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# COMPLICATIONS AMONG COLORECTAL CANCER SURVIVORS: SF-6D PREFERENCE-WEIGHTED QUALITY OF LIFE SCORES

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## Abstract

**Background—**Societal preference-weighted health-related quality of life (HRQOL) scores enable comparing multi-dimensional health states across diseases and treatments for research and policy.

**Objective—**To assess the effects of living with a permanent intestinal stoma, compared to a major bowel resection, among colorectal cancer (CRC) survivors.

**Research Design—**Cross-sectional multivariate linear regression analysis to explain preference-weighted HRQOL scores.

**Subjects—**Six-hundred-forty CRC survivors (≥5 years) from three group-model HMOs; ostomates and non-ostomates with colorectal resections for CRC were matched on gender, age (±5 years), time since diagnosis, and tumor site (rectum vs. colon).

**Measures—**SF-6D scoring system applied to Medical Outcomes Study Short Form-36 version 2 (SF-36v2); City of Hope Quality of Life-Ostomy (mCOH-QOL-O); Charlson-Deyo comorbidity index.

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**Methods—**Survey of CRC survivors linked to respondents' clinical data extracted from HMO files.

**Results—**Response rate was 52%. Ostomates and non-ostomates had similar sociodemographic characteristics. Mean SF-6D score was 0.69 for ostomates, compared to 0.73 for non-ostomates (p <.001), but other factors explained this difference. Complications of initial cancer surgery, and prior-year comorbidity burden and hospital use were negatively associated with SF-6D scores, while household income was positively associated.

**Conclusions—**CRC survivors' SF-6D scores were not associated with living with a permanent ostomy after other factors were taken into account. Surgical complications, comorbidities, and metastatic disease lowered the preference-weighted HRQOL of CRC survivors with and without ostomies. Further research to understand and reduce late complications from CRC surgeries as well as associated depression is warranted.

### Keywords

colorectal cancer; survivorship; HRQOL; stomas; ostomies; utilities



Colorectal cancer (CRC) is the third most common cancer in the United States (excluding skin cancer) and the third leading cause of cancer deaths. About 147,000 new CRC cases were diagnosed in 2008 (1). While surgery is highly effective, it often involves changes to bowel functioning, including loss of control with soiling. This may occur whether the patient has a resection with permanent intestinal stoma (ostomy) or an anastomosis. Many patients refuse or delay colorectal cancer surgery for fear of living with an Ostomy (2, 3), even at the risk of on-going medical problems and cancer progression that will ultimately bring about their demise. An ostomy has pervasive effects on everyday life—wearing an ostomy bag underneath one's clothing, possibility of repeated skin irritations, difficulties with diet selection and bowel control, as well as reduced social, emotional, sexual and occupational functioning—that combine to reduce overall functioning and quality of life (4–7).

Our research has shown that ostomies are associated with substantially poorer HRQOL among CRC survivors (6–8). Despite their importance, economic evaluations of the long-term and late effects of primary cancer surgical procedures among CRC survivors have not been extensively explored. Our primary aim was to examine the determinants of societal preference-weighted HRQOL, as measured by the SF-6D (9–11), among CRC survivors (≥5 years) with and without permanent colostomies. We were particularly focused on whether permanent ostomies had a meaningful effect on SF-6D scores among CRC survivors relative to anastomoses.

## METHODS

Methods for our Health-Related Quality of Life in Long-Term Colorectal Cancer Survivors Study are presented elsewhere (8). This study was conducted at three regions of a national integrated healthcare delivery system with defined populations of CRC survivors: Kaiser Permanente Hawaii (KPH), Northern California (KPNC), and Northwest (KPNW). We employed a cross-sectional, survey research design: 679 CRC survivor respondents (284 with ostomies; 395 "non-ostomates" with anastomoses) completed a mixed mode (mail or telephone) questionnaire that included HRQOL scales and socio-demographic, health, medical care utilization, and self-care items. We obtained a response rate of 52% (679/1308). Eligible participants included: a) KP members aged 18 years and older diagnosed with CRC between 1976 and 1999; b) health-plan members on at least the fifth anniversary of their index CRC diagnosis during 2002–2005; c) those with an intestinal stoma or anastomosis (survivors with a previous temporary intestinal ostomy were

excluded); and d) non-ostomates matched to ostomates using cancer site (coded as rectum and rectosigmoid [ICD-0 codes C20.0, 19.9] versus colon ICD-0 codes [ICD-0 C18.x]); time since cancer diagnosis (within 5 years or closest possible match); age (within 5 years or closest possible match); and gender.

