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The relationship of two postoperative complication grading schemas with postoperative quality of life after elective colorectal surgery

Teodora C. Dumitra, MD, MSc[a,b,c], Maude Trepanier, MD[a,b], Julio F. Fiore Jr, PhD[a,b], Pepa Kaneva, MSc[a,b], Franco Carli, MD[a,b], Gerald M. Fried, MD[a,b], Liane S. Feldman, MD[a,b], Lawrence Lee, MD, PhD[a,b,c,*]

[a] Department of Surgery, McGill University Health Centre, Montreal, QC, Canada
[b] Steinberg-Bernstein Centre for Minimally Invasive Surgery and Innovation, McGill University Health Centre, Montreal, QC, Canada
[c] Division of Clinical Epidemiology and Biostatistics, McGill University, Montreal, QC, Canada

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ABSTRACT

Introduction: Several grading schemes are available to assess surgical complications, but their relationship with patient-reported outcomes is not well understood. Therefore, our objective was to examine the effect of two complication grading schemas on health-related quality of life in colorectal surgery patients.
Methods: An analysis of adult patients undergoing elective colorectal surgery from 2005 to 2013 was performed. Health-related quality of life was measured using the SF-36 preoperatively and at 4 weeks and 8 weeks postoperatively. The 30-day morbidity was classified using Clavien-Dindo grading (I–IV) and the Comprehensive Complication Index (0–100). The main outcomes were the postoperative changes in physical summary scores and mental summary scores. Multivariate logistic and fractional polynomial regression analyses were used to determine the relationship between complication severity and health-related quality of life.
Results: A total of 402 patients were included in the study. Overall morbidity was 46%. Patients with complications had lower physical summary scores and mental summary scores at 4-weeks and 8-weeks postoperatively compared with patients without complications ($P < .05$). On multivariate regression, there was no dose-response relationship between Clavien-Dindo grade and postoperative physical summary scores and mental summary scores. Adjusted changes in the physical summary scores and mental summary scores had a more appropriate, dose-response relationship with the Comprehensive Complication Index scores.
Conclusion: In patients undergoing colorectal surgery, there is a more consistent relationship between the Comprehensive Complication Index and postoperative health-related quality of life compared with the Clavien-Dindo classification.

Introduction

Operative morbidity is an important postoperative outcome, but it is inconsistently defined. The Clavien-Dindo classification is most commonly used, in which complications are graded on an ordinal scale (I–V) based on the treatment provided to manage the complication.[1] Studies have shown a clear relationship between higher grades of complication and hospital durations of stay[2] and costs.[3] Because the Clavien-Dindo grade reports the single most severe postoperative complication, it does not account for multiple complications and their potential cumulative effect on patient outcomes.

To overcome some of these limitations, the Comprehensive Complication Index (CCI) was proposed as an alternative to the Clavien-Dindo classification. The CCI reflects the total complication burden by assigning a weight to each complication, accounting for each Clavien-Dindo grade, thereby resulting in a cumulative score from 0 to 100.[4,5] Specific weights were assigned by incorporating both patients' perspectives of their experience of complications and physician perspectives. For instance, a single Clavien-Dindo I complication gives a CCI score of 8.9, a Clavien-Dindo grade IIIa gives a CCI score of 26.2 which is less than 2 Clavien-Dindo grade II complications in the same patient (CCI = 29.6). The CCI has a stronger correlation with postoperative duration of hospital stay[6]

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* Reprint requests: Lawrence Lee, MD, PhD, Department of Surgery, McGill University Health Centre, 1650 Cedar Avenue, D16-116, Montreal, QC, Canada, H3G1A4.
E-mail address: larry.lee@mcgill.ca (L. Lee).

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and overall costs[7] than the single Clavien-Dindo grade for a variety of operative interventions. The CCI may be a more sensitive measure of morbidity, because it accounts for all postoperative complications and scores their severity on an additive linear rather than ordinal scale.

These audit measures, such as duration of stay and costs, however, may not be as meaningful to patients.[8] The recent focus on patient-centered care and patient-reported outcomes (PROs) emphasizes health-related quality of life (HRQoL) as an important outcome target for quality improvement. Grading schemes for the severity of complications, therefore, should reflect the impact on HRQoL during the postoperative recovery as well as correlate with clinical outcomes like duration of stay and cost. The relationship between these complication grading schemes (Clavien-Dindo and CCI) on PROs has not been well described.

