

The Development of a Patient Decision Aid for Patients with Rectal Cancer

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Abstract

Context: Rectal cancer treatment decisions involve tradeoffs between outcomes like living with a permanent stoma versus long-term bowel dysfunction. The needs of rectal cancer patients and practitioners to partake in shared decision making are unknown. For such a complex decision, a patient decision aid that prepares patients to make informed, values-based decisions is warranted.

Methods: 1) A systematic review, to characterize the prevalence of long-term dysfunction 2) Needs assessments, conducted with rectal cancer patients and practitioners, 3) Development of a decision aid.

Results: 1) Significant variability exists in reporting rectal cancer outcomes. The rate of bowel dysfunction is high. 2) Rectal cancer patients recall little of the outcomes discussed preoperatively. They do not perceive having any surgical options. Practitioners are inconsistently engaging patients in shared decision-making. 3) A patient decision aid was developed that a) incorporated systematic review results and; b) addressed the needs, barriers and facilitators raised.

Conclusions: Shared decision-making in rectal cancer surgery is limited. A decision aid to improve patient decision-making was developed.

Acknowledgements

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Chapter One

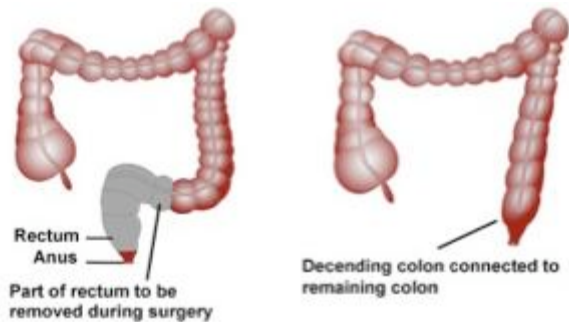
Thesis Introduction

Colorectal cancer is the third most common solid malignancy and rectal cancer comprises roughly a third of these cases. One in 15 Canadians is expected to develop colorectal cancer during his/her lifetime. (Canadian Cancer Society, 2008) Despite steady increases in incidence rates, deaths from colorectal cancer continue to decline significantly. Patients are going on to live with the sequelae of their treatments bringing survivorship issues to the forefront of research. For rectal cancer, these improvements in survival are secondary to the ongoing successes of neoadjuvant (before surgery) chemo- and radiation therapy, along with innovations in surgical stapling devices, and the development of specialized colorectal centers. (Swedish Rectal Cancer Trial, 1997; Folkesson et al., 2005; Kapiteijn et al., 2001) Following rectal cancer resection the mainstays of rectal reconstruction are the anterior resection (AR) and the abdominoperineal resection (APR). In the AR, once the diseased portion of the rectum is removed the two free ends of the bowel are reattached (anastomosis). (Figure 1a) In a percentage of patients a temporary stoma is created to divert the fecal stream from this new connection, allowing it to heal. A stoma is an opening of the bowel to the abdominal wall, where fecal contents are eliminated into a bag. This temporary stoma is then reversed following the patient's recovery, usually 4-6 months postoperatively. In the APR the bowel ends are not reattached and the entire rectum and perineum are removed. The free end of the bowel is brought out to the skin as a permanent stoma. (Figure 1b)

Figure 1. Types of rectal resection a) anterior resection b) abdominoperineal resection

(Figures accessed from: <http://www.csmc.edu/15017.html> November 29, 2010)

a) Anterior resection



b) Abdominoperineal resection



With continued innovation in surgical technique and neoadjuvant therapy, surgeons are able to push the limits of the AR, reattaching the colon to smaller remnants of rectum, with ultralow and even coloanal anastomoses. Often touted as a surgical quality indicator, colorectal surgeons are challenged to minimize the rate of APR, but is this justified, and at what cost? Following an AR up to 60% of patients suffer from some element of the AR syndrome. This syndrome, consists of erratic

defecatory function, including incontinence, which has significant effects on quality of life. (Peeters et al., 2005; Dahlberg, Glimelius, Graf, Pahlman, 1998; Marijnen et al., 2005, Ortiz & Armendariz, 1996) There is a large body of literature investigating rectal cancer surgery outcomes and prognostic factors. However, there is wide variability in the reporting of these risk factors and outcomes. Despite the availability of validated assessment tools, consistency and transparency in reporting are absent making it difficult for clinicians to draw valid conclusions. This disparate body of research remains to be aggregated and summarized to guide future research in rectal cancer surgery outcomes.

With the functional morbidity associated with the AR it is not surprising that a recent Cochrane review was unable to demonstrate a better quality of life among rectal cancer patients treated with an AR as compared to those treated with an APR. (Pachler & Wille-Jorgensen, 2005) Outcomes such as fecal incontinence, urgency and the daily need for pads pose significant costs to patients both socially and financially. (Vironen, Kairaluowma, Aalto, Kellokumpu, 2006) With equivalent survival and significant quality of life trade-offs, the type of surgery for rectal cancer resection is a values-based decision. Traditionally, the choice of rectal resection was based on multiple factors: 1) patient specific – gender, preoperative sphincter function, 2) tumor specific – stage, potential distal resection margin, and 3) surgeon preference. (Cornish et al., 2007) Patients have historically played a passive role in the decision making process. However, it is clear that patients desire and deserve to be more involved in their health care decisions. Patients want to be better informed, yet medical literature is often inaccessible, difficult to understand, and at times

conflicting. Patient decision aids have been proven to improve patient knowledge, lower decisional conflict related to feeling uninformed and/or unclear about personal values and reduce the proportion of people who were passive in decision making and/or remained undecided post-intervention. (O'Connor et al., 2009) Furthermore, exposure to a decision aid with probabilities resulted in a higher proportion of people with accurate risk perceptions and more so, when the probabilities were presented quantitatively. Decision aids have been shown to reduce the uptake of more aggressive surgical treatments by 24%. (O'Connor et al., 2009) Since there is currently no decision aid to support rectal cancer surgery decision-making, one is needed to facilitate informed, values-based decision making on whether or not to proceed with a permanent colostomy or anastomosis following rectal cancer resection.

Thesis Objectives

1. Conduct a systematic review of the literature to accurately characterize the prevalence of long-term (≥ 1 year) gastrointestinal functional outcomes, and prognostic factors for those outcomes, following anterior resection for rectal cancer in adults.
2. Describe the decisional needs of patients and practitioners when considering the decision of rectal resection for rectal cancer.
3. Develop a patient decision aid based on: a) patients' and practitioners' needs; b) current evidence; and c) international standards for patient decision aid development.

Chapter Two: Systematic Review

The Long-Term Gastrointestinal Functional Outcomes Following Curative Anterior Resection in Adults with Rectal Cancer: A Systematic Review and Meta-Analysis

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Introduction

Over the past few decades rectal cancer patients have seen significant improvements in survival. Patients are going on to live with the sequelae of their treatments bringing survivorship issues to the forefront of research. With the continued successes of neoadjuvant chemo- and radiation therapy, along with innovations in surgical stapling devices, colorectal surgeons are able to push the limits of the anterior resection (AR), with ultralow and even coloanal anastomoses. However, following an AR up to 60% of patients suffer from some element of the AR syndrome, consisting of erratic defecatory patterns including incontinence, with significant effects on quality of life.(Peeters, 2005; Dahlberg, 1998; Marijnen et al., 2005; Ortiz, 1996)

Many factors contribute to a patient's ultimate functional outcome, but none have been studied more than the effect of radiation. Recently, researchers have begun to focus on the prevalence of late intestinal toxicity following the two most common radiation regimens – preoperative short-course (radiation dose of 25 Gray (Gy), 5Gy/fraction) and preoperative long-course (radiation dose of 46-50 Gy, 1.8-2Gy/fraction) radiation. Clearly controversy exists regarding the best option and which patients will benefit, with European guidelines (Glimelius & Oliveira, 2009) recommending short course therapy and the majority of North American guidelines (NCCN guidelines; CancerCare Ontario; BC CancerCare) recommending long-course therapy, and with different stage indications. Many institutions in North America offer both treatment options often selecting patients for a particular radiation

regimen based on clinical experience and judgment but not evidence. Radiation regimen as a risk factor for late bowel dysfunction needs to be clarified.

Presently, there is a large body of literature investigating rectal cancer surgery outcomes and prognostic factors. However, there is wide variability in the reporting of these risk factors and outcomes. Despite the availability of validated assessment tools, consistency and transparency in reporting are absent, confounding clinician assessments of the validity and accuracy of the reported results.

Objectives

The objectives of this review are: 1) to qualitatively analyze the long-term functional outcomes and assessment tools used in evaluating rectal cancer patients following AR, 2) to aggregate this large body of literature and quantify the prevalence of late bowel dysfunction and 3) to identify risk factors for long-term incontinence.

Methods

Protocol

Study inclusion criteria, variables for data abstraction and methods of analysis were specified *a priori* in the review protocol. (Protocol available upon request from corresponding author.) The PRISMA checklist was used to help guide this report (Moher et al., 2009).

Eligibility Criteria

Reports of randomized trials, cohort studies, cross-sectional designs, and case series were included. Inclusion criteria were: English language; adults with rectal cancer who underwent curative AR - excluding patients with metastatic or recurrent disease from the functional assessment; reporting of at least one bowel function outcome separate from any generic quality of life questionnaire; and a minimum of one year follow up.

Information Sources and Search

An electronic literature search of Medline (OVID 1950 to June 2009, week 4), EMBASE (Ovid 1980 to June 2009, week 27) and CINAHL (1981 to June 2009) was conducted. (See appendix 1 for search strategies) The developed search strategies were peer-reviewed by a senior medical librarian who specializes in systematic reviews and search strategies. Two reviewers (AS, SL) independently reviewed all records by title and abstract followed by full-text articles for those meeting the screening criteria.

Data Collection Process and Items

Two reviewers (AS, SL) independently abstracted data on study details (authors, year of publication, journal, funding sources, location), patient characteristics (age, gender, length of follow up), function assessment tool used (validated, name of tool), outcomes (incontinence, urgency, frequency, nocturnal bowel movements, ability to differentiate gas from stool, clustering, incomplete

evacuation, pad usage) and possible risk factors for incontinence (radiation, previous vaginal deliveries, history of anorectal surgery, anastomotic height and anastomosis type). The primary outcome of interest was incontinence to solid stool, liquid stool, or gas. Attempts were made to contact authors of all relevant studies to provide missing data.

Risk of Bias in Individual Studies

A single reviewer assessed the risk of bias in the included studies. The Cochrane Risk of Bias tool (RoB) (Higgins & Altman, 2008) was used for randomized trials and the Downs-Black quality assessment tool (Downs & Black, 1998) for non-randomized studies. For non-randomized studies a score $\geq 17/30$ was considered higher quality. The RoB tool comprises six domains: sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and “other sources of bias.” The tool was intended to assess the validity of results based on the features associated with the design and conduct of the study, rather than reporting. Table 1 identifies common sources of bias and the relevant domains of the RoB tool that assess each bias. (Higgins, 2008)

Table 1. A classification scheme for bias (based on Table 8.4.1 in The Cochrane Handbook for Systematic Reviews of Interventions)

Type of bias	Description	Relevant domains in the Risk of Bias Tool
Selection bias	Systematic differences between baseline characteristics between the groups	Sequence generation Allocation concealment

Performance bias	Systematic differences between groups in the care that is provided, or in exposure to factors other than the interventions of interest	Blinding Other sources of bias
Attrition bias	Systematic differences between groups in withdrawals from a study	Incomplete outcome data Blinding
Detection bias	Systematic differences between groups in how outcomes are determined	Blinding Other sources of data
Reporting bias	Systematic differences between reported and unreported findings	Selective outcome reporting

The Downs – Black “Checklist for Measuring Quality” contains 27 ‘yes’-or-‘no’ questions across five sections. The tool provides both an overall score for study quality and a numeric score out of a possible 30 points. The five sections address: study quality (10 items), external validity (3 items), study bias (7 items), confounding and selection bias (6 items), and power of the study (1 items).

Summary Measures and Synthesis of Results

Few studies presented their original data in a format amenable to meta-analysis. Articles that presented data as a median and range were converted to means according to Hozo et al., 2005. A single weight-adjusted mean or proportion for each variable or outcome was computed for each of the non-randomized studies. For the randomized trials, each arm that met the inclusion criteria was included in the meta-analysis as a separate study. To derive pooled estimates of proportions for the outcomes explored, random effects models were used. Pooling was conducted

using Comprehensive Meta Analysis Version 2.2.046 (NJ, USA). A category of incontinence of any kind was included to capture studies that did not describe the type(s) of incontinence assessed. Furthermore, according to the Consensus Conference on Fecal Incontinence, fecal incontinence includes incontinence of solid, liquid stool and gas as it results from the same physiology and is quite bothersome to patients. (7th International Meeting of Coloproctology, Saint Vincent, Italy, 2002) For studies that provided information regarding the type of incontinence the category with the highest rate of incontinence was included for this analysis. The individual categories were also pooled separately. For studies that included a scale measuring severity or frequency, any complaint other than never or none was included as a positive occurrence of incontinence. Given that this review assessed measures of prevalence, publication bias was not evaluated.

Additional Analyses

To explore the impact of possible prognostic factors on the rate of incontinence, meta-regressions were conducted using logistic normal random effects models weighted by the inverse of the sum of the within trial variances and the residual between trial variances (using PROC NLMIXED) in SAS version 9.1 (SAS Inc, Cary, NC). Variables were identified *a priori* and were selected from those reported in the literature along with expert consultation. The following prognostic factors were considered at the study level: mean age of the patients, gender distribution, mean length of follow up, the proportion of patients who received preoperative radiation (short and long course assessed together and separately),

the proportion of patients who received postoperative radiation, anastomotic height classified as ultralow (<4 cm from the anal verge) and low (≥ 4 cm), the proportion of patients with a straight anastomosis, and study quality. Univariate meta-regressions were computed for each prognostic factor. To generate best-fit lines in meta-regression graphs, an approximate correction was used to convert conditional means from the logistic normal model into marginal mean curves. (Zeger, Liang, Albert, 1988)

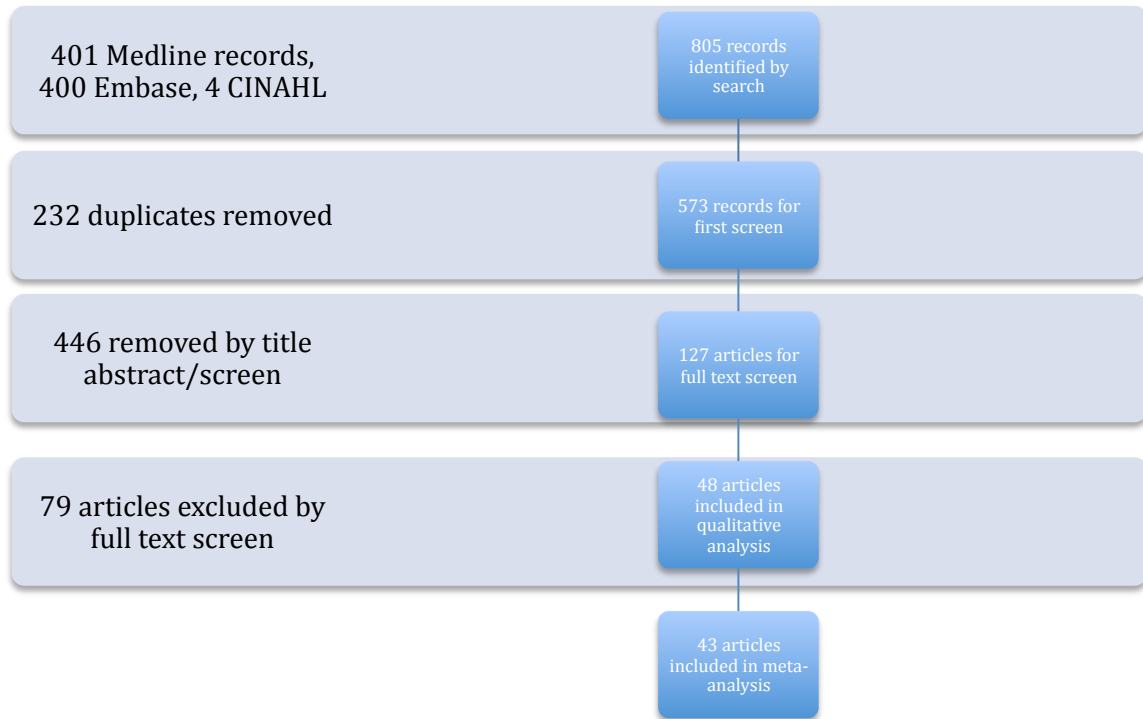
A sensitivity analysis was conducted to determine the effect of surgical time period on the rate of incontinence. Based on the popularization of the total mesorectal excision in 1993, studies with the majority of the study time period prior to 1993 were analyzed separately from those with the majority of the study time period post 1993.

Results

Study Selection

From screening 805 records, 127 full text articles were retrieved with 48 articles included in the systematic review and 43 in the meta-analysis (Figure 2). All included studies were considered representative of the typical adult patients undergoing curative rectal cancer resection.

Figure 2. PRISMA flow diagram



Study Characteristics and Risk of Bias Assessment

The 48 included studies involved 3349 participants living in 17 countries with a median follow up of 37.0 months (IQR 12.0, 57.2) and surgeries conducted between 1978-2004. Fifty eight percent of patients were male and the mean (SD) age at time of follow up was 63.2 (9.9) years. Study characteristics and quality are summarized in Table 2.

