

REVIEW



Systematic review of the impact of demographic and socioeconomic factors on quality of life in ostomized colorectal cancer survivors

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ABSTRACT

Background: Formation of a fecal stoma may be necessary to ensure radical resection in colorectal cancer (CRC) patients but will substantially impact the health-related quality of life (HRQoL) in about 20% of cases. Little is known about patient-related risk factors for reduced HRQoL in patients with a permanent stoma. We, therefore, reviewed the current literature on how demographic and socioeconomic factors affect HRQoL in CRC survivors with a stoma.

Material and methods: The databases Pubmed, Embase, CINAHL, and PsycINFO were systematically searched. Two independent reviewers extracted and quality-assessed eligible publications. Studies assessing HRQoL using a validated questionnaire at least 6 months after surgery for CRC were included if data on the impact of demographic and/or socioeconomic factors on HRQoL were analyzed and presented.

Results: Eligible studies predominantly presented small cross-sectional cohorts. Age showed equivocal results; hence, some studies found younger patients had inferior HRQoL compared with older patients, and others found no difference. Subdivision into age groups differed widely. Several studies found that both generic and stoma-specific HRQoL was lower in females compared with males. Most studies found that socioeconomic factors did not affect HRQoL while one study found lower education correlated to reduced HRQoL. Categorization of these factors also varied widely.

Conclusions: This is to our knowledge the first systematic review on the impact of patient-related factors on HRQoL in long-term CRC survivors. We found that a stoma had more impact in younger ostomates than older and that HRQoL in females was reduced more than in males. Conclusions regarding other factors were difficult due to few studies and contradictory results. Further research in this subject is much needed in order to target preventive measures when planning surgery in patients in high risk of reduced HRQoL.

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Introduction

The treatment of colorectal cancer (CRC) often involves the formation of a fecal stoma. In low rectal cancers involving or threatening the sphincteric apparatus, an abdominoperineal excision (APE) leaving the patient with a permanent end colostomy is considered best practice. In other cases, a surgical complication such as anastomotic leakage necessitates the formation of a permanent or temporary stoma. With the advances in treatment of CRC in recent decades and with the demographic changes in our population the number of long-term cancer survivors living with late effects from cancer treatment and surgery is expected to increase. Therefore, there has been an increasing recognition of the effects of cancer treatment and the impact on the patients' health-related quality of life (HRQoL) as a relevant long-term outcome measure.

HRQoL is a subjective multidimensional concept that depends on the patients' own perception of health status and possibilities in the context of their culture and value

system. It can be measured with a generic instrument or an instrument specific to the type of patient or condition.

Having a stoma affects HRQoL negatively in 19–23% of patients [1,2]. Several clinical factors related to the disease or treatment are already known to affect the HRQoL in stoma patients. Previous studies have found that patients ostomized as part of cancer treatment have a better generic and stoma-specific long-term HRQoL than patients ostomized because of a benign condition [3,4]. The postoperative course of HRQoL has been mapped longitudinally in several studies showing an improvement in the first 6–12 months postoperative whereupon the quality of life seems to stabilize [5–7]. In the case of CRC survivors with a stoma the HRQoL beyond 12–24 postoperative months has been shown to improve beyond the population norm indicating better HRQoL in long-term survivors of a malignant disease [6]. Preoperative counseling and marking of stoma placement reduces complication rate and leads to better HRQoL compared to patients who received no preoperative counseling or marking of stoma placement [8,9]. Patients with a stoma

cancer OR carcinoma OR adenocarcinoma OR
neoplasm OR tumor OR tumour

AND

colorectal OR rectal OR rectum OR colon OR bowel
OR intestinal OR intestine OR gastrointestinal

AND

stoma OR ileostomy OR colostomy OR ostomy OR
ostomate

AND

'health-related quality of life' OR 'quality of life' OR
'life quality' OR HRQoL OR QoL

AND

demographic OR socioeconomic OR
economic OR gender OR age

Figure 1. Search strategy in the web-based databases.

formed in the emergency setting fare worse than patients undergoing elective surgery [5]. However, little is known about the impact of patient-related factors like demographic differences i.e., age and gender, and socioeconomic factors: education, employment, and household income. We hypothesize that coping mechanisms differ depending on age, gender, and educational status thus affecting the impact a stoma has on HRQoL and that both the physical and mental burden of a stoma is correlated to employment status and household income. To our knowledge, this has only been sporadically investigated and no review of the literature has been done on the subject. Hopefully a better understanding of patient-related risk factors will enable surgeons and stoma-care nurses to implement targeted preventive measures in patients in the highest risk of stoma-related negative impact on HRQoL even preoperatively. Therefore, we decided to perform a review of the literature on this topic to outline the current knowledge and to make recommendations for future research.