The main objective of this study was to examine the relationship between the 2 grading systems (the Clavien-Dindo system and the CCI) and HRQoL in adult patients undergoing elective colon or rectal surgery. We hypothesized that there would be an incremental, dose-response relationship between postoperative HRQoL and the severity of complications. That is, we expected that the 4-week and 8-week changes in physical and mental HRQoL scores would be greater with increasing severity of complications as measured by the Clavien-Dindo and CCI scores.

Methods

Participants and setting

We performed a secondary analysis of data collected during four prospective trials at 2 university-affiliated, tertiary-care institutions from 2005 to 2013. These 2 trials investigated preoperative exercise training[9,10] with 1 trial investigating thoracic epidural analgesia versus intravenous lidocaine for perioperative pain management[11] and the other investigating enhanced recovery versus conventional care.[12] The study populations consisted of adult patients older than the age of 18 years who underwent scheduled resections of the colon and/or rectum. Patients were excluded if they did not speak or understand English or French, 1 of the 2 official languages. Patients were also excluded if they had neurologic or cognitive impairments that precluded them from answering questionnaires.

Measures

We collected demographic data, including age, sex, body mass index (BMI), and comorbidities. Comorbidities were classified using the American Society of Anesthesiologists (ASA) physical status score. Underlying diagnosis was classified as malignancy, inflammatory bowel disease (IBD), or other benign diseases. The type of operative procedure, creation of a new stoma, operative approach (laparoscopic or open), and administration of adjuvant chemotherapy were recorded. Hospital length of stay was calculated from the date of the elective surgery to the date of hospital discharge. All postoperative complications were recorded prospectively within 30 days of the index operation, and each complication was graded using the Clavien-Dindo classification of postoperative complications.[1] Clavien-Dindo Grades III and IV were combined together because of the restrictions in the number of events. All charts were reviewed retrospectively to confirm that no complications were missed. The total complication burden for each patient was scored using the publicly available CCI calculator[5] (AssesSurgery GmbH 2019, Baar, Switzerland), incorporating the number and severity of all postoperative complications within 30 days of the index operation. Although the Clavien-Dindo system is based on an ordinal scale, selecting the single most severe postoperative complication, the CCI score summarizes the complete spectrum of complications in a single score, ranging from 0 to 100.[4]

Outcomes

All participating patients completed an HRQoL questionnaire preoperatively (baseline) and at 4 weeks and at 8 weeks postoperatively. HRQoL was assessed using the SF-36 questionnaire,[13,14] measuring 8 health dimensions: physical functioning (PF), the roles of physical, bodily pain, general healthy, vitality, and social functioning, and the roles of emotional and mental health. Of the summary scores, 2 were calculated—the physical component summary score (PCS) and the mental component score (MCS) —and were normalized using the 1998 US population normal to a mean of 50 and standard deviation (SD) of 10.[15] The SF-36 has been used elsewhere[16,17] in clinical and research settings to measure quality of life after an operation. A recent study has demonstrated its validity in patients undergoing colorectal surgery,[18] with scores on the PF domain correlating adequately with other measures of exercise capacity. The main outcome was the change in the PCS and MCS scores from the baseline of the SF-36 at 4-weeks and 8-weeks postoperatively.

Statistical analysis

Summary descriptive statistics using means with 95% confidence intervals or median interquartile range when appropriate were used to characterize the study population. The mean SD PCS and MCS scores were calculated at baseline and at 4 and 8-weeks postoperatively overall and by Clavien-Dindo grade and compared using analysis of variance. Mean scores (95% confidence interval) were compared for patients with and without complications using the Student's *t*-test. Missing data were handled using multiple imputations using chained equations (10 imputations). By using this method, missing items are estimated using a regression model from other observed data and repeated 10 times to generate 10 different imputated data sets. Uncertainty around the imputated point estimates incorporate the between (data sets) and within (variable) variances according to Rubin rules.[15] Multiple linear regression was used to determine the independent effect of Clavien-Dindo complication grade on the change in 4- and 8-week PCS and MCS, adjusted for age, sex, baseline PCS or MCS score, BMI, ASA, diagnosis, operative approach, stoma creation, and duration of stay. Absolute PCS and MCS scores at 4- and 8- weeks were used as the dependent variable in multiple regression analyses, adjusting for baseline scores.[19] We also investigated the effect of the timing of the complication by including an interaction term occurrence of the complication (<7 days or ≥ 7 days postoperatively). Subgroup analysis was performed using PF subscale scores, as well as by diagnosis (malignancy and IBD, because we hypothesized that these patients may have had different baseline scores). Because the relationship between CCI and HRQoL scores was hypothesized a priori to be nonlinear and to preserve the continuous nature of the covariates introduced, a multivariable fractional polynomial plot was used to graph the adjusted change in PCS and MCS scores by the CCI score. This model combines backward elimination with a systematic search for the most suitable transformation to represent the influence of each continuous covariate on the outcomes, accounting for missing data using multiple imputations. Goodness of fit of this model was compared with that of simple linear regression of CCI as well as the regression model using the Clavien-Dindo grading schema using adjusted-R2. A sensitivity analysis was also performed using complete cases in the multivariate linear regression. All