Table 2. Characteristics of included studies, a) RCTs, b) Observational studies

2a)

Source	Primary location	Patient no.	Time period of surgery	Study design	Patient age at time of study mean (range), years	Mean follow up, months	Risk of bias*
Hallbook et al. 1996	Upsaala, Sweden	89	1990-1993	RCT	68.1 (29-86)	12.0	Uncertain
Ho et al. 1996	Singapore City, Singapore	33	1991-1995	RCT	61.2	12.0	High
Ho et al. 2001	Singapore City, Singapore	35	1995-1997	RCT	61.7	24.0	Uncertain
Oya et al. 2002	Saitaman, Japan	39	1995-1998	RCT	61.0 (42-80)	12.0	Uncertain
Machado et al. 2005	Stockholm, Sweden	71	1995-1999	RCT	65.5 (33-87)	24.0	Uncertain
Jiang et al. 2004	Taipei, Taiwan	35	1998-1999	RCT	63.5	23.0	Uncertain
Rink et al. 2007	Leverkusen, Germany	10	1998-2001	RCT	62.5 (45-80)	60.0	High
Laurent et al. 2005	Paris, France	36	1999-2001	RCT	61.4	12.0	Uncertain
Kimura et al. 2006	Yokohama, Japan	23	1999-2001	RCT	58.9	12.0	Uncertain
Fazio et al. 2007	USA, Germany, Australia	297	2000-2004	RCT	60.3	24.0	Low
Ortiz et al. 1995	Pamplona, Spain	30	---	RCT	63.4	12.0	High
Sailer et al. 2002	Wurzburg, Germany	39	---	RCT	65.5	12.0	High

2b)

Source	Primary location	Patient no.	Time period of surgery	Study design	Patient age at time of study mean (range), years	Mean follow up, months	Risk of bias*
Kariv et al. 2008	Cleveland, USA	29	1978-2004	Cohort	54.5	122.8	Low
Lundby et al. 1997	Arhus, Denmark	93	1979-1985	Cross-sectional	75.0 (42-90)	162.3	High
Phillips et al. 2004	Bastingstoke, UK	92	1979-1999	Cohort	82.0 (75-98)	12.0	High
Graf et al. 1996	Upsaala, Sweden	70	1980-1993	Cross-sectional	61.0 (28-81)	65.0	Low
Pollack et al. 2006	Danderyd, Sweden	64	1980-1993	Cross-sectional	73.7	168.0	Low
Dehni et al. 1998	Paris, France	57	1984-1992	Cross-sectional	71.2 (38-93)	74.5	Low
Fegiz et al. 1994	Rome, Italy	44	1985-1992	Cohort	67.0 (16-92)	12.0	High
Nathanson et al. 2003	New York, USA	109	1986-1997	Cohort	60.1 (24-90)	47.5	Low
Dahlberg et al. 1998	Upsaala, Sweden	171	1987-1990	Cross-sectional	70.7 (38-89)	79.5	Low
Killmorgen et al. 1994	Rochester, USA	100	1988-1991	Cross-sectional	65.0 (44-85)	40.8	Low
Chew et al. 1997	New South Wales, Australia	15	1989-1996	Cross-sectional	62.0 (24-88)	37.8	High
Bretagnol et al. 2004	Bordeaux, France	37	1990-2000	Cross-sectional	65.0	12.0	Low
Hida et al. 2007	Osaka, Japan	94	1991-1996	Cohort	61.0 (46-80)	60.0	Low
Sato et al. 2006	Aichi, Japan	43	1991-1999	Cohort	58.1 (38-84)	12.0	High
Matzel et al. 1997	Erlangen, Germany	48	1993-1994	Cross-sectional	63.4 (41-84)	19.1	High
Tsunoda et al. 1999	Tokyo, Japan	22	1993-1996	Cohort	62.5 (49-79)	12.0	Low
Burdeos et al. 2004	Valencia, Spain	37	1993-1998	Cross-sectional	67.5 (48-84)	36.0	High
Ho et al. 2003	Hong Kong, China	87	1993-2000	Cohort	---	24.1	Low
Guren et al. 2005	6 centers, Norway	228	1993-2001	Cross-sectional	72.0	64.0	Low
Araki et al. 1999	Kurume, Japan	45	1994-1997	Cohort	62.3 (34-82)	12.0	High
Takase et al. 2002	Saitama, Japan	16	1994-1999	Cohort	---	12.0	Low
Matzel et al. 2003	Erlangen, Germany	94	1995-1998	Cohort	60.0	24.9	High
Peeters et al. 2005	5 centers, Netherlands	378	1996-2000	Cohort	62.3 (27-86)	61.1	Low
Sato et al. 2007	Aichi, Japan	88	1996-2004	Cohort	59.0 (36-86)	12.9	High
Matsuoka et al. 2005	Tokyo, Japan	42	1998-2003	Cohort	63.0 (34-87)	14.0	High
Pietrzak et al. 2007	Krakow, Poland	58	1999-2002	Cohort	63.0 (35-75)	14.0	Low
Vironen et al. 2006	Jyvaskyla, Finland	53	1999-2003	Cross-sectional	69.4 (41-87)	22.0	Low

Tsang et al. 2006	Hong Kong, China	36	1999-2004	Cohort	65.1 (40-85)	24.0	High
Murata et al. 2005	Vancouver, Canada	34	1999-2004	Cohort	66.2 (50-88)	63.0	High
Bohm et al. 2008	Aachen, Germany	12	2000-2003	Cross-sectional	57.8 (41-69)	35.3	Low
Kishimoto et al. 2007	Kurume, Japan	8	2001	Cohort	62.0 (48-84)	12.0	High
Lewis et al. 1995	Leeds, UK	50	---	Cross-sectional	67.0 (43-86)	12.0	High
Nesbakken et al. 2002	Oslo, Norway	30	---	Cohort	68.0 (45-83)	12.0	Low
Rasmussen et al. 2003	Herlev, Denmark	43	---	Cohort	66.0 (41-79)	12.0	High
Amin et al. 2003	Bastingstoke, UK	92	---	Cohort	67.5 (60-78)	31.2	Low
Montesani et al. 2004	Rome, Italy	93	---	Cross-sectional	62.5 (34-84)	58.3	High

*Cochrane risk of bias tool used for RCTs, Downs-Black tool used for observational studies (score of $\geq 17/31$ considered as low risk of bias)

Two-thirds of studies (n=32) provided enough data to determine the number of patients lost to follow up. On average 6.6% (SD 7.4%) of patients were lost to follow up and 47.9% of studies had less than 10% loss to follow up.

Results of Individual Studies and Synthesis of Results

The vast majority of studies used modified or newly developed questionnaires despite the availability of validated scoring systems to assess bowel function. The most commonly used validated scoring system was the Wexner scale (Jorge & Wexner, 1993) (19%) followed by the Kirwan scale (Kirwan, Turnbull, Fazio, Weakley, 1978) (8%). Four studies used published but non-validated questionnaires and 65% used modified or newly developed questionnaires. In reporting, there were significant inconsistencies in the prognostic factors and outcomes described in the primary studies as well as the definitions used to convey their severity. For example, only one study reported on patient obstetrical history or previous anorectal surgery. (Bohm et al., 2008)

Given the large between-study variability with wide ranging heterogeneity (Figure 3), statistically pooled results should be interpreted with caution. However, these results are provided because they represent current best evidence for clinical care and guide sample-size calculations for future studies. At a minimum of one-year follow up, the pooled incidence of incontinence of any kind was 35.2% (95% CI 27.9, 43.3). The pooled incidence of solid fecal incontinence was 13.7% (95% CI 10.3, 18.0). Table 3 lists the reported range for each outcome as well as its pooled proportion.

Figure 3. Meta-analysis of reported incidence rates of incontinence

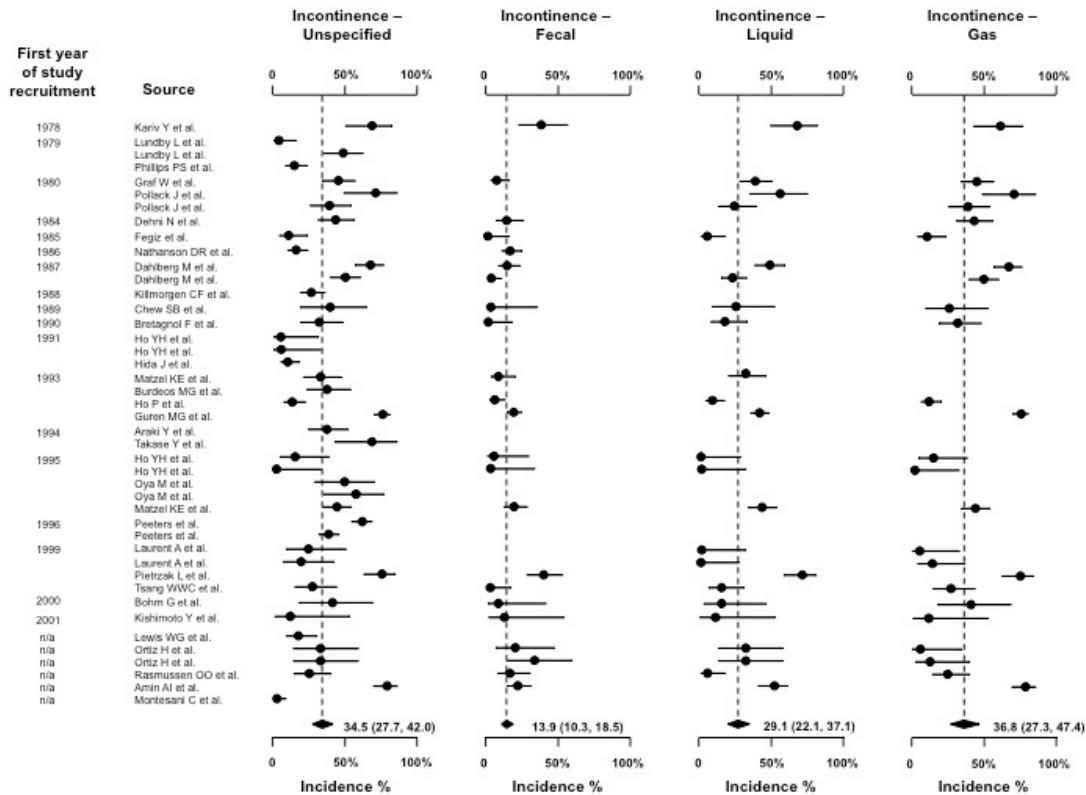


Table 3. Reported outcomes and pooled proportions

Outcome (n studies)	Range of proportions reported by primary studies (%)	Pooled proportion (%)	95% CI (%)
Incontinence of any kind (43)	3 – 79	35	(28, 42)
Incontinence of solids (23)	0 – 40	14	(10, 19)
Incontinence of liquids (25)	0 – 60	29	(22, 37)
Incontinence of gas (25)	9 – 76	37	(27, 47)
Clustering of bm (23)	6 – 88	59	(50, 68)
Incomplete evacuation (15)	2 – 85	55	(38, 70)
Urgency (43)	0 – 69	35	(29, 43)
Pad usage (36)	6 – 55	33	(27, 38)
Inability to differentiate gas from stool (23)	2 – 62	26	(20, 34)
Nocturnal bm (5)	14 – 27	24	(16, 34)
4+ bm/day (15)	10 – 60	18	(12, 26)

Meta-Regression

In an attempt to explain the heterogeneity in the incidence of long-term incontinence reported at the primary study level a number of variables were analyzed for an association with higher incidences of incontinence. Given the relatively fewer number of studies and patients that reported solid fecal incontinence, no associations were detected between the variables and this outcome. Table 4 demonstrates the various prognostic factors and their associations with the different types of incontinence (univariate analysis). Using incontinence of any kind as the outcome there was a significant association between preoperative radiation and higher incidences of incontinence ($p=0.009$), (figure 4a) but no association between postoperative radiation and long-term incontinence ($p=0.60$)

(figure 4b). Short course radiation therapy (SCRT) but not long course radiation therapy (LCRT), was significantly associated with higher rates of long-term incontinence ($p=0.006$ and $p=0.56$, respectively) (figures 4 c,d). Similarly, SCRT was a risk factor for liquid and gas incontinence ($p=0.03$). Ten studies evaluating SCRT in 692 patients, and 8 studies evaluating LCRT in 604 patients were included in this analysis. There was no significant difference in mean follow up between these studies with 57 months in the SCRT studies versus 44 months in the LCRT studies ($p=0.58$). Study design, randomized versus observational, was not associated with different rates of incontinence ($p=0.31$). However, within each study type, higher quality studies were associated with higher reported rates of incontinence (RCT $p=0.004$, observational $p=0.006$). A sensitivity analysis was conducted to determine the impact of study time period on the rate of incontinence. Using a cut off of 1993, based on the sentinel paper on total mesorectal excision by Heald and colleagues (MacFarlane, Ryall, Heald, 1993), no difference in incontinence was detected between the studies with surgeries conducted prior to 1993 and those with surgeries conducted following 1993 ($p=0.55$).

Table 4. Prognostic factors for incontinence on univariate meta-regression

Variable	Incontinence of any kind p value	Fecal Incontinence p value	Liquid Incontinence p value	Gas Incontinence p value
Preoperative radiation	0.009	0.77	0.05	0.09
Short course - 25Gy	0.006	0.30	0.03	0.03
Long course - 50.4 Gy	0.56	0.48	0.22	0.08
Postoperative radiation	0.6	0.51	0.47	0.13
Female gender	0.09	0.68	0.04	0.03
Follow up	0.16	0.56	0.03	0.01
Straight anastomosis	0.43	0.28	0.1	0.06
Anastomotic height (< 4cm vs ≥ 4 cm)	0.1	0.6	0.24	0.06
Observational study (vs RCT)	0.31	0.24	0.12	0.02
RCT quality	0.004	0.28	0.05	0.04
Observational study quality	0.006	0.11	0.002	0.001

Figure 4. Studies reporting the proportion of patients with radiation and outcome of incontinence, a) preoperative radiation, b) postoperative radiation, c) short course preoperative radiation, d) long course preoperative radiation

The area of each circle is proportional to the number of patients in each study. Curve is best-fit line from meta-regression (see methods)

Figure 4a

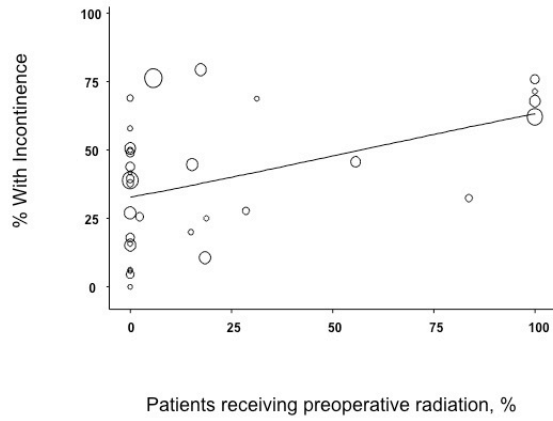


Figure 4b

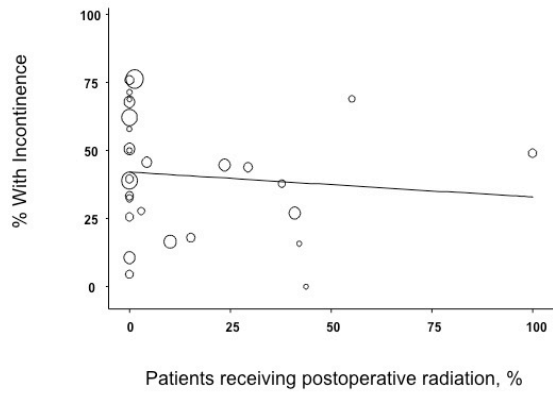


Figure 4c

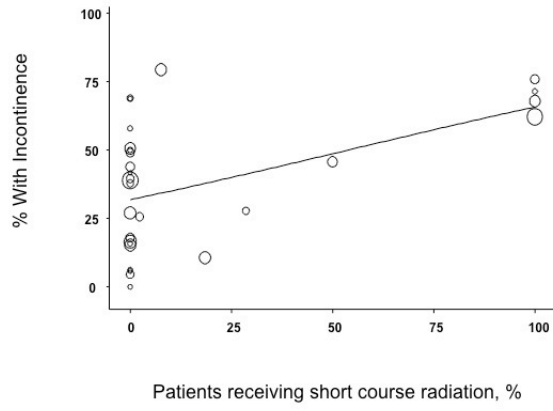
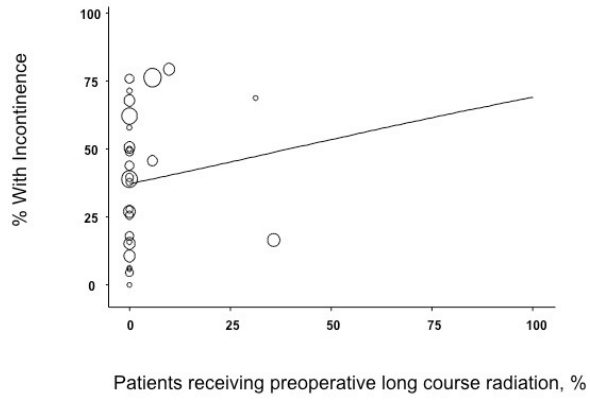


Figure 4d



Discussion

Summary of Evidence

To the best of our knowledge this is the first systematic review of the long-term bowel function outcomes following AR for rectal cancer. We observed variability and lack of consistency in reporting risk factors and outcomes as well as the heterogeneity in the functional results. Despite the availability of validated assessment tools researchers continue to develop their own methods, diluting the quality of rectal cancer research. Inadequately reported research has been shown to bias estimates of effectiveness, offering some explanation for the variability in outcomes seen here. (Mathieus, Boutron, Moher, Altman, Ravaud, 2009) Data from this review reported a significant rate of incontinence following AR as well as the substantial rates for various other sequelae such as urgency, the routine use of pads, and increased bowel movement frequency. These outcomes have negative effects on quality of life and are consistent with the results of a recent Cochrane review. (Pachler, 2005)

AR syndrome following rectal cancer treatment is a spectrum of morbidity as seen clearly by the broad ranges of incidences reported. Though many risk factors for poorer bowel dysfunction have been postulated, this review highlights the major risk factor of preoperative radiation treatment and in particular SCRT. Given the relatively fewer number of studies that reported high proportions of patients receiving either long course preoperative radiation or postoperative radiation, along

with the outcome of incontinence, it is difficult to draw meaningful conclusions for these risk factors. (Figure 4)

A recent review highlighted the discordant rates of late bowel dysfunction between patients undergoing SCRT versus LCRT. (Mohiuddin, Marks J, Marks G, 2008) With median follow-ups of 80, 61, and 180 months respectively, the Swedish Rectal Cancer Trial (Dalberg, 1998), Dutch Trial (Peeters, 2005) and Stockholm I and II (Graf et al., 1996) trials reported rates of long-term fecal incontinence of 62%, 65% and 57% following SCRT. The EORTC 22921 trial, evaluating LCRT, reported a much lower incidence of fecal incontinence, 9%, following a median of 65 months. (Bosset, 2006) The only completed trial to date evaluating SCRT versus LCRT was not powered to detect any differences in long-term toxicity. (Bujko et al., 2006) However, after a median of 48 months the relative risk of severe late toxicity including bowel dysfunction for SCRT was 1.49 (95% CI 0.67, 3.07). The Berlin Rectal Cancer Trial (Siegel et al., 2009), Stockholm III trial (ClinTrials, NCT00904813) and The Australian Gastrointestinal Trials Group TROG 01.04 (ClinTrials, NCT00145769) are currently evaluating these 2 treatments head-to-head to clarify the disparity in long-term toxicity.

A review of current practice guidelines in North America and Europe highlights the need for clarification. In the United States, the National Comprehensive Cancer Network recommends LCRT for patients with stage 2 and 3 disease. (NCCN guidelines) The European Society for Medical Oncology recommends early stage 2 disease undergo surgery alone, and late stage 2 and all stage 3 disease

receive SCRT. (Glimelius, 2009) The Canadian recommendations exemplify the confusion with some provinces recommending LCRT for stage 2 and 3 disease and others recommending SCRT for the same. (CancerCare Ontario; BC CancerCare)

This systematic review included studies over a long time period in order to capture long-term follow up with accurate prevalence rates; however, the minority of studies (11/48) included patients with surgeries done before 1990. Differences in surgical technique over time (creation of a reservoir, total mesorectal excision) and radiation protocol (adjuvant vs. neoadjuvant) exist. We attempted to control for “time” in the meta-regression. Additionally, the sensitivity analysis did not demonstrate any difference in incontinence rate between studies conducted before or in the “TME era”. This review draws attention to a serious need for better risk factor assessment including questioning patients about their obstetrical history and previous anorectal surgery. Moreover, the lack of consistency in reporting anastomosis type and height along with the heterogeneity in the way anastomosis height was reported, decreased the ability of this review to detect a significant association. Future studies should provide a mean tumor/anastomosis height and avoid reporting “low” or “high” or $< X$ cm versus $\geq X$ cm. Lastly, study quality for both randomized and observational studies was a significant predictor of incontinence. This highlights the sensitive nature of these outcomes and that rigorous methodology is required to elicit these outcomes from patients accurately and reliably.

Limitations

This review has a number of limitations. First, the included studies constitute a heterogeneous body of evidence with different methodologies and outcome definitions. Conclusions drawn from this review need to be interpreted cautiously. The results represent current best evidence for clinical care and guide methodological considerations for future studies. Second, the meta-regression was limited by the covariates included in the primary studies and thus only a univariate meta-regression was possible. Third, relationships between prognostic factors and incontinence are observational associations that can only generate hypotheses and stimulate future research. Finally, meta-regression results are subject to an aggregation bias – such that relationships of patient data averaged across studies may not be the same as the relationships for individual patients within each study.

