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REVIEW ARTICLE

Effective palliation and quality of life outcomes in studies of surgery for advanced, non-curative gastric cancer: a systematic review

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Abstract
Background Relief of symptoms should be the primary focus of palliative treatment as defined by the World Health Organization. Evaluating the effectiveness of palliative interventions should incorporate this goal and include quality of life (QOL) outcome assessments. A systematic review of the surgical gastric cancer literature was performed to summarize the effectiveness of palliative surgical interventions in addressing QOL.
Methods An electronic literature search of EMBASE, Medline, and the Cochrane Database of Controlled Trials was performed from January 1, 1985 to December 1, 2009. English language abstracts and articles were reviewed independently by two reviewers. A systematic approach to data abstraction and presentation was followed.
Results No articles were identified as reporting true QOL outcomes using reliable, validated QOL instruments in surgically managed, advanced gastric cancer patients. Nine articles were identified as reporting outcomes measuring effectiveness of palliation. Commonly reported pre-procedure symptoms were weight loss, abdominal pain, vomiting, obstruction, and bleeding. Time to oral intake was reported in 5 of 9 studies, ranging from a mean of 2.9 days (laparoscopic gastrojejunostomy) to 8 days (surgical bypass). Length of postoperative inpatient stay ranged from a mean of 7 days (gastrojejunostomy) to 28 days (surgical bypass). Other measures of effective palliation included measures of clinical success, hospital readmission rates, and post-procedure analgesic intake.
Conclusion A paucity of literature exists regarding the QOL of surgically managed gastric cancer patients. Prospectively designed studies using credible QOL measures are necessary to better inform the treatment decision-making process for these patients.

Keywords Quality of life · Gastric cancer · Surgery · Palliation

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Introduction

The majority of patients with gastric cancer in low-incidence countries present with a burden of cancer too

advanced for curative treatment. In these patients, the primary goal of intervention is relief of symptoms [1–5]. Symptoms experienced by patients with advanced gastric cancer include those related to malnutrition (anorexia, cachexia, weight loss), bleeding (hematemesis, melena, anemia), and pain and obstruction (vomiting, dyspepsia, dysphagia) [2, 6, 7]. Palliation is defined by the World Health Organization (WHO) as neither hastening death nor prolonging survival while providing relief from pain and other distressing symptoms [8]. Interventions directed at symptom relief include chemotherapy, radiotherapy, complete or partial gastrectomy, surgical bypass, and radiological and endoscopic options (e.g., stent placement, cauterization, gastrostomy tubes) [1, 9].

Randomized controlled trials evaluating the effectiveness of the various surgical options in this population do not exist and an optimal management strategy has yet to be determined. Although resection is associated with slightly improved survival, high rates of procedure-related complications and mortality are associated with surgical interventions for advanced gastric cancer patients and selection bias likely exists with respect to which patients are chosen for resection [10–13]. Parallel research investigating the ability of these interventions to relieve symptoms is required and is of critical importance for determining the optimal treatment strategies. A systematic literature review of quality of life (QOL) outcomes was therefore completed to summarize the existing literature reporting on surgical interventions for patients with advanced, non-curative gastric cancer.

Methods

Data sources

Electronic literature searches were conducted in Medline and EMBASE from January 1, 1985 to December 1, 2009 according to the search algorithm provided in Appendix A. Search terms included: [exp Stomach Cancer/ or (((gastric or stomach) adj1 cancer$) or ((gastric or stomach) adj1 carcinoma) or ((gastric or stomach) adj1 adenocarcinoma) or ((gastric or stomach) adj1 neoplasm$)).mp] and [exp palliative therapy/ or exp terminal care/ or palliat$.mp. or "stage iv".mp. or advanced disease.mp.] and [clinical trial/ or controlled clinical trial/ or exp comparative study/ or meta-analysis/ or multicenter study/ or exp practice guideline/ or randomized controlled trial/] not [Case Report/ or review]. A separate search of the Cochrane Central Register of Controlled Trials (1998–2009) was performed using the search term "gastric cancer". Searches were limited to English language and primary reports. No attempt was made to locate unpublished material.

Study selection and review process

To be eligible, studies had to meet the following criteria: (1) patients with non-curative, advanced gastric cancer; (2) surgical intervention related to the primary tumor; (3) endpoints including symptoms, nutrition, time in hospital, and overall wellbeing; and (4) outcomes reported for patients with gastric cancer only. Studies were excluded according to the following exclusion criteria: (1) reviews, meta-analyses, systematic reviews, abstracts, editorials or letters, case reports, and guidelines; or (2) studies with less than 30 patients. No data quality restrictions were imposed and both analytical and observational study designs were included. All electronic search titles, selected abstracts, and full-text articles were independently reviewed by a minimum of two reviewers (NC, LH, and AM). Reference lists from review papers and relevant articles were also examined for additional studies that met our inclusion criteria. Disagreements on study inclusion/exclusion were resolved with a consensus meeting.

