Schenker et al. found a wide range of communication interventions that improve patient comprehension in informed consent, such as written information, audio-visual/multimedia programs, patient navigation by a nurse practitioner, extended discussions, and test/feedback techniques.[22] These methods serve to empower a patient before a consultation with the surgeon in which the information can subsequently be individualized to that patient. Then, the surgeon can explore the patient's preferences and tailor the final decision to what fits the patient best, which forms the basis of SDM.[15]

Improving SDM

Although in our survey Dutch surgeons underlined the necessity of SDM in the decision on surgical treatment for colorectal cancer, an absence was seen in clinical practice (*chapter 3*). An important reported barrier towards using SDM concerns surgeons' lack of familiarity with the concept (*chapter 3*), which confirms prior research in other domains.[23-26] SDM is considered especially important for patients who present with a serious illness, such as colorectal cancer, or when different treatment options are available.[3] Not only is it essential for respecting autonomy (enabling individuals to make reasoned informed choices), but it is also needed for beneficence (the balancing of benefits of treatment against the risks and costs) and non-maleficence (avoiding harm).[27] Moreover, evidence suggests that patients tend to make more conservative decisions than their doctors, thus SDM may also reduce unwarranted hospital variation in treatment patterns.[28] Finally, it has been suggested that SDM may lead to better health outcomes and lower litigation rates, although this evidence remains limited.[29] Dutch gastroenterological surgeons need to be made aware of the fact that patients with colorectal cancer are currently not informed nor involved appropriately. As stated by Stiggelbout et al, and expressed in the Salzburg Statement, the implementation of SDM in (surgical) practice will need a culture change and enhanced awareness among doctors, their professional societies, and patients.[27,30]

Patient selection

The fact that nowadays 70% of patients undergoing low anterior resection for rectal cancer receive a defunctioning stoma, suggests routine use in current surgical practice. As stomas also cause morbidity and discomfort to patients, and are very costly in the long run, frequent

use is only justifiable when it in fact lowers anastomotic leakage rates. The previously described protective effect of a defunctioning stoma on the risk of anastomotic leakage could be confirmed in this thesis (*chapter 2, chapter 4*). However, this effect may be most apparent in high-risk patients, while there is a limited effect in low-risk patients. The beneficial effect of a defunctioning stoma was proven in a randomized controlled trial from Matthiessen et al. However, they studied a cohort with a risk of anastomotic leakage of 28%, which is high when compared to an average risk of anastomotic leakage of 9% found in literature (*chapter 1*). In these high-risk patients, a defunctioning stoma had a Number Needed to Treat of 5.5. In low-risk patients however, the NNT may increase to 55. The fact that last decade's increase in defunctioning stomas from 57 to 70% did not lower anastomotic leakage rates (*chapter 5*) even further suggests that the effect is most apparent in high-risk patients only.

Whom to select?

Adequate patient selection may therefore be the key towards better outcomes. Several attempts to identify possible risk factors for anastomotic leakage have been published in recent years (*chapter 8*). However, studies found that surgeons lack accurate prediction of anastomotic leakage in a single patient.[31,32] The clinical judgment of the operating surgeon (denominated as 'gut feeling') seems to localize a subset of patients at risk of developing complications in general, whereas many patients with no risk factors at all may develop anastomotic leakage. Apparently, the actual cascade leading to anastomotic leakage remains a black box.

Although patient-related risk factors such as height of the anastomosis, a malnourished status, steroid use and male gender have often been described as important risk factors in literature, hospital differences in anastomotic leakage rates could not be explained by