The survey instrument included the modified City of Hope Quality of Life -Ostomy (mCOH-QOL-O) questionnaire (12) and the SF-36 version 2 of the MOS SF-36) (9, 13, 14). Data from the multi-item scales of the mCOH-QOL-O and SF-36v2 in these study subjects are presented elsewhere (7, 15, 16). For the analyses presented here, we used a depression item (0 = “none at all” to 10 = “severe”) from the mCOH-QOL-Ostomy and applied the SF-6D scoring function to the SF-36v2 responses (QualityMetric Health Outcomes Scoring Software 2.0, copyright QualityMetric, Lincoln, Rhode Island, USA 2004–2007).

The SF-6D score served as our dependent variable. It is a continuous variable with a possible a range from 0.29 to 1.0 on a scale where 0 = dead and 1.0 = perfect health. Health states between these extremes were defined by 11 items in six domains of the SF-36v2. Cardinal utility values were derived using visual analog scales and standard gamble techniques for a representative sample of a general population (10, 11). SF-6D score norms for the US population range from a low of 0.75 for 85-year-old males to a high of 0.81 for 35-year-old females (standard errors = 0.01) (13, 17). Walters and Brazier have provided guidance that differences of 0.033 or more in mean SF-6D scores are clinically important (18–24). Preference-weighted HRQOL scores reflect the relative desirability of health states as judged by a general population sample. Population-based preferences are seen as being most relevant for implementing public health and population-based clinical interventions.

Medical histories were obtained from KP clinical and administrative databases. From these databases, we collected type of stoma, length of time since diagnosis, site of tumor, and pre- and post-operative treatment. The Charlson-Deyo comorbidity index (25) was constructed from inpatient and outpatient ICD-9-CM codes during the year prior to date of survey administration. Early complications of primary CRC surgery, such as bleeding and post-operative infection, were those recorded within 30 days of the date of first CRC surgery, and were counted only once during each surgical episode (15). Late complications were those first recorded 31 days or more after the primary CRC surgery and included, for example, hernia, urinary retention, hemorrhage, skin conditions around the stoma, and intestinal obstruction (15).

We estimated multivariate linear regression models to explain variation in observed SF-6D scores using Stata® version 10.0 (Statacorp, College Station, TX). The study protocol and questionnaires were approved by the Institutional Review Boards at the University of Arizona, KPHI, KPNC, and KPNW.

## RESULTS

Ostomates’ mean SF-6D score was 0.69, compared to 0.73 for non-ostomates ($p < 0.001$). SF-6D score norms for comparable age groups in the general US population ranged from 0.76 to 0.80 (11, 17–24), with CRC survivors having meaningfully lower SF-6D scores. Despite recruitment efforts to match on cancer location, ostomates disproportionately had more rectal cancers than non-ostomates. Descriptive statistics for 284 CRC survivors with permanent ostomies (“ostomates”) and 395 CRC survivors with anastomoses (‘non-ostomates”) are shown in Table 1. Ostomates and non-ostomates did not differ at time of the survey on age, gender, race/ethnicity, follow-up years, body mass index (BMI), or the rate of chemotherapy for the initial tumor. Ostomates had more comorbid conditions ($p=0.03$) and were more likely to have received radiation therapy ($p<0.0001$) for their initial tumor than

non-ostomates. Ostomates were significantly more likely to have complications at all time points after surgery, i.e., within 30 days (p=0.003), 31–365 days (p=0.001), and greater than 1 year (p=0.0001) compared to non-ostomate patients.