Material and methods

This review was conducted in accordance with the PRISMA statement [10] and the study protocol was registered at PROSPERO with the registration number CRD42018093139.

During March 2018, the electronic databases Pubmed, Embase, CINAHL, and PsycINFO were systematically searched. The search strategy is shown in [Figure 1](#).

Studies were included in the review if a validated generic or specific HRQoL instrument was used to evaluate HRQoL in colorectal cancer survivors with a stoma ≥ 6 months after ended surgical and oncological treatment. This cutoff was chosen based on previous studies showing substantial

postoperative improvement in HRQoL the first 6 months postoperatively whereupon it seems to stabilize [6]. Furthermore, statistical analysis had to be performed on the impact of demographic factors (age or gender) and/or socio-economic (education, employment status, or household income) on the ostomates' HRQoL and the results explicitly presented as a primary or secondary outcome either in the result section or in a table. Only articles in English published in peer reviewed journals were included. No limits were set regarding publication date. In total, 694 references were identified from the databases. After 169 duplicates were removed, all publications were screened independently by two authors (H. Ø K. and A. T.) first by title and abstract. This led to the exclusion of 420 studies. Subsequently full text reading led to the exclusion of 105 studies. As a result eight publications met the criteria [11–18]. All references of these publications were screened for further eligible studies and none were identified. Two of the publications that met all inclusion criteria [17,18] were subsequently excluded as the study cohorts were identical or overlapping with other included studies leaving six studies eligible for the review. Any disagreements in the screening process were solved by consensus between the authors. [Figure 2](#) shows a flowchart of the screening and extraction process.

An assessment of the methodological quality of all eligible studies was performed independently by two authors (H. Ø K. and A. T.) based on a 14-item checklist for systematic reviews developed by Mols et al. [19]; each time a study met a checklist criterion a point was assigned ending up in a score from 0 to 14 points. Methodological quality was considered high if a study scored ≥ 10 points, moderate if the score was 7–9 points and low if the score was ≤ 6 points. In the cases of studies with overlapping cohorts, only the publication with the highest methodological quality was included in the review. Any disagreements in quality score were solved by consensus between the two assessing authors.

There was great variation in the included studies regarding which instruments were used for assessment of HRQoL and also regarding subdivision into categories of age and socioeconomic status, therefore a meta-analysis was not possible.

Results

Characteristics of the included studies are shown in [Table 1](#). Of the included six studies, five were cross-sectional, and one was longitudinal. Small cohort studies with less than 100 CRC survivors with a stoma were found in four. The methodological quality was good (10–13 points) in all included studies. In five of the studies, demographic/socioeconomic factor's impact on HRQoL was the primary outcome. Both generic and specific HRQoL instruments were included in four of the six studies.

The instruments most often used were European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 and EORTC QLQ-CR38. The EORTC QLQ-C30 is a generic 30-item HRQoL-instrument for cancer patients