Conclusions

Anterior resection for rectal cancer is associated with significant long-term bowel dysfunction. Different definitions of reported outcomes and their severity complicate the interpretation and utility of results from many of the primary studies as well as the pooled results from this review. Uniformly adopted definitions and the use of validated assessment tools is required to improve our understanding of the outcomes following rectal resection in addition to risk factors for these outcomes. Preoperative radiation is a significant risk factor for late incontinence. Further trials may help to clarify the risk of late toxicity between short course and long course radiation.

Chapter Three: Patient Needs Assessment

Introduction

In rectal cancer the potential benefits of treatment, namely improved survival and reduced risk of local recurrence must be balanced against the risks of adverse consequences such as chronic bowel, urinary and sexual dysfunction. Clinical trials provide quantitative information about the incidence of the various outcomes but the relative importance of each outcome to the individual patient varies. (Miller, Cantos, Peoples, Pearlstone, Skibber, 2000) The imperative to ascertain patients' actual preferences directly is particularly important when one considers treatment for which the impact on quality of life may overshadow the survival efficacy. With advancements in surgical technique and improvements in neoadjuvant chemoradiation the treatment of colorectal cancer has become embedded with difficult decisions in which modest changes in survival must be weighed against significant effects on quality of life from chemotherapy toxicity to a permanent colostomy. In order for patients to accurately weigh the risks and benefits of various treatments during the decision making process they must first comprehend the informed consent discussion. Research has shown that patients' comprehension of informed consent for surgical procedures is less than optimal. (Byrne, Napier, Cuschieri, 1988; Cassileth, Zupkis, Sutton-Smith, March, 1980; Mark & Spiro, 1990; Paling, 2003). Failure to obtain adequate informed consent compromises patient autonomy, places patient safety at risk and has been said by some to possibly constitute negligence or battery. (Schenker, Fernandez, Sudore, Schillinger, 2010)

Previous research has focused mainly on survival, recurrence and functional outcomes, but few have assessed the decisional needs of patients with rectal cancer or the information patients are retaining from the informed consent process.

Objectives

The objectives of this study were a) to describe the decisional needs of adult patients with rectal cancer when deciding on surgical treatment of their disease, b) to identify gaps in patients' comprehension of the informed consent discussion.

Methods

Conceptual Framework

The Ottawa Decision Support Framework (ODSF) formed the basis for the patients' needs assessment. (O'Connor & Jacobsen, 2001) The ODSF has been used to guide previous needs assessments of both individual and population decision-making. It has three main elements: a) decisional needs, b) decision quality, and c) decision support. (Tables 5 and 6) The ODSF asserts that unresolved decisional needs will have adverse effects on decision quality. However, decision support can improve decision quality by addressing unresolved needs with clinical counseling, decision tools, and/or coaching. This study focuses on the first element, identifying decisional needs.

Table 5. Ottawa Decision Support Framework

Assess Needs (Determinants of Decisions which are Sub-Optimal for Decision Making)	Provide Decision Support	Evaluate Decision Quality
<p>Perception of Decision</p> <p>Knowledge</p> <p>Expectations</p> <p>Values</p> <p>Decisional conflict</p> <p>Stage of decision making</p> <p>Predisposition</p> <p>Perceptions of Others</p> <p>Perceptions of others' opinion & practices</p> <p>Support</p> <p>Pressures</p> <p>Roles in Decision making</p> <p>Resources to Make Decision</p> <p><u>Personal</u></p> <p>Previous experience</p> <p>Self-Confidence</p> <p>Motivation</p> <p>Skill in decision making</p> <p><u>External</u></p> <p>Support (information, advice, emotional, instrumental, financial, professional help) from social networks and agencies</p> <p>Characteristics</p> <p><u>Client</u>: age, sex, marital status, education, occupation, culture, locale, medical diagnosis & duration, health status</p> <p><u>Practitioner</u>: age, sex, education, specialty, culture, practice locale, experience, counselling style</p>	<p>Provide access to information</p> <p>Health situation</p> <p>Options</p> <p>Outcomes</p> <p>Other's opinion and choices</p> <p>Re-align expectations of outcomes</p> <p>Clarify personal values for outcomes</p> <p>Provide guidance/coaching in:</p> <p>Steps in decision making</p> <p>Communication with others</p> <p>Handling pressure</p> <p>Accessing support & resources</p>	<p>Decision making</p> <p>Reduced decisional conflict</p> <p>Improved knowledge</p> <p>Realistic expectations & norms</p> <p>Clear values</p> <p>Agreement between values & choice</p> <p>Implementation of chosen option</p> <p>Satisfaction with decision making</p> <p>Outcomes of Decision</p> <p>Persistence with choice</p> <p>Improved quality of life</p> <p>Reduced distress</p> <p>Reduced regret</p> <p>Informed use of resources</p>

Table 6. Definitions of needs in ODSF

Participants' Perceptions of the Decision	
Knowledge	Cognizance of the health problem or situation, opinion and outcomes
Expectations of outcomes	Perceived likelihood or probability of outcomes of each option
Values for outcomes	Desirability or personal importance of outcomes of options
Decisional conflict	Uncertainty about course of action to take
Stage of decision making	Phase of decision making in the context of stages of change: pre-contemplation (not thinking about change or choices); contemplation (considering options); preparation (taking steps towards change, may be considering options); action (change for less than 6 months); maintenance (change for at least 6 months)
Predisposition	Degree to which a person is leaning strongly towards choosing an option or is uncertain
Participants' perception of others involved in Decision Making	
Perception of others' opinion and practices	Perceptions of what others decide or what others think is the appropriate choice. For the client, important others may include their spouse, family, peers, and practitioner(s). For the practitioner, it may include the client, professional peers, and personal network.
Support	Informational, emotional, and tangible help from important others to bolster and sustain decision making.
Pressure	Perception of persuasion, influence, coercion from important others to select one alternative
Role in decision making	The way a participant is or wants to be involved in decision making with others; do they wish to make the choice themselves after considering others opinions, do they want to share decision making with someone else, do they want others to make the decision for after considering their opinion.
Participants' Resources for Decision Making	
Personal	
Previous Experience	Previous exposure to the situation, options, outcomes, decision making process
Self-confidence	Belief in one's abilities in decision making, including shared decision making
Motivation	Readiness and interest in decision making, including shared decision making
Skill	Ability in making and implementing a decision
External	Assets from others that are required to make and implement the decision
Type	Available and access to information, advice, emotional support, instrumental help, financial assistance, and health & social services

Source	social networks, professional networks, support groups, voluntary agencies, and the formal health care, education, and social sectors
Participants' Characteristics	
Client/Patient	Age, gender, education, marital status, ethnicity, occupation, locale, diagnosis & duration of condition, health status (physical, emotional, cognitive, social)
Practitioner	Age, gender, ethnicity, clinical education and specialty, practice locale, years of experience, counselling style

Study Design

Following approval from The Ottawa Hospital Research Ethics Board, a needs assessment was conducted until the point of data saturation. A retrospective cross-sectional design was used to describe the needs of patients who had made a recent treatment decision regarding rectal cancer surgery.

Sample and sample size

A convenience sample of rectal cancer patients from The Ottawa Hospital (TOH) with a recent rectal resection was interviewed. The Department of Colorectal Surgery at The Ottawa Hospital treats approximately 100 rectal cancer patients per year, and the majority of cases require an anterior or abdominoperineal resection. With this volume we expected to complete the needs assessment in roughly six months with a planned sample size of 30 patients. Given the relative lack of decision support in this area, data saturation was estimated at 30 individuals.

Inclusion Criteria

Patients eligible for this study were:

- Adults > 18 years of age

- English speakers
- Had rectal cancer surgically treated by anterior resection or abdominoperineal resection in the past year
- Had a curative resection
- Consented to participate

Setting

Patients were recruited at the Cancer Assessment Center at The Ottawa Hospital while waiting for their follow up appointment with the surgical team. The Cancer Assessment Center uses a comprehensive clinical pathway to standardize peri-operative management and improve patient education. Patients have two preoperative visits with the surgical team (surgeon and advanced practice oncology nurse) and also have the opportunity to attend educational group discussions with enterostomal therapy nurses, oncology nurses, social workers, and other recently diagnosed patients. During each of the visits with the health care team the surgical outcomes are discussed as part of a staged informed consent process. These discussions highlight the usual risks of rectal cancer surgery, including bowel, bladder and sexual dysfunction. All patients receive standardized information packages consisting of pamphlets and suggested websites so they may review the information at their own pace.

Data Collection Method

Data collection consisted of a review of the patient's medical chart and a face-to-face interview. The chart review was conducted to extract data about the

patient's disease status, surgical procedure and adjuvant treatment. A data collection sheet (Appendix 2) was developed and was used to extract the following data: 1) treatment options presented, 2) information pertaining to the stage of disease; 3) neo/adjuvant treatment; 4) details of surgery (date, surgeon, technical information). We elected to conduct face-to-face interviews with patients to elicit their decision making needs (as opposed to self-administered questionnaires) since: (1) interviews provide the opportunity for participants to freely express their feelings and attitudes about their experience; (2) the interviewer can probe for more information about determinants/contributing factors; (3) the interviewer can observe non-verbal behaviour; and (4) interviews provide an environment that builds rapport between the participant and the interviewer. Finally, face-to-face interviews may be a more effective way to enlist cooperation of participants. (Fowler, 1993; Witkin & Altschuld, 1995).

Interview Guide Development

A semi-structured interview guide was developed to elicit information from the patients about their treatment decision-making needs. Participants were asked to reflect on their needs during their recent treatment decision and to consider what they might need for any future treatment decisions.

The interview questions were adapted from a standard template for eliciting needs based on the Ottawa Decision Support Framework. (Jacobsen & O'Connor, 1998) Perceptions of the decision (options; benefits; risks; difficulties); usual roles in decision making; barriers and facilitators in accessing and/or providing decision

support; and potential strategies for overcoming barriers were assessed. The interview guide was adapted to the current decision making context based on: the clinical expertise of the researcher, advice from a panel of experts in colorectal surgery and decision support. (Appendix 3) The questions were open-ended but were followed by probes with structured response categories.

Specific Needs Assessment Questions in the Interview Guide

ODSF: Perception of the decision. In the first section of the interview guide, participants were asked questions pertaining to: the treatment options they were offered; their feelings about the making the decision (with probes regarding the behavioural manifestations of decisional conflict); and factors contributing to decisional difficulty (with probes regarding factors contributing to decisional conflict). Participants were asked about their perceptions of the likely advantages and disadvantages of options (expectations) as well as specific questions regarding treatment outcomes (with probes for the most common adverse outcomes). If the patient did not perceive that s/he was offered an option the interviewer would skip directly to the questions regarding the specific treatment outcomes to assess their retention of the informed consent process.

ODSF: Perception of others. This section was omitted if the patient did not perceive that s/he had been offered an option. Participants were asked about actual and preferred roles in decision-making in relation to others such as family, friends and health care providers. The patient's preferred role in making treatment decisions was measured using Degner's Control Preference Scale (CPS) (Degner &

Sloan, 1992)(Interview guide - appendix 2,). The CPS consists of five statements that describe different roles patients can assume in making treatment-related decisions. The reliability of the CPS was established in a sample of 436 cancer patients and 482 members of the general public (Degner, 1992). Content validity of the tool was based on previous research findings from a four year field study of factors that influence treatment decisions (Degner & Beaton, 1987).

In order to obtain information about the actual role the participants had when making their decisions about treatment for rectal cancer the CPS was changed from “I prefer to ...” to the past tense “I made the decision....” Participants were asked to choose what best described the role they had in making their recent decision about surgical treatment for rectal cancer.

Participants were also asked who else was involved in the decision and how they were involved.

ODSF: Resources. The participants who made a decision were asked about what personal and external resources helped in making their decision. The interviewer provided a list of potential resources to the participants for consistency. They were also asked to identify what hindered them in making the decision, as well as what additional resources would have been beneficial. For those who did not perceive an option, they were asked what resources they consider helpful for future patients faced with multiple surgical options for the treatment of rectal cancer.

ODSF: Participants' characteristics. Participants were asked to provide their age and level of education at the end of the interview.

Validity of the interview guide

As described earlier, the ODSF served as the framework for the development of the interview guide which contributed to its content validity. Face and content validity of the interview guide was established by review with an expert in patient decision making and the ODSF and an expert in colorectal surgery.

Data Collection Procedures

Recruitment: Patients were approached by the advanced practice nurse and asked if the primary investigator/research assistant involved in the study could approach them.

Interview: Interviews were conducted either before or after the participant's follow up appointment with the surgeon and took place in the Cancer Assessment Center's boardroom. Participants were not provided with a copy of the interview guide. All interviews were transcribed and audio-taped. The researcher or research assistant conducted the interviews. The interviews were conducted in English.

Protection of Human Rights: The study was conducted in accordance with the Guidelines of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (Interagency Advisory Panel on Research Ethics, 2003). Participants who agreed to take part in the study received a letter of information/consent. (Appendix 4)

Data Analysis

For chart data and interview questions with pre-coded responses, descriptive statistics (frequencies and percentages) were used to summarize the results. The responses to open-ended questions were to be subjected to a content analysis. The data was limited in that patients did not identify having a decision. Subsequently, the open-ended questions were unanswered and a content analysis was not conducted.

Results

32 patients were approached from November 2009 – July 2010 and 30 patients agreed to participate. Patient demographic data is shown in Table 7a and surgical data in Table 7b. Of the 30 participants the typical participant was male, age 65, with an anterior resection and diverting loop ileostomy, performed 1.5 months previously, with a highschool education or less, and an advanced rectal cancer with a preoperative stage of 3 or 4.

Table 7. Patient demographics (a) and surgical data (b)

a)

<i>Total number of participants</i>	30
Median age yrs (range)	65 (42-89)
Median time between surgery and interview months (IQR)	1.5 (1, 6.5)
Gender M:F	24:6
Education	
Primary School	11 (37%)

Secondary School	5 (17%)
Post-secondary School	10 (33%)
Graduate School	4 (3%)
Preoperative AJCC Stage	
1	10 (33%)
2	4 (13%)
3	13 (43%)
4	3 (10%)
Pathologic AJCC Stage	
0	2 (7%)
1	14 (47%)
2	7 (23%)
3	5 (17%)
4	2 (7%)
Neoadjuvant therapy	24 (80%)
Long course chemoradiation	16
Short course radiation	6
Long course chemotherapy only	2
Number not completed	0
Adjuvant therapy	15 (50%)
Chemotherapy	14
Radiation	1
Number not completed	4

b)

<i>Surgery</i>	<i>N (%)</i>
Abdominoperineal resection	10 (33)
Anterior resection	20 (67)
Diverting loop ileostomy	18/20 (90)

End colostomy	1/20 (5)
Mean tumor height cm (SD)	7.2 (3.2)
Mean anastomosis height cm (SD)	5.3 (2.2)
Anastomosis type straight:J pouch	17:2 (no handsewn)

Perception of the Decision

Perception of the options: None of the 30 participants perceived that they had been offered an option of surgical treatments. Highlighting the patients' passive role in surgical decision-making, participants commented: "I don't know if I was given an option". They (the doctors) said this is what we're going to do." (pt 20)", "Dr. X made the recommendation and my father took it". [pt 3], "I trusted the doctor, whatever he said." (pt 12), and:

"The doctor explained to me that the position of the tumour required that everything come out. I really didn't get the feeling from his tone of voice that there was a choice...but that he was leaving it open that if it shrank. But then during one of the final exams he just said, no, I've made up my mind, it's going to be a permanent colostomy". (pt 7)

One subject verbalized the difficulty s/he had not having an option:

"It was hard for me because in my profession I'm asked for options for clients on a regular basis, and so for me not to have an option, I've never experienced that in my life – where I couldn't find a way out or some other way around". (pt 7)

Some of the participants voiced wanting to be more actively involved in the decision making process. For example, participant 2 stated, “There’s people come in here that hardly know...then it’s in the doctors hands. But I think you should know what’s going on”. It’s your body, you have the final say”.

Knowledge of rectal cancer surgical outcomes

Survival

The majority of participants, 20 (67%), had a vague idea of their chance of survival and described it in words like “good”, “very good” or “excellent”. The minority of participants, 4 (13%), were not aware of the probability of survival or cure following the surgery. Six (20%) participants could recall their chance of survival in terms of specific numbers or percentages.

Bowel function

The majority of patients were not aware of a discussion regarding risks to bowel function. Two participants demonstrate the lack of knowledge:

“[I’d like to know] if I’m going to be having accidents cause I never even thought of that – I just thought I go with normal bowel movement...the consistency of it, am I going to have diarrhea? – that’s some questions I’d like to have answered”.(pt 20)

“I have no idea. I don’t think I had any conversations, anything about, like even, I don’t even know what process I’m getting hooked up by. I just know I have to go back and have the same surgery again”. (pt 8)

A third of patients could recall some discussion but no specific risks.

“They did mention it’s probably not going to be the same as before”, (pt 10),
and,

“...eventually it’ll go back closer to normal, but it won’t ever be what it used to be – it’ll always be looser. As for incontinence, I don’t remember them ever discussing that”. (pt 16)

Alternatively, some participants could recall having a discussion but what they recalled was false. “They said it (bowel function) would be relatively normal”. (pt 7), “I think every indication given is that it’s going to be normal, I think that’s the assumption anyway”. (pt 18) The minority of patients were aware of specific risks to bowel function.

Stoma function

The minority of participants were aware of specific complications related to stoma function.

Satisfaction with bowel function

This question was originally included to assess participants’ satisfaction with their bowel function without a stoma. Only three patients were without a stoma at the time of the interview. This question was therefore omitted from analysis.

Sexual function

The majority of participants were not aware of any discussion regarding sexual function. “I don’t think they went down that road”. (pt 18) The remaining patients could recall having a discussion but only 7 (23%) could recall any specific risks.

“It wasn’t discussed. Maybe it was – there was something there, I can’t remember”, (pt 8),

or,

“I was told it should be alright, that there was a 1% chance that there could be a complication with the nerve”. (pt 7)

Urinary function

The majority of participants were not aware of any risks to urinary function.

Quality of life

The majority of patients could recall a discussion regarding overall quality of life following surgery. For most, the discussion was centered around return to activity, work and regular day-to-day life. Two participants summarize their recollection of what they were told to expect in terms of quality of life:

“After six months I’d be able to do whatever I want to do”. (pt 12),

“They told me my quality of life would be just as good as anybody else’s, you know, once you get used to it”. (pt 19)

Table 8. Patient awareness of postoperative functional outcomes

<i>Surgical Outcomes</i>	<i>N (%)</i>
Survival	
Not aware	4 (13%)
Aware, no specifics	20 (67%)
Aware, specifics	6 (20%)
Bowel Function	
Not aware	14 (47%)
Aware, no specifics	10 (33%)
Aware, specifics	6 (20%)
Sexual Function	
Not aware	14 (47%)
Aware, no specifics	9 (30%)
Aware, specifics	7 (23%)
Urinary Function	
Not aware	17 (57%)
Aware, no specifics	9 (30%)
Aware, specifics	4 (13%)
Stoma Function	
Aware of complications	12 (40%)
Quality of Life	
Not aware	8 (27%)
Aware	22 (73%)

Patients with two months or less since surgery were analyzed separately from patients two months or greater from surgery to assess for any discrepancies in their recall, based on the median number of months between surgery and the interview. For all three major outcomes: bowel function, sexual function and urinary function, there was no significant difference between the number of patients that recalled having a discussion regarding each outcome. For each outcome the number of patients that recalled having a discussion was (≤ 2 months: >2 months): bowel function 8:8, sexual function 10:6, urinary function 6:7.