Contrary to our expectation, having a permanent ostomy was not associated with lower SF-6D scores when other determinants were included in the model (Table 2). We tested for gender by ostomy interaction effects (observed in a separate analysis for certain health outcomes (7)), but found no evidence of such interactions. Late complications of initial CRC surgery were associated with lower SF-6D scores. Having both early and late (continuing) complications appeared to be associated with even lower SF-6D scores (Likelihood Ratio Test (LRT) of the three complications indicators gave a $\chi^2$ of 8.15 [p = 0.043]). Stage was significantly associated with SF6D scores (LRT of the four stage indicators gave a $\chi^2$ of 10.3 [p = 0.016]); patients with missing staging values had significantly lower SF-6D scores than patients with localized stage.

Worse self-reported depression was associated with lower SF-6D scores. Number of prior-year inpatient days and the Charlson-Deyo Comorbidity Index for the 12 months prior to the survey both independently contributed to lower SF-6D scores. Higher incomes were associated with higher SF-6D scores LRT on all five income variables gave a $\chi^2$ value of 18.55 [p = 0.001]), with a monotonically increasing relationship across the ordered income classes. Survivors with missing income data did not have SF-6D scores significantly different from survivors who reported annual incomes less than $30,000. Older age was associated with lower SF-6D scores. Our model explained a significant proportion of the variance in SF-6D scores (adjusted $R^2$ = 0.36) and had a reasonably good fit to the data (F-ratio = 25.1 [p < 0.001]). Gender, race, ethnicity, education, employment status, tumor site, chemotherapy, and radiation therapy revealed no independent associations with SF-6D scores and did not improve goodness-of-fit.

## DISCUSSION

Having an ostomy was not associated with lower SF-6D scores when other relevant variables were taken into account. One possible explanation is the difference in prevalence of surgical complications in ostomates versus non-ostomates: 30 to 365 days—14% vs 6%; >1 year—38% vs 23%. Non-ostomates also have been reported in previous studies to have relatively high rates of bowel dysfunction (26). Other studies conducted by this team showed that ostomy-specific problems such as fistulas, skin irritations, and leakage, predicted lower HRQOL among cancer survivors (7, 27) Among patients with rectal cancer alone, complications of ostomy, but not anastomosis, were associated with reduced overall HRQOL (15). Complications of initial CRC surgery can undermine long-term HRQOL and more research is needed to ascertain the extent to which these interventional complications can be prevented.

Depression is a significant predictor of SF-6D scores among CRC survivors. More research is needed to identify comparatively effective screening and intervention strategies for depression among CRC survivors with multiple health problems. Previous work by mental health researchers at a large group-model HMO suggests that 1) giving primary care and specialist physicians a clinical depression screening tool for use in the exam room, and 2) implementing a pharmacologic treatment guideline for major clinical depression can be effective strategies to improve detection and treatment rates in the course of routine health care encounters (28–33).

Income remains a significant predictor of SF-6D scores after adjusting for surgical treatment strategy in a population with equivalent comprehensive health insurance coverage and

medical homes (i.e., having a regular primary care provider, comprehensive health insurance benefits, and an integrated delivery system). This finding is consistent with another analysis performed on these data (16). The likely direction of causation is two-way: survivors with better health have the ability to earn higher incomes (16), which, in turn, provides enhanced medical care, self-care, housing, diet, and other choices.