these factors (*chapter 8*). We found that the influence of treatment factors on the variation in anastomotic leakage rates was substantial. These findings imply that anastomotic leakage rates may be much more related to treatment factors and in hospital care processes, than to characteristics of the patient population treated in a certain hospital. An important note is that the database lacked data on some important host-related factors, such as smoking, alcohol consumption, nutrition status and preoperative leukocytosis.
Previous studies have also found an association of hospital- or surgeon-related factors with the occurrence of anastomotic leakage: several authors have described per-operative factors, such as blood loss and duration of the operation as important predictors for anastomotic leakage. [33-37] Longer duration and more blood loss than anticipated may be a proxy of a more difficult procedure, suggesting that anastomotic leakage rates might be related to surgical technical skills. Also, an increased strain and limited vascular supply at the anastomotic sites have been considered to contribute to the pathophysiology of leakage33. This, again, would be more related to technical aspects than patient-factors. The ultimate challenge for outcome researchers is to understand the complex clinical mechanisms that lead to success or failure, so that the excellence of best practices can be transferred to all hospitals performing these procedures.

Hospital variation

The lack of clear guidelines on 'whom to select' for an anastomosis with or without defunctioning stoma may partly explain the variation we found in this thesis in the use of defunctioning stomas between hospitals in the Netherlands (*chapter 5, chapter 6*). Another possible explanation may be found in differences in the threshold to construct a defunctioning stoma (to avoid the risk of anastomotic leakage) between surgeons. Some surgeons may be 'cowboys', others 'chickens'.

Interestingly, neither at a hospital level nor at a national level, correlation exists between a risk averse strategy (high stoma rate) and favourable outcomes (*chapter 6*).
Feedback of information on stoma and anastomotic leakage rates, relative to those of peers (benchmarking), provides clinicians an insight in the efficiency of their current treatment strategy. Sharing knowledge between clinicians on the optimal selection strategy, which probably can be found in hospitals with both low stoma rates and favourable postoperative outcomes, should be promoted.

Clinical auditing

The Dutch Surgical Colorectal Audit has proven to be a robust system to measure, report and enhance quality of colorectal cancer surgery in the Netherlands. It has led to a remarkable reduction of hospital variation in guideline adherence within a time period of three years only (*chapter 7*). In addition, significant improvements in outcome were shown, with a more than 20 per cent drop in the risk of postoperative mortality and a 14 per cent reduction in the risk of severe postoperative morbidity (*chapter 7*).
In the USA, a similar reduction in surgical morbidity and mortality was seen in the Veteran Affairs hospitals, after introduction of the National Surgical Quality Improvement Program (NSQIP).[38] In Norway, local recurrence rates after rectal cancer surgery decreased from 28 to 7% after introduction of a national audit program.[39] A systematic review performed by our study group confirmed the positive effect of audit and feedback on the quality of surgical care. [40]
The surgical Hawthorne effect - measurement and feedback in itself may improve surgical outcomes – may underlie these trends towards improvement, as was also shown in a study from O'Connor et al, where postoperative mortality rates after CABG decreased directly

after surgeons were provided with feedback.[41] It has also been stated that when feedback is accompanied with benchmark information and meaningful suggestions for improvement, the effect is even stronger.[42] In accordance with the format of the DSCA, the Dutch Institute of Clinical Auditing (DICA) was founded to enhance other clinical audit initiatives in the Netherlands. The main goal of the DICA is to support other clinical audits by facilitating legal, technical, methodological and logistic issues. Several new audits have been initiated since the introduction of the DSCA: the breast cancer audit (NBCA), the upper GI cancer audit (DUCA), the lung surgery audit (DLSA), the aneurysm audit (DSAA), the carotid audit (DACI), the pancreatic cancer audit (DPCA), the lung radiation audit (DLRA), the cerebrovascular audit (CVBA),the hepatobiliary audit (DHBA), the melanoma treatment audit (DMTR), the european pediadric surgical audit (EPSA), and the obesity treatment audit (DATO).

Outcome measures

Determining outcomes that measure and represent actual quality of care remains challenging. Each medical condition or population of patients will need their own specific set of outcome measures. Quality of care for procedures that are both common and relatively high-risk, as is the case with colorectal surgery, may be assessed using outcome measures such as anastomotic leakage or mortality. Postoperative mortality is the most often used outcome measure to benchmark surgical performance.[43-45]

Case-mix adjustment

When comparing mortality rates between hospitals, there is the

necessity of case-mix adjustment, as some hospitals treat more severely ill patients than others. A study from Kolfschoten et al showed that case-mix significantly varies among hospitals in the Netherlands.11 To adjust for these differences in case-mix, the DSCA has included baseline characteristics in its dataset, such as age, ASA-classification, emergency surgery, and tumour stage (*chapter 8*). These 'case-mix factors' however add to registration burden, which at this moment may hinder a sustainable auditing process.