Anticipated Needs Regarding Future Decisions

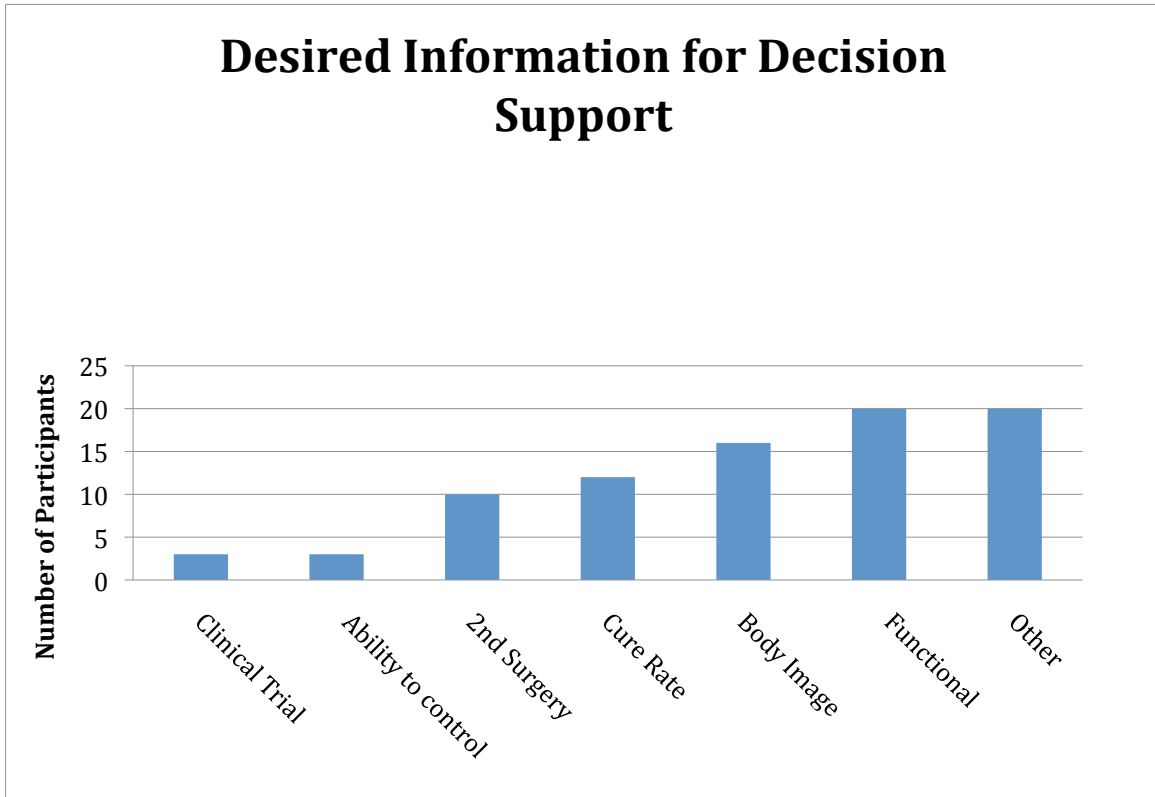
Participants were asked to make recommendations about how practitioners in the future could best help them or other patients make decisions about surgical treatment for rectal cancer.

Needs Relevant to Knowledge

The majority of participants identified wanting information on more values-based outcomes such as body image and functional results. The minority of participants would like information regarding the ability of the surgery to alleviate their symptoms, the need for a second surgery or cure rate (Figure 5). Other desired information included pictures of scars, what to expect regarding the perineal incision – appearance, complications relating to wound healing, information and images regarding stomas, in particular the chance it will be permanent, short-term outcomes, and any necessary diet changes. Participant 16 highlighted his desire to be more involved in the decision making discussion, “I think if I had the option, I

think a little more detail on the risks would have been helpful...like the impotency and the bowel function, you know, all that kind of stuff’.

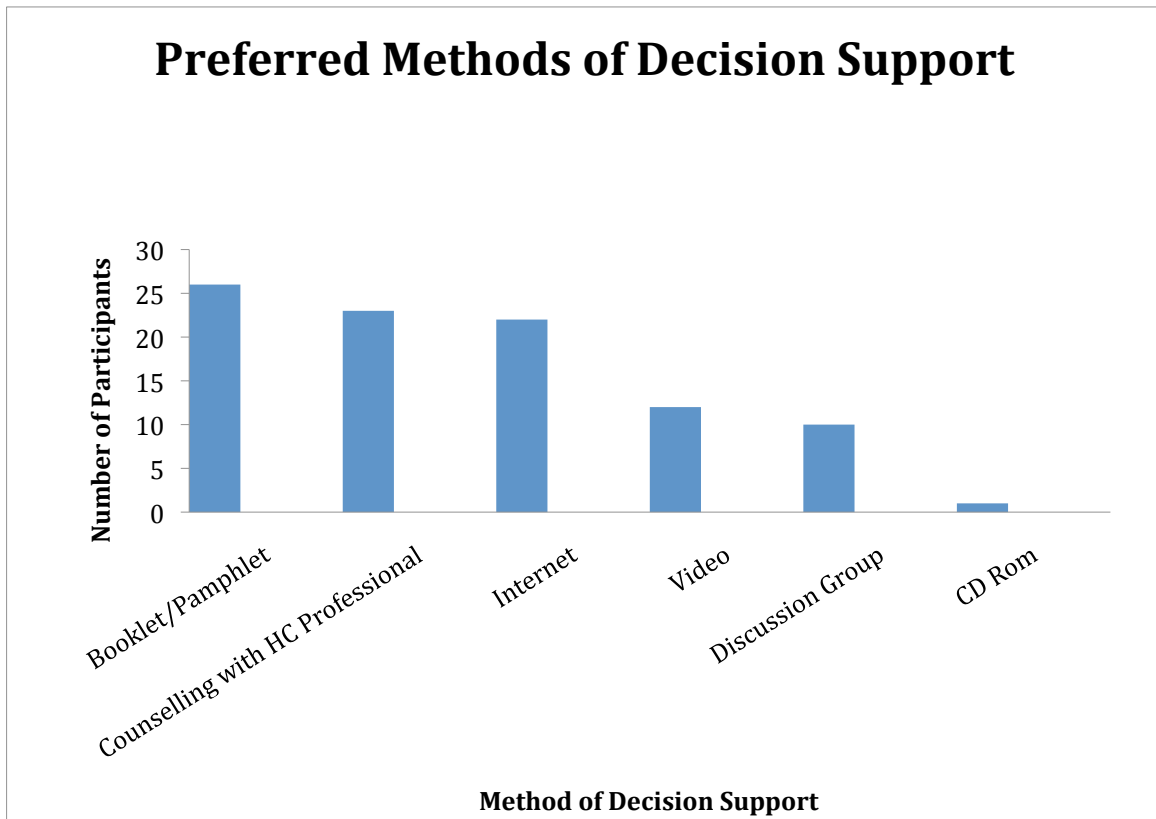
Figure 5. Desired information for decision support



Preferred Methods of Decision Support: The majority of patients found booklets and pamphlets useful as well as discussions with the healthcare team and the Internet. (Figure 6.) Highlighting the issues with the current decision support available at The Cancer Center, participant seven noted, “Well they told me the information, but I was a bit in shock and probably some denial and really didn’t hear it, and went looking on my own”. Similarly, other participants commented: “They provided a lot of booklets here, but you can only read so much, and you don’t want to scare yourself anyway”, (pt 21), “For myself, an awful lot of it went through one

ear and shortly out the other ear”, (pt 14), and “I did a little bit on the internet, but I didn’t really want a whole lot to be honest with you because I didn’t want to scare myself”, (pt 20).

Figure 6. Preferred methods of decision support



Discussion

This study demonstrates that rectal cancer patients do not perceive that they have a choice of surgical options. Despite a comprehensive educational oncology pathway patients retain little of the informed consent discussion. Participants would like information that is portable that they can review at their own pace. Finally, this study highlights the dichotomy between the outcomes that surgeons and patients value most.

The patients' lack of perception of choice reflects the current role of the surgeon in the decision making process – the primary decision maker. The trade offs between expected benefits and side effects in rectal cancer surgery are almost exclusively made by clinicians and not by patients. These tradeoffs are not usually even made explicit to patients. If patient values are to be incorporated in treatment decision making this requires patients to participate in the consultation and voice their values. Other studies have shown that doctors do not have the ability to adequately judge patients' values for outcomes of care. (Cotler et al., 2001; Montgomery & Fahey, 2001; Brothers, Cox, Robison, Elliott, Nietert, 2004; Stalmeier et al., 2007; Till, Sutherland, Meslin. 1992) Furthermore, in a study investigating patients' preferences for radiation therapy to treat rectal cancer, 88% of patients did not think that clinicians could weigh the value of quality compared to length of life. (Pieterse, Baas-Thijssen, Marijnen, Stiggelbout, 2008) The participants attributed this to the clinicians' lack of insight into patients' values.

As demonstrated by this study, rectal cancer patients are most interested in information regarding quality of life such as body image, functional outcomes, and the appearance of stomas and scars. Clinicians are most focused on attaining a cure, by excising the disease in its entirety supplemented by chemotherapy and radiation, alleviating the symptoms caused by the tumor (such as rectal bleeding), and the need and risk of a second surgery for either complications or reversal of a temporary stoma. This gap between the outcomes that patients and clinicians value most has been demonstrated by other studies investigating colorectal cancer treatment decision-making. Solomon et al., 2003, demonstrated that patient

preferences for treatment differed significantly from those of both surgeons and oncologists. Patients were less willing to gamble the risk of death or trade time alive than physicians. Similarly, Masya et al., 2009, demonstrated differences in preferred outcomes of treatments for rectal cancer between surgeons, patients, medical and radiation oncologists.

However, if given the opportunity to make a choice, it is unclear from the current literature whether rectal cancer patients would be receptive. Certainly, the literature has shown that particular subtypes of patients are less likely to want to be involved in medical decision-making. (Elkin, Kim, Casper, Kissane, Schrag, 2007) For example, Pieterse et al., 2008, found a significant association between a lower patient education level in rectal cancer patients and their desire to relinquish decision-making to the clinician. This was supported by a systematic review that identified a number of factors limiting patient involvement in decision-making, including: older age, male gender and lower education level. (Hubbard, Kidd, Donaghy, 2008). The rectal cancer population is comprised of older patients, with a median age of 70, and a male predominance. (Altekruse, 2009, SEER data). The cohort of patients analyzed in this study mirrors the demographics of the general population of rectal cancer patients and also highlights the relatively low level of education with greater than 50% of patients having at most a high school education. Thus it behooves us as practitioners to tailor the decision-making process to each individual patient, providing more guidance or independence as required by the individual. Patients' who attain their desired role preference have been shown to experience less anxiety from pre-consultation to post-consultation and are more

likely to be satisfied with the doctor-patient interaction, as compared to those whose involvement is less than anticipated. (Heyland, Tranmer, Fledman-Stewart, 2000; Keating, Guadagnoli, Landrum, Borbas, Weekes, 2002)

Along with identifying the lack of decision-making during the preoperative discussion, this study demonstrates the poor retention of the outcomes discussed. A number of studies have similarly demonstrated patients' poor comprehension of the informed consent discussion for surgical procedures. (Byrne 1988; Cassileth 2003; Mark 1990). On average 50% of participants could not recall having a preoperative discussion regarding the risks to bowel, urinary, or sexual function. This is similar to the finding by Fink et al., 2010, that the average patient comprehension of the informed consent process is 48%. Our data is surprising however given the comprehensive program underway at The Cancer Assessment Center at The Ottawa Hospital. It is unclear from this study why the participants retained so little of the informed consent discussion. In their review of predictors of informed consent, Fink et al., 2010, identified age ≥ 70 , lower level of education, black race, and less than 15 minutes spent discussing informed consent as independent predictors of poor comprehension. Thus despite the effort of the Cancer Assessment Center patients continue to sign consent forms for invasive, life-changing procedures, without understanding the consequences. There are many avenues for improvement including targeting patients with the above risk factors as well as addressing other decisional needs identified by the Ottawa Decision Support Framework but not elicited through this study. Given the absence of a true decision in this cohort, the

study was limited in its ability to probe barriers to decision making, including unaddressed decisional needs.

In this study, participants were asked to suggest decision support formats that would be most helpful for future patients faced with the decision of rectal cancer surgery. Participants identified media that are portable and easily reviewed on their own time. With increasing time constraints in the clinic, information that the patients can review at home and then later discuss with the health care team seems like an attractive option. However, as highlighted by Schenker et al, 2010, one of the major factors for improved comprehension of the informed consent discussion was increased discussion time. To discharge patients with a booklet or suggested website and not spend time reviewing their understanding and addressing any questions will not suffice.

Limitations

One of the major limitations of this study was the a priori assumption that patients would perceive a choice of surgical options. This study has clarified the current role of the surgeon in the decision making process and highlighted the need for better training for medical professionals in decision support. However, without perceiving a decision we were unable to assess the participants' desired role in decision-making, nor could we assess many of their decisional needs.

This study was limited by its small sample size making it difficult to draw substantial conclusions about whether the participants were representative of the general rectal cancer population. However, the demographic data suggests they are

similar and certainly other research in comprehension of informed consent had similar results.

The results of this study could be influenced by social desirability bias. In social desirability, individuals provide answers they think the interviewer would approve of or would want to hear. This could have affected the study results if the participants felt the investigator was looking for a null answer.

Conclusions

Surgeons continue to act as the sole decision makers in rectal surgery. Patients are retaining little of the informed consent process and are undergoing invasive, life-altering procedures with little understanding of the consequences. There is a dichotomy in the outcomes that patients and clinicians value most. Practitioners should strive to improve the decision making process for rectal cancer patients.

Chapter Four: Practitioner Needs Assessment

Introduction

Involving patients in treatment related decision-making is in line with the increasing acknowledgement of the patients' right to autonomy and self-determination. Shared decision-making (SDM) has many definitions, but in essence involves the presentation of options and discussion of the patients' values. (Makoul & Clayman, 2006; Mounjid, Gafni, Bremond, Carrere, 2007) SDM lies between paternalism and autonomous decision-making and is considered an important component of patient centered care (Edwards, 2003). This is supported by evidence that clinicians do not have the ability to adequately judge patients' values for outcomes of care. (Cotler, 2001; Montgomery & Fahey, 2001; Brothers, 2004; Stalmeier, 2007) If we are to consider the patients' values in the treatment plan patients' must actively participate in the consultation and voice them. However, there is considerable uncertainty about what patients' and clinicians understand by patient participation. (Guadagnoli & Ward, 1998)

Oncology patients report wanting to be involved in SDM, however, this preference is often not achieved when consulting with their medical and surgical oncologists. (Brown et al., 2004; Beaver K et al., 1996; Degner et al., 1997; Bruera, Wiley, Palmer, Rosales, 2002) The literature suggests that oncologists are comfortable with SDM yet their reported use is considerably less than their reported comfort. (Shepherd, Tattersall, Butow, 2007). It is unclear whether this is secondary to patient or physician barriers. The decision-making preferences of oncology

patients have been widely studied (Say, Murtagh, Thomson, 2006) but information is limited on the attitudes and practice of oncologists when discussing treatment.

Objectives

The objective of this study was to assess the needs of colorectal surgical oncology practitioners when discussing the surgical management of rectal cancer with their patients. We aimed to identify perceived barriers and facilitators for SDM as well as possible directions for improving SDM in rectal cancer surgery.

Methods

Conceptual Framework

The conceptual framework is described elsewhere (page 28). The Ottawa Decision Support Framework asserts that unresolved decisional needs will have adverse effects on the quality of decision-making. Decision support addresses unresolved needs in the form of clinical counseling, decision tools, and/or coaching. This study focuses on identifying decisional needs.

Study Design

Following approval from The Ottawa Hospital Research Ethics Board, a needs assessment was conducted until the point of data saturation. A retrospective cross-sectional design was used to describe the needs of practitioners who are involved in the surgical management of rectal cancer.

Sample and sample size

A convenience sample of expert practitioners from across North America was identified. Colorectal fellowship trained surgeons, considered leaders in the field, were identified through the Canadian and American Societies of Colon and Rectal Surgery. Advanced practice colorectal oncology and enterostomal therapy nurses were selected from The Ottawa Hospital Cancer Assessment Center. It was estimated that given the lack of decision support currently in this area data saturation would be obtained by approximately ten interviews.

Inclusion Criteria

Practitioners eligible for this study were:

- English speakers
- Involved in the decision making process for rectal cancer patients faced with the decision of surgery
- Surgeons – must perform both anterior resections and abdominoperineal resections to treat rectal cancer
- Consented to participate

Data Collection Method

Each participant was interviewed once using a semi-structured questionnaire based on the validated Ottawa Decision Support Framework. In person interviews were completed when possible, otherwise phone interviews were conducted. The interviews were recorded to ensure accurate data capture.

Interview Guide Development

A semi-structured interview guide was developed to elicit information from the practitioners about their decision-making needs. Practitioners were asked a series of questions aimed at clarifying the decision-making process with rectal cancer patients faced with the option of surgery. In particular, the questionnaire sought to clarify the practitioner's understanding of, and role in, addressing the decisional needs and support of patients. The questionnaire was pilot tested to verify ease of use.

The interview questions were adapted from a standard template for eliciting needs based on the Ottawa Decision Support Framework. (Jacobsen & O'Connor, 1998) Perceptions of the decision (options; benefits; risks; difficulties); usual roles in decision making; barriers and facilitators in accessing and/or providing decision support; and potential strategies for overcoming barriers were assessed. The interview guide was adapted to the current decision making context based on: the clinical expertise of the researcher and advice from experts in colorectal surgery and decision support. (Appendix 7) The questions were open-ended but were followed by probes with structured response categories.

Validity of the interview guide

The validity of the interview guide is described elsewhere (page 36).

Data Collection Procedures

Recruitment and Interview: Practitioners were first contacted by email and invited to participate in the study. On response, a mutually agreeable time was

arranged and a telephone interview was conducted. One practitioner had a face-to-face interview. Participants were not provided with a copy of the interview guide. All interviews were transcribed and audio-taped. The primary investigator conducted the interviews for cost reasons. The interviews were conducted in English.

Protection of Human Rights: The study was conducted in accordance with the Guidelines of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (Interagency Advisory Panel on Research Ethics, 2003). Participants who agreed to take part in the study received a letter of information/consent. (Appendix 6)

Data Analysis

The responses were summarized using descriptive statistics (frequencies and percentages). Two reviewers analyzed the taped and transcribed interviews and any discrepancies were resolved by consensus.

Results

Eleven practitioners were recruited between November 2009 and January 2010, and ten agreed to participate (91%). The single surgeon who did not participate was unable to due to time constraints. Seven surgeons and three advanced practice nurses were included in the study. Table 9. describes the demographic data of the included practitioners.

Table 9. Practitioner demographic data

Total number of practitioners	10
Gender M:F	6:4
Colorectal fellowship	7/7 surgeons
Academic practice	
Canada	5
USA	5
Years of practice - surgeon	
6-10 years	1
11-20 years	3
21+	3
Years of practice - nurse	
6-10 years	1
11-20	0
21+	2

Perception of the decision

When questioned about their practice pattern all seven surgeons responded that they preferentially perform sphincter preserving procedures, i.e anterior resection (AR). For all seven this also included handsewn anastomoses for very low tumors, but only 3 (43%) would perform an intersphincteric resection. (An intersphincteric resection involves excising the rectum with the internal sphincter, leaving only the external sphincter behind for bowel control.) For those who would not perform an intersphincteric resection practitioner 5 summarized their

reasoning with “you are playing with fire”, alluding to the poor functional outcomes seen postoperatively.