## LIMITATIONS

The cross-sectional associations presented herein cannot be used to understand the temporal relationship between the dependent and independent variables; in addition, the observed associations could result from multiple omitted variables. Our survey response rates varied by KP Region and related to differential use of telephone follow-up to reduce missing data. CRC non-ostomy survivors in Hawaii demonstrated the lowest response rate, which may also relate to cultural disparities. Another limitation relates to the known floor effects of the SF-36 (and, therefore, the SF-6D) (34–47). While we were able to distinguish among known groups (e.g., presence vs. absence of complications of initial CRC surgery), the distribution of observed SF-6D scores may be truncated at the low end—some of the subjects were more ill than can be captured by the measure. The SF-36 works very well for subjects with mild to moderate burdens, but often understates the severity of heavier burdens. Our sample of 640 CRC survivors with complete data is a relatively small sample size to support modeling complex phenomena with highly skewed distributions—the data became relatively sparse in the most interesting population segment. Concerns about heavy response burden on older participants led us to exclude questions about medical and social history from the time of cancer diagnosis, which left a large time gap between cancer diagnosis and questionnaire administration. Our qualitative data analysis on a subsample of CRC patients clearly indicates that, for some survivors, the development of unrelated chronic illnesses and frailty associated with aging become dominant health concerns, which interact with ostomy care (6).

## CONCLUSIONS AND FUTURE RESEARCH

The Institute of Medicine’s report on cancer survivorship called for more research on the long-term medical and behavioral implications of living as a cancer survivor (4). We found that CRC survivors with permanent stomas or anastomoses have clinically meaningful lower SF-6D scores than the general population of the same age and gender. Living with a permanent stoma, however, is not associated with lower scores for CRC survivors when other factors are taken into account. Prior-year comorbidities and hospital use, income, age, missing stage at diagnosis, and complications from CRC surgery were associated with SF-6D scores. The higher rate of surgical complications among ostomates calls for increased attention to survivorship care planning, especially with respect to monitoring the development of long-term surgical complications. Preventing complications of initial CRC surgeries is likely to improve long-term health utility (15, 27). Other analyses of surgical complications using this data set have demonstrated that survivors with ostomies experience more long-term complications initially, but that over time long-term complication rates converge among both patient groups (15). Future research should be designed to focus on reductions of late complications of CRC surgery, perhaps targeting those with ostomies.

Finally, preference-based HRQOL measures (e.g., SF-6D) are useful for surveillance of cancer survivors because health state declines are weighted by societal preferences, which, in turn, can be used to guide priorities for subsequent clinical screening and intervention. Time-series analyses of preference-based HRQOL scores among CRC survivors are needed to identify cause-and-effect changes.

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## Table 1

Characteristics of Sampled and Participating CRC Survivors with and Without Ostomies

| Characteristic | Ostomate Participants (N = 284) | Non-ostomate Participants (N = 395) | P-value |
|---|---|---|---|
| **Mean age at time of survey (SD)** | 72 (10) | 71 (11) | |
| <60 years | 14.5% | 17.3% | Reference |
| 60–69 years | 23.3% | 27.3% | 0.93 |
| 70–79 years | 36.0% | 30.4% | 0.14 |
| ≥80 years | 26.2% | 25.0% | 0.37 |
| **Gender** | | | |
| Male | 58.8% | 59.0% | Reference |
| Female | 41.2% | 41.0% | 0.96 |
| **Race/ethnicity** | | | |
| White, non-Hispanic | 74.3% | 78.7% | Reference |
| African American/Black, non-Hispanic | 3.5% | 3.5% | 0.67 |
| Hispanic/Latino (all races) | 7.4% | 3.5% | 0.05 |
| Asian Pacific Islander | 9.5% | 8.4% | 0.96 |
| Other | 5.3% | 5.8% | 0.41 |
| **Follow-up, from the date of index colon/rectal cancer diagnosis to date of interview, years*** | | | |
| 5–9 | 45.0% | 46.1% | Reference |
| 10–14 | 25.8% | 30.9% | 0.11 |
| 15+ | 29.2% | 23.0% | 0.06 |
| Missing | (13 patients) | | |
| **Body Mass Index** | | | |
| ≤26 | 57.0% | 55.4% | Reference |
| 27–29 | 21.1% | 19.2% | 0.43 |
| ≥30 | 21.9% | 25.4% | 0.27 |
| **Prior Year Charlson-Deyo Comorbidity Index** | | | |
| 0 | 34.5 | 45.6 | Reference |
| 1 | 14.4 | 14.2 | 0.86 |
| 2+ | 51.1 | 40.3 | 0.03 |
| **Depression (City of Hope) scaled item (0 = none at all, 10 = severe, mean (SD))** | 2.4 (2.8) | 1.9 (2.4) | 0.02 |
| **Tumor location** | | | |
| Colon | 12.3% | 37.5% | Reference |
| Rectum | 87.7% | 62.5% | <0.0001 |
| Missing | 16 patients | 0 | |
| **Chemotherapy for initial tumor** | | | |
| Yes | 35.2% | 37.2 | 0.59 |
| No | 64.8% | 62.8% | |