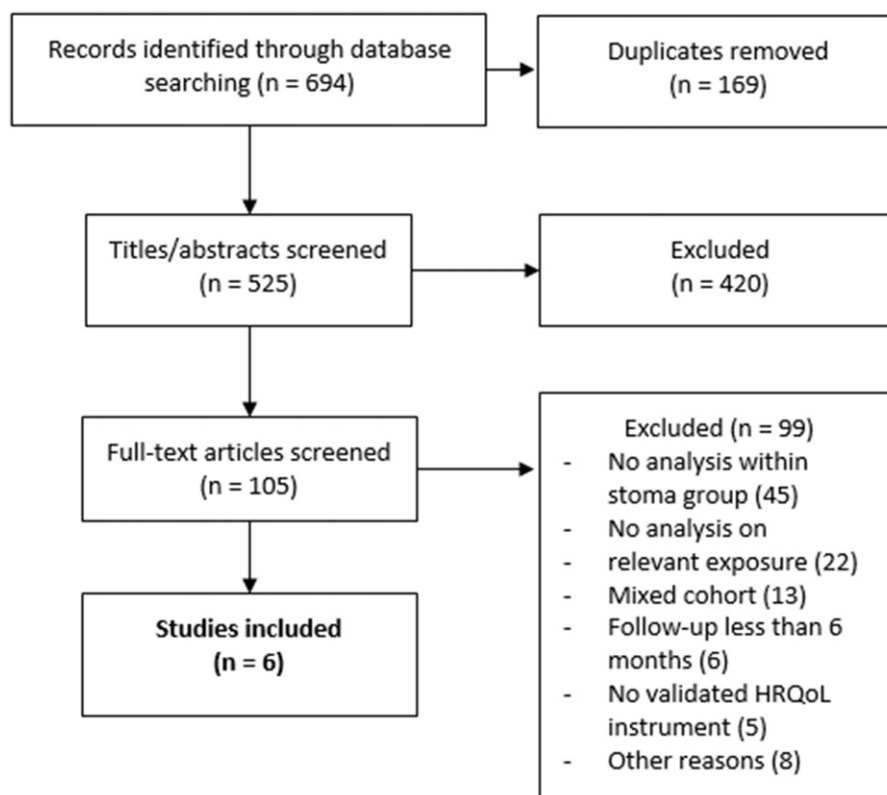


Figure 2. Flowchart of the screening and selection process.

Table 1. Baseline characteristics of included studies.

Author (year)	Country	Study design ^a	CRC ostomates, n	HRQoL instrument(s)	Response rate	Follow-up (years)	Meth. quality Score ^b
Hamashima (2002) [14]	Japan	C	38	EuroQol	67.1%	>5	11
Kement et al. (2014) [15]	Turkey	C	44	SF-36	100%	15.3±9.7	12
Krouse et al. (2009) [16]	USA	C	246	COH-QOL-o ^c SF-36 v.2	54%	>5	11
Mahjoubi et al. (2012) [13]	Iran	C	96	EORTC C30 EORTC CR38	undisclosed	2.7	10
Sideris et al. (2005) [12]	France	C	42	EORTC C30 EORTC CR38	80%	4.9	12
Verweij et al. (2018) [11]	The Netherlands	L	494	EORTC C30 EORTC CR38	73%	4.5±2.3	13

^aC: cross-sectional; L: longitudinal.

^bAccording to Mols et al. [20].

^cCOH-QOL-o: The City of Hope Quality of Life-Ostomy questionnaire.

containing five functional scales, a global health status scale, three symptom scales, and six single items. The EORTC QLQ-CR38 is a 38-item questionnaire specific to colorectal cancer patients including ostomates and assesses disease symptoms, side effects of treatment, body image, sexuality, and future perspective [20,21]. Two of the studies used the Medical Outcomes Study 36-Item Short-Form a generic HRQoL-instrument producing eight multi-item scales along with a physical component summary score and a mental component summary score [22]. In one study The City of Hope Quality of Life-Ostomy questionnaire was used, a 90-item stoma specific questionnaire including demographic, non-scaled, and scaled items. The non-scaled items assess among others marital status, work, and household income. The scaled items are mapped into four HRQoL domains [23]. One study used the EuroQol EQ5D a generic questionnaire consisting of five dimensions, one item per dimension, and a visual analog scale on perceived health [24]. In the following sections the

results will be presented separately for each of the investigated risk factors. A summary of all significant findings is presented in Table 2.

Demographic factors: Age was examined as a risk factor for reduced HRQoL in CRC survivors with a stoma in five of the included studies. Three of these studies found no effect of age on HRQoL. Kement et al. [15] found no significant correlation between age and SF-36 scales scores in their study on 44 APE patients. Sideris et al. [12] used the EORTC QLQ C30 and CR38 and found that age had no effect on any QOL scores in subgroup analysis on their 42 stoma patients. Also, Krouse et al. [16] using The City of Hope Quality of Life-Ostomy and SF-36 v.2 on 246 stoma patients found no correlation between age and HRQoL in multivariate analysis.