Table I
Characteristics of patients included in the study

Variables	Total (n = 402)
Age (y), mean (SD)	61.5 (13.9)
Gender, male	220 (55)
BMI, mean (SD)	27 (5.0)
ASA	
I	62 (15)
II	258 (64)
III+	82 (21)
Laparoscopic approach	231 (58)
New stoma	119 (30)
Indication for surgery	
Malignancy	268 (67)
IBD	48 (12)
Other benign	86 (21)
Adjuvant chemotherapy	71 (18)
Overall complication rate	186 (46)
Clavien I	78 (19)
Clavien II	74 (18)
Clavien III/IV	34 (9)
CCI, median (IQR)	8.8 [0–20.9]
Length of stay, median (IQR)	7 (3–8)

NOTE: Data presented as *n* (%) unless specified.
BMI, body mass index (kg/m^2); *ASA*, American Society of Anesthesiologists physical status score; *IBD*, inflammatory bowel disease; *CCI*, Comprehensive Complication Index; *IQR*, interquartile range.

statistical analysis was performed using STATA v 14.2 software (StataCorp, College Station, TX, USA). Statistical significance was set at a *P* value of .05.

Results

A total of 402 patients were included in this study cohort. Patient and operative characteristics and clinical outcomes are presented in Table I. Overall, 46% of the study cohort had at least 1 postoperative complication within 30 days of the index operation, a rate similar to earlier studies.[17] The majority of these complications were minor complications (19% were Clavien-Dindo grade I and 18% were Clavien-Dindo grade II); whereas 9% of the study cohort had complications grade III and IV. There was no 30-day mortality. The median CCI score of the cohort was 8.8 (interquartile range 0–20.90).

The mean preoperative, 4-week, and 8-week postoperative PCS and MCS scores by the Clavien-Dindo grade are shown in Figs 1 and 2 and Table II. Baseline scores were available in 98% of patients (n = 392); however, there were 21% and 35% missing data at 4 and 8 weeks, respectively. Patients with any postoperative complications had significantly lower PCS and MCS scores at 4 weeks as well as at 8 weeks postoperatively when compared with patients without complications (Table III). Patients with a diagnosis other than malignancy or IBD had greater PCS scores at baseline (IBD 47.3 [SD 9.7], malignancy 49.2 [SD 9.6], and other diagnoses 52.4 [SD 8.86], P <.005). The mean PCS score at baseline differed between noncomplicated and the 3 Clavien-Dindo groups, with Clavien-Dindo grade II being the lowest (P = .035); whereas the mean MCS scores did not differ at baseline (Table II).

On multiple regression, the changes in postoperative PCS and MCS scores were independently affected by baseline scores at both 4 and 8 weeks (Table IV). At 4 weeks postoperatively, PCS scores were significantly decreased by Clavien grades III or more; whereas at 8 weeks, the PCSs were significantly decreased by grade II complications. MCS scores were significantly decreased by complications of grade II or more at 4 weeks and by complications of grade III or more at 8 weeks postoperatively. Similar results were

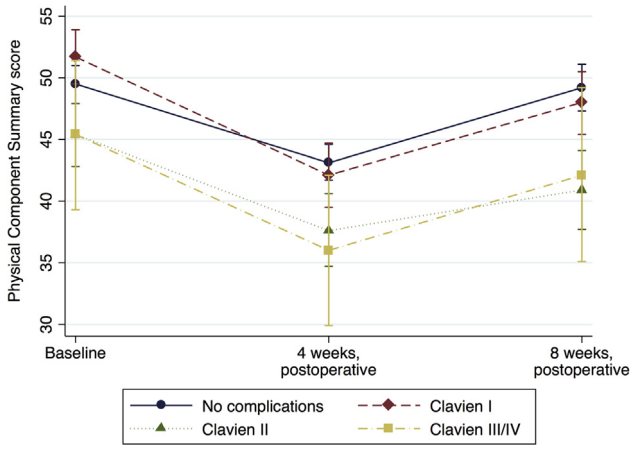

Fig 1. Mean physical component summary score over time by Clavien-Dindo. complication grade (mean and 95% confidence interval).