| Characteristic | Ostomate Participants (N = 284) | Non-ostomate Participants (N = 395) | P-value |
|---|---|---|---|
| **Radiation therapy for initial tumor** | | | |
| Yes | 35.6% | 19.0% | <0.0001 |
| No | 64.4% | 81.0% | |
| **Complications from date of surgery to 30 days post-surgery** | | | |
| Yes | 18.3% | 10.1% | 0.003 |
| No | 81.7% | 89.9% | |
| **Complications from 31 days to 365 days post surgery** | | | |
| Yes | 13.7% | 5.9% | 0.001 |
| No | 86.3% | 95.1% | |
| **Complications from 1 year post surgery to date of interview** | | | |
| Yes | 37.7% | 23.3% | 0.0001 |
| No | 62.3% | 76.7% | |

**Table 2**

Regression Results for SF-6D Scores

| Variable | Coeff. | Std. Err. | P>\|t\| | [95% Conf. Interval] | |
|---|---|---|---|---|---|
| **Income < $30,000** | Ref | | 0.001* | | |
| **Income $30,000–$49,999** | 0.027 | 0.012 | 0.018 | 0.005 | 0.050 |
| **Income $50,000–$74,999** | 0.046 | 0.014 | 0.001 | 0.019 | 0.074 |
| **Income > $75,000** | 0.056 | 0.015 | 0.000 | 0.027 | 0.085 |
| **Income Missing** | 0.020 | 0.016 | 0.206 | −0.011 | 0.051 |
| **Age (years)** | −0.001 | 0.000 | 0.005 | −0.002 | ≤0.000 |
| **Anastomosis** | Ref | | | | |
| **Permanent ostomy** | −0.008 | 0.009 | 0.379 | −0.027 | 0.010 |
| **Charlson-Deyo Comorbidity Index** | −0.007 | 0.002 | 0.006 | −0.012 | −0.002 |
| **Depression (City of Hope),** Scaled Item (0 = none at all, 10 = severe) | −0.025 | 0.002 | 0.001 | −0.0212 | −0.028 |
| **No complications** | Ref | | 0.043* | | |
| **Late complications only** | −0.024 | 0.010 | 0.017 | −0.044 | −0.004 |
| **Early complications only** | −0.019 | 0.015 | 0.217 | −0.050 | 0.011 |
| **Both late and early complications** | −0.039 | 0.021 | 0.064 | −0.081 | 0.002 |
| **Stage localized** | Ref | | 0.016* | | |
| **Stage regional** | 0.002 | 0.009 | 0.802 | −0.015 | 0.020 |
| **Stage distant (metastases)** | 0.086 | 0.032 | 0.008 | 0.022 | 0.149 |
| **Stage missing** | −0.035 | 0.022 | 0.111 | −0.077 | 0.008 |
| **Prior year hospital days** | −0.004 | 0.001 | 0.000 | −0.006 | −0.002 |
| **Intercept** | 0.616 | 0.036 | 0.000 | 0.545 | 0.686 |

*P value for $\chi^2$ of Likelihood Ratio Test of the vector of indicators as a group.

Adjusted $R^2$ = 0.3614

Number of observations = 640 (A total of 19 cases were omitted from this analysis because the respondents did not provide sufficient responses on the SF-36v2 to compute SF-6D scores.)

F(15,624) = 25.11

Prob > F = 0.0000