Rectal Cancer and Quality of Life

Aspects on Communication and Patient Education

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När natten kommer
står jag på trappan och lyssnar,
stjärnorna svärma i trädgården
och jag står i mörkret.
Hör, en stjärna föll med en klang!
Gå icke ut i gräset med bara fötter;
min trädgård är full av skärvor.

Edith Södergran, Dikter, 1916

Abstract

Background This thesis reports the results of three studies based on a prospective cohort study of an unselected population of patients with rectal cancer, and one study based on an exploratory study of a new patient education method as preparation for colorectal cancer surgery. The aim of study I was to investigate whether patient's or doctor's delay had an impact on quality of life at diagnosis, and in study III the development of quality of life after treatment for rectal cancer was investigated. The aim of study II was to explore the patient's experience of communication before, during and after diagnosis of rectal cancer. Study IV used another patient cohort and explored the experience of patients participating in a new patient education method, before treatment for colorectal cancer.

Methods In study I, II and III data from a repeated-measures longitudinal study was used. In study IV, data on information and patient education was taken from a cohort study of patients planned for surgery for colorectal cancer. The statistical methods of study II and IV were descriptive and in study I and III regression models were used.

Results Despite that patients did not get information on the planned treatment's possible side-effects on the urinary and sexual function, the patients reported good communication with their surgeon. Timely access to treatment for rectal cancer did not have an effect on quality of life when consideration was taken to depression and negative intrusive thoughts. The quality of life was recovered to the same as the reference population after 12 months, but bother from urinary, stoma and bowel function hampered quality of life for the individual. Patients attending a group consultation before surgery for colorectal cancer appreciated the group setting and reported that it increased their sense of control and active participation in their treatment.

Conclusion Information on potential side-effects of rectal cancer treatment is lacking. The preoperative group consultation as a method for patient education, seems like a feasible complement to the standard consultation to give information before colorectal cancer surgery.

Keywords
Rectal neoplasms, quality of life, colorectal surgery, patient education, patient care bundles

Sammanfattning på svenska

Bakgrund

Ett stort antal människor i Sverige drabbas varje år av ändtarmscancer och närmare bestämt upptäcktes 2019 totalt 2073 nya fall. Ändtarmscancer är en elakartad tumör av typen carcinom och uppträder i körtelvävnad. Tumören är lokaliserad i ändtarmen som är de sista 15 centimetrarna av tarmen innan analöppningen.

Botande behandling av ändtarmscancer innebär så gott som alltid kirurgi i någon form. Olika kirurgiska tekniker tillämpas beroende på tumörens specifika lokalisation i ändtarmen och om den vuxit in i omgivande organ t ex vagina eller bäckenbottenmuskulatur. Två av tre patienter får strålbehandling innan operation, ibland i kombination med cellgiftsbehandling. En del får cellgifter efter operationen. Kirurgi i bäckenet kan medföra att tarm-, urin-, och sexfunktionen försämras och en del patienter får stomi, en tarmöppning på bukväggen också kallad ”påse på magen”.

Överlevnaden har förbättrats de senaste decennierna till följd av förbättrad kirurgisk teknik, bättre kartläggning av tumören med hjälp av röntgen och tillägg av strålning innan operation. Detta innebär, då det numera är många människor som överlever ändtarmscancer, att det blir många som lever med biverkningarna av behandlingen. De senaste åren har livskvaliteten bland patienterna som genomgått behandling för ändtarmscancer börjat studeras i större utsträckning. Genom att bland annat kartlägga hur funktionsnedsättningarna påverkar livskvaliteten kan behandlingen i ökad utsträckning anpassas efter patientens behov.

Syfte

Syftet med avhandlingen är att belysa olika infallsvinklar på livskvalitet hos patienter med ändtarmscancer och mer specifikt, att undersöka sjukvårdens kommunikation med och information till patienter med ändtarmscancer. Dessa ämnen belyses i denna sammanläggningsavhandling där fyra delarbeten ingår.

Metod

Arbete I, II och III presenterar resultat från en studie med patienter med ändtarmscancer som rekryterades vid 16 kirurgkliniker under 2012-2015 i Danmark och Sverige, QoLiRECT (*Quality of Life in RECTal cancer*) studien. Patienterna fyllde i omfattande frågeformulär som tagits fram enligt en intervjubaserad metod specifikt för den här studien. Det frågeformulär som skapades skickades till patienterna vid fyra olika tidpunkter: vid diagnos samt uppföljning efter ett, två och fem år. Frågorna berörde livskvalitet, personliga förhållanden och egenskaper samt tarm-, urin- och sexfunktion.

Arbete IV fokuserar mer tydligt på information och där presenteras resultaten från en helt annan studie, INFOM (*Informationsmottagnings-)* studien. Denna studie involverade patienter med ändtarmscancer samt patienter med tjocktarmscancer. Det genomgående målet med denna studie var att undersöka patienternas upplevelse av att delta i gruppmottagning innan behandling för tjock- eller ändtarmscancer.

Resultat

I det första arbetet med QoLiRECT-studien framkom det att patienter som haft symptom längre tid än 4 månader innan de sökt sjukvård och de patienter som hade lång väntetid till behandling, hade låg livskvalitet. Detta resultat kom från enkla statistiska modeller och när hänsyn togs till andra möjliga störfaktorer som depression och negativa påträngande tankar, var dessa resultat inte längre valida.

Det tredje QoLiRECT-arbetet var en undersökning av patienternas livskvalitet under de första 24 månaderna efter ändtarmscancerdiagnos. Resultatet visade att vid diagnos så skattade patienterna sin livskvalitet lägre än en slumpvis utvald referenspopulation. Vid 12- och 24-månadersuppföljningen hade livskvaliteten återhämtat sig.

I det andra QoLiRECT-arbetet undersökte vi hur patienter med ändtarmscancer upplevde kommunikationen med läkare och sjuksköterskor på kirurgmottagningen. Samtliga patienterna var nöjda med kommunikationen. Endast 32% (335/1050) respektive 24% (248/1053) av patienterna uppgav att de diskuterat behandlingens möjliga biverkningar på urinfunktion och sexfunktion.

För att undersöka hur patienter med tjock- och ändtarmscancer upplevde att delta i en gruppmottagning innan behandling, startades studien

INFOM. Resultatet visade att så gott som alla patienter som gick på gruppmottagningen skulle rekommendera den till någon annan och 72% uppgav att det var positivt att träffa andra patienter.

Slutsats

Livskvaliteten för patienter med ändtarmscancer är låg vid diagnos men har 12 månader senare återhämtat sig. På individnivå däremot, finns det flera faktorer som skulle kunna påverka livskvaliteten vid olika tidpunkter under sjukdomsförloppet. Vid diagnos framstår depression, tecken på stress i form av negativa påträngande tankar samt en låg känsla av sammanhang (ett salutogeniskt begrepp) som möjliga faktorer med negativ inverkan.

Flera faktorer påverkar risken för låg livskvalitet 24 månader efter ändtarmscancerdiagnos. Upplevd dålig urin-, tarm- och stomifunktion och ett eventuellt återfall av cancersjukdomen medför i allmänhet kraftigt försämrad livskvalitet. Uppföljningen av patienter som genomgått behandling för ändtarmscancer bör således ta hänsyn till dessa faktorer.

Patienter med ändtarmscancer är visserligen nöjda med kommunikationen med kirurgläkaren på kirurgmottagningen, men att behandlingen kan påverka urin- och sexfunktionen tas inte upp vid besöket eller glömmer patienten bort informationen. Därmed finns utrymme för förbättring där gruppmottagning, med patienter och anhöriga, framstår som ett gott alternativ för att informera så att patienten får insikt om sin sjukdom och behandling. Detta vet vi ökar deras känsla av kontroll över situationen och gör att de känner sig mer aktiva i sin egen behandling.

