Value of outcomes research in colorectal cancer care

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Chapter 1

GENERAL INTRODUCTION AND THESIS OUTLINE

GENERAL INTRODUCTION

Colorectal cancer is a major contributor to cancer-related deaths worldwide[1]. In the Netherlands over 15,000 patients get diagnosed with colorectal cancer every year, three-fourth of these patients qualify for curative surgical treatment.[2, 3] Treatment of colorectal cancer is shifting towards a patient-tailored approach and all patients should now be discussed in a multidisciplinary team.[4] As the heterogeneity of patients and tumor characteristics increases, there is a growing need for timely and reliable information that measures the quality of treatment in these populations; so-called real world and real time information.

Traditionally surgeons are concerned with measuring quality and outcomes of surgical interventions.[5] As a result multiple changes have been made in the past regarding the surgical treatment of colorectal cancer with a measurable effect on patient outcomes. In rectal cancer surgery for instance, implementation and standardization of the total mesorectal excision (TME) technique using surgical training programmes has led to major improvements in local disease control and survival rates.[6]

Next to adjustments in surgical technique we are currently involved in optimization of colorectal cancer care by reorganizing the way healthcare is provided. Procedural volume for example has gained much attention in relation to outcomes of surgery, as hospital volume is seen as a proxy for surgical experience and the expertise of the involved multidisciplinary team.[7] The Dutch Society of Surgery responded with an obligatory volume of at least 20 resections for rectal cancer per year per hospital, thereby stimulating centralisation of this procedure. Furthermore there is a development towards subspecialisation of surgeons and healthcare workers in colorectal cancer care. Due to this specialisation healthcare professionals are focussed to stay up to date with the latest developments in the field and are more likely to rapidly implement innovative techniques and ideas.

Outcomes research

Outcomes research is a type of public health research, which studies variation in end results (outcomes) of different providers and the differences in (infra)structure and care processes leading to better or worse outcomes. It applies to clinical and population based research that studies and seeks to optimize the end results of healthcare in terms of benefits to the patient and society.

“Do no harm” is an important aim in medicine; all care provided should have a beneficial effect on a patient’s well-being.[8] Healthcare is therefore captured in evidence-based guidelines, which dictate conditions for optimal care and form an important aspect of quality assurance. In the Netherlands the evidence-based guidelines on colorectal cancer surgery are developed by a multidisciplinary board and periodically revised.[9]

For a long time it was not exactly known to which extent hospitals followed these guidelines and if this lead to variation in outcomes between providers. As a result the Dutch Surgical Colorectal Audit (DSCA) was founded in 2009, a national audit that is developed and managed by colorectal surgeons and gets its input through a web-based system.[10] The DSCA provides risk-adjusted benchmarked feedback evaluating quality of care on a hospital level and compares hospitals with their peers. It gives medical teams information about their performance and stimulates processes that need to be developed or improved.[11] Furthermore the DSCA identifies hospital variation in the Netherlands on a structure – process and outcome level. Studying this hospital variation provides us with valuable information that can be used to improve healthcare.[12]

For instance data from the DSCA show that outcomes after colorectal cancer surgery have improved significantly since the start of the audit. There has been a significant reduction in postoperative morbidity and mortality for colorectal cancer patients as well as a reduced duration of postoperative admission time.[10, 13] Moreover as a result of clinical auditing variation in guideline compliance between hospitals reduced, which had a measurable effect on quality of care (chapter 4). Clinical audits include large numbers of patients and contain patients with a high risk for unfavourable outcomes due to the absence of exclusion criteria, which are normally encountered in randomized controlled trials (RCT’s).[14] Due to these characteristics, clinical audits are rich databases that provide a unique source of real-time, real-world data and could complement the information from RCT’s.

This thesis will describe different areas of medical research for which clinical audit data is used and will furthermore discuss the inherent statistical problems encountered in population studies.

THESIS OUTLINE

Part I: Risk-adjustment in clinical auditing

Valid comparisons between hospital outcomes are essential for the audit, especially when these outcomes become transparent to the public, healthcare insurers and healthcare authorities. The heterogeneity of patients and tumors affects hospital outcomes. In oncology there is a trend towards centralisation of specific patient subgroups based on the rarity and complexity of their disease. To analyse the effect of this centralisation on casemix correction for outcome comparisons, the first part of this thesis studies differences in the effect of variables in the currently used casemix model between referral and non-referral hospitals.

Part II: Quality improvement in the Dutch colorectal cancer care

The second part of this thesis focuses on quality improvement in Dutch colorectal cancer care. Chapter 3 shows how the audit is used to monitor a quality improving initiative. As mentioned before the ASN implemented a compulsory minimal volume standard for rectal cancer surgery per hospital. This study describes the influence of hospital volume on circumferential resection margin (CRM) involvement - the most significant prognostic factor for local recurrence, distant metastasis and survival - after rectal cancer surgery.

Chapter 4 evaluates the rates of CRM reporting by Dutch hospitals and CRM involvement after the implementation of the DSCA. Chapter 5 identifies changes in the use of preoperative radiotherapy for rectal cancer in the Netherlands after the revision of the national colorectal cancer guideline. This guideline revision was stimulated by data from the audit showing significant overtreatment of early stage rectal cancers.

Part III: Data from clinical audits as a supplement to RCT's

The third part of this thesis shows the complementary function of the clinical audit in providing data for clinically relevant research.

Chapter 6 analyses the rate of postoperative morbidity and mortality after open versus laparoscopic surgery for colorectal cancer in specific subgroups of patients, including patients with a high preoperative risk for adverse outcomes. This chapter shows a possible method to deal with the inherent statistical problems that accompany population studies.

Chapter 7 displays the quality of laparoscopic rectal cancer surgery in the Netherlands at present by comparing the data from the DSCA to the COLOR II trial. We performed a matched cohort study and show postoperative results after laparoscopic rectal cancer surgery a decade from start of the COLOR II trial.

Chapter 8 shows the outcomes of patients with locally advanced colon cancer in the Netherlands, a population that is underreported in literature. The clinical audit provides important information on the quality and outcomes of their care.

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