Surgeons were asked to identify the main advantages and disadvantages of the AR and abdominoperineal resection (APR). They highlighted many values-based outcomes such as avoidance of a permanent stoma and patient preference, for AR, and poorer body image but possibly improved quality of life (for those with baseline sphincter dysfunction) for APR. (See Table 10.)

Table 10. Advantages and disadvantages of AR and APR

<i>Procedure</i>	<i>Advantage</i>	<i>Disadvantage</i>
Anterior Resection	<ul style="list-style-type: none"> • Avoidance of a permanent stoma (stigma and complications) • Retain normal mechanism for bowel movements • Improved body and sexual image • Patient preference 	<ul style="list-style-type: none"> • Suboptimal bowel function • Need for a second operation (ileostomy reversal) • Increased morbidity – risk of anastomotic leak
Abdominoperineal Resection	<ul style="list-style-type: none"> • Better bowel function • Improved quality of life for patients with baseline sphincter dysfunction • Avoidance of a second surgery • Decreased postoperative morbidity (no anastomosis) 	<ul style="list-style-type: none"> • Permanent stoma – complications (hernias), financial cost • Poor perineal wound healing • Poor body image • ? Poorer oncologic outcome

Surgeons were then challenged to consider different scenarios for which they would actively involve the patient in decision-making between a sphincter

preserving procedure (AR) or a permanent colostomy (APR). Five surgeons (71%) identified specific patient characteristics for which they would engage the patient in the decision-making process. These characteristics include: baseline sphincter dysfunction, mobility issues, co-morbidities increasing the risk of a second operation, advanced age, and “a lifestyle that may be better suited to an APR”. Two surgeons (29%) stated that they would not offer patients an option to choose between the two procedures despite both being technically feasible. The two surgeons commented:

“Patients always turn to you for advice, they don’t want to make the decision on their own, they want the doctor to make the decision” (pt 6)

“No, [for me] it is determined by tumor factors.” (pt 5)

Roles in decision-making

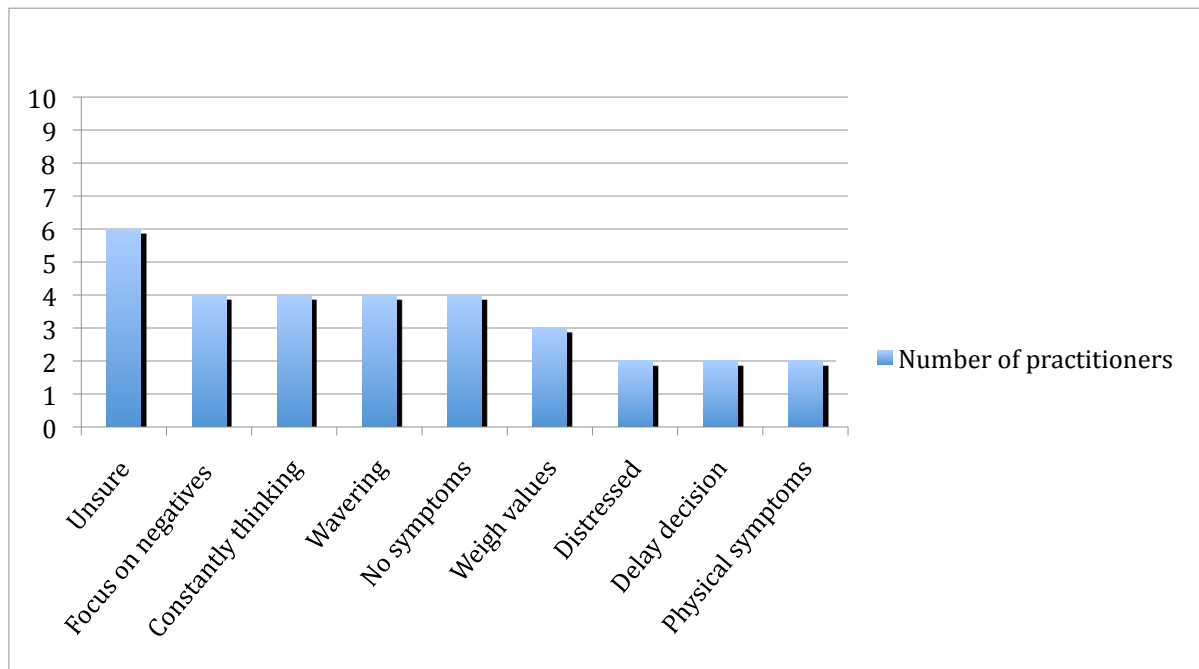
All three nurses and 2 surgeons felt their role is to provide information, advice and support for the patient to make the decision on his/her own. Three surgeons felt their role is to share the decision with the patient, while 2 surgeons make the decision for the patient, albeit taking the patient’s opinion into account.

Practitioners identified the other key members in the shared decision-making process, other than the patient and the surgeon: family (10/10), enterostomal therapy nurses (6/10), patients’ friends (5/10) and advanced practice oncology nurses (4/10). Other mentioned supports include alternative care specialists, social workers and fellow patients. All practitioners agreed that the role of these key members was to provide support, education and advice for patients.

Decisional Conflict

Focusing on the practitioners' perception of the patients' ability to make a decision between an AR and an APR, they were questioned regarding behavioral manifestations of decisional conflict. Four practitioner (40%), all surgeons, felt the majority of patients would have no problems making a decision between an AR or an APR. The lack of decisional conflict is attributed here to patients' keen avoidance of a stoma and thus confidence in their decision to undergo sphincter salvage. In addition, one surgeon commented: "following our conversation patients are clear and confident in their decision."(pt 7) Among the remaining practitioners they felt the patient would be unsure of the decision and would exhibit various features of decisional conflict. (Figure 7).

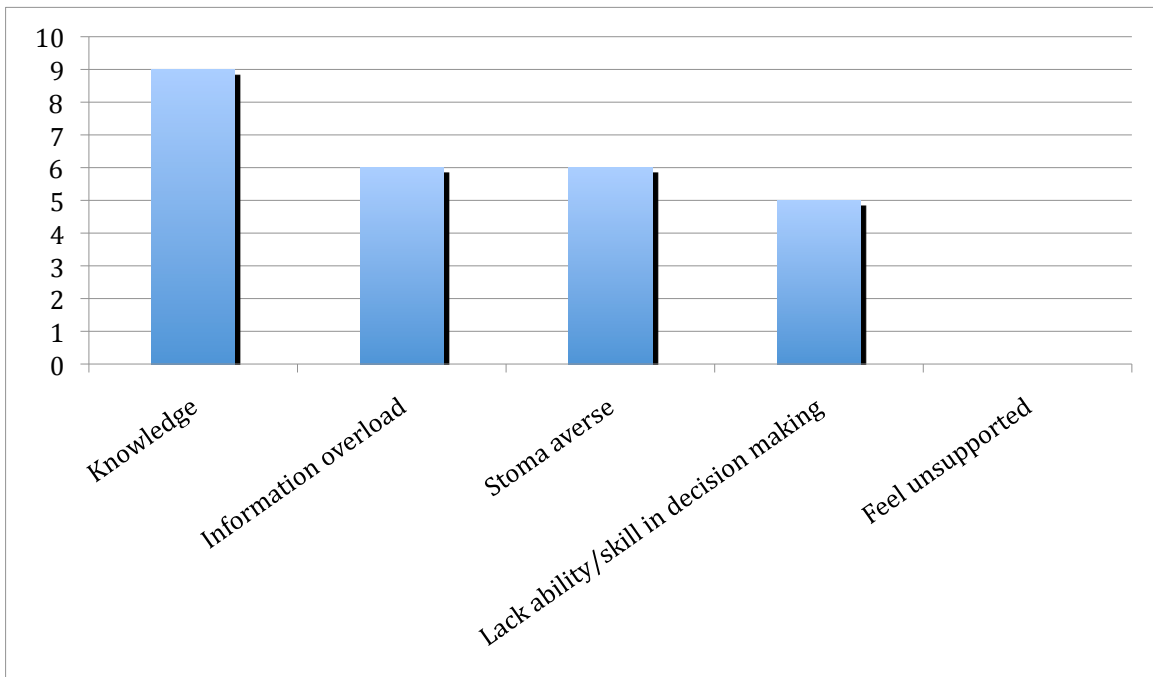
Figure 7. Practitioners' perception of patients' decisional conflict



Barriers to shared decision-making

Practitioners highlighted nearly all aspects of decisional needs as likely barriers to shared decision-making. The most commonly identified barrier was patients' lack of knowledge. Other major obstacles cited include information overload, patients' values or inclination to avoid a stoma and lack of ability or skill in decision-making. (Figure 8.) Other less frequently identified barriers include the urgent time frame of decision-making, patients' lack of insight, unrealistic expectations and the lack of outcomes evidence to support choosing one option over the other. For the advanced practice nurses, both commented on their own lack of knowledge of the procedures and outcomes as barriers to shared-decision making. None of the practitioners identified a lack of patient support as a possible barrier.

Figure 8. Patient barriers to shared decision-making



Facilitators of shared decision-making

Practitioners identified many facilitators for improved shared decision-making, some that cannot be changed (i.e. patient characteristics) and some that can be improved upon. Facilitative patient characteristics included intelligent, open-minded, and motivated patients. The most commonly identified “not fixed” facilitator was access to trusted information – either via the Internet or reading materials. Staged meetings were also commonly identified, as was access to advanced practice or enterostomal therapy nurses. Practitioners identified patients who came prepared with questions as facilitators to improved shared decision-making. Other less frequently mentioned factors were patients’ previous experience with someone who had rectal cancer, a supportive family, and a trusted or recommended surgeon.

Support and resources for shared decision-making

In order to participate in shared decision making practitioners identified that patients seek out information on the options, benefits and risks. The majority of practitioners, (9/10), agreed that patients assess the personal importance of the various risks and benefits. Patients turn to family members for support in decision-making. The minority seeks information on how other patients decided.

Practitioners identified a number of avenues utilized by patients for decision support. Patients seek information on the options, benefits and risks via the Internet and written information packages in addition to discussions with the surgical team. Patients seek information from a trusted source, but as identified by one

practitioner “what this is (the trusted source) is changing”(pt 4). Only a single surgeon identified the preoperative consultation alone as sufficient for decision-making.

All ten practitioners identified counseling with a health care practitioner as key to supporting shared decision-making. The majority of practitioners identified the surgeon, enterostomal therapy nurses and advanced practice oncology nurses as critical players in the shared decision-making process. Discussion groups, in particular for patients likely to receive an ostomy, were felt to be useful by half of the practitioners. Others commented they can be “a mixed bag” (pt 1), and “ [we] need to standardize the patients to avoid horror stories” (pt 6).

Access to information was identified as crucial; in particular, access to information on the health condition, options, benefits and risks. The majority of practitioners, (9/10), felt presenting probabilities of the outcomes would be useful – though survival data needs to be individualized. Along with education and realigning expectations, practitioners responded that patients need information to help them consider their personal values and align their decision making with those values. Few practitioners identified patients as needing guidance in the steps of decision-making (3/10).

The majority of practitioners, (8/10), chose the Internet as the forum of choice for education and decision support. Fifty percent also supported reading materials as well as videos that could be incorporated into a website to provide patients with images. All practitioners agreed that medical experts should be the

ones disseminating the information and there should be no link to Industry or For-profit agencies.

Discussion

Although many of the identified benefits and risks of an anterior resection or abdominoperineal resection are values based outcomes, colorectal surgeons in our study, were not routinely engaging the patient in shared decision-making (SDM). With a surgeon preference for sphincter preserving surgery the majority of patients are led to believe that is their only option. The minority of patients, those with baseline sphincter dysfunction, co-morbidities, or “a lifestyle suited to an APR”, may be offered a choice, but that is variable and surgeon dependent. There are many individuals, involved in the decision making process, with the majority providing support, education and advice. Identified barriers to shared decision making were mainly patient factors, including a lack of knowledge, the stigma associated with a stoma, and information overload. Identified facilitators included patient factors such as motivated, intelligent patients, and system factors such as staged meetings and access to trusted information. Outside of the discussion with the health care team, the practitioners suggested the Internet as the main forum for patients to obtain decision support and resources.

Similar to other studies, the majority of practitioners in this study identified themselves as partaking in SDM, however, on presenting specific scenarios it became clear that in fact they often are not. From the literature it is apparent that oncology practitioners, and surgeons in particular, report a higher level of comfort

with SDM than actual use of SDM. (Shepherd, 2007; Charles, Gafni, Whelan, 2004) In the article by Charles et al., 2004, the surgeons reported comfort level with SDM was 20% higher than their reported use. Many of the barriers reported in the literature to explain the reduced uptake of SDM were reported in this study as well.

Practitioners highlighted unresolved decisional needs such as behavioral manifestations of decisional conflict, patient lack of knowledge, and information overload at the first consultation as some of the barriers to SDM. Shepherd et al., 2008, in particular identified that surgeons most often indicate patient difficulties as the largest obstacle; difficulties such as misunderstanding or a lack of understanding of the problem, options and outcomes; anxiety; denial and patient indecision. Furthermore, that same study identified colorectal oncology clinicians as reporting a higher incidence of system barriers such as a lack of time, patients misunderstanding the nature of the consult, patients misunderstanding the nature of the decision making process and physician difficulties in framing the options.

This latter point is especially interesting given the lack of surgical options perceived by rectal cancer patients despite the typical availability of two surgical options, an AR and an APR. (Chapter 3, page 39) Certainly there are no shortages of barriers identified by health care practitioners to the SDM process. Gravel et al. 2006, summarized the five most commonly identified barriers to SDM as: 1) time constraints, 2) lack of applicability due to patient characteristics, 3) lack of applicability due to the clinical situation, 4) perceived patient preference for a model of decision making that does not fit SDM, and 5) not agreeing with asking the patient about their preferred role in decision making. (Legare, Ratte, Gravel,

Graham, 2008) Additionally, the lack of any real choice also featured strongly as a barrier to implementing SDM in clinical practice. In rectal cancer surgery where both AR and APR are fraught with difficult outcomes, perhaps this last point is one of the major barriers, though not explicitly stated by the practitioners.

It is interesting to note, that the nurses in this study identified a barrier not mentioned by the surgeons, that of their own lack of knowledge. The nurses included in the study were senior advanced practice oncology nurses, thus this barrier was surprising. However, on review of the literature other senior oncology nurses echo this feeling. Barthow, Moss, McKinley, McCullough, 2009, interviewed senior oncology nurses in New Zealand and identified multiple barriers to their involvement in SDM including: degree of knowledge, the nurses' personal values or attitudes about the offered treatments, and structural factors such as access to interdisciplinary discussions and the availability of current patient information. Nurses are critical to the SDM process and particularly in the setting of multi-disciplinary cancer care and pathways where patients receive their health care systematically as part of a regulated cancer care process. Nurses often become quite familiar with the patients and families as they navigate the treatment pathway. (Coffey, 2006; Davison & Degner, 1998) This relationship, along with their knowledge, skills and experience in oncology makes them crucial to the interdisciplinary team effort to support patient and family decision-making regarding treatment options. (Carroll, 1998; Hack, Degner, Watson, Sinha, 2006) As physicians we would be doing our patients an injustice in not addressing this

concern and improving the nurses' knowledge of the treatments their patients receive and their outcomes.

Along with the list of barriers identified, practitioners also acknowledged a number of facilitators of SDM: patient factors such as motivated, intelligent patients, surgeon factors such as a trusted or recommended surgeon, and system factors such as access to trusted information, staged meetings with the health care team and the presence of enterostomal therapy and advanced practice nurses. Patient trust of their surgeon has been identified as a key facilitator when reaching a treatment decision in colorectal cancer. (Salkeld, Solomon, Short, Butow, 2004) Trust has been shown to develop through excellent communication and by responding to the patients' preferences for information and involvement. (Coulter, 1999; Keating et al., 2002; Thom et al., 2001; Trachtenberg, Dugan, Hall, 2005) Oncology patients report wanting to be involved in treatment decision making however their preference is often not achieved when consulting with their physicians. (Brown, 2004; Beaver, 1996; Degner, 1997; Bruera, 2002) In order to facilitate improved decision making, colorectal practitioners need to be more aware of their patients' role preferences and need to spend time communicating the necessary information so that patients' may achieve this role. Staged-meetings with the health care team were identified by most of the practitioners as a major facilitator of the SDM process. Furthermore, this may help alleviate the barrier of information overload at the first consultation as well as the issue of time constraint. SDM is seen by many practitioners as time consuming, however, a number of studies have demonstrated that collaborative decision making does not increase consultation time and may in fact save time with

shorter subsequent consultations. (Edward, Elwyn, Mulley, 2002; Say, Thomson, 2003; Greenfield, Kaplan, Ware, 1985)

Gravel et al., 2006, identified a number of the facilitators mentioned in this study and highlighted the most common five: 1) motivation of health professionals, 2) perception that SDM will lead to a positive impact on patient outcomes, 3) perception that SDM is useful and/or practical, 4) patient preference for decision making fitting an SDM model, and 5) characteristics of the patient. Of note, the first three facilitators identified by this systematic review have to do with the practitioner and his/her willingness to partake in SDM. This is in contrast to the facilitators identified by this study, which are mainly patient and system factors. Shared decision-making is considered a crucial component of patient centered care and practitioners need to incorporate this into their daily practice. Interventions aimed at encouraging SDM in clinical practice by targeting the practitioners are warranted.

Practitioners identified discussions with the health care team as the main source of decision support and resources for rectal cancer patients. Following that, they identified the Internet as an excellent resource, provided the information accessed by the patients is regulated and known to be accurate, reliable and not influenced by Industry or For-profit agencies. Practitioners believe that access to information on the health condition, options, benefits and risks would be useful for patients. However, there were mixed opinions on the inclusion of probabilities for those outcomes. Excluding quantitative estimates of the magnitude of a probable

benefit or risk has been shown to result in patients poorly understanding the trade offs between the benefits and side effects, by either over or under estimation.

(Ravdin, Siminoff, Harvey, 1998; O'Connor, 2009) Any decision support tool aimed at improving patient knowledge and understanding of the outcomes following a procedure should include accurate estimates obtained from best evidence.

Limitations

The possibility of participant bias cannot be excluded and may have inflated the percentage of practitioners said to partake in SDM. Practitioners may have been influenced by the concept of social desirability where they may have provided answers they thought the interviewer wanted to hear. (Polit & Beck, 2004) Attempts were made to reinforce that their responses and participation would be kept confidential, however, the possibility of bias cannot be excluded. Furthermore, the practitioners' answers may have been influenced by a self serving bias, in that individuals choose to see themselves as how they wish they were. (MacDonald & Standing, 2002) Thus inflating their participation in SDM knowing it is the focus of the current culture of patient centered care.

Conclusions

Practitioners in colorectal surgery strive to participate in shared decision-making, though variably do, secondary to practitioner, patient and system factors. A number of these barriers and facilitators were identified and will provide direction for future decision support projects. Discussions with the health care team were considered the most valuable in terms of decision support and resources followed

by the Internet. These two areas will be the focus of future improvements to decision support to enable shared decision-making.