List of papers

This thesis is based on the following studies, referred to in the text by their Roman numerals.

I. Walming S, Block M, Bock D, Angenete E.

Timely access to care in the treatment of rectal cancer and the effect on quality of life

Colorectal Dis. 2018 Feb;20(2): 126-133.

II. Walming S, Asplund D, Block M, Bock D, Gonzalez E, Rosander C, Rosenberg J, Angenete E.

Patients with rectal cancer are satisfied with in-hospital communication despite insufficient information regarding treatment alternatives and potential side-effects

Acta Oncol. 2018 Oct;57(10): 1311-1317.

III. Walming S, Asplund D, Bock D, Gonzalez E, Rosenberg J, Smedh K, Angenete E.

Quality of life in patients with resectable rectal cancer during the first 24 months following diagnosis

Colorectal Dis. 2020 Dec; 22(12): 2028–2037.

IV. Walming S, Angenete E, Bock D, Block M, de la Croix H, Wedin A, Haglind E.

Preoperative group consultation prior to surgery for colorectal cancer – an explorative study of a new patient education method

J Cancer Educ 2021. Online ahead of print.

Contents

Abbreviations

APE	Abdominoperineal resection
ASA	American Society of Anaesthesiologists classification
CI	Confidence interval
COPD	Chronic obstructive pulmonary disease
CRF	Clinical record form
DAG	Directed acyclic graphs
ELAPE	Extra-levator abdominoperineal resection
EQ-5D	EuroQoL EQ-5D self report questionnaire
ICD	International Statistical Classification of Diseases and Related Health Problems
INFOM study	Information in group consultation study
LASSO	Least absolute shrinkage and selection operator
MAR	Missing at random
MCAR	Missing completely at random
MNAR	Missing not at random
OR	Odds ratio
PROM	Patient-reported outcome measures
QoL	Quality of life
QoLiRECT study	Quality of life in rectal cancer study
SD	Standard deviation
SF-36	Short Form 36
UICC	the Union for International Cancer Control TNM classification
WHO	World Health Organisation

1. Introduction

1.1 Rectal cancer

Rectal cancer is classified as an adenocarcinoma, according to the pathologic examination, and the tumour is located up to 15 cm from the anal verge. Adenocarcinomas located upstream of the rectum is referred to as sigmoid cancer and classified as colon cancer. Tumours classified as squamous cell carcinoma located in the distal rectum are classified as anal cancer. Patients with rectal cancer in Denmark and Sweden are registered in national quality registries; the registries are the Danish Colorectal Cancer Group database [3] and the Swedish ColoRectal Cancer Registry [4].

1.1.1 A relatively common cancer in Denmark and Sweden

In 2019, 2073 new cases of rectal cancer were registered in the Swedish ColoRectal Cancer Registry. In 2018, the corresponding number for the Danish registry were 1369 patients. Of the total number of cancers diagnosed in Sweden during 2016, 3.4% were rectal cancers, making it the ninth most common cancer nationally. Rectal cancer has a higher incidence in men than in women [5].

1.1.2 Treatment includes surgery, radiotherapy and chemotherapy

The primary treatment for rectal cancer is surgery. According to the rectal cancer registry in Sweden 80% (9182/11452) of patients diagnosed 2007-2012 underwent elective or emergency surgery. A somewhat smaller proportion underwent resection of the tumour, 74% (8499/11452). Of the resected patients, 87% (7049/8100) were treated with curative intent and the remaining proportion with palliative or undetermined intent [6]. A study on treatment and outcomes of rectal cancer diagnosed in 2010-2012 concluded that 68% of Danish patients and 71% of Swedish patients underwent surgery with resection of the tumour.

Data from the Swedish ColoRectal Cancer Registry revealed that 66% (5369/11452) of patients diagnosed with rectal cancer during 2007-2012 received neoadjuvant radiation therapy, either as only treatment or in combination with chemotherapy [6]. Only chemotherapy before surgery was given to 1% (70/11452).

1.1.3 Prognosis have ameliorated in recent decades

The prognosis for survival of rectal cancer has improved in the last decades (Figure 1). A study including data from all Nordic rectal cancer registries concluded that survival improved in all five countries during the observed period, 1990 to 2010 [7]. The same study concluded that the 5-year relative survival of patients with rectal cancer followed until 2017, were 71% and 68% for men in Denmark and Sweden respectively, and 69% and 65% for women.

The prognosis of rectal cancer is highly dependent on the stage of the disease at diagnosis. Based on data from patients diagnosed with rectal cancer in 2010-2012, the 1-year survival of UICC stage I was 99.8% and stage IV 61.5%. The 3-year survival for UICC stage I was 99.3% and stage IV 26.7% [8].

In Denmark, a standardized clinical pathway for colorectal cancer was introduced in 2008 [9, 10]. In Sweden, a similar standardized referral system was introduced in 2016 [11]. The aims for the introduction of cancer patient pathways in

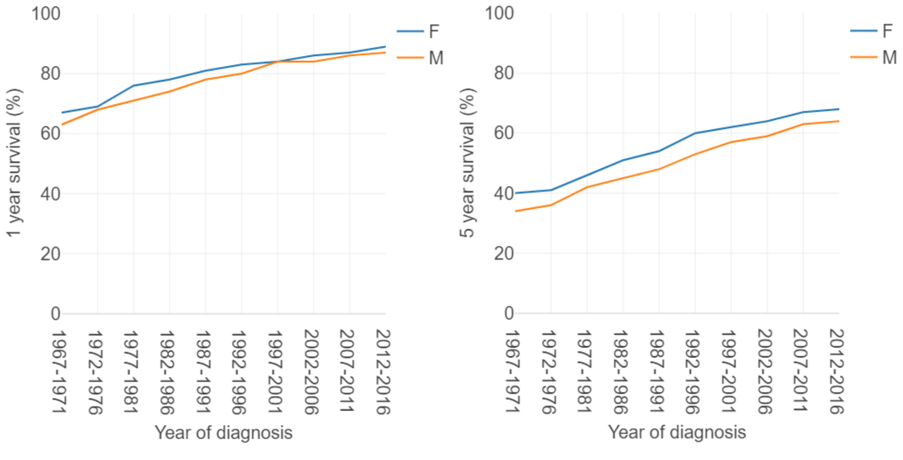


Figure 1. One and five year relative survival of rectal and anal cancer in Sweden 1967-2016. Data from the NORDCAN project [1, 2]. Age standardized, ages 0-89. F= female, M= male.

Denmark were to increase cancer survival rates, improve the health status of the patients with cancer and to increase patient satisfaction by ensuring treatment as fast as possible [10]. The aims for the introduction of the Swedish equivalent were to shorten the time before the start of treatment, increase patient satisfaction with cancer care and to increased equity in cancer care [12].

1.2 Quality of life

Traditionally, studies of rectal cancer have focused on clinical outcome measures such as complications, survival and local recurrence. However, as the number of patients surviving has increased in recent decades (Figure 1), the incentive to investigate the cancer survivors' quality of life has increased [13].

1.2.1 Patient-reported outcome measures (PROM)

A patient-reported outcome (PRO) is any report of the status of a patient's health condition that comes directly from the patient themself, without interpretation by a clinician or anyone else [14]. The outcome can be measured in absolute terms (e.g. severity of symptom, sign or state of a disease) or as a change from a previous assessment.