Mahjoubi et al. [13] found in their study on 96 ostomates using the EORTC QLQ-C30 and QLQ-CR38 a significant correlation using the one-way ANOVA of moderate size in younger (<44.5 years) females compared to older females in role

Table 2. Result summary; correlation of HRQoL to explanatory variables.

Study (HRQoL-instrument)	Age	Gender	Education	Employment	Income
Hamashima (2002) [14] (EuroQol-EQ5D)	–	Affected by stoma in females but not in males	–	–	–
Kement et al. (2014) [15] (SF-36)	Not affected by age.	Females have lower score compared to men in 3 domains and mental component	Not affected by education	–	Not affected by income
Krouse et al. (2009) [16] (COH-QOL-o and SF-36)	Not correlated to age in multivariate analyses.	COH-QoL-o: Affected in 3 domains in females and 1 in males SF-36: Affected in 7 domains in females, 0 in males	Not affected by education in multivariate analyses	Not affected by employment in multivariate analyses	Not affected by household income in multivariate analyses
Mahjoubi et al. (2012) [13] (EORTC QLQ-C30 EORTC QLQ-CR38)	Better sexual function in the young. Lower score in 3 function domains and 3 symptom scales in young compared to older females.	Females had worse body image and lower score in 2 function domains and 3 symptom scales	Not affected by education	–	–
Sideris et al. (2005) [12] (EORTC QLQ-C30 EORTC QLQ-CR38)	Not affected by age.	More dyspnea in female ostomates	Worse body image if <9 years of education. More GI-symptoms if >13 years of education	Not affected by employment	–
Verweij et al. (2018) [11] (EORTC QLQ-C30 EORTC QLQ-CR38)	Younger ostomates (≤ 65 years) lower HRQoL across more domains than older	–	–	–	–

function, social function, and emotional function. Also older females compared to younger females had better body image, better future perspective and fewer stoma-related problems, less appetite loss, and less gastrointestinal symptoms. These age-differences were not observed in males, but more sexual enjoyment problems were observed in both older males and females compared to their younger counterparts.

Verweij et al. [11] compared ostomized and non-ostomized CRC survivors divided into three age groups ≤ 65 years, 66–75 years, and ≥ 76 years. They found no significant difference in HRQoL when comparing the age groups within the stoma cohort. However, when comparing ostomates to CRC survivors without a stoma and to the normative Dutch population, there were significant differences in several domains of EORTC. The clinical relevance of the findings were evaluated according to Cocks et al. [25] stating that a difference in means of 5–14 points in a domain was of small clinical relevance. A difference of 14–22 was of medium clinical difference and a difference in means of >22 points was of large clinical relevance. Compared to non-ostomate CRC survivors the stoma patients in the ≤ 65 age group suffered worse physical, role and social functioning, worse global health status and experienced more financial difficulties, all differences were of small clinical relevance. The ostomates of 66–75 and ≥ 76 years had worse physical functioning compared to non-ostomates and the ostomates ≥ 76 years experienced less constipation compared to their non-ostomized counterparts. The differences in the 66–75 and ≥ 76 year age groups were of small clinical relevance. When comparing to the normative Dutch population the group of ostomates ≤ 65 years had significantly lower social functioning, which was of large clinical relevance, significantly worse physical functioning, more financial difficulties, more dyspnea, and diarrhea of medium clinical relevance. And significantly worse role functioning,

cognitive functioning, and more fatigue of a small clinical relevance. In the 66–75-year age group, a reduced score among stoma patients of medium clinical relevance was found in social functioning and diarrhea and a reduced score of small clinical relevance in physical functioning, role functioning, and more fatigue. In the oldest group, a significant difference of small clinical relevance was found in physical functioning, social functioning, and insomnia. These results indicate that the impact of a stoma on HRQoL is more pronounced in the youngest group of ostomates both regarding magnitude and the number of domains affected compared to the older.