Data extraction

A systematic approach to data extraction was used to produce a descriptive summary of participants, interventions, and study findings. The following data points were collected during the review: study characteristics (country, study design, years of data collection), patient characteristics (age, description of population, cancer stage, number of patients, treatment strategy), QOL or palliation endpoints (including symptoms, length of hospital stay, oral intake, ability to perform daily tasks, analgesic intake). The first reviewer (AM) independently extracted the data and a second reviewer (NC) checked the data extraction. No attempt was made to contact authors for additional information.

Data analysis

Due to the heterogeneity in endpoints and methods of assessing QOL-related outcomes, the results could not be assessed quantitatively. Main trends and critical themes were qualitatively summarized and presented.

Results

A total of 1939 articles were identified from the electronic searches and review of reference lists. After removal of duplicates and screening for relevant titles and abstracts, a total of 201 articles were submitted for a full-text review. Nine articles met the eligibility requirements and were included in the review (Fig. 1) [12–20]. All included

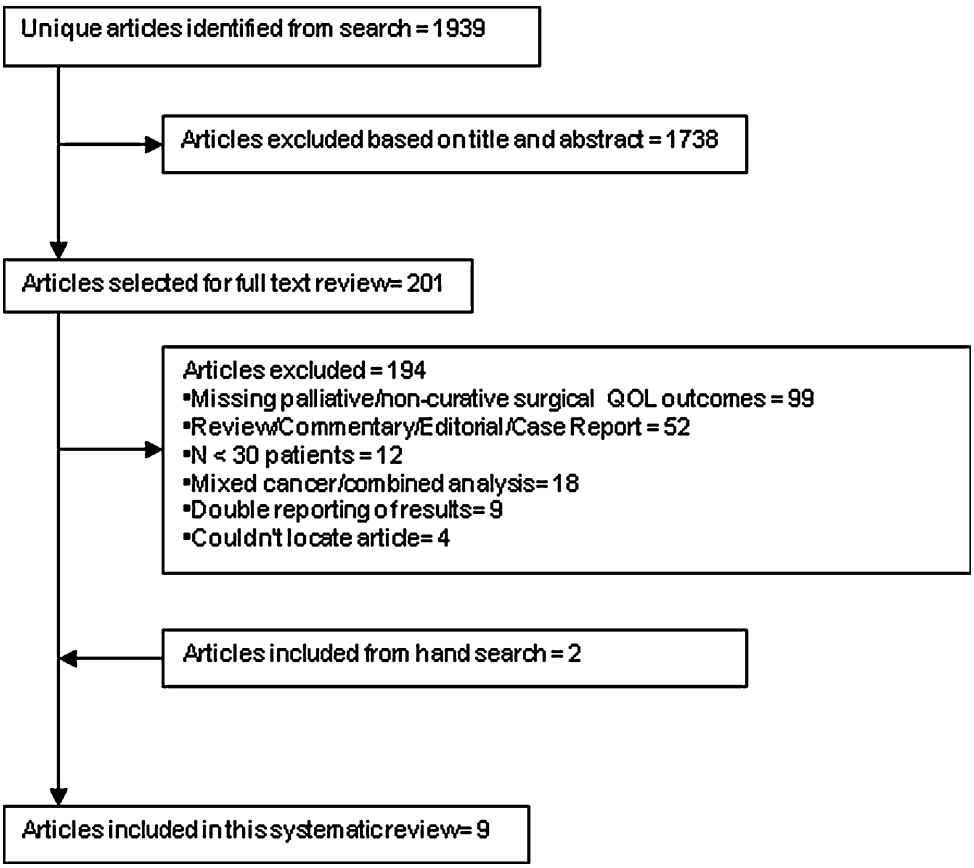

Fig. 1 Article selection flow. *QOL* quality of life

articles were retrospective, single-institution case series, except for one [19] that included a prospective collection of patient-reported outcomes for a subset of patients using a questionnaire (Table 1). None of the studies were from North America or Europe. The patient population under investigation was described as having unresectable disease in 4 studies, advanced disease in 3, incurable in 1 study, and non-curative in 1 study. Patient age ranged from a mean of 56 to a median of 69 years. Although stage was not reported in 6 studies, stage IV disease was predominant in the studies that reported this variable (77.4–100% of patients). Operative strategies for palliation varied. The majority of articles evaluated surgical bypass (8 studies) and less frequently total or subtotal gastrectomy (5 studies).