In contrary to patient-reported outcomes, the term quality of life is quite often considered not completely well defined [13]. In the absence of any universally accepted definition, some argue that most people in developed countries are familiar with the expression quality of life and have an understanding of what it comprises. The term health-related quality life is often used in scientific research, but it is unclear which aspects of quality of life should be included. Most agree that the relevant aspects of quality of life vary from study to study. It can include general health, physical functioning, physical symptoms and toxicity, emotional functioning, cognitive functioning, social well-being and existential issues [14].

The WHO defines quality of life as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. The WHO states that it is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment [15].

Generic quality of life instruments are designed to be applicable across a wide range of populations and interventions [16]. Specific quality of life instruments are designed to be relevant to particular interventions or in certain subpopulations (e.g. individuals with rectal cancer).

Table 1. Summary of the PROM instruments used in the QoLiRECT and INFOM studies. Some of the most common instruments used in the papers in the reference list of this thesis are also presented.

Generic

	EUROQOL's EQ-5D	SF-36 / RAND-36	7-point Likert scale of generic QoL
Development method	Psychometric	Psychometric	Clinimetric
Items	5	36	1
Recall period	Today	Last month	Last month

Specific

	EORTC QLQ-C30 and QLQ-CR29	FACT-C	City of Hope Quality of Life: Ostomy Questionnaire	LARS score	Sense of Coherence	AUDIT	Saltin-Grimby Physical Activity Level Scale
Development method	Psychometric	Psychometric	Psychometric	Psychometric	Clinimetric	Clinimetric	Clinimetric
Items	59	36	90	5	29	10	1
Recall period	Last week	Last week	Not specified	Not specified	Not specified	Last year	Not specified

1.2.2 Clinimetric and psychometric methods

The term clinimetric was introduced in 1982 to define instruments with indices, rating scales and other expressions used to measure symptoms, physical signs and other distinct clinical phenomena [17]. Clinimetric indices may serve several purposes in research as well as in the clinic, including diagnostic criteria of disease, instructions for decisions that lead to diagnostic or therapeutic actions (guidelines), description of alterations recorded in repeated measurements and prognostic estimation. The clinimetric instruments used in this thesis are presented in Table 1.

One example of a clinimetric scale is the Apgar score, a scoring system developed in 1953 with the intention to assess the effect of obstetrical practices on the clinical condition of neonates immediately after birth [18, 19]. The scoring system was developed based on the five signs traditionally used by anaesthesiologists to monitor a (grown-up) patient's condition throughout surgery: heart rate, respiratory effort, reflex irritability, muscle tone, and colour. A rating of 0, 1, or 2 was given to each sign, a score of 0 indicated that the sign was absent and a total score of 10 indicated a neonate in excellent condition.

Feinstein, who presented the concept of clinimetrics in 1982, argued that one important factor separating clinimetric scales from psychometric ones, was the method for development [20]. More recently, it has been stated that clinimetric methods for development of instruments should be adopted for concise instruments that can be used by clinicians to measure the health status of their patients. The instrument should be based on heterogeneous items of subjective observations, and the patient input on the development level and high face-validity is important [21].

Clinimetric instruments can be divided into general and ailment-oriented [17]. General instruments refer to general health and functional states, that are not specific for certain diseases or conditions. The ailment-oriented instruments refer to specific diseases and clinical manifestations. The same type of breakdown is used for psychometric measurement methods, but referred to as generic and disease-specific [22]. The clinimetric and psychometric measurement instruments used in this thesis are specified in Table 1, categorized as *generic* or *specific*.

Psychometric methods, much used in psychological measurements, use several items (i.e. questions) for assessing underlying dimensions called factors [23]. Statistical methods are used for determining the underlying dimensions of data, such as factor analysis. Internal consistency, which is used to address the homogeneity of an instrument, can be tested with statistical methods such as

Cronbach's α. One example of an instrument developed with psychometric methods is the Hospital Anxiety and Depression Scale (HADS), introduced in 1983. It consists of 14 questions, with two underlying factors, and is used for identifying depression and anxiety in the setting of somatic medicine [24]. Psychometric evaluation has shown good item-total correlations within the two subscales (i.e. relatively high Cronbach alphas).

1.2.3 Features of PROM instruments

Features determining the sensibility of a clinimetric instrument have been suggested to be the following: well-defined purpose and framework, comprehensibility, clarity of instructions (replicability), discrimination properties, face validity, content validity and easy practical implication [25]. The clinical meaning of discrimination properties is that the instrument should be able to detect changes, with clinical relevance, in health status over time, reflected in its responsiveness and sensitivity.

To ensure the instruments for measuring patient-reported outcome data reliably and validly represent the patient's perspective on health-related outcomes, minimum standards for the psychometric methods have been suggested. The ISOQOL [26] recommend that documentation should be available on; the reliability, content validity, construct validity, responsiveness, and interpretation of scores. In addition, they recommend that the instrument should not be too burdensome for the investigator and the patient and it should have a documented recommendation for translations of the instrument.

1.2.4 PROMs in national quality registries of rectal cancer

As of today, the registration of PROMs in the national colorectal cancer registries in Sweden and Denmark has not started. However, a review completed in 2015 [27], concluded that 93 national quality registries in Sweden included some form of PROM. The most common generic PROMs were the EuroQol's EQ-5D and the SF-36. According to the review, among the 108 national quality registries reviewed, 15 did not include any PROM; however, most of them reported planning to do so in the near future. Preparations for beginning to use PROMs in the Danish Colorectal Cancer Group database and the Swedish ColoRectal Cancer Registry, is ongoing.

1.2.5 Quality of life after treatment for rectal cancer

In a study cohort, one third of individuals surviving 12 to 36 months after diagnosis of colorectal cancer reported being in perfect health, that is to say no problems on the five dimensions of EQ-5D (which are mobility, self-care, usual activities, pain/discomfort, anxiety/depression) [28]. However, as the patients with colonic cancer reported perfect health in 37% of cases, only 29% of the patients with rectal cancer did.

In a study of 6413 patients with rectal cancer, about 50% reported problems on the EQ-5D domains pain/discomfort and usual activities [29]. One year after colorectal cancer diagnosis, the study population and the population controls reported identical mean scores of global health/quality of life and physical functioning of the EORTC QLQ-C30.

1.2.6 Patient and healthcare characteristics related to quality of life

Patients planned for treatment with non-curative intent [30] and patients with metastatic cancer have reported poorer quality of life in terms of symptom burden and physical functioning [31]. In some studies of patients with rectal cancer, individuals with metastatic disease at diagnosis are excluded [32] and in other studies, patients with recurrence at follow-up are excluded [33]. Recurrence after treatment for rectal cancer, both local and distant metastases, has been reported to correlate with low quality of life [34, 35].

As the treatment for rectal cancer can include surgery and radiotherapy, possibly affecting the nerves and organs near the rectum, the functional outcomes have been studied. A study on the QoLiRECT cohort revealed that presence of a stoma contributed to reduced sexual activity after treatment for rectal cancer [36]. Radiotherapy in combination with surgery as treatment for rectal cancer, as compared to surgery as only treatment, has a negative effect on sexual functioning in women [37].

In the QoLiRECT cohort, 29% of women and 14% of men reported urinary incontinence one year after diagnosis [38]. In another cohort, 57% of women and 36% of men reported urinary incontinence three years after abdominoperineal resection [39].

In a study on 150 patients who underwent surgery for rectal cancer, preoperative radiation therapy was found to be a risk factor for faecal incontinence [33]. In the same study, no difference was seen regarding the generic quality of life between patients who had underwent anterior resection and abdominoperineal resection.