Therefore, future automated retrieval of data from electronic patient files, or structural data management support for health care professionals is essential. Identifying outcome measures that are influenced to a smaller extent by case-mix, and more by treatment and hospital related factors, may be useful (*chapter 8*). First, it will decrease the necessity of collecting data on case-mix factors and thereby lower registration burden. Second, instead of measuring variation due to chance or differences in case-mix, the outcome indicator discriminates hospitals based on their actual performance. Anastomotic leakage may be such an indicator.

Structure and process outcomes

After adjustment for case-mix and treatment factors, Dutch hospitals still vary in both anastomotic leakage and mortality rates, (*chapter 8*), which makes both outcome measures suitable for discrimination. This however also suggests that other unknown characteristics of the hospital, its staff and the care they deliver may contribute to the observed differences. Adopting the Donabedian paradigm50, a balanced indicator set needs to include information on structures, processes and outcomes. Process components refer to the interactions between the doctor and the patient, for example the delivery of adequate staging investigations to detect distant metastases. Structural factors describe the setting in which the care is delivered. These structural variables, for instance, availability

of a high-level ICU, or on-site radiotherapy department, can be related to patient outcomes, especially by the influence they have on the process of care.

International developments

Outcome measures can indicate meaningful differences between hospitals nationally, which may help identifying relevant areas of improvement. The next step would be to standardize health outcomes data globally, so that internationally doctors can learn from another and apply new solutions to treating patients. The International Consortium for Health Outcomes Measurement (ICHOM) has recently launched standardized sets for different conditions with the purpose to transform health care systems worldwide by measuring and reporting patient outcomes in a standardized way.[46]

Composite measures

Although an individual outcome or process indicator may give useful information for targeted quality improvement programs, a hospital may have a high score on one indicator, but a low score on another indicator. For example, a surgeon or clinic that has zero anastomotic leakage rates at the cost of constructing defunctioning stomas or end-colostomies in all patients will not be regarded as the best practice. In reality, there is probably an optimum percentage of defunctioning stoma's and end-colostomies to be created, and leakage rates should always be seen in the light of these percentages.

More comprehensive measures including both processes and outcomes, or the use of composite measures are needed for true assessment of hospital performance. Several studies have investigated the relation between process and outcome measures to determine whether a

good score on composite process measures is associated with favourable short-term outcomes, however with inconsistent results.[47,48] Kolfschoten et al. investigated the validity of a composite measure, combining process and outcome measures using the database of the Dutch Surgical Colorectal Audit.[49] They found that a hospital's good score on the composite measures based on process indicators was correlated with more favourable risk-adjusted short-term outcomes. Additional studies with empirical testing of different composite measures to better understand their ability to discriminate quality of care are warranted.

Patient reported outcomes

The choice between an anastomosis with or without a defunctioning stoma or an end-colostomy can and should always be influenced by patient preferences. Therefore, patient reported outcomes measures (PROMs) are of additive value in this context. PROMs may provide a means of gaining an insight into the way patients perceive their health and the impact that treatments or adjustments to lifestyle have on their quality of life.
Although PROM-research has proved to be highly wanted for current modern research on clinical outcomes[50], it is important that this be performed in a standardized manner and based on valid, reliable and clinically useful measures.51Moreover, methods of communicating patient-reported outcomes to patients should be investigated, in order to increase their clinical use for the benefit of both doctors and patients.[52] Also, response rates are an issue. Systems to increase patient participation in the evaluation of their health care process should be developed, such as web based patient logs or compensating on insurance fees.