The impact of the patients' gender on HRQoL in ostomates was addressed in five of the included studies. Hamashima [14] in a study including 38 patients with a permanent stoma assessed HRQoL with the generic instrument EQ5D and found the presence of a stoma affected HRQoL negatively in females but did not affect HRQoL in males.

Kement et al. [15] found in their cohort of 44 colostomates assessed by the SF-36 that females had a significantly lower score in general health perception, role emotion, mental health perception, and mental component compared to males.

In the study by Mahjoubi et al. [13] using EORTC QLQ C30 and CR38, a better body image scores and physical function, sexual function and sexual enjoyment were found in males. Males tolerated stoma-related problems, general gastrointestinal symptoms, and chemotherapy side effects significantly better than females. The score for radiation induced effects on micturition was worse in males as the only domain compared to females.

Sideris et al. [12] found in their survey of 42 stoma patients assessed by the EORTC C30 and CR38 significantly more dyspnea in female ostomates compared to female non-ostomate rectal cancer survivors, this difference was not

found in males and no other differences were seen in any other QoL-scores.

Krouse et al. [16] compared HRQoL in 246 ostomates to 245 non-stoma controls using The City of Hope Quality of Life-Ostomy and SF-36 v2 and found female ostomates scored significantly worse in the social domain, psychological domain, and in overall QoL compared to females without a stoma. The difference in the psychological and social domains exceeded the minimally important difference. Males with a stoma scored worse in the social domain compared to non-ostomates as the only domain reaching significance in males. In physical well-being among younger (<75 years) females, the adjusted mean score was lower among ostomates compared to non-ostomates. In females 75 years or older, there was no significant difference.

When assessing HRQoL with the SF-36 v2, Krouse et al. found significantly worse physical function, general health, and role-emotional scales in females. Among females, statistically significant adjusted difference means exceeding the minimally important difference were observed in physical function, general health, role-emotional, mental health, and the Physical Component Summary scale and Mental Component Summary scale. Among males, no differences reached significance or exceeded minimally important difference between ostomates and non-ostomates.

Socioeconomic status: Krouse et al. [16] explored the impact of education, employment status, and annual household income and found none to correlate significantly with HRQoL in multivariate analysis. In the study by Kement et al. [15] on 44 colostomates, HRQoL was not affected by education or income level. Mahjoubi et al. [13] found no significant correlation between education and HRQoL. Sideris et al. [12] found ostomates with 9–13 years of education had more financial difficulties compared to non-ostomates. Patients with fewer than 9 years of education reported a worse body image than non-ostomates and non-stoma patients with more than 13 years of education complained of more gastrointestinal symptoms than those with a stoma.

Discussion

As HRQoL is increasingly considered an important long-term outcome measure in the treatment of cancer, this should also be taken in consideration in the preoperative treatment decision making for curable disease. This review concerning the impact of demographic and socioeconomic factors on HRQoL in CRC survivors with a stoma indicates that patients of female gender and young age are in the highest risk of clinically relevant reduced HRQoL in several HRQoL-domains.

Two of the included studies found that younger age was correlated with worse HRQoL. In one study, age was significantly related to HRQoL in bivariate analysis but not in multivariate analysis and two studies found no correlation between age and HRQoL. Two of the studies that found no correlation did, however, not describe any comparison to a control or normative population [12,15]. It is well known that the course of HRQoL changes over a lifetime in the normative population with a decline in most domains with an

increasing age, therefore, HRQoL scores should be compared to a reference population within age groups [11]. Thus, we find it probable that the age difference found in the study by Verweij et al. is tangible as the changes in HRQoL with age is taken into account and we find it probable that younger age is correlated with greater impact on HRQoL than is the case in older ostomates. This is in accordance with the study by Pittman et al. [8] who found older age a predictor of less difficulty adjusting to a stoma in their cohort of 239 ostomates. With the limited number of studies on this subject, however, more research is needed to establish this, preferably large sized longitudinal studies with subgroup bivariate analysis considering the course of HRQoL with age in a reference population.