In a study on patient who underwent abdominoperineal resection for rectal cancer, 93% (64/69) stated they could live a full life with their stoma; however, 40% (27/65) also stated it would affect them negatively if their present stoma problems would remain throughout life [40]. According to another study on patients who underwent the same surgical procedure, the stoma affected physical activities to a higher degree when the patient had a bulge or a hernia around the stoma [41].

Among patients with colorectal cancer attending a cancer clinic, 25% (44/177) reported having treatment for depression, either an antidepressant drug or by seeing a mental health professional [42]. Major depression among patients with colorectal cancer seems to be more common in women and patients under 60 years of age. However, the same study concluded that 73% (1130/1574) of patients diagnosed with major depression were not receiving any treatment.

Previous prospective studies on the patient's satisfaction with disease-related information and the prevalence of depression have shown that well-informed patients have less anxiety and depression[43]. In a study on oncologic patients with depression or pain, depression was independently associated to a reduced quality of life [44].

1.3 Patient-doctor communication and education

Sixty percent of the patients with colorectal cancer recalled the information on stage of the tumour and planned treatment, that was provided during the consultation with their surgeon [45]. Factors associated with limited recall of the information provided at the consultation were high anxiety levels, higher age and lower education.

Patients with rectal cancer have reported that the information on diagnosis, treatment choices, disease process, and recovery was incomprehensible or too scarce; for some information topics this was reported in up to a quarter of all cases. In relation to quality of life, patients reporting unclear communication had lower scores on role, as well as emotional and social functioning, and the trend persisted during long-term follow-up [46].

Unclear or incomplete information given to patients with rectal cancer can result either from lack of information given at the consultation, or from the patient not recalling the information. Either way, in recent years different methodologies for optimizing patient education have been launched and evaluated.

1.3.1 Methods for patient education in colorectal cancer

A randomized controlled trial, where the intervention was to receive an information pack consisting of 14 leaflets on various aspects of the disease and the treatment of rectal cancer, revealed that anxiety levels, according to the HADS (Hospital Anxiety and Depression Scale), were lower in the intervention group 6 months after surgery [47]. When evaluating a 100-page information booklet for patients with colorectal cancer contemplating adjuvant chemotherapy and/or radiation therapy, 82% of the patients reported they would pass the booklet on to other family members or friends [48]. This can be assumed to support that members of the patient's family and friends of the patient, also have information needs regarding the disease and associated treatment.

Preoperative intensive education of patients planned for colorectal resection for cancer with a stoma resulted in shortened hospital stay, compared to the traditional postoperative education [49].

A quasi-experimental study on a patient-centred written information tool has been proven to shorten length of hospital stay after surgery for colorectal cancer and decrease the number of visits to the emergency department [50].

Intervention studies of different methods for patient education, with outcome measures such as anxiety and outcomes of behavioural recovery, have been performed [51]. However, due to the heterogeneity in the outcome measures, meta-analysis of data has not been feasible [51].

The most compelling evidence for the efficacy and cost-effectiveness of group consultations can be found in the perinatal care. Several randomized trials indicate that group consultations improve knowledge and healthier pregnancy weight gain, as well as reduces maternal depression [52]. Evidence of improved outcomes in the care of chronic conditions such as diabetic care, hypertension care, chronic pulmonary obstructive disease (COPD) and coronary artery disease [52] is also available.

2. Aims

The overall aim of the thesis was to investigate the quality of life of patients with rectal cancer. Further, the aim was to describe patient and healthcare related factors associated with quality of life with an emphasis on patient-doctor communication and patient education.

The specific aims of the four studies were:

I. To investigate if a delay in a patient's first contact with healthcare, and subsequent delay in diagnosis, affected their self-assessed quality of life before start of treatment [53].

II. To describe the patient-reported experience of communication with healthcare personnel at the outpatient clinic during the first 12 months after rectal cancer diagnosis.

To describe the communication regarding treatment alternatives and potential side-effects of the planned treatment at diagnosis and at the 12 months follow-up [54].

III. To describe the quality of life of patients with rectal cancer during the first 24 months after diagnosis.

To identify risk factors that could predict low quality of life during the 24 months after rectal cancer diagnosis [55].

IV. To investigate how the patients with newly diagnosed colon or rectal cancer experienced the preoperative group consultation.

3. Patients and Methods

3.1 A prospective cohort study on rectal cancer

The QoLiRECT study is an acronym for *quality of life in rectal cancer* and is a cohort study of patients with newly diagnosed rectal cancer. Invited to participate in the study were all patients with a biopsy confirming adenocarcinoma 15 cm from the anal verge. Neither tumour stage nor intended treatment constituted an exclusion criterion; all patients were invited. However, being of at least 18 years and an ability to read/understand Danish or Swedish were prerequisites for inclusion in the study. Data were collected from questionnaires and the quality registries for rectal cancer in Denmark[3] and Sweden[4]. The questionnaires were sent with mail at diagnosis, before start of treatment, as well as 12, 24 and 60 months later. The questionnaires were accompanied with a freepost envelope.

Figure 2. Illustration of the longitudinal study design of the QoLiRECT study.

3.1.1 The research question

The application to the ethical review board of Gothenburg was approved in 2011. At that point of time, quality of life in patients with rectal cancer had been studied to some extent, but the effects on quality of life of different surgical techniques were not fully known. Besides clinical factors, such as treatment methods, studies by the research group on psychosocial factors such as negative intrusive thoughts [56] were known to affect quality of life. In addition, many studies were cross-sectional and therefore lacked data on the development of PROM before, during and after treatment [57, 58].

Those gaps of knowledge in this research field rendered the present study design: a repeated measures design with the first measurement before start of treatment and consecutive measurements at pre-decided intervals over 5 years. The timeframe of the study correlates to the clinical pathway of the patient undergoing treatment for rectal cancer, when the patients are in close contact with the healthcare. To explore the factors important for the patient's quality of life generates knowledge, possibly to be used for improving the treatment of rectal cancer.

3.1.2 The development of the PROMs used in the study

The study-specific questionnaire was developed according to a clinimetric method adopted from the epidemiologic research field [59, 60]. The method has previously been used in studies of patients surviving cancers located in the pelvic cavity [61-64], where symptom documentation can be used as basis for therapy modification. The development consists of several steps, in brief:

1. A qualitative prestudy

   Data for the abdominoperineal extralevator resection (APER) study were collected by four semi-structured interviews with patients with rectal cancer [65] [66, 67]. These specifically developed questions for patients with rectal cancer were reused in the QoLiRECT questionnaires. However, for each of the questionnaires used in the QoLiRECT study at diagnosis and follow-ups at 12 and 60 months, new interviews were conducted and the process repeated.

2. Qualitative sorting

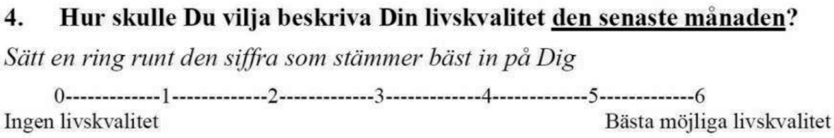
   The interviews were sorted qualitatively by verbatim transcription of the recorded interviews, dividing the transcripts into quotations, and then grouping of quotations into categories until reaching saturation (e.g. no new categories were generated) [65].

3. Creating the questions and the questionnaire

   Based on the categories and subcategories found, questions were created. Each topic (e.g. a specific symptom) was investigated by a separate question followed by questions on occurrence, intensity and duration.