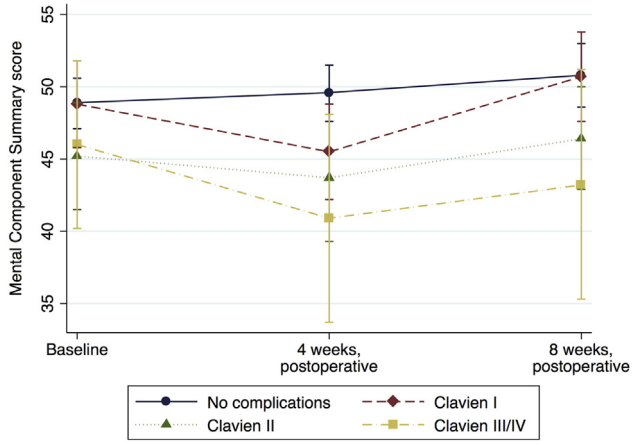

Fig 2. Mean mental component summary score over time by Clavien-Dindo complication grade (mean and 95% confidence interval).

noted when analyzing absolute PF subscale scores and when analyzing patient subgroups by diagnosis (malignancy versus nonmalignancy, Supplemental Tables I and II). The timing of complications after the index operation (<7 days or ≥7 days) was not an independent predictor of change in PCS or MCS scores postoperatively. The sensitivity analysis revealed similar results, using complete cases and multiple imputed data.

When using the CCI as the complication grading schema, multivariable fractional polynomial plots demonstrated a more linear decrease in MCS scores with increasing CCI scores after adjusting for confounders, both at 4 weeks (adjusted $R2$ = 0.051 vs 0.022) and 8 weeks (adjusted $R2$ = 0.037 vs 0.023) postoperatively compared with simple linear regression. Adjusted PCS scores at 4 weeks decreased with increasing CCI scores, but this relationship was not as prominent at 8 weeks postoperatively (Fig 3). Furthermore, the relationship between HRQoL and CCI was not linear because model fit characteristics of the multiple fractional regression were better for both MCS scores compared with multiple linear regression models, adjusting for the same covariates. Moreover, multivariable fractional polynomial regression of CCI had a consistently better model fit compared with Clavien-Dindo grading for both PCS (adjusted $R2$ = 0.069 vs 0.033 at 4 weeks, 0.040 vs −0.011 at 8 weeks) and MCS scores (adjusted $R2$ = 0.051 vs 0.023 at 4 weeks, 0.037 vs −0.014 at 4 weeks). This observation suggests there would be a better prediction of postoperative PCS and MCS scores using the CCI grading system compared with the Clavien-Dindo grading system.

Table II
SF-36 PCS and MCS means preoperatively, at 4 weeks and at 8 weeks postoperatively

Variables	PCS baseline	PCS 4 weeks	PCS 8 weeks	MCS baseline	MCS 4 weeks	MCS 8 weeks
Overall	48.4 (0.66)	41.6 (0.61)	47.1 (0.67)	48.4 (0.77)	47.9 (0.78)	50.3 (0.68)
No complications	50.1 (0.66)	44.3 (0.66)	49.1 (0.77)	49.0 (0.71)	50.5 (0.76)	51.3 (49.7)
Clavien-Dindo I	52.4 (0.87)	43.2 (1.13)	48.6 (1.20)	47.4 (1.28)	47.2 (1.42)	51.2 (1.35)
Clavien-Dindo II	46.7 (1.12)	39.8 (1.35)	41.1 (1.48)	46.5 (1.46)	45.4 (1.79)	48.0 (1.51)
Clavien-Dindo III/IV	47.4 (1.94)	37.1 (1.83)	42.8 (2.92)	48.5 (1.86)	43.1 (2.70)	45.0 (3.11)

NOTE: Data presented as mean (SD).
PCS, physical component score; *MCS*, mental component score.

Table III
Mean PCS and MCS in patients with and without complications

Variables	Complications	No complications	*P* value
Preoperative PCS	49.2 (0.70)	50.1 (0.66)	.320
Preoperative MCS	47.2 (0.86)	49.0 (0.71)	.055
4-week PCS	40.8 (0.81)	44.3 (0.66)	.001*
4-week MCS	45.8 (1.04)	50.5 (0.76)	.0002*
8-week PCS	44.6 (0.96)	49.1 (0.77)	.0003*
8-week MCS	48.9 (0.99)	51.2 (1.35)	.033*

NOTE: Data presented as means (SD).
PCS, physical component score; *MCS*, mental component score.
* Statistically significant, $P < .05$.