Chapter Five: Development of the patient decision aid

Introduction

Colorectal cancer is the third most common solid malignancy and accounts for 13% of all male cancer diagnoses and 12% of all female cancer diagnoses in Ontario. (Ontario Cancer Registry) Rectal cancer comprises any tumor in the last 15 cm of the large intestine. It is a particularly difficult cancer to treat given its confines in the bony pelvis and its proximity to the muscles involved in continence and the nerves involved in bowel, bladder and sexual function. The two mainstays of rectal cancer surgery are the anterior resection (AR) and the abdominoperineal resection (APR) (Figure 1). Traditionally, the choice of rectal resection was based on multiple factors: 1) patient specific – gender, preoperative sphincter function, 2) tumor specific – stage, potential distal resection margin, and 3) surgeon preference. Patients have historically played a passive role in the decision making process. However, it is clear that patients desire and deserve to be more involved in their health care decisions. (Cornish et al., 2007)

Shared-decision making (SDM) aims to include both the patients and their health cared providers in the decision-making process. It encourages patients to play an active role in decisions concerning their health, which is the ultimate goal of patient-centered care. (Howie, Heaney, Maxwell, 2006) SDM includes the following components: (Elwyn, Edwards, Kinnersley, 1999)

- Establishing a context in which patients' views about the treatment options are valued and deemed necessary

- Transferring technical information and making sure the patients understand this information
- Helping patients base their preference on the best evidence
- Eliciting patients' preferences
- Sharing treatment recommendations
- Making explicit the component of uncertainty in the decision-making process.

Patient decision aids, a platform for shared decision-making, have been proven to improve patient knowledge, lower decisional conflict related to feeling uninformed and/or unclear about personal values and reduce the proportion of people who were passive in decision making and/or remained undecided post-intervention. (O'Connor et al., 2009a) Furthermore, exposure to decision aids with probabilities resulted in a higher proportion of people with accurate risk perceptions and more so, when the probabilities were presented quantitatively. (O'Connor 2009a) Currently, there are no practical tools available to engage rectal cancer patients in the decision-making process regarding the most appropriate surgical treatment for them.

Objectives

The objective of this study was to develop a take home, self-administered decision aid incorporating patients' values, as an adjunct to counseling with the health care team.

Methods

Development of the decision aid

Six standard steps were used to develop the decision aid: (Stacey, O'Connor, DeGrasse, Verma, 2003; O'Connor & Edwards, 2009b)

1. Identify the need for the decision aid
2. Determine its feasibility
3. Clarify the objectives of the decision aid
4. Choose a theoretical framework to guide its development
5. Select methods to support decision making
6. Select design and measures to be used to develop and evaluate decision aids

Need for a decision aid

Rectal cancer is a relatively common malignancy and the need for surgery to treat the disease is common. The decision about which surgery to perform is focused on important outcomes such as long-term bowel function (incontinence, urgency, frequency of bowel movements), the ability to withstand extensive surgery and possibly a second operation (for temporary stoma reversal), and the need for a permanent stoma. The decision involves value tradeoffs. A needs assessment conducted with rectal cancer patients who recently underwent surgery to treat their disease identified a lack of awareness of the treatment options and their outcomes as well as a general lack of patient involvement in the decision making process. A needs assessment conducted with rectal cancer practitioners identified their desire to partake in shared-decision making yet the patient population for whom they

consider this applicable is limited. Practitioners are implicitly evaluating the patients' preferences for particular outcomes and along with surgeon and tumor factors are recommending a single treatment option.

A decision aid is needed to encourage practitioners to communicate with their patients all of the surgical options, even if they assume the patient will prefer one over the other. This will enable patients to understand the surgical treatments, outcomes and tradeoffs between them, thus realigning expectations and improving patient satisfaction with the decision-making process and ultimate outcome.

Feasibility

The development of a rectal cancer decision aid was determined to be feasible given the availability of research evidence on the outcomes of the two procedures, access to expert practitioners and a setting to disseminate the decision aid. The evidence table used to create the decision aid is attached as appendix 7. Through the Department of Colorectal Surgery at The Ottawa Hospital, the investigator had access to colorectal surgeons across North America via the American and Canadian Colon and Rectal Surgeons Associations. Furthermore, through the support of these associations we have a venue to disseminate this decision aid across North America following evaluation through The Ottawa Hospital Cancer Assessment Center.

Objective of the decision aid

The objective of the decision aid was to supplement the rectal cancer surgery decision-making process by providing patients with a tool to help them consider the options and associated values based outcomes on their own time. This will subsequently improve the consultation with the health care team by preparing patients for the discussion, and enabling patients' to make high quality decisions about the surgical option best for them. A high quality decision is defined as one that is informed, consistent with personal values, acted on, and one in which the patient expresses satisfaction, not only with the decision itself but also with the process used to reach it. (O'Connor et al., 1998)

Theoretical Framework

The Ottawa Decision Support Framework (ODSF) is an evidence-based theoretical framework and was used to guide the development of the decision aid. (O'Connor, 1998; O'Connor et al., 1992) The ODSF was chosen because it focuses on determinants of decisions that can be addressed by interventions and has been previously validated in similar circumstances.

Methods to Support Decision-Making

The decision support methods selected include providing information on the clinical problem, options and outcomes, with tailored probabilities; explicit values clarification; and guidance in the steps of deliberation and communication of their decision. The Ottawa Decision Aid template was used. This template has been found

to improve decision-making in randomized trials (O'Connor, 2009a; Vandemheen et al., 2009), and before/after studies. (Johnston, Durieux-Smith, O'Connor, Benzies, Fitzpatrick, Angus, in press)

The Ottawa Decision Aid Template divides the decision aid into four components: 1) Introduction to the decision, 2) Describing the benefits, risks and probabilities, 3) Clarifying and communicating values, and 4) Identifying unresolved decisional needs and the next steps.

Introduction to the Decision

The title introduces the question to be answered and the target audience is then identified. A brief description of the condition that leads a person to consider the options follows. Outcome descriptions [e.g. stoma] are described from the patient's point of view.

The options are then explained so that a reader understands how they are involved. Because information cannot be tailored to an individual level, the reader is asked to identify personal factors that may affect the appropriateness of the options and the likelihood of benefits and risks

Finally, the reader is guided in the four steps in deliberation: understanding risks, clarifying values, identifying unresolved needs, and planning next steps.

Describing Benefits, Risks, Probabilities

The best available evidence regarding major benefits and risks is provided. Probabilities are provided. For an interactive version, more detailed descriptions of highlighted outcomes are provided with a mouse click or mouse over.

Clarifying and Communicating Values

In the previous sections, outcomes were described so that it easier to judge their value. In the third section, values for each benefit, risk, or side effect are elicited using an importance rating which is scaled from 0 to 5. Readers can add other reasons that are important to them. They are asked to consider which option has the reasons that matter most. Finally, readers indicate their preferred option.

Unresolved Needs and Next Steps

In this section, the readers' knowledge, and perceptions of feeling informed, clear about values and supported in decision making are elicited to identify unresolved needs. Readers are then asked to consider the next steps.

At the bottom of the decision aid the answers to the knowledge test and author information is provided. Readers are referred to technical documents for further information. Author information, disclosures, and date of publication are also included.

Design and Measures to be Used to Develop and Evaluate the Decision Aid

Development panel

We established a panel to help with the development of the decision aid. The group comprised of: a) an expert in decision support and decision aids; an expert in colorectal surgery; and myself who had gained some expertise in the evidence regarding outcomes. The development panel used the Ottawa Decision Aid template to build the tool. Through a series of iterations, it was revised for optimal content

validity and acceptability in terms of information, length, clarity, appropriateness and usefulness to patients.

Review panel.

Due to feasibility constraints of this student project, the review panel consisted of two experts: an expert in colorectal surgery who had not been previously involved in its development and a patient who had previously treated for rectal cancer. Dr. Patricia L. Roberts was the colorectal expert. She was the president of the American Board of Colon and Rectal Surgery, in 2010, and a practicing colorectal surgeon for over twenty years. Mr. Z is a patient previously treated for rectal cancer.

The expert patient (Mr. Z) felt the tool was easy to work through and had no suggested revisions. He cautioned about using the tool in place of the consultation with the health care team. It will be the role of the practitioner disseminating the decision aid to advise patients that this tool is an adjunct to the decision-making process and does not replace counseling with the health care team. Additionally, a disclaimer will be attached to the ultimate web-based tool, advising patients that this decision aid is an adjunct to decision support and is not to replace consultation with their health care practitioners.

The expert practitioner (Dr. Roberts) suggested revising the term bowel reconnection to something more commonly used. A thorough search of Google, trusted colorectal surgery websites (National Institutes of Health, American Society of Colon and Rectal Surgeons) and patient blogs, was undertaken to assess the terms

commonly used by patients and educational pages. The term “bowel reconnection” was changed to “bowel hook up” and anastomosis. Other suggestions included more diagrams of the different surgical procedures and some minor rephrasing. On the paper version we are limited in terms of space and the number of images that can be included, however, the ultimate web-based version will incorporate images and animated video clips.

Results

The decision aid was developed between February – August 2010. The final version follows. The readability of the decision aid is assessed at a grade 9 level (+/- 1.5 grades) according to the SMOG criteria. (McLaughlin, 1969)

Should I have my bowels “hooked up” (anastomosis) when removing my rectal cancer?

A decision aid for patients with rectal cancer

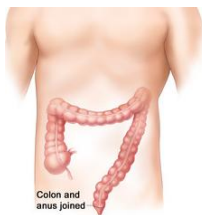
This decision aid is for you if:

- You have rectal cancer treatable by surgery
- Your surgeon has suggested having your bowels hooked back up at surgery

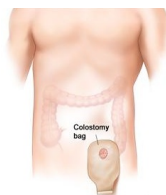
What is rectal cancer?

- Rectal cancer is a tumour located in the last 15 cm of the intestine.
- It is a difficult cancer to treat as it grows close to the muscles involved in the control of bowel movements and gas.
- The first goal of treatment is to remove all of the tumour for the best chance of survival.
- The second goal of treatment is to achieve acceptable bowel function.
- Although having your bowels hooked up is commonly recommended there is another option of having a permanent stoma (bag). These options are described next.

What are your options to remove the tumor?



Bowel hook up (Anterior Resection): The rectum is removed and the two healthy ends of bowel are reconnected. Your surgeon may need to create a temporary stoma (bag) to allow the hook up to heal. This temporary stoma produces more liquid stool with little odour. After 4-6 months the temporary stoma is reversed. After recovery, bowel movements are likely to be less predictable, more frequent, including at night, and urgent. Most people are able to manage this change. Some patients have poor control and have another operation for a permanent stoma. Patients who have radiation are more likely to experience changes in their bowel habits.



Permanent stoma (Abdominoperineal Resection): The rectum and anus are removed. The area of the anus is permanently closed and the bowel is not hooked up. The bowel is brought out to the skin and a stoma bag is attached. Following recovery, bowel movements will become more regular and predictable (e.g. morning and night). The bag controls smells and release of gas. Daily stoma care is necessary such as cleaning the area, changing the bag and applying creams. The costs of these materials may be covered. Most people resume their normal activities.

What other health factors may affect your choice? Check any that apply.

Do you have problems with your bowels?

Accidental leaks of gas:	<input type="checkbox"/> sometimes <input type="checkbox"/> more than once a week <input type="checkbox"/> daily	Accidental leaks of solid stool:	<input type="checkbox"/> sometimes <input type="checkbox"/> more than once a week <input type="checkbox"/> daily
Accidental leaks of liquid stool:	<input type="checkbox"/> sometimes <input type="checkbox"/> more than once a week <input type="checkbox"/> daily	Wear a pad because of any of the above:	<input type="checkbox"/> sometimes <input type="checkbox"/> more than once a week <input type="checkbox"/> daily
<input type="checkbox"/> none of these apply to me			

Do you have problems getting to the bathroom?




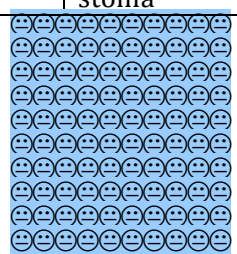

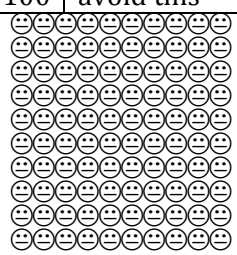
<input type="checkbox"/> difficulty walking	<input type="checkbox"/> wheelchair bound	<input type="checkbox"/> job/lifestyle limits easy access to bathrooms
<input type="checkbox"/> none of these apply to me		



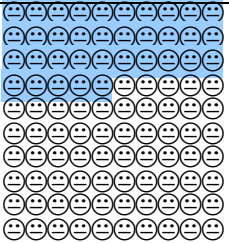
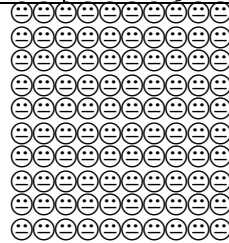
Working through the 4 steps of this decision aid may help you decide.

Step 1: What are the benefits and harms of each option?

What does the research show?

Blocks of 100 faces show a 'best estimate' of what happens to **100 people** after surgery and up to 4 years after who have their bowels reconnected or a permanent colostomy. Each face(☹) stands for one person. The shaded areas show the number of people affected. There is no way of knowing in advance if you will be one of those affected. You should discuss with your surgeon if you have any risk factors for these outcomes.

		
Benefits	Bowel hook up	Permanent stoma
85 fewer people have a permanent stoma if they have their bowels reconnected.	12 get a permanent stoma	100 get a permanent stoma
By avoiding a permanent stoma you also avoid the complications of a permanent stoma such as:	85 avoid a permanent stoma	0 avoids a permanent stoma
<ul style="list-style-type: none"> • hernia of the stoma • bowel sliding out through the stoma • skin irritation around the stoma • problems with healing or infection where the anus was closed 		
Risks		
3 more people who have their bowels reconnected with a temporary stoma return to the operating room (OR) because of a life-threatening leak at the connection site. This may mean extra treatments, longer hospital stay and a longer recovery. You may need to be treated in the intensive care unit.	3 return to the OR	0 return to the OR
This number is higher for people who do not have a temporary stoma when their bowels are reconnected. In this case, 11 more people will return to the OR.	97 avoid this	100 avoid this
		

		
Risks continued	Bowel hook up	Permanent stoma
<p>35 more people will complain of some form of incontinence following bowel hook up. The majority has minor incontinence (accidents) to gas and liquid stool. 14 people (out of 100) experience major incontinence to solid stool.</p> <p>All of these people choose to wear a protective pad in their underwear.</p>	<p>35 wear a pad</p>	<p>0 wear a pad</p>
	<p>65 avoid a pad</p> 	<p>100 avoid a pad</p> 
	<p>Problems from either surgery:</p> <p>Some people who have either surgery report worsening of their urinary or sexual function. The number of people who report this problem is the same for both surgeries.</p> <p>Urinary problems include difficulty emptying the bladder. There may also be problems of leaking urine, which is more common in women.</p> <p>For men, sexual problems may include impotence or ejaculation problems. For women, sexual problems may include vaginal dryness, pain during intercourse, problems with arousal or achieving orgasm.</p>	

Step 2. Which reasons to choose each option matter most to you?

Common reasons to choose each option are listed below.

Mark ✓ how much each reason matters **to you** on a scale from 0 to 5.

'0' means it is **not** important to you. '5' means it is **very** important to you.



Reasons to...	Not Important	Very Important
Choose to have your bowels hooked up		
How important is it for you to have bowel movements the usual way?	① ② ③ ④ ⑤	① ② ③ ④ ⑤
How important is it to you to avoid the inconvenience of caring for a stoma? (e.g. emptying the bag, cleaning the area, applying creams and buying bags)	① ② ③ ④ ⑤	① ② ③ ④ ⑤
How important is it for you to avoid the complications of a permanent stoma? (including wound healing problems, stoma hernias, and skin irritations)	① ② ③ ④ ⑤	① ② ③ ④ ⑤



Reasons to ...	Not Important	Very Important
Choose a permanent stoma		
How important is it that your bowel movements are more predictable, less frequent and less urgent?	① ② ③ ④ ⑤	① ② ③ ④ ⑤
How important is it for you to avoid incontinence to stool or gas?	① ② ③ ④ ⑤	① ② ③ ④ ⑤
How important is it to for you to avoid having multiple surgeries?	① ② ③ ④ ⑤	① ② ③ ④ ⑤
List other reasons that are important	① ② ③ ④ ⑤	① ② ③ ④ ⑤
List other reasons that are important	① ② ③ ④ ⑤	① ② ③ ④ ⑤

Now, thinking about the reasons that are most important to you...

Which option do you prefer? Check one.

- To have my bowels hooked up
- Permanent stoma
- I don't know

Step 3: What else do you need to prepare for decision-making?



Knowledge

Find out how well this decision aid helped you learn the key facts.

Check the best answer.

	Bowel hook up	Permanent stoma	Don't know
1. Which option has the <u>highest</u> chance of needing a second surgery?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Which option cannot be reversed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Which option has the highest chance of hernia and wound healing problems?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Which option has the <u>highest</u> chance of incontinence (accidents) of stool or gas?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Check your answers at the bottom of the page.

Do you know enough about the benefits and side effects of each option?

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>



Values

Are you clear about which benefits and side effects matter most to you?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------



Support

Do you have enough support and advice from others to make a choice?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------



Uncertainty

Do you feel sure about the best choice for you?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

Step 4: What are the next steps?

Check your next steps:

- I am ready to discuss my decision with my doctor.
 - I need to discuss the options with my doctor and family in more detail.
 - I need to read more about my options.
 - Other, please specify _____
-

This information is not intended to replace the advice of a health care provider.

Answers for the key facts: 1. Bowel hook up 2. Permanent stoma 3. Permanent stoma 4. Bowel reconnection

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Discussion

The resulting decision aid for rectal cancer patients is a self-administered tool that guides patients to: understand their options; clarify the personal value of the benefits and risks; and identify questions for their practitioners as well as unresolved needs. This decision aid aims to engage patients and practitioners in SDM and improve the informed consent process. Valid informed consent requires patients understand the proposed intervention, including risks, benefits and alternatives. (Matiasek & Wynia, 2008) Unfortunately, the informed consent process is frequently inadequate and prior research has demonstrated that patient comprehension of the key elements of informed consent is poor. (Byrne, 1988; Cassileth, 1980; Mark, 1990; Paling, 2003) Additionally, the reported (in this thesis) needs assessment conducted with rectal cancer patients at The Ottawa Hospital, demonstrated that approximately 50% of patients have no recollection of the major outcomes discussed during informed consent. Though slightly different than decision-making, informed consent has many of the same problems and can benefit from improved communication, in particular of the options, risks and benefits.

Currently, cancer patients routinely provide written informed consent for surgery. The process of informed consent does not necessarily indicate that patients are involved in making their treatment decision; rather the signature indicates that they agreed to the treatment, which may have been a treatment recommendation made by the physician. (Stacey D, Samant R, Bennett C, 2008) However this may be changing. Legislation has been passed in Washington State regarding informed consent and the need to acknowledge that SDM occurred in the informed consent process. (SB 5930 Washington State, 2007) The

description of SDM within this legislation includes patient engagement in decision-making, use of patient decision aids, and the need to ensure patients' understanding of the seriousness of the disease and the available treatment alternatives. Thus beyond a decision support tool, this decision aid will play a major role in the informed consent process for rectal cancer surgery.