Separate questionnaires used for measuring alcohol consumption (the AUDIT scale [68]), orientation to life (the Sense of Coherence scale [69]) and health-related quality of life (the EQ-5D-3L [70]), were also included. For measuring physical activity, the Saltin-Grimby Physical Activity Level Scale was used [71]. Questions on present well-being were placed at the first pages, since questions that raise emotions might affect the answers concerning present health [72].

The questionnaire distributed as baseline was translated with forward/backward translation [73]. Bilingual people currently living in Denmark or Sweden, with the same mother tongue as the targeted population, were recruited for the translation of the questionnaire.



4. Hur skulle Du vilja beskriva Din livskvalitet den senaste månaden?

Sätt en ring runt den siffra som stämmer bäst in på Dig

0------------1------------2------------3------------4------------5------------6

Ingen livskvalitet — Bästa möjliga livskvalitet

Figure 3. Cutting from the questionnaire used in the QoLiRECT study. The question on quality of life used as primary outcome in paper I and III.

4. Validation of the questionnaire

   To ensure that the questionnaire was easily readable and the questions comprehensible, a small number of Swedish and Danish patients completed the questionnaire with a research nurse present. External experts, such as other researchers and nurses at the surgical outpatient clinic, were asked to review the questionnaire to confirm that important issues for the research questions were covered.

5. Modifying the questions and questionnaire

   The questions and questionnaire were edited according to the comments from the face-to-face validation and the expert group.

3.1.3 Statistical methods and the statistical workup

In quantitative research, the statistical methods depend on the specific scientific question as well as the characteristics of the data, the type of variables and assumptions of the distributional properties of data [74]. In papers I and III, the primary outcome variable was generic quality of life designed as a 7-step Likert-scale, anchored by “worst possible” to “best possible” (Figure 2). The outcome variable was dichotomized and binomial distribution assumed. In paper III, the aim was to investigate risk factors for low quality of life 24 months after diagnosis. To be able to do that, a mapping of all a priori assumptions regarding causal relationships was performed by DAG (directed acyclic graphs) illustrated in Figure 5. In DAGs, each point represents a variable, and directed causal pathways are illustrated by arrows [75]. Thus, the DAG provides qualitative information about the conditional relationships of the variables displayed and illustrates potential sources of confounding [76].

In studies I and III, the outcome variables were dichotomized. The scale was originally ordinal with 7 options, and the cut-off on the scale was between 4 and 5, forming two groups. The rationale for this was that reported quality of life on the far-end of the scale is considered clinically relevant [77]. Some arguments against the use of dichotmization are that the method risks loss of individual differences and potential loss of power[78].

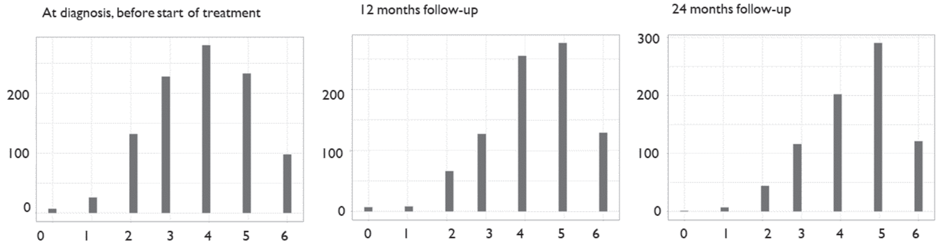


Figure 4. Histograms of the distribution of answers on the 7-step Likert scale on quality of life. Answering alternatives are display on the x-axis and number of patients on the y-axis.

3.1.2.1 *Inherent limitations of the statistical model for the risk factor analysis in paper III*

The statistical model used in paper III was a regression model with quality of life as primary outcome. However, it did not completely fulfill the characteristics of a prognostic model since five of the 17 included covarites were registered 24 months after inclusion in the study. Nevertheless, the model was developed for prediction of the outcome of future patients.

One known limitation of the regression model with binary outcome data is that it provides probabilities for groups of patients and not for the individual patient. Therefore, the results from paper III gives at hand that the probability of high quality of life 24 months after diagnosis, were between 0.69 and 0.72 for women. Thus, although we have a validated model for prediction of probabilities on a group level, the ability to provide a prognosis for the individual patient is limited [79].

3.1.2.2 *Variable selection for multivariate linear models*

Subject-specific background knowledge is important for guiding variable selection. Indeed, it can be argued that to some extent, the variable selection is planned already at the designing of the study. The study design will generate the variables that later will be available for analysis. As to variable selection among the ones available, the main purpose of the statistical model decides the method for variable selection [80].

In paper I, the variables included in the model were selected according to previously published papers on the same study [30]. The variables included as covariates in the study were chosen on background knowledge. In paper III, the variables to be included were selected by subject-specific knowledge from previously published studies, then the variables to be included in the multivariate model were selected by the LASSO method [81].

Figure 5. DAG (directed acyclic graphs) illustrating the statistical model for the risk factor analysis in paper III. Each point represents a variable and each arrow a possible causal pathway.

3.1.2.3 The reference population

In the repeated measures analysis in paper III, data from a reference population were used. Studying a population of patients with rectal cancer and the frequencies of impairment in sexual, urinary, bowel, and stoma functions will reveal how large a portion reports the impairment. However, it is probable that impairments of sexual, urinary and bowel functions are, to some extent, present in a non-rectal cancer population as well. A study of a random sample of the Swedish population born 1924-1983 was carried out [82] to examine quality of life, health and urogenital function. The questionnaire used contained many of the questions used in the QoLiRECT study. The result has been used in several studies as a reference of the prevalence of urogenital function and dysfunction in a non-disease specific population.

3.2 A cohort study on patient education

The INFOM study[83], abbreviated from *information in group consultation*, was designed to assess the patients' experience of the group consultation before start of treatment for colorectal cancer. Naturally, the patients were informed of and asked for their participation in the study at the group consultation. In addition, the patients not attending the group consultation were asked to participate at the outpatient clinic they normally attend before surgery. This created two groups of patients, the ones attending the group consultation and the ones not attending the group consultation.

3.2.1 The research question

During 2017, a new consultation form was introduced at the colorectal unit at the Sahlgrenska University Hospital in Gothenburg. The idea originated from the observation that some information, supposed to be given at the regular visit to the colorectal clinic, was omitted due to shortage of time. In addition, giving patients information about scientific studies at the outpatient clinic, in connection to a visit with large amounts of critical information, was not considered optimum. The group consultation was initiated and organized in a conference room at the hospital. All patients informed of their diagnosis, either colon or rectal cancer, were invited and given the opportunity to bring their family members. The group consultation was held regularly, every Friday.

The session begin with the surgeon presenting some pictures with the aforementioned information. When apposite, information on smoking habits and surgery was presented as well. After the presentation, time was given for the patients and family members to ask questions on all things concerning the cancer and the associated treatment. When there were no more questions, information was given, orally and in writing, about ongoing clinical research projects. The group consultation has been optional and has not changed any of the patients' planned treatment. The patients and their families were deemed appreciative of the event by the participating healthcare staff. However, this was not enough for making it part of the standard healthcare for the patients with colon and rectal cancer.

3.2.2 The PROMs used in the study

All patients received a questionnaire including 50 questions. To map out the demography of the patient cohort, questions on age, sex, education, marital status and occupation were included. To investigate the patient's sources of information about their new diagnosis, several questions on this were included. The patients who attended the group consultation received questions about their experience. The questionnaire was developed according to a well-established method [59, 60]. It has been used in several studies in the study group previously and is described on page 12.