Discussion

With increasing attention being focused on patient-centered, value-based care, there is a growing interest in PROs as a key component to guide initiatives in quality improvement.[20]. There is a gap in the outcomes that are considered important between patients and health care professionals.[8] Health care professionals are more interested in clinical outcomes such as duration of hospital stay, complications, and health care costs, but patients value the return to normal functioning and quality of life.[21] It would, therefore, be of clinical importance if the relationship between the commonly used complication grading schema and patient-reported HRQoL could be established.

Our study focused on the relationship between postoperative complications, which occurred in 46% of this study cohort, and HRQoL. Patients with complications had lower PCS scores and MCS scores at 4 and 8 weeks postoperatively; however, when assessing these complications by severity, the impact of the Clavien-Dindo grading system on PCS and MCS scores was inconsistent. There were not consistently significant adjusted differences in PCS and MCS scores compared with the baseline because the Clavien-Dindo grade increased. There are several potential reasons for this finding. The main issues with the Clavien-Dindo classification include the fact that it is reported on an ordinal scale, it only includes the most severe complication (ie, it is not cumulative), and the grade is based on the treatment received.[5] For example, a severe wound infection that requires a prolonged duration of dressing changes is classified as a grade I complication; whereas an anastomotic bleed that requires only endoscopic control is categorized as a grade IIIa complication. Although this may be relevant from the perspective of duration of stay or cost, the impact on patient HRQoL is not as intuitive as suggested by the results of this study. In our study, however, there were relatively few grade III–IV complications which may bias the results.

Comparatively, we reported a stronger relationship between complication burden as measured by the CCI and the 4-week and 8-week HRQoL. This relationship was evidenced in our analysis both graphically and through a better prediction of postoperative PCS and MCS scores using the CCI compared with the Clavien-Dindo grading system. Most patients had CCI scores between 0 and 30, thus increasing the uncertainty of this correlation with CCI scores greater than 50. The results of this present study suggest the CCI could be a better a more inclusive measure of morbidity, because it accounts for the overall burden of complications weighted, using both the perspectives of both the clinician and the patient.

Several additional explanations for the findings of this study are feasible. We used both SF-36 summary scores (PCS and MCS) for our analyses, but only the PCS scores followed the expected postoperative trajectory (decline at 4 weeks compared with the baseline followed by a return to the baseline at 8 weeks[22,23]); whereas the MCS scores did not. This trend could explain in part why we did not identify an appropriate dose relationship between the Clavien-Dindo complication grade and the 4-week HRQoL. Subgroup analysis, however, using the PF subscale (which has been shown to follow this hypothesized trajectory after abdominal operations[24]) also led to similar results. We also considered the indication for operation as a potential confounder. Patients with IBD and diverticular disease are often symptomatic at the time of operation and have a lower HRQoL at baseline; whereas patients with malignancy are often asymptomatic.[25] Large improvements in HRQoL may be expected as a result of the operation,[25] which may bias potential effects of complications in this specific group of patients. This condition was reflected in our subgroup analysis, where we noted that patients with malignancy had a more substantial change in PCS and PCS scores compared with nonmalignancy patients.

The results of this study should be interpreted in view of other limitations. We observed only 2 time points at which the HRQoL was measured. It is unclear whether additional measurements before 4 weeks would have identified a more obvious, dose-response relationship. Complications that occur earlier may have less of an impact at 4 weeks than those occurring later; however, in our results, the interaction term for the timing of complications did not affect the results of the model. We also detected some missing data (21% at 4 weeks postoperatively and 35% at 8 weeks postoperatively). We attempted to minimize their impact using multiple imputations that yielded similar results to the complete case analysis. Other unmeasured confounding factors could have affected the HRQoL, especially at 8 weeks, such as delivery of adjuvant systemic therapy in patients with malignancy, although this would have affected only a small proportion of patients. Moreover, all patients in this study were enrolled in prospective trials that may have impacted their quality-of-life scores. Although they are an overall small percentage of patients at our center, the First Nations population from Northern Quebec could not be captured, because most of these patients do not speak one of the official languages (English or French) of the Province of Quebec. Future studies should also include First Nations patients to account for this unique population and provide an instrument of QoL in all available languages. Patients with neurologic or cognitive impairments are also an important demographic that could be represented using QoL reporting from the perspective of the caregiver. Also, the results of this study may not be generalizable to other