Future Directions

Creation of web-based interactive patient decision aid

Using the current decision aid as the foundation, an interactive, web based patient decision aid will be created. This interactive version will present information on the disease, treatment options and outcomes. It will allow patients to access as much or as little information on particular outcomes as they desire. For example, patients who are satisfied with “with an anterior resection there are risks to sexual dysfunction” can skip to the next section, whereas patients who would like to know more about the specific risks and probabilities can continue on. This tailored decision support tool will empower the patient to gain as much knowledge on his/her own time schedule as s/he desires. Patients will be able to record questions they would like to discuss with the health care team and print them out at the end. The results from the knowledge assessment will be printed as well to help guide the consultation and fill in any knowledge gaps. Based on the advice of Dr. Patricia Roberts, there will be more images and animated video clips of the different surgical procedures, scars and stomas. Additionally, we intend to include patient stories to help patients with the values based portion of the decision aid. This tool will be created

with the advice of experts in decision aid development, experts in colorectal surgery and patient input.

Field-testing of the decision aid

In order to improve the validity of this decision aid, as well to comply with the International Patient Decision Aid Standards (IPDAS) evaluation criteria the interactive web-based decision aid will be field-tested against the current standard. We will evaluate patients' changes in knowledge, decisional conflict measures and expectations. Changes among subgroups presenting with differing baseline needs such as knowledge, choice predisposition, and educational level will be explored. We will also explore the concordance between patients' values and their selected option.

Conclusion

A patient decision aid for adult patients with rectal cancer was created in accordance with IPDAS development standards and based on the Ottawa Decision Support Framework. This decision aid has the potential to empower rectal cancer patients to partake in shared decision making with the health care team. It will enable values based decision making between an anterior resection and an abdominoperineal resection. Further research is needed to meet IPDAS evaluation standards.

Disclosure

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Appendices

Appendix One – Search Strategies

*Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R)
<1950 to Present> Run July 3rd, 2009*

- 1 exp colorectal Neoplasms/ (111820)
- 2 ((rect\$ or colorect\$) adj2 (neoplasm\$ or cancer\$ or carcinoma\$ or adenocarcinoma\$ or tumor\$ or tumour\$ or malignan\$)).tw. (58792)
- 3 or/1-2 (121799)
- 4 ((anterior or mesorectal or low) adj5 (resect\$ or excis\$)).tw. (6607)
- 5 Laparoscopy/ (41437)
- 6 (laparoscop\$ adj5 surg\$).tw. (14652)
- 7 (lar or tme).tw. (2231)
- 8 or/4-7 (53683)
- 9 3 and 8 (4559)
- 10 Fecal Incontinence/ (6224)
- 11 Defecation/ (4732)
- 12 anterior resect\$ syndrome\$.tw. (21)
- 13 ((fec\$ or faec\$ or anal or stool) adj2 incontinen\$).tw. (4008)
- 14 (bowel adj2 (frequen\$ or urgen\$)).tw. (707)
- 15 "Recovery of Function"/ (15181)
- 16 (bowel function or evacuation rate\$).tw. (1677)
- 17 ((nocturnal or night\$) adj bowel).tw. (19)
- 18 (pain\$ adj2 bowel).tw. (246)
- 19 ((gastro\$ or gi or rect\$ or anorect\$) adj (outcome\$ or function\$)).tw. (2483)
- 20 exp "signs and symptoms, digestive"/ (105223)
- 21 (diarrhea or constipation or flatulence).tw. (49395)
- 22 or/10-21 (159744)

- 23 22 and 9 (498)
- 24 limit 23 to english language (401)
- 25 from 24 keep 1-401 (401)

Database: EMBASE <1980 to 2009 Week 27> - Run July 3rd, 2009

- 1 rectum anterior resection/ (781)
- 2 ((anterior or mesorectal or low) adj5 (resect\$ or excis\$)).tw. (5483)
- 3 laparoscopic surgery/ (29145)
- 4 (laparoscop\$ adj5 surg\$).tw. (12200)
- 5 (lar or tme).tw. (2070)
- 6 or/1-5 (39561)
- 7 exp colon cancer/ (88429)
- 8 exp rectum cancer/ (62200)
- 9 ((rect\$ or colorect\$) adj2 (neoplasm\$ or cancer\$ or carcinoma\$ or adenocarcinoma\$ or tumor\$ or tumour\$ or malignan\$)).tw. (51048)
- 10 or/7-9 (105026)
- 11 10 and 6 (3970)
- 12 Feces Incontinence/ (6221)
- 13 defecation disorder/ or defecation urgency/ or painful defecation/ (905)
- 14 ((fec\$ or faec\$ or anal or stool) adj2 incontinen\$).tw. (3495)
- 15 (bowel adj2 (frequen\$ or urgen\$)).tw. (640)
- 16 (bowel function or evacuation rate\$).tw. (1488)
- 17 (pain\$ adj2 bowel).tw. (238)
- 18 ((gastro\$ or gi or rect\$ or anorect\$) adj (outcome\$ or function\$)).tw. (2193)
- 19 diarrhea/ (79260)
- 20 constipation/ (28168)
- 21 flatulence/ (4328)

- 22 (diarrhea or constipation or flatulence).tw. (37516)
 23 or/12-22 (120583)
 24 11 and 23 (470)
 25 limit 24 to english language (408)

CINAHL search strategy

#	Query	Results
S21	(S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19) and (S9)	4
S20	S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19	181
S19	pain* N2 bowel	88
S18	evacuation rate*	2
S17	bowel function	206
S16	bowel N2 frequency or bowel N2 urgency	60
S15	incontinen*	7912
S14	gastrointestin* outcome* or gi outcome* or gastrointestin* function* or gi function*	685
S13	(MH "Recovery")	6449
S12	(MH "Signs and Symptoms, Digestive (Non-Cinahl)+")	9013
S11	(MH "Defecation")	370
S10	(MH "Fecal Incontinence")	1123
S9	(S5 or S6 or S7) and (S4)	19
S8	S5 or S6 or S7	200
S7	low n5 resect* or low n5 excis*	83
S6	mesorectal n5 resect* or mesorectal n5 excis*	33
S5	anterior n5 resect* or anterior n5 excis*	121
S4	S1 or S2 or S3	1373
S3	rect* N2 neoplasm* or rect* N2 cancer* or rect* N2 carcinoma* or rect* N2 adenocarcinoma* or rect* N2 tumor* or rect* N2 tumour* or rect* N2 malignan*	918
S2	colorect* N2 neoplasm* or colorect* N2 cancer* or colorect* N2 carcinoma* or colorect* N2 adenocarcinoma* or colorect* N2 tumor* or colorect* N2 tumour* or colorect* N2 malignan*	5623
S1	(MH "Colorectal Neoplasms+")	7806

Appendix Two – Patient needs assessment data extraction form

Study Identification Number _____

Gender M/F

Month/Year of surgery _____

Surgeon: _____

Surgery Type Anterior resection Abdominal-perineal resection

Surgeon dictated that an option was offered? Y/N

Diverting ileostomy Y/N

Month/Year of reversal _____

If not reversed, reason specified:

Tumor height: _____

Anastomosis height: _____

Anastomosis type: stapled handsewn intersphincteric resection

Other:

TNM stage T_____ N_____ M_____ AJCC stage

Neoadjuvant therapy Y/N

Type: _____

Completed Y/N

Adjuvant therapy Y/N

Type: _____

Completed Y/N

Appendix Three – Patient needs assessment interview guide

Needs Assessment Interview Guide

Interview Questions for Patients with Rectal Cancer

Thank you for agreeing to participate in this study. My name is Adena Scheer; I am a surgery resident working with (physician's name) and a Master's student in Epidemiology at the University of Ottawa.

I am conducting a study to learn more about the needs of patients when they are making decisions about surgery for rectal cancer. This information will be used to help plan ways to better support patients facing this decision.

All of the information collected will be kept confidential. I expect it to take about 20-30 minutes. As we go through the interview, please let me know if you are feeling tired, unwell, or if you need a break. Please remember that this is a voluntary survey and if for any reason you wish to stop, please let me know and we will stop the interview immediately.

Do you have any questions before we start?

Start time of interview:__:__

PERCEPTION OF THE DECISION:

1. Thinking about the time when you were diagnosed with rectal cancer what surgery options were you offered?

[Probe: Ascertain whether the patient was offered the option of a permanent colostomy or bowel reattachment +/- a temporary ileostomy]

*** If patient was not given an option skip to section 2 ****

2. How did you feel when making this decision?

[Probe: unsure about what to do worried what could go wrong distressed or upset constantly thinking about the decision wavering between choices or changing your mind delaying the decision questioning what is important to you feeling physically stressed (tense muscles, racing heartbeat, difficulty sleeping) Anxious unqualified to make the decision confused

3. Sometimes there are certain things that make a decision difficult. What things made this decision difficult for you?

Probe: Were you: lacking information about options, pros and cons lacking information on the chances of benefits and harms unclear about what is important to you lacking information on what others decide feeling pressure from others lacking support from others lacking motivation or not feeling ready to make a decision lacking the skill or ability to make this type of decision other too distressed to think straight too anxious putting others needs ahead of our own (not wanting to be a burden) wanting to choose on the basis of family needs/preferences

4. At the time when you were considering surgery what was your understanding of the main pros (advantages) and cons (disadvantages) of the two surgical options? Let's start with the first option, what were the reasons for and against choosing that option?

Options	Advantages	Disadvantages
Anterior Resection ("hooked up" +/- a temporary stoma)		
APR (permanent colostomy)		

5. Let's focus on the procedure you had. What were you told to expect in terms of your chance of cure or survival after the surgery?

6. What were you told to expect in terms of your bowel function after the surgery?

[Probe: Before and after diverting ileostomy reversal (if applicable) |_] Symptoms of anterior resection syndrome – incontinence to gas/stool, increased bowel movement frequency, urgency, wearing a pad, inability to differentiate between gas and stool, |_] Stoma related complications – accidents, nocturnal bowel movements, smell |_] Issues related to having a temporary ileostomy – accidents, output]

7. How satisfied are you with your bowel function?

[Probe: Did level of satisfaction change post ileostomy reversal?]

8. What were you told to expect in terms of your sexual function after the surgery?

9. What were you told to expect in terms of your urinary function after the surgery?

10. What were you told to expect in terms of your quality of life following the surgery?

[Probe: if patient had an ileostomy and reversal have they noticed a difference]

RESOURCES:

11. Think back to when you were first told about the surgical options for your rectal cancer. How did you go about making this decision?

[Probe: Did you: get information on options get information on how likely the options are meet with patients already treated for rectal cancer preoperative teaching sessions with health professionals speak with an enterostomal therapy nurse find ways to handle pressure while deciding get support from others advice from loved ones follow MD's advise other]

How much time did you have to make the decision?

Was this sufficient for you?

12. What things really helped you make this decision?

[Probe: **Personal resources:** previous experience with the situation trusting yourself (self-confidence) motivation skill in decision making physical health general emotional health good analytic skills (cognitive health) good social connections (social health)

External resources: availability and access to information advice emotional support help with practical things financial assistance

Sources: social network professional network (specify: _____) support groups ET nurse formal health care system education sessions social sector (Friends) employer]

13. What things got in the way of (hindered you) making this decision?

[Probe: other responsibilities emotional stability lack of confidence depression anxiety conflicting needs (ill partner/children) confusion/conflicting feelings other's needs]

14. Is there something that could have helped you to overcome these obstacles?

PERCEPTION OF OTHERS

15. There are 5 different ways in which patients participate in decisions about their health. Please choose the way that best describes how the decision for the surgical treatment of your rectal cancer was made. (Appendix 1)

I made the decision about which surgery I received

I made the final decision about my surgery after seriously considering my doctor's opinion

I left all decisions regarding my surgery to my doctor

After voicing my opinion I left the final decision to my doctor

My doctor and I shared the responsibility for deciding which surgery is best for me

16. Can you describe to me how you would have preferred to make this medical decision? (Show control preference scale – Appendix 2)

17. Who was involved in helping you make this decision? How was s/he involved? What was his/her opinion?

Individual	Help provided
	<input type="checkbox"/> gave you information on your cancer <input type="checkbox"/> gave you information on choices <input type="checkbox"/> gave information on how likely the choices are <input type="checkbox"/> provided you with information about the pros and cons of each option, <input type="checkbox"/> helped you consider how important each choice is to you, <input type="checkbox"/> provided you with information on how or what others decided <input type="checkbox"/> suggested ways to help handle pressure <input type="checkbox"/> provided you with support <input type="checkbox"/> support to loved ones <input type="checkbox"/> other:
	<input type="checkbox"/> gave you information on your cancer <input type="checkbox"/> gave you information on choices <input type="checkbox"/> gave information on how likely the choices are <input type="checkbox"/> provided you with information about the pros and cons of each option, <input type="checkbox"/> helped you consider how important each choice is to you, <input type="checkbox"/> provided you with information on how or what others decided <input type="checkbox"/> suggested ways to help handle pressure <input type="checkbox"/> provided you with support <input type="checkbox"/> support to loved ones <input type="checkbox"/> other:
	<input type="checkbox"/> gave you information on your cancer <input type="checkbox"/> gave you information on choices <input type="checkbox"/> gave information on how likely the choices are <input type="checkbox"/> provided you with information about the pros and cons of each option, <input type="checkbox"/> helped you consider how important each choice is to you, <input type="checkbox"/> provided you with information on how or what others decided <input type="checkbox"/> suggested ways to help handle pressure <input type="checkbox"/> provided you with support <input type="checkbox"/> support to loved ones <input type="checkbox"/> other:

[Probe: ET nurse, patients who already made the decision, preoperative teaching sessions]

Section 2 – for patients who answered no to question 1 (no option given/perceived)

2. Let's focus on the procedure you had. What were you told to expect in terms of your chance of cure or survival after the surgery?

3. What were you told to expect in terms of your bowel function after the surgery?

[Probe: Before and after diverting ileostomy reversal (if applicable) |_] Symptoms of anterior resection syndrome – incontinence to gas/stool, increased bowel movement frequency, urgency, wearing a pad, inability to differentiate between gas and stool, |_] Stoma related complications – accidents, nocturnal bowel movements, smell |_] Issues related to having a temporary ileostomy – accidents, output]

4. How satisfied are you with your bowel function?

[Probe: Did level of satisfaction change post ileostomy reversal?]

5. What were you told to expect in terms of your sexual function after the surgery?

6. What were you told to expect in terms of your urinary function after the surgery?

7. What were you told to expect in terms of your quality of life following the surgery?

[Probe: If not satisfied with surgical outcome would s/he prefer a permanent stoma]

PATIENT CHARACTERISTICS:

Age: ____

Gender: ____

Last completed grade: _____

In the event that I need to clarify any part of our discussion today or the overall findings, could I call you to do so? Yes ____ No ____

Thank you for your valuable contribution!

End of interview: __:____

Interview Guide Appendix 1:

I made the decision about which surgery I received

I made the final decision about my surgery after seriously considering my doctor's opinion

I left all decisions regarding my surgery to my doctor

After voicing my opinion I left the final decision to my doctor

My doctor and I shared the responsibility for deciding which surgery is best for me

Interview Guide Appendix 2:

Adapted from Degner LF, Sloan JA, Venkatesh P. The Control Preferences Scale.
Canadian Journal of Nursing Research. 1997; 29: 21-43.



I would have preferred
to make the final
selection about which



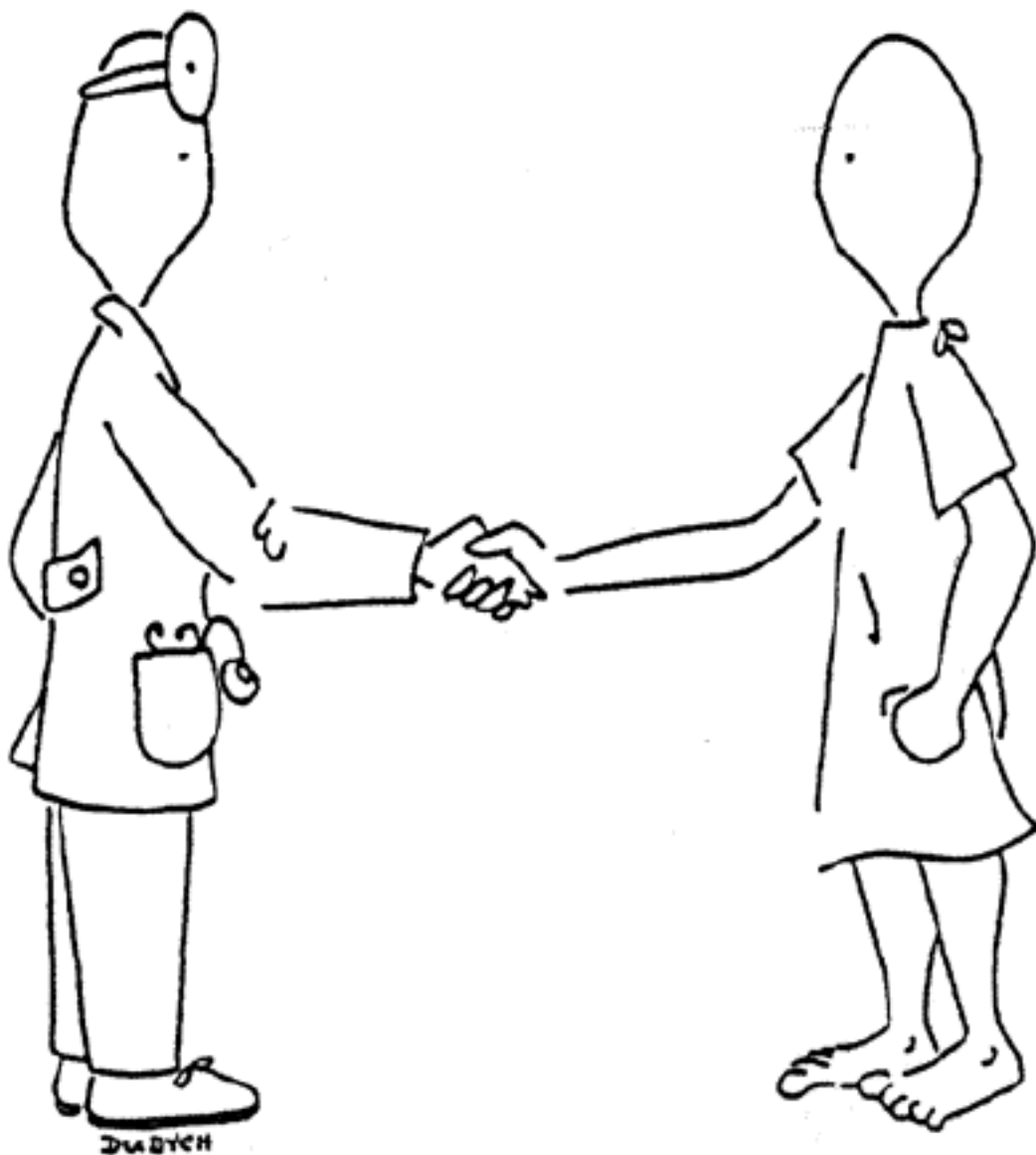
I would have preferred to make the final selection of which treatment I received after seriously considering my Doctor's opinion.



I would have preferred to leave all decisions regarding my treatment to my Doctor.



I would have preferred that my Doctor made the final decision about which treatment to use after seriously considering my opinion.



I would have preferred that my
Doctor and I shared
responsibility for deciding which
treatment is best for me.

Appendix Four – Patient information/consent form

Information Sheet and Consent Form

Patient's Decision Making Needs Related to Surgical Treatment for Rectal Cancer

Background of Study

There is limited research looking at patient participation in making decisions about rectal cancer surgery. Currently, no studies exist that investigate how patients make decisions about the choice of surgical treatment for their rectal cancer when faced with more than one option.

Purpose and Design

This study is being conducted with patients who have undergone surgical treatment for rectal cancer at The Ottawa Hospital. The study will explore how patients faced with more than one surgical option for rectal cancer treatment go or would go about making the decision. The study will also look at what has (or might have) been helpful when making such a decision. The summary of the results will be used to make recommendations and to develop interventions in order to better support patients who are making these decisions.