3.3 Ethical considerations

3.2.1 Informed consent in clinical research

Historically, the lack of informed consent has led to several violations of the integrity of the participants in clinical studies in Sweden, as well as in other places. An example of this were the experiments on psychiatric patients at the Beckomberga hospital in Stockholm, performed during 1933 and 1934. Nine male patients were infected with a pathogen today known as *Chlamydia trichomatis.* The experiments were performed with the help of the consultant psychiatrist of the Beckomberga hospital. At the time the experiments were carried out, they were not considered controversial [84]. However, experiments with smallpox vaccine performed as early as in 1887 on children at an orphanage in Stockholm received attention and was criticized for not being ethically correct, both in Sweden and abroad [84].

Modern ethicists agree that informed consent depends on three factors: disclosure of information, capacity for decision making and voluntariness [85]. The Declaration of Helsinki launched in 1964, states that while family members or community leaders may support decision-making, the choice ultimately rests with the individual. In other words, physicians previously adopted a paternalistic mindset towards clinical research participants, but autonomous decision-making is now accepted [85].

Even though research regulations and guidelines have developed during the past decades, challenges remain. Documentation of informed consent has traditionally relied on patient information leaflets and consent forms. However, there are reports that these texts are becoming longer and more complex. Participants most at risk of knowledge deficits are older, sicker patients, those with a lower education and those living in a low-income country [85].

The information leaflet and written consent form of the INFOM study follow the present recommendations from the Swedish Ethical Review Authority and are found in Appendix I. Patients not able to speak Swedish or Danish were not included in neither the QoLiRECT nor the INFOM study.

4. Summary of Results

4.1 The patients in the longitudinal cohort study

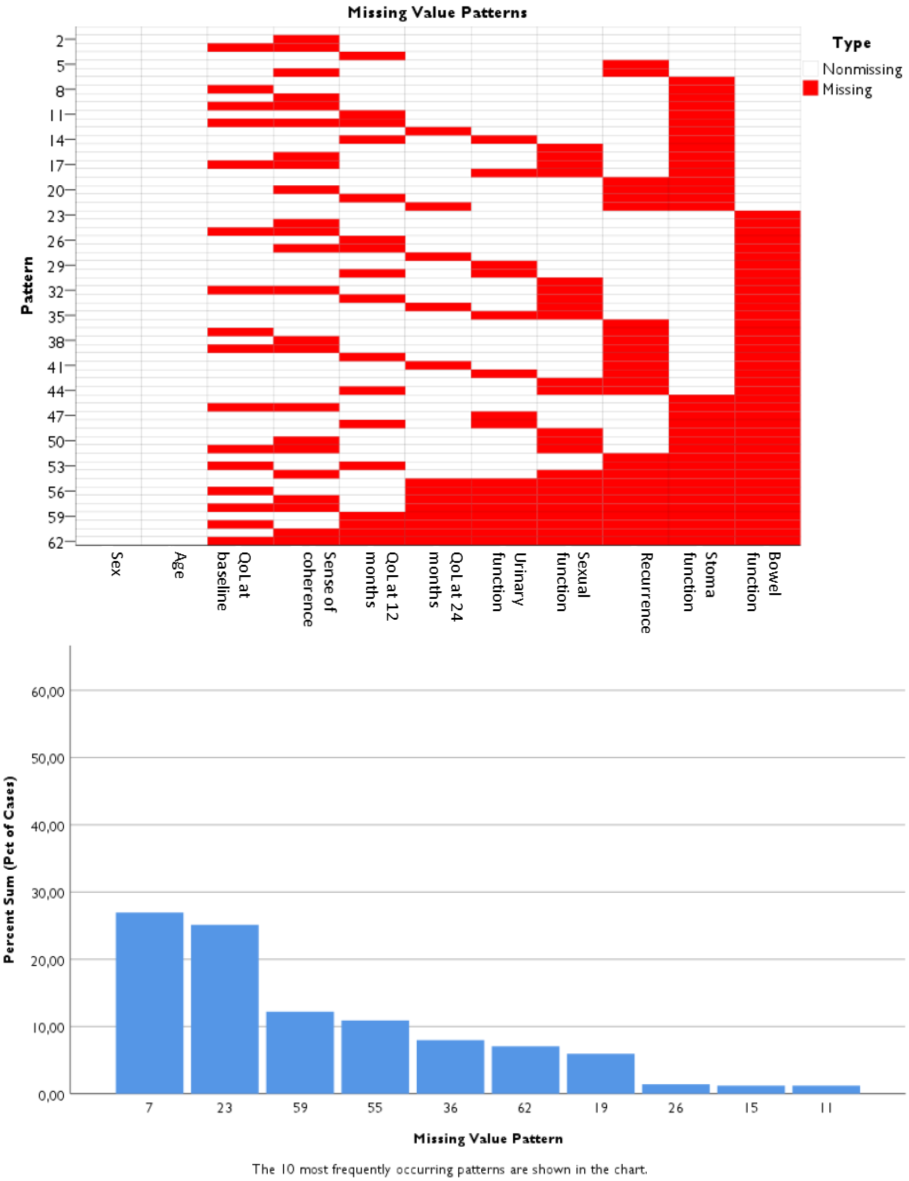
4.1.1 Treatment methods for rectal cancer in the Danish and Swedish rectal cancer registries

The inclusion of patients in the QoLiRECT studies began in 2012 and the inclusion ended in 2015. The total number of included patients was 1248. In 2014, 1674 patients were registered in the Danish rectal cancer registry [86] and 2063 patients were registered in the Swedish equivalent [87].

In 2014, 84% (1399/1674) of the patients in the Danish rectal cancer registry underwent surgery. In the Swedish registry, the corresponding figure was 72% (1481/2063). In total, 48% (665/1399) of the Danish patients underwent anterior resection, whereas 30% (415/1399) underwent extra-levator abdominoperineal resection (ELAPE), intersphicteric or another form of abdominoperineal resection (APE). In Sweden from 2007-2012, 36% underwent anterior resection and 50% underwent abdominoperineal resection (APE) [6]. In the QoLiRECT cohort, 49% (502/1029) underwent anterior resection whereas 32% (331/1029) underwent abdominoperineal resection (APE) [38].

According to the Danish registry, 67.9% (817/1204) of patients that underwent surgery in 2014 were operated through laparoscopic access. The same year, about 24% of the rectal resections for cancer in Sweden were through laparoscopic access, according to the Swedish rectal cancer registry [87]. Of the patents in the QoLiRECT study cohort who underwent surgery, 52% (491/952) were operated through laparoscopic access [38].

A comparison between the patients included in the QoLiRECT study, and the ones who were not, has been made previously using available data from the registries. In brief, 2242 patients at the including surgical clinics were missed and no clinically important differences between included and non-included patients were found regarding sex, age or tumour height. However, the patients not included tended to have a higher ASA grade, as a marker for more advanced comorbidity, and have more advanced tumour stage [30].



The 10 most frequently occurring patterns are shown in the chart.

Figure 6. Patterns of missing values. The 11 variables displayed are the ones included in the risk factor analysis in paper III. In addition, the quality of life at baseline and the follow-ups at 12 and 24 months.

4.1.2 Of the 1248 patient included, 788 were analysed in the risk factor analysis 24 months after diagnosis

For research with PROM outcomes, the missing data may be informative and ignoring the patterns of missing, may bias the results [88, 89]. Missing data is classified as missing completely at random (MCAR), missing at random (MAR) or missing not at random (MNAR).

Identifying the mechanism of missing data helps to apply the most appropriate analysis method [90]. In the context of quality of life as the outcome variable, MCAR occurs if the missingness is unrelated to the quality of life status of the respondent. MNAR describes missingness that is related to unobserved quality of life; an example applicable to this study would be missing values arising because severely ill patients felt too weak to complete questionnaires. The patients who at inclusion were planned for palliative intention of treatment were omitted in the analysis of the 24 months follow-up since MNAR in that subgroup was assumed.