Cancer patient organizations in the Netherlands have already committed themselves to collaborate in integrating PROMS in the clinical audits in the near future. A transparent view on true value of

hospitals in the Netherlands however calls for an even more integrated approach, as Porter et al. defined value in health care as outcomes relative to costs.[53] The next step would be to guarantee availability of medical and patient reported outcomes, so that these can be weighed against cost.

Audits for patient choice

While the main aim of audit systems is to encourage doctors to improve the quality of care they provide, the comprehensive set of information can be well used to promote patients' involvement in choosing their hospital or provider, and in deciding on their course of treatment. In the Netherlands, implementation of two acts on regulated competition in 2006 assigned the responsibility to well-informed patients to 'vote with their feet' by selecting the healthcare providers they preferred.[54,55] Ideally, patients can use the comparative information available in the audit, to choosing only those healthcare providers that offer 'best' care. Unfortunately there still is a scarcity of public available meaningful information, even though performance indicators introduced by the Healthcare Inspectorate and Zichtbare Zorg Ziekenhuizen are publicly reported since 2003. 56 Steps towards true transparency of reliable audit data have however been taken. The Association of Surgeons of the Netherlands (ASN) has introduced a roadmap towards transparency in 2011, starting with public reporting of process indicators, followed by hospital specific outcome measures such as (case-mix adjusted) morbidity and mortality rates. An important condition for external transparency is the validity and reliability of the data in the audit, which is insured by the consistent quality checks on the registered data in the online system of the audits and the annual external validation with the National Cancer Registry (*chapter 8*).

Audit data can also be used to enhance patient involvement in treatment decisions. Providers can use the information to inform patients of their risks of medical and surgical complications. Since the dataset contains 200 variables concerning the patient, co-morbidity, diagnostics, disease-specific details, treatment, and outcomes (*chapter 7*), the data might be used to calculate an individual patient's risk of outcomes, and subsequently help patients to make informed choices and their treatment.[57] Such risk prediction models have been developed to predict the outcomes of treatment in other domains of care using specific clinical parameters.[58] A well-known model is 'Adjuvant! Online' for patients with early breast cancer, which predicts survival after surgery with and without adjuvant therapy.[59,60] The program gives the estimated prognosis and expected treatment benefit in a comprehensive format and can help to inform patients and to involve them in decision making about therapeutic options.[61] Similarly, patients undergoing surgery for colorectal cancer can be supported in the decision concerning stoma or anastomosis construction, by estimating their risks of unfavorable outcomes. The possibility of developing such a tool, by using the rich and detailed information from the DSCA, should be investigated. Furthermore, although these prediction models are increasingly used in the clinical consultation for breast cancer patients, little is known about the frequency and way in which risks are communicated in the consultation. Future studies should focus on the understanding of patients of such risk communication and the effect of its use on decision making and treatment choice.[62]

Conclusions

The findings in this thesis may form the basis for some important statements on decision-making and quality improvement in colorectal cancer surgery. First, Dutch surgeons should be made aware of the fact

that, at present, patients are not informed nor involved appropriately in surgical treatment decision making. Patients' preferences concerning different aspects of treatment, such as mortality, morbidity, discomfort, long-lasting functional effects, cure of disease, and hospital readmission rates should be taken into account. The risk of anastomotic leakage versus the consequences of a stoma seems of critical importance in decision-making. Methods to enhance thorough preoperative counselling should be developed. Surgeons can use short-term risk information provided by audit systems, such as the DSCA, although long-term outcomes need to be taken into account as well. Furthermore, not a risk averse strategy per se, but optimal patient selection may be the key towards preferable outcomes in colorectal cancer surgery. In high-risk patients, an end-colostomy may be the best decision to prevent short-term anastomotic leakage. Routine creation of defunctioning stomas to limit the risk of anastomotic leakage is not desirable, especially considering its unfavourable one-year outcomes. The next step in order to improve quality of colorectal cancer care is to identify best practices, or better even, algorithms for adequate patient selection, and to share this knowledge between different doctors and hospitals.

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