Study Procedures

You are being asked to participate in this study because you have recently undergone surgery for rectal cancer at The Ottawa Hospital. If you agree to participate you will be interviewed about the surgical option(s) you faced and any decisions you made about the surgical treatment of your rectal cancer. You will also be asked questions about the surgical information that was and is important to you regarding rectal cancer surgery and what support you received or would need to make that decision.

The interview will last about 20-30 minutes and will take place in a quiet patient exam room in the clinic at The Ottawa Hospital. You may take a break at any time during the interview or choose not to answer particular questions. The interview will be tape-recorded and the researcher may also take notes to ensure we review your answers accurately. The audiotape may be transcribed to ensure your answers are accurately interpreted.

Information will also be collected from your medical chart about your surgery, the stage of your disease and the type of treatments you received and/or are presently to treat your rectal cancer.

Your answers and information obtained from your chart will be summarized along with other participant's answers and will be kept strictly confidential.

Benefits of the Study

There is no benefit from participating in this study. The anonymous information you and others provide may help the health care team plan future programs to support patient's decision making.

Inconvenience/ Risks of the study

There are no known physical or psychological risks associated with participating in this study. You may choose not to answer any question that you would rather not answer. If you have concerns about some of the issues raised in the interview please speak with the researcher who will attempt to answer any questions or refer you on where necessary.

Right to Confidentiality

A unique study number will identify the transcript, the notes from the interview and the data collected during the review of your medical chart. In no way will the data be linked to your name. You will not be identified in any publications or presentations resulting from this study.

All information you provide will be kept confidential; only the researcher and members of the research team will have access to the data. The transcripts and the tape recordings will be kept in a locked filing cabinet in the researcher's office. Once the study is completed the tape recordings will be destroyed. The coded transcripts (without identifying information) will be kept for a period of fifteen (15) years.

Right to information and to withdrawal from the Study

If you need more information on this study you can page me, Adena Scheer or contact my thesis supervisors Dr. Robin Boushey or Dr. Annette O'Connor.

You are under no obligation to participate in the study; you may choose not to participate in the study or to withdraw from the study at any time. You may choose not to answer some questions during the interview. Not participating in this study will not affect your medical care in any way.

You may contact the Chairperson of the Ottawa Hospital Research Ethics Board, for information regarding person's rights as a research subject.

Consent

“I have read this Information Sheet/Consent Form (or have had this document read to me), and have had an opportunity to ask the researcher any questions I had about the study.

My questions and/or concerns have been answered to my satisfaction and I agree to participate in this study. If I decide at a later stage in the study that I would like to withdraw my consent, I may do so at any time.

A copy of this Information Sheet/Consent Form will be provided to me should I want to review the information at a later date, if I need to contact someone about the study or my participation in the study, or simply for my records.

Signatures

Participant's Name

Participant's Signature

___/___/___

Date

Investigator/delegate's Name

Investigator/delegate's Signature

___/___/___

Date

Appendix Five – Practitioner Interview Guide

Needs Assessment Interview Guide

Interview Questions for Practitioners Treating Patients with Rectal Cancer

Thank you for agreeing to participate in this study. My name is Adena Scheer; I am a surgery resident working with Dr. Robin Boushey and a Master's student in Epidemiology at the University of Ottawa.

I am conducting this study to learn more about the decision making needs of patients and practitioners involved in surgical decision making for rectal cancer. This information will enable improved planning of decision support for patients.

All of the information we collect in this interview will be kept confidential. I appreciate your cooperation and this won't take more than 10-15 minutes.

DECISION

1. For the treatment of mid or distal rectal cancer which surgical procedures do you preferentially perform?

[Probe: Do you consider the option of a handsewn coloanal anastomosis |_] Intersphincteric resection[_]

2. Let's focus on the decision to perform a low or ultralow anterior resection (LAR/ ULAR) versus an abdominoperineal resection (APR). Is there a patient population for whom you would offer the option of an APR despite it being technically feasible to do an anastomosis?

Is there a group of patients to whom you would not offer a LAR/ULAR despite it being technically feasible?

3. Let's focus on the situation of a mid or distal rectal cancer where both a LAR/ULAR and an APR are possible. How is this decision usually made with the patient?

4. Lets talk about the difficulty patients would have making a decision between undergoing a LAR/ULAR or APR. In your experience how do patients feel (or would feel) when making this decision?

[Probe behavioural manifestations of decisional conflict]

Do patients feel:

- unsure about what to do
- worried what could go wrong
- distressed or upset
- constantly thinking about the decision
- wavering between choices or changing their mind
- delaying the decision
- questioning what is important to them
- feeling physically stressed, tense muscles, racing heartbeat, difficulty sleeping]

5. What makes the decision difficult for patients?

[Probe factors contributing to decisional conflict]

Are patients:

- Lacking information about options, benefits, risks
- Lacking information on the chances of benefits and harms
- Confused from information overload
- Unclear about what is important to them
- Feeling unsupported in decision making
- Feeling pressure from others
- Lacking motivation or not feeling ready to make a decision
- Lacking the ability or skill to make a decision

<p>7. What is your usual role in making this decision?</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p>[Probe role:]</p> <p>Do you usually:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Make the decision for the patients <input type="checkbox"/> Share the decision with the patients <input type="checkbox"/> Provide support or advice for patients to make the decision on their own
---	---

8. What factors make it difficult for you to support patient participation in decision making?

9. What factors make it easier for you to support your patients' participation in decision making?

<p>10. Who else besides yourself and the patient is usually involved in making this decision?</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p>[Probe:]</p> <ol style="list-style-type: none"> 1. spouse 2. family 3. friend 4. enterostomal therapy (ET) nurse 5. other health care provider 6. patients who have previously been treated for rectal cancer 7. other, specify _____
--	--

<p>11. What is their usual role in making this decision (i.e. the person mentioned above)?</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p>[Probe role:]</p> <p>Do you they usually:</p> <ol style="list-style-type: none"> 1. Make the decision for the patients 2. Share the decision with the patients 3. Provide support, education or advice for patients to make the decision on their own 4. Don't know 5. Other, specify
---	---

<p>12. How do patients usually go about making such a decision?</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p>[Probe decision making behaviour:]</p> <p>Do they:</p> <ol style="list-style-type: none"> 1. Get information on options 2. Get information on the chances of benefits and risks 3. Consider the personal importance of the benefits and risks 4. Get information on how others go about deciding 5. Get support from others 6. Find ways to handle pressure
--	--

13. What would help patients to make this decision?

14. What will hinder patients (get in the way of) making this decision?

15. Is there anything else that would help overcome barriers to decision making?

16. I will list possible ways to help some people with a decision, which ones do you think might be useful to your patients?

<input type="checkbox"/> Counselling from a health practitioner →	IF YES, specify what types [probe: ET nurse]
<input type="checkbox"/> Discussion groups with patients previously treated →	IF YES, specify what type of organization or group
<input type="checkbox"/> Information materials	<p>IF YES, specify content</p> <ul style="list-style-type: none"> <input type="checkbox"/> Health condition <input type="checkbox"/> Options <input type="checkbox"/> Benefits <input type="checkbox"/> Risks <input type="checkbox"/> Probabilities of benefits/risks <input type="checkbox"/> Help considering the personal importance of benefits versus risks <input type="checkbox"/> Guidance in the steps of deliberation and communication <input type="checkbox"/> Other, specify _____ <hr/> <p>IF YES, specify format</p> <ul style="list-style-type: none"> <input type="checkbox"/> Booklet, pamphlets <input type="checkbox"/> Internet <input type="checkbox"/> Videos/DVDs <input type="checkbox"/> Other, specify _____ <hr/> <p>IF YES, who do you think should prepare information about the decision</p> <ul style="list-style-type: none"> <input type="checkbox"/> Health societies for specific condition (e.g. Canadian Cancer Society) <input type="checkbox"/> Expert medical and health practitioners, including ET nurses (American/Canadian Society of Colorectal Surgeons) <input type="checkbox"/> Not for profit companies that produce health information [e.g. Healthwise] <input type="checkbox"/> For profit companies that produce health information [e.g. WEB MD; BMJ Best Treatments.ORG]

17. Is there anything else that would help you to do a better job supporting your patients' involvement in decision-making?

CHARACTERISTICS OF PRACTITIONER

18. How long have you been in practice

- 0-5 years
- 6-10 years
- 11-20 years
- 21 +

19. Sex

1. Male
2. Female

20. Colorectal fellowship: yes/no

21. Other fellowship: specify _____

22. Practice Location specify _____

[THANK RESPONDENT]

Appendix Six – Practitioner Information/Consent form

Information Sheet and Consent Form

Surgeon’s Decision Making Needs Related to Surgical Treatment for Rectal Cancer

Background of Study

There is limited research looking at patient participation in making decisions about rectal cancer surgery. Currently, no studies exist that investigate how surgeons involve patients in making decisions about the choice of surgical treatment for their rectal cancer when faced with more than one option.

Purpose and Design

This study is being conducted with surgeons who treat patients with rectal cancer in North America. The study will explore how surgeons go or would go about involving patients in making the decision for rectal cancer treatment when faced with more than one surgical option. The study will also look at what has (or might have) been helpful when making such a decision. The summary of the results will be used to make recommendations and to develop interventions in order to better support patients and surgeons who are making these decisions.

Study Procedures

You are being asked to participate in this study because you are a surgeon that treats patients with rectal cancer. If you agree to participate you will be interviewed about the surgical option(s) available and how you and your patients make decisions about the surgical treatment for rectal cancer. You will also be asked questions regarding decision support for making these decisions.

The interview will last about 20 minutes and will take place over the phone at your convenience. You may take a break at any time during the interview or choose not to answer particular questions. The interview will be tape-recorded and the researcher may also take notes to ensure we review your answers accurately. The audiotape may be transcribed to ensure your answers are accurately interpreted.

Your answers will be summarized along with other participant’s answers and will be kept strictly confidential.

Benefits of the Study

There is no benefit from participating in this study. The anonymous information you and others provide may help the health care team plan future programs to support patient's decision making.

Inconvenience/ Risks of the study

There are no known physical or psychological risks associated with participating in this study. You may choose not to answer any question that you would rather not answer. If you have concerns about some of the issues raised in the interview please speak with the researcher who will attempt to answer any questions or refer you on where necessary.

Right to Confidentiality

A unique study number will identify the transcript, the notes from the interview and the data collected during the review of your medical chart. In no way will the data be linked to your name. You will not be identified in any publications or presentations resulting from this study.

All information you provide will be kept confidential; only the researcher and members of the research team will have access to the data. The transcripts and the tape recordings will be kept in a locked filing cabinet in the researcher's office. Once the study is completed the tape recordings will be destroyed. The coded transcripts (without identifying information) will be kept for a period of fifteen (15) years.

Right to information and to withdrawal from the Study

If you need more information on this study you can page me, Adena Scheer or contact my thesis supervisors Dr. Robin Boushey or Dr. Annette O'Connor.

You are under no obligation to participate in the study; you may choose not to participate in the study or to withdraw from the study at any time. You may choose not to answer some questions during the interview.

You may contact the Chairperson of the Ottawa Hospital Research Ethics Board, for information regarding person's rights as a research subject.

Consent

"I have read this Information Sheet/Consent Form (or have had this document read to me), and have had an opportunity to ask the researcher any questions I had about the study.

My questions and/or concerns have been answered to my satisfaction and I agree to participate in this study. If I decide at a later stage in the study that I would like to withdraw my consent, I may do so at any time.

A copy of this Information Sheet/Consent Form will be provided to me should I want to review the information at a later date, if I need to contact someone about the study or my participation in the study, or simply for my records.

Signatures

Participant's Name

Participant's Signature

___/___/___

Date

Investigator/delegate's Name

Investigator/delegate's Signature

___/___/___

Date

Appendix Seven – Evidence form for decision aid

Technical Background Document for Facts and Numbers behind the Rectal CA Decision Aid

Outcome	Definition	Option	Time Frame	N Participants (N Studies)	Population	EVENT RATE		MODELLING			SOURCE	Study Design
						#	base	rate out of 100	notes	rate out of 100 in decision aid		
								100		100		
Anastomotic leak	clinical signs such as peritonitis, pelvic abscess, faecal discharge from a drain and rectovaginal fistula	AR stoma - NRS		4407 (21)	LAR for rectal cancer, complete resection and stapled anastomosis; complete donuts; negative air leak; reasons to proceed with stoma - variable: surgeon decision, defective donuts, +ve leak test, technical difficulties, poor bowel prep, rads	412	4407	9.35		9	Tan WS 2009	Meta-analysis NRS
	clinical signs such as peritonitis, pelvic abscess, faecal discharge from a drain and rectovaginal fistula	AR no stoma - NRS		5750 (21)	LAR for rectal cancer, complete resection and stapled anastomosis; complete donuts; negative air leak; reasons to proceed with stoma - variable: surgeon decision, defective donuts, +ve leak test, technical difficulties, poor bowel prep, rads	800	5750	13.91		14	Tan WS 2009	Meta-analysis NRS
Return to OR secondary to anastomotic leak	re-operation secondary to anastomotic leak	AR stoma - NRS		3542 (15)	Patients with LAR and leak requiring a return to the OR	101	3542	2.85		3	Tan WS 2009	Meta-analysis NRS
	re-operation secondary to anastomotic leak	AR no stoma - NRS		4151 (15)	Patients with LAR and leak requiring a return to the OR	443	4151	10.67		11	Tan WS 2009	Meta-analysis NRS
Permanent stoma - despite initial surgery AR	Stoma at 42 months with no scheduled reversal	AR with stoma - RCT		116 (1)	Patients with LAR and randomized to defunctioning ileostomy	14	116	12.07		12	Matthiessen P 2007	RCT
	Stoma at 42 months with no scheduled reversal	AR with no stoma - RCT		118 (1)	Patients with LAR and randomized to no defunctioning stoma	19	118	16.10		16	Matthiessen P 2007	RCT
Peristomal Hernia	Incisional hernia related to abdominal wall stoma - clinically detected, end colostomy	APR, Hartmann	60.3 mths (12-128)	2317 (16)	Patients with end colostomy (mostly - small percentage of loop colostomy included) for any cause - malignancy etc	345	2317	14.89	pooled proportion, 95% CI (10.1, 24.1)	15	Carne PWG 2003, Salvadalena G 2008	Systematic review NRS
Urinary Incontinence	any from mild to severe	AR	5 years	785	Dutch Patients with rectal cancer (15 cm or less) randomized in the Dutch TME trial to PRT + TME or TME alone. Must have participated in qol and PRT s/e studies. Excl patients with recurrence	123	310	39.68		40	Lange MM 2008	Cross-sectional

		APR	5 years	785	Dutch Patients with rectal cancer (15 cm or less) randomized in the Dutch TME trial to PRT + TME or TME alone. Must have participated in qol and PRT s/e studies. Excl patients with recurrence	44	133	33.08		33	Lange MM 2008	Cross-sectional
Difficulties emptying bladder	any from mild to severe	AR	5 years	785	Dutch Patients with rectal cancer (15 cm or less) randomized in the Dutch TME trial to PRT + TME or TME alone. Must have participated in qol and PRT s/e studies. Excl patients with recurrence	89	303	29.37		29	Lange MM 2008	Cross-sectional
		APR	5 years	785	Dutch Patients with rectal cancer (15 cm or less) randomized in the Dutch TME trial to PRT + TME or TME alone. Must have participated in qol and PRT s/e studies. Excl patients with recurrence	41	129	31.78		32	Lange MM 2008	Cross-sectional
Male sexual function	General Sexual dysfunction	AR	24 months	233	Dutch Patients with rectal cancer (15 cm or less) randomized in the Dutch TME trial to PRT + TME or TME alone. Must have participated in qol and PRT s/e studies. Excl patients with recurrence	relative score			p=0.233 on univariate analysis for effect of surgery type		Lange MM 2009	Cross-sectional
	General Sexual dysfunction	APR	24 months	116	Dutch Patients with rectal cancer (15 cm or less) randomized in the Dutch TME trial to PRT + TME or TME alone. Must have participated in qol and PRT s/e studies. Excl patients with recurrence	relative score			p=0.233 on univariate analysis for effect of surgery type		Lange MM 2009	Cross-sectional
	Ejaculatory dysfunction	AR	24 months	233	Dutch Patients with rectal cancer (15 cm or less) randomized in the Dutch TME trial to PRT + TME or TME alone. Must have participated in qol and PRT s/e studies. Excl patients with recurrence	relative score			p=0.920 on univariate analysis for effect of surgery type		Lange MM 2009	Cross-sectional
	Ejaculatory dysfunction	APR	24 months	116	Dutch Patients with rectal cancer (15 cm or less) randomized in the Dutch TME trial to PRT + TME or TME alone. Must have participated in qol and PRT s/e studies. Excl patients with recurrence	relative score			p=0.920 on univariate analysis for effect of surgery type		Lange MM 2009	Cross-sectional
	Erectile dysfunction	AR	24 months	233	Dutch Patients with rectal cancer (15 cm or less) randomized in the Dutch TME trial to PRT + TME or TME alone. Must have participated in qol and PRT s/e studies. Excl patients with recurrence	relative score			p=0.129 on multivariate analysis for effect of surgery type (univariate 0.037)		Lange MM 2009	Cross-sectional
	Erectile dysfunction	APR	24 months	116	Dutch Patients with rectal cancer (15 cm or less) randomized in the Dutch TME trial to PRT + TME or TME alone. Must have participated in qol and PRT s/e studies. Excl patients with recurrence	relative score			p=0.129 on multivariate analysis for effect of surgery type (univariate 0.037)		Lange MM 2009	Cross-sectional
Female Sexual Function	General Sexual dysfunction	AR	24 months	89	Dutch Patients with rectal cancer (15 cm or less) randomized in the Dutch TME trial to PRT + TME or TME alone. Must have participated in qol and PRT s/e studies. Excl patients with recurrence	relative score			p=0.584 on univariate analysis		Lange MM 2009	Cross-sectional

	General Sexual dysfunction	APR	24 months	26	Dutch Patients with rectal cancer (15 cm or less) randomized in the Dutch TME trial to PRT + TME or TME alone. Must have participated in qol and PRT s/e studies. Excl patients with recurrence	relative score			p=0.584 on univariate analysis		Lange MM 2009	Cross-sectional
	Dyspareunia	AR	24 months	89	Dutch Patients with rectal cancer (15 cm or less) randomized in the Dutch TME trial to PRT + TME or TME alone. Must have participated in qol and PRT s/e studies. Excl patients with recurrence	relative score			p=0.293 on univariate analysis		Lange MM 2009	Cross-sectional
	Dyspareunia	APR	24 months	26	Dutch Patients with rectal cancer (15 cm or less) randomized in the Dutch TME trial to PRT + TME or TME alone. Must have participated in qol and PRT s/e studies. Excl patients with recurrence	relative score			p=0.293 on univariate analysis		Lange MM 2009	Cross-sectional
	Vaginal dryness	AR	24 months	89	Dutch Patients with rectal cancer (15 cm or less) randomized in the Dutch TME trial to PRT + TME or TME alone. Must have participated in qol and PRT s/e studies. Excl patients with recurrence	relative score			p=0.431 on univariate analysis		Lange MM 2009	Cross-sectional
	Vaginal dryness	APR	24 months	26	Dutch Patients with rectal cancer (15 cm or less) randomized in the Dutch TME trial to PRT + TME or TME alone. Must have participated in qol and PRT s/e studies. Excl patients with recurrence	relative score			p=0.431 on univariate analysis		Lange MM 2009	Cross-sectional