The results from the analysis of missing data (Figure 5) revealed no pattern of missing in relation to the assessments of quality of life at baseline and the 12 and 24 months follow-ups. Thus, the missing data can be assumed to be MAR or MCAR. When Little's test of MCAR [90] was performed (p=0.08), this gave additional support to the conclusions.

Table 2. Summary of the main outcomes and the main results of the papers included in the thesis

Study	Data source	Patient characteristics	Primary outcome	Time-point of data collection	Principal statistical method	Primary results	Response rate
I	the QoLiRECT study	Patients with rectal cancer, irrespective of planned treatment	Quality of life	Baseline*	Binary logistic regression	Unadjusted analysis found that duration of symptoms >4 months and long waiting time to diagnosis was correlated to low quality of life. However, these results did not remain in the adjusted analysis	1054/1248 (84%)
II	the QoLiRECT study	Patients with rectal cancer, irrespective of planned treatment	Experience of communication at the surgical out-patient clinic	At baseline* and the 12 months follow-up	Descriptive	99% of the patients reported good communication with the physician at the out-patient clinic at baseline*. However, only 32% and 24%, respectively, stated that they discussed possible effects of the treatment on the urinary function and sex function.	• Baseline: 1054/1248 (84%) • 12 mo: 920/1248 (74%)
III	the QoLiRECT study and the Swedish general population study	Patients with rectal cancer, planned for curative treatment. A random selection of Swedes	Repeated measures of quality of life, compared to a reference population	At baseline* and at the12 and 24 months follow-ups	Generalized linear mixed effects model with binomial distribution	The patients with rectal cancer assessed their quality of life as poorer than the reference population at baseline*. However, at the 12 and 24 months follow-ups, the quality of life had recovered	QoLiRECT • Baseline: 1012/1110 (91%) • 12 mo: 878/1110 (79%) • 24 mo: 788/1110 (71%) General population study • 1078/2094 (51%)
IV	the INFOM study	Patients with colonic or rectal cancer, planned for surgical treatment	Experince of the group consultation	At baseline*	Descriptive	95% of the patients attending the group consultation would recommend it to others and 72% stated it was a postive experience to meet others in the same situation	109/124 (88%)

*At diagnosis, before start of treatment

5. Discussion

This thesis evaluates the results of a prospective cohort study of patients with rectal cancer with quality of life as its primary outcome as well as the results of a study on patient's experience of group consultation as a patient education method before colonic or rectal resection for cancer. The different approaches to the quality of life of patients with rectal cancer presented in the four studies included in this thesis, constitute the basis for the following discussion.

5.1 Aspects on quality of life

Delay of diagnosis and delay of start of treatment did not have an impact on quality of life before start of treatment for rectal cancer, when sense of coherence, depression and negative intrusive thoughts were taken into consideration. Our initial hypothesis was that low quality of life could partly be explained by patient's delay to first contact with healthcare or doctor's delay of diagnosis. However, the results do not support this, but rather suggest that quality of life before start of rectal cancer treatment is influenced by stress and depression, and is dependent on the patient's coping capability. Still, there may of course be many reasons to develop standardized care pathways, not least to improve survival [91, 92].

Based on the longitudinal development of quality of life, it can be considered reasonable to tell patients with newly diagnosed rectal cancer planned for treatment with curative intent, that their quality of life probably will be recovered to the same as the average person's 12 months later. Yet, this statement is of course only valid on group level. Previously, there have been attempts to determin prognostic models for quality of life after treatment for rectal cancer [32]. Consequently, prognostic models only take baseline factors into consideration, and factors occurring later such as stoma problems or recurrence of disease cannot be included in such a study design.

Although on group level, the quality of life of patients treated with curative intent for rectal cancer is recovered after 12 months, there are consistent effects of the treatment on the urinary tract, the bowel and the stoma function that hamper quality of life for the individual. However, it seems it is not the actual level of function that impact quality of life, but the patient's perceived bother of the urinary, bowel and stoma function, which is supported in other studies [40]. A study on women treated for gynaecological, rectal or anal cancer confirmed that patients reporting daily urinary or faecal leakage practiced less physical activity than others [93]. That means a gap for interventions opens; by improving the patient's perceived poor function, we could possibly ameliorate their quality of life through means such as increased ability to perform everyday activities and increased physical activity. Ability to perform activities of daily life and physical activity level is often included in multi-item instruments used for assessment of quality of life [94].

5.2 Aspects on communication and patient education

About 70% of patients with rectal cancer reported having discussed the planned treatment's possible effects on the bowel function with their surgeon, whereas only every fourth patient reported having discussed the possible impact on the urinary function and sex function. Interestingly, all patients with rectal cancer report good communication with their surgeon and the nurse at the out-patient clinic.

Preoperative group consultation for patients planned for surgery for colorectal cancer, increases the patients' sense of control and active participation in their own treatment. Previously, it has been shown that preoperative stoma education was more effective than the traditional postoperative one, as it reduced the length of hospital stay [49]. Intrusive thoughts were found to have an impact on quality of life before start of treatment for rectal cancer. Interestingly, intrusive thoughts were found to be a mediator for depression in a randomized trial on patients with breast cancer, where intrusive thoughts were reduced by an education intervention. The educational intervention resulted in a long-lasting improvement in depressive symptoms and physical functioning [95].

6. Conclusion

The aim of the QoLiRECT study was to investigate the quality of life in an unselected population of patients with rectal cancer. Of the 1085 patients that were included, 73 patients were planned for treatment with non-curative intent. The relatively small number of recruited patients from this subpopulation indicates that missing data were not at random, thus rendering comparative analyses difficult between patients planned for curative and non-curative treatment.

Previous studies of patients treated for rectal cancer with different surgical techniques have not reported any difference between groups. The results of the QoLiRECT study further highlights the importance of psychosocial aspects such as sense of coherence, intrusive thoughts as a sign of stress and reported bother of functional outcomes, as factors determining the quality of life of rectal cancer survivors.

Merely one fourth of patients reported that they discussed the planned treatments possible effect on the urinary and sexual function. This calls for improvement, the group consultation constituting a feasible method for supplementation of preoperative information.

7. Future Perspectives

7.1 As surgeons, what use do we have of PROMs?

In the 20th century, survival and local recurrence rates were the primary interest in rectal cancer research. However, in the recent decades, as the survival rates have improved, studying self-assess outcomes of patients with rectal cancer has gained increasing attention. As new knowledge about the patients with rectal cancer and their quality of life are discovered, we learn that quality of life predicts survival in patients with colorectal cancer [96-98]. Also, psychosocial factors such as anxiety and depression has been associated with wound complications and longer hospital stay [99].

In recent years, results from studies on psychological preparation before surgery indicate that factors such as postoperative pain and length of stay can be possible to influence by such interventions [100]. More specifically, pre-operative anxiety and depression have been found to predict short-term operative outcomes, length of stay and long-term pain [101]. Further, depressive symptoms have been found to negatively impact wound healing [102]. On the other hand, self-efficacy, a positive outlook and patient-perceived control have been associated with earlier functional recovery [101].

In a randomized controlled trial on patients planned for resection for colorectal cancer, an intervention was carried out including exercise, nutrition and coping strategies to reduce anxiety, but no effect on any of the subscales of SF-36 or HADS were seen. However, the trial was not designed with enough power to detect a difference in these outcomes, the primary outcome was functional walking capacity [103].