Table IV
Multivariate regression of predictors of change in PCS and MCS scores

Variables	Change in PCS at 4 weeks	Change in PCS at 8 weeks	Change in MCS at 4 weeks	Change in MCS at 8 weeks
Age	−0.01 (−0.09 to 0.07)	0.04 (−0.05 to 0.12)	0.08 (−0.03 to 0.18)	0.03 (−0.07 to 0.13)
Male	0.73 (−1.15 to 2.60)	**2.54 (0.38–4.70)**	0.30 (−1.90 to 2.50)	1.94 (−0.47 to 4.36)
BMI	0.07 (−0.12 to 0.26)	0.10 (−0.11 to 0.31)	0.09 (−2.84 to 2.21)	0.07 (−0.14 to 2.85)
Diagnosis				
Benign (ref)	Ref	Ref	Ref	Ref
Malignancy	1.72 (−0.91 to 4.33)	−0.86 (−3.70 to 1.97)	−0.64 (−3.60 to 2.32)	−1.05 (−4.44 to 2.33)
IBD	2.17 (−2.55 to 6.89)	0.40 (−4.19 to 4.98)	0.80 (−5.33 to 6.92)	0.63 (−3.89 to 5.15)
ASA				
≤2 (ref)	Ref	Ref	Ref	Ref
≥3	1.32 (−1.07 to 3.72)	−2.21 (−4.70 to 0.28)	−0.29 (−3.50 to 2.92)	−0.06 (−2.92 to 2.80)
Baseline score	**−0.62 (−0.73 to 0.52)**	**−0.66 (−0.78 to 0.54)**	**−0.56 (−0.68 to 0.45)**	**−0.62 (−0.73 to 0.50)**
Approach				
Open	Ref	Ref	Ref	Ref
Laparoscopic	**2.55 (0.51–4.58)**	1.62 (−0.78 to 4.02)	−0.32 (−2.84 to 2.21)	−1.27 (−4.34 to 1.80)
Stoma creation	−1.87 (−4.33 to 0.59)	−2.44 (−4.90 to 0.01)	−1.36 (−4.35 to 1.63)	0.35 (−2.31 to 3.01)
Complications				
None	Ref	Ref	Ref	Ref
Grade I	−0.58 (−2.98 to 1.83)	−0.77 (−3.37 to 1.83)	−2.54 (−6.18 to 1.08)	−0.44 (−3.42 to 2.53)
Grade II	−0.99 (−3.62 to 1.64)	**−3.84 (−7.00 to 0.73)**	**−3.93 (−7.66 to 0.20)**	−1.68 (−5.20 to 1.83)
Grade III+	**−5.20 (−8.88 to 1.53)**	−1.44 (−5.60 to 2.71)	**−6.88 (−11.47 to 2.30)**	**−5.20 (−10.06 to 0.34)**
Length of stay	**−1.32 (−0.26 to 0.01)**	**−0.12 (−0.26 to 0.01)**	0.01 (−0.15 to 0.15)	−0.03 (−0.18 to 0.11)

NOTE: Data presented as coefficients (95% CI). Bold values are statistically significant.
PCS, physical component score; *MCS*, mental component score; *BMI*, body mass index (kg/m^2); *IBD*, inflammatory bowel disease; *ASA*, American Society of Anesthesiologists physical status score.