All included studies that investigated gender differences found that females had significantly lower HRQoL in several domains compared to males. Both studies using the SF-36 found females to have worse general health, role emotional, mental health perception, and mental component summary [15,16]. Krouse et al. had a response rate of 54% and responders and non-responders could not be compared, thus the potential response bias could not be assessed. When comparing the responding ostomates and non-ostomates they were demographically similar, still there was a difference in HRQoL between the genders. Mahjoubi et al. [13] assessed HRQoL with the EORTC questionnaires and found clinically significant differences in body image and physical function and in several symptom scores. This indicates that a stoma has both more physical and mental impact in females than in males. These results are in accordance with previous findings that females fare worse than males when having a stoma. Kasperek et al. [2] assessed HRQoL in a cross-sectional study on 143 APE patients answering the EORTC QLQ-C30 and CR38 and a non-validated question: 'How would you rate your quality of life now compared to before surgery'. Concerning the non-validated question, the study reported male sex to be associated with worse HRQoL, but this was not reported with any of the EORTC domains. Possible explanations for the differences in HRQoL between the genders may be in different coping mechanisms, but more research with validated instruments is needed to establish the gender differences in the impact on HRQoL in ostomates and to examine the reasons for the differences. The study by Baldwin et al. [18] that was excluded because the cohort of stoma patients overlapped with the study by Krouse et al. included a mixed method analysis on the impact on sleep disruption and fatigue between genders. They found a stoma had higher impact on sleep disruption and fatigue in females than in males, but both an open-ended question: 'Please share with us the greatest challenge you have encountered in having a stoma' and focus group interviews showed the same worries and challenges were present with both genders. We encourage more qualitative and mixed method research in this field to hopefully identify and explore specific gender specific challenges and to suggest targeted preventive measures to sustain or recover good HRQoL in both genders.

From the studies included in this review, it is not evident if socioeconomic status affects the HRQoL in CRC survivors with a stoma. Three of the included studies investigated the impact of education, employment, and/or household income on HRQoL and found no correlation [13,15,16]. One study found correlation between short education and worse body image, 9–13 years of education, and more financial difficulties and more gastrointestinal symptoms in patients with a long education in an exploratory analysis [12]. Three of the included studies showed that ostomates experience an increased financial burden compared to non-ostomates [11,12,16], but if this perceived burden depends on educational level, employment status, or income is not known. Pittman et al. investigated the impact of socioeconomic factors in their study of 239 ostomized veterans and found more stoma complications and more difficulty adjusting to having a stoma among employed patients, patients living alone and veterans with an income of less than \$30,000 per year. However, patients ostomized for benign conditions were included which may affect the outcome.

The perceived financial burden of a stoma has been reported in previous studies [3] and is a logic consequence of having to acquire stoma appliances. The financial concerns may impact HRQoL and is included in most HRQoL questionnaires. Based on the contradictory findings in the studies included in this review, we cannot draw any conclusion if socioeconomic status has a significant impact on HRQoL in CRC survivors with a stoma, but more research is needed in this area with validated measures for socioeconomic status and taking into consideration that many countries provide stoma appliances fully or partially free of charge for the ostomates.

There are some limitations to this review. In general, the methodological quality of the included studies was high, and five of the six included studies reported demographic and/or socioeconomic factors' impact on HRQoL as a primary outcome. However, most of the studies presented rather small stoma cohorts and some were prone to selection or response bias based on the inclusion method or response rate. This type of review may also suffer from publication bias, as numerous studies have been performed on stoma-cohorts, but if the investigated risk factors did not show an impact it may not have been reported at all in the publications even though it was examined. We performed a thorough search of the literature with several scoping searches to make sure the strategy was robust before the final search strategy was established. The inclusion criteria for the review were somewhat meticulous as we wanted to avoid the potential bias arising from the e.g., the distress from the early postoperative period, a mix of patients ostomized from malign and benign conditions and an unvalidated HRQoL-instrument. We consider this a strength and the fact that only eight publications were eligible for the review underscores the need for research of high methodological quality in this field. We also find it a strength that two authors independently screened the literature and quality assessed eligible publications.

We highly encourage more research in this field with well validated stoma-specific HRQoL-instruments preferably with a

weighed score and with large cohorts to establish if demographic or socioeconomic factors impact the HRQoL in long-term CRC survivors with a stoma and qualitative studies to explore reasons for the presented age and gender differences.

Disclosure statement

No potential conflict of interest was reported by the authors.

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