As of today, there is not enough evidence to suggest recommendations for practice on psychological preparation before surgery. Further studies are needed to determine which specific intervention types might be used to improve which post-surgical outcome. Ongoing studies will reveal if surgery for colon cancer can be safely delayed, if so enabling prehabilitation such as treatment with an antidepressant drug before surgery.

7.2 Which PROM to use in national quality registries of rectal cancer, then?

In a review of the most common available instruments of generic quality of life instruments, the authors suggested that there was no superior performing instrument [16]. They recommended that the decision of which one to use is dependent on the purpose of the measurement.

When studying the quality of life of patients with rectal cancer using generic instruments, there could be a risk of not being able to detect differences between groups. To increase the possibility of detecting discrepancies, the use of disease-specific quality of life instruments has been suggested [13].

In a literature review on quality of life instruments used in randomized controlled trials of chemotherapy treatment of unresectable metastatic colorectal cancer, the number of adverse events did not have an impact on quality of life [104]. The authors concluded that generic quality of life instruments are insufficient for detecting changes in quality of life in patients with metastatic colorectal cancer. It is probable that generic quality of life instruments in patients with colorectal cancer, do not provide information of sufficient clinical relevance.

Acknowledgement

This thesis is the result of much effort and dedication, written during an autumn characterized by the restrictions of daily life caused by the coronavirus pandemic. Even though at the moment, the coronavirus pandemic seems somewhat never-ending, one day it will be over because simply, this too shall pass. And when it does, the great challenge for the healthcare, and the patients, will once again be cancer. In particular, for the patients with colorectal cancer the challenge is to live their life to the full, despite the cancer. This thesis is a small contribution, but hopefully a step in the right direction. I would like to thank

Eva Angenete. For giving me the opportunity to work with the QoLiRECT study and for challenging me to keep on improving.

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The author
Helsingborg, the 20th of January 2021

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Appendix

Scandinavian Surgical Outcomes Research Group
www.ssorg.net

Patientinformation för studien om Informationsmottagningen

Det finns inom sjukvården väl etablerade rutiner för utredning och behandling av tumör i tjocktarm och ändtarm. Det finns inte lika ingående kunskap om hur de patienter som fått besked om sjukdomen upplever att få information om behandlingen på en gruppmottagning. Med gruppmottagning menas ett mottagningsbesök i grupp med andra patienter och anhöriga där information ges och det finns möjlighet att diskutera och ställa frågor till läkare och sjuksköterska. Det finns rapporter som talar för att denna form av mottagning kan vara betydelsefull och att den kan utgöra ett stöd för patienterna.

Bakgrund och syfte

Syftet med den här studien är att kartlägga hur patienter som fått besked om att de har tumör i tjocktarm eller ändtarms upplever att delta i ett mottagningsbesök i grupp med andra patienter och närstående.

Patienter som inte deltar i Informationsmottagningen ingår för att kartlägga hur de upplever den information de fått om sin sjukdom och den planerade behandlingen.

Förfrågan om deltagande

Om du går på Informationsmottagningen kommer du att tillfrågas om att delta i studien där. Om du inte går på Informationsmottagingen kommer du att tillfrågas om att delta i studien vid ditt besök på den Preoperativa mottagningen. Deltagandet är helt frivilligt.

VÄSTRA
GÖTALANDSREGIONEN
SAHLGRENSKA UNIVERSITETSSJUKHUSET

GÖTEBORGS
UNIVERSITET

Hur går studien till?

Studien innebär att du besvarar ett frågeformulär. Förutom det kommer vi att samla in vissa uppgifter om sjukdomen och behandlingen från det nationella kvalitetsregistret för cancer i tjock- och ändtarm och även från din sjukhusjournal, för att kunna sätta sådana kliniska uppgifter i relation till din upplevelse.

Om du accepterar att delta i studien kommer du få ett frågeformulär. Det tar 20-30 minuter att fylla i frågorna som framför allt handlar om den information du fått om din sjukdom och den planerade behandlingen. Vår avsikt är att du ska besvara frågeformuläret i hemmet och sända tillbaka det med det frankerade kuvert som medföljer.

Vilka är riskerna?

Ingen behandling eller uppföljning för din sjukdom ändras på grund av att du deltar i studien, det vill säga vården blir densamma oavsett om du deltar eller inte.

Det kan vara så att du kan uppleva vissa frågor som alltför närgångna. Du kan avstå från att svara på enskilda frågor. Du kan själv avbryta ditt deltagande när som helst och du behöver inte motivera ett sådant beslut. Om du beslutar dig för att delta kommer vissa uppgifter om din sjukdom och behandling att samlas in från det nationella patientregistret och vid behov enstaka uppgifter ur din journal.

Finns det några fördelar?

All behandling kommer att ske på samma sätt oavsett om du deltar i studien eller inte och det kommer på så sätt inte innebära några fördelar för dig att delta.

Hantering av data och sekretess

De uppgifter som insamlas för studien, liksom dina svar på frågeformulären, kommer att lagras i ett dataregister där din identitet är ersatt med ett studienummer. Vid databearbetning av resultat kan en enskild individ inte identifieras. Dina svar och dina resultat kommer att behandlas så att inte obehöriga kan ta del av dem. Personuppgifter kodas och kodnyckeln förvaras åtskild från all data. Ansvarig för dina personuppgifter är styrelsen för Sahlgrenska Universitetssjukhuset.

Enligt EU:s dataskyddsförordning har du rätt att kostnadsfritt få ta del av de uppgifter om dig som hanteras i studien, och vid behov få eventuella fel rättade. Du kan också begära att uppgifter om dig raderas samt att behandlingen av dina personuppgifter begränsas. Om du vill ta del av uppgifterna ska du kontakta ansvarig forskare professor Eva Haglind på tel. 031-343 41 49 eller via e-post[1]. Dataskyddsombud är Susan Lindahl, hon nås på tel. 031-343 27 15 eller via e-post[2]. Om du är missnöjd med hur dina personuppgifter behandlas har du rätt att ange klagomål till Datainspektionen, som är tillsynsmyndighet.

Hur får jag information om studiens resultat?

Om du önskar information om studiens resultat kan du kontakta ansvariga forskare. Det kommer dock att dröja ett par år innan resultaten analyserats och publicerats i vetenskapliga tidskrifter.

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[1] eva.haglind@vgregion.se

[2] sahlgrenska.universitetssjukhuset.dso@vgregion.se

Försäkring och ersättning

Försäkring gäller enligt rutinsjukvård. Ingen ersättning ges till deltagande patienter.

Frivillighet

Om du beslutar dig för att vara med i studien står det dig helt fritt att ändra detta beslut när som helst och du behöver inte förklara varför. Du kan då också begära att alla uppgifter tas bort ur våra register.

Ansvariga forskare för studien

Eva Haglind	Sofie Walming
Överläkare, professor	Läkare, doktorand
Tel: 031–343 41 90	

Ansvarig forskningssjuksköterska

Anette Wedin
Sjuksköterska
Tel: 031–343 63 80 eller 031-343 64 62

Samtliga vid
Kirurgi, Område 2
Sahlgrenska Universitetssjukhuset/Östra

Samtyckesformulär för patienter till studien

Din upplevelse av Informationsmottagningen

En undersökning av patienters upplevelse av information given i grupp innan behandling för cancer i tjocktarmen och ändtarmen

Härmed intygar jag att jag, efter att ha fått information om vad studien innebär, har beslutat mig för att delta.

Informerat av ____

Datum: ____

Ort ____

Underskrift ____

Namnförtydligande ____

Personnummer____