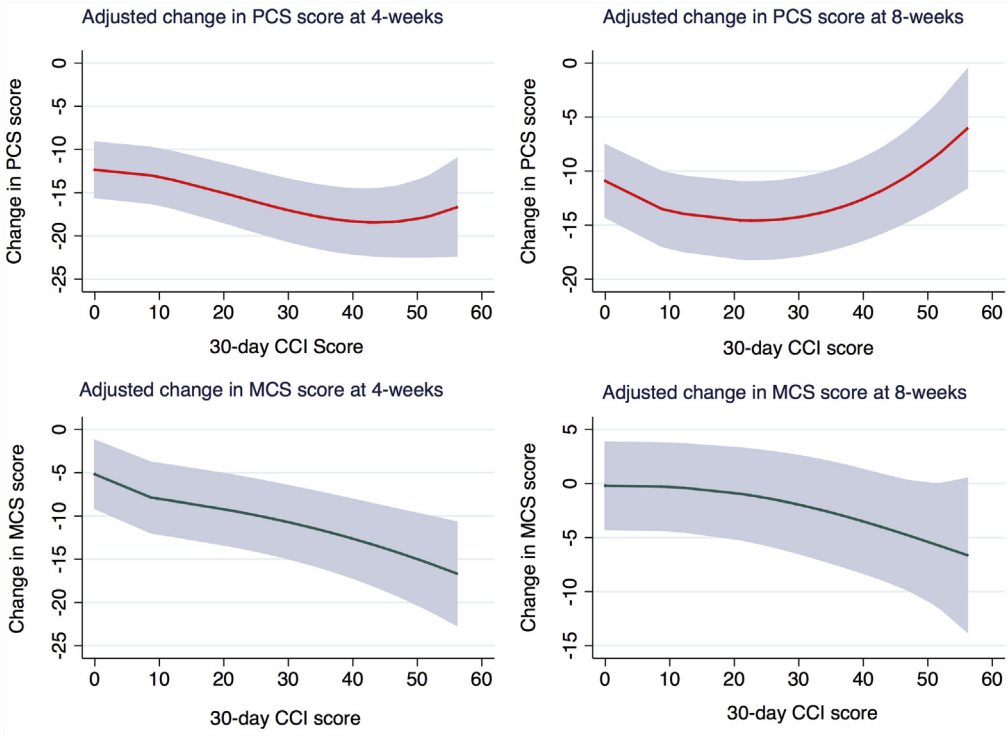

Fig 3. Adjusted change in physical and mental summary scores at 4 and 8 weeks postoperatively, using multivariate fractional polynomial plots. Adjusted for age, gender, BMI, ASA, diagnosis, surgical approach, stoma creation, and length of stay.

surgical populations, because the patient cohort in this study only included major, elective colorectal resections performed in a high-volume specialist referral center.

Conclusion

The findings of this study suggest that postoperative complications negatively impact HRQoL after colorectal surgery, and the impact of complications as graded by the Clavien-Dindo classification system on HRQoL does not follow a consistent pattern. Rather, this study reported that the relationship between HRQoL and CCI is more appropriate. This study adds to the growing body of literature demonstrating that the CCI is a better and more inclusive tool for reporting morbidity given its more consistent relationship with quality of life.

The findings of our study may have important implications for outcome reporting, because this means of classifying postoperative morbidity could be used as a more accurate methodology in

comparative effectiveness research to improve patient care. These findings should be further reproduced in other surgical populations and with other PRO measures.

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Conflict of interest/Disclosure

Drs Dumitra, Trepanier, Fiore Jr, Carli, Fried, and Feldman and Mrs Kaneva have no conflicts of interest to disclose.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.1016/j.surg.2019.05.058.

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Discussion

Dr Anthony Stallion (Bloomfield Hills, MI): I want to thank the Central Surgical Association for the opportunity to discuss this paper. Thank you to our moderator Dr Otterson for the privilege of the floor. Congratulations to President Shoup for an outstanding meeting.

Thank you to the authors for getting me the manuscript in advance for review. You are to be commended for your work. As one who treats patients at the other end of the spectrum, it is comforting to know that as I enter into the cohort that you are studying, the things that are important to me as a potential patient are being addressed. I, like so many others when faced with illness, want to have confidence that I will be able to return to a high quality of life and function. I am happy to know that this issue is at the forefront of the minds of those who will be caring for me.

I enjoyed your presentation, and this is a well-written manuscript. Your work is based on the use of prospectively collected data from multiple studies to evaluate the accuracy of two different postoperative complication grading scales—the Comprehensive Complication Index (CCI) and Clavien-Dindo—as predictors of functional outcomes or quality of life. So, you appropriately pointed out in your introduction that the usual measures such as length of stay and cost are not as meaningful for patients who want to return to a meaningful life after surgery.

This study looked at quality-of-life indicators preop as well as at 4 and 8 weeks postop which give a glimpse into the recovery for major procedures. I am concerned that, given you state such a high morbidity rate of 46% and the age of the population, this does not go quite far enough to evaluate the subject at their new baseline or new normal.

Given the surgical populations that you studied, I think that there are some missed opportunities in the study, such as looking at the effect of preoperative exercise training, the presence of a stoma, and the use of epidural anesthesia on the patient's perception of the ultimate outcome. Also, not accounting for the effect of malignancy and adjuvant therapy as an influence on ultimate outcome or quality of life should be considered.

I want to caution using ASA (American Society of Anesthesia) criteria as a predictor or proxy for comorbidities. The ASA is more a reflection of the status of the patient at the time of surgery, which often is related to the acute disease process and not always a direct reflection of other comorbidities.

I agree with your conclusions that the CCI is a better predictor of outcomes, which, at first blush, is what is expected since the CCI looks at multiple domains versus the Clavien-Dindo, which only considers the morbidity of greatest magnitude.

I would consider tempering your conclusions, which are too broad a generalization, regarding the use of the CCI as a better morbidity-outcome reporting tool. It may be better concluded that it may be better when evaluating the subjective quality of life of this particular patient population, which is the scope of this study.

With all of that said I have a few questions:

1. Several of the exclusion criteria included the inability to speak or understand English or French. In the medical setting, you do not have the ability to choose from where your patients come but want equally good care and outcomes. Excluding these patients can potentially skew the accuracy of the results. Those that are of a different cultural background are important to validate the results and assumptions for a qualitative study such as this. How cultural backgrounds may impact QOL reporting is important and can you address?
2. Another criterion was the exclusion of patients with neurologic or cognitive impairment. I assume this means only those that had impairment prior to the study. It would be good to report the result of this cohort of patients to understand the impact of the surgery and complications on baseline neurologic impairment and perceived quality of life. Do you have this data and, if so, share with us what you found?
3. How do you envision CCI being used in either outcomes research or quality control programs?
4. With the knowledge of the CCI better correlating with and predicting future outcomes, how do you see this impacting patient care? Is there a natural point or points of intervention? Essentially, how does this translate into better patient care?

Again, I commend you on an excellent job and the opportunity to review the manuscript. Also, I want to thank the Central Surgical Association for the opportunity to be a discussant.

Dr Teodora C. Dumitra: Thank you, Dr Stallion. Regarding the exclusion criteria, the patients were excluded when they were enrolled in the RCTs or prospective studies that we included. In Quebec, almost all patients speak English or French. It still encompasses a very multicultural and diverse population. The only population that this does not capture, which would be extremely interesting to study are the first-nation population that live in northern Quebec. Unfortunately, they do not speak English or French, and as most of the questionnaires involve answering many, many questions, you would expect that would be a requirement. It would be very interesting to assess them as a separate cohort as they are a particular and individual population.

The second question regarding the patients that had cognitive impairment, again, as these trials did involve active participation of patients, so, for example, two of the trials were assessing preoperative exercise and how that influences the postoperative recovery, and one of the trials looked at enhanced recovery versus conventional care pathways. Three of these trials do involve the active participation of patients. If they were deemed to not be able to actively participate in their care, they were excluded at that time.

It would actually be very interesting to look at the health care burden of these patients and that impact on health-related quality of life if we cannot assess it directly.

Your third question regarding the use of CCI in patient care, the way the CCI was designed and how the weights are actually assigned to each score, it was all based on multiple stakeholders, so it included not only health care professionals but it also included patient input. They determined the weights assigned to certain complications. In that aspect, it already encompasses a patient perspective.

When we look at the results of this study, we think that the use of the CCI would actually be a better use not only to correlate with length of stay and health care costs, which are the important outcomes to the physicians, but it also correlates with patient-reported outcome. It really does give us a more global perspective of morbidity in patients, and it would actually allow us to use it in comparative effectiveness research to better patient care. I hope I answered your questions.

Dr Vic Velanovich (Tampa, FL): Excellent study. We are in the midst of a study looking at the effects of surgical site infections on quality of life. Although we're not completed with it, we have some preliminary results which show that, once the infection is actually healed, the quality of life actually returns to a normal or better than normal because the patient is improved. So my question is, is there a difference, because you measure this at 4 and 8 weeks, is there a difference in the quality-of-life outcomes in those patients that had continued ongoing complications versus the one that suffered complications and now is completely resolved?

My second question has to do with preoperative symptoms. In general, when we operate on people, they have some preoperative symptoms. Some are asymptomatic, but most have preoperative symptoms. We have previous data which shows that, as long as you take care of their preoperative symptoms, no matter if they even suffered a complication, their quality of life has improved. So do you have any data on that?

Dr Teodora C. Dumitra: Those are very interesting questions, and we wondered if the timing of the complication correlated with the health-related quality-of-life score. We did a subanalysis, and we tried to control for the timing of complication, whether it occurred within 7 days of the surgery or if it occurred more than 7 days of the surgery, which would make it 3 weeks prior to the first measurement of the health-related quality-of-life score. We noted that it actually did not affect the results at all, so we didn't include it in the study. It was not determined as a confounder.

Unfortunately, that data were not captured in this database. We just have the complications that occurred in that 30-day period, and, of course, if the patient was hospitalized or admitted to the intensive care unit, that would definitely have a different impact than someone who was just there for a line infection, for example.

It would be very interesting to have repeated measures of health-related quality-of-life at more frequent time points. If it were to be measured on a weekly basis, we would be able to correlate it with the particular complication that occurred at that time. That would be extremely interesting to assess.

Your second question regarding preoperative symptoms, but we did assess independently patients with inflammatory bowel disease as well as patients with malignancy. We tried to compare those two groups, and we actually noted that there was no significant difference, and we had the exact same results for those patients. We see here patients with malignancy and patients without malignancy, most of which were patients with inflammatory bowel disease. After adjusting for their baseline score, which was slightly lower in patients with nonmalignancy, we did note that there was no significant difference in the results observed. Obviously, it would be good to note exactly which preoperative symptoms were present at the time and how those correlated with the PCS and NCS scores but, unfortunately, we do not have those data.