Preoperative symptoms were recorded with a detailed description in 4 of the 9 studies [13, 18–20]. Weight loss, abdominal pain, vomiting, bleeding, obstruction, dysphagia, hematemesis/melena, and anorexia were reported most frequently. One study reported specifically the absence of symptoms in 13.2% of non-curatively managed patients [13]. An additional 3 of the 9 studies reported that all patients had unresectable, symptomatic gastric outlet obstruction (GOO) requiring palliation [14–16].

None of the studies used a validated measurement tool to assess true QOL outcomes; however, effective palliation of non-curative interventions was measured in all studies. Instead, hospital chart abstraction and follow-up visits were used to collect palliative clinical endpoints in 8 studies [12–18, 20] and an unvalidated questionnaire was used to collect information in 1 study [19]. Time to oral intake was the most common outcome used and it was reported in 5 of the 9 studies (Table 2). Results ranged from a median of 2.9 days (laparoscopic gastrojejunostomy) [14] to 8 days (surgical bypass) [16]. One study reporting on the management of GOO through surgical bypass noted that one patient was not able to return to a normal, solid diet due to complications incurred during the surgical bypass procedure [16, 20]. Samarasam et al. [19] reported that only 83% of gastrectomy patients and 24% of surgical bypass patients returned to a normal diet during the postoperative period, while Stupart et al. [20] reported that 90% of surgical bypass patients returned to a normal diet before discharge. Relief of obstruction was reported by Medina-Franco et al. [13] as being achieved in 85% of total gastrectomy patients and in 60% of surgical bypass patients. Relief of obstruction was defined as the ability to eat by mouth until death or last follow-up [13]. Similarly, clinical success was defined by Maetani et al. [16] as the ability to adequately maintain hydration and nutritional status independent of parenteral support, and this was achieved in 77% of patients receiving surgical bypass for gastric outlet obstruction.

Table 1 Study and population characteristics of included articles

Study	Country	Patient characteristics	Treatment (*N*)	Mean age (years)	Stage (%)	
					III	IV
Choi [14]	Korea	Unresectable AGC + GOO	OGJ (38)	OGJ: 60.4	NR	
			LGJ (30)	LGJ: 58.7		
Lo [15]	Singapore	UGC + GOO	BP (51)	67	NR	
Maetani [16]	Japan	UGC	BP (22)	66.1	NR	
Medina-Franco [13]	Mexico	AGC	TG (24)	56	0	100
			BP (10)			
Miyagaki [17]	Japan	AGC	G (52)	69[a]	NR	
Ouchi [18]	Japan	AGC	G (64)	G: 64.3	3	97
			BP (15)	BP: 64.6		
			EL (16)	EL: 59.8		
Samarasam [19]	India	Incurable GC	G (78)	51[a]	14.6	77.4
			BP or EL (21)			
Stupart [20]	South Africa	UGC + GOO	BP (67)	60[a]	NR	
Wang [12]	Taiwan	Non-curative GC	TG (107)	63.4[a]	NR	
			DG (150)			
			BP (64)			

N number of patients, *NR* not reported/necessary information not provided, *AGC* advanced gastric cancer, *UGC* unresectable gastric cancer, *GC* gastric cancer, *GOO* gastric outlet obstruction, *OGJ* open gastrojejunostomy, *LGJ* laparoscopic gastrojejunostomy, *BP* surgical bypass, *G* gastrectomy, *TG* total gastrectomy, *DG* distal gastrectomy, *EL* exploratory laparotomy

[a] Median age

Table 2 Effective palliation: oral intake

Study	Outcome measured	Treatment group (*N*)	Outcome result
Lo [15]	Mean time to regain diet	BP (51)	6.5 days (3–18)
Choi [14]	Mean time to oral intake	OGJ (38)	4.7 days (4–16)
		LGJ (30)	2.9 days (2–11)
Maetani [16]	Median time to oral diet	BP (22)	8 days (6–10)
Samarasam [19]	Normal diet post-op (time period NR)	G (78)	83%
		BP or EL (21)	24%
Stupart [20]	Able to consume normal diet on discharge	BP (67)	90%

BP surgical bypass, *OGJ* open gastrojejunostomy, *LGJ* laparoscopic gastrojejunostomy, *G* gastrectomy, *EL* exploratory laparotomy

Mean or median length of postoperative inpatient stay was evaluated in 4 studies as a surrogate for QOL for a variety of surgical procedures (Table 3). Length of stay ranged from a mean of 7 days (surgical bypass) [21] to 28 days (surgical bypass) [16]. Maetani et al. [16] reported that fewer than 25% of patients remained in the hospital post-surgical bypass without the possibility of discharge.

Various other physical measures were collected (Table 4). Samarasam et al. [19] created and mailed a questionnaire to postoperative patients that included 4 physical measures of QOL: ability to do normal activity, experiencing vomiting, experiencing hematemesis, and experiencing melena (Table 4). With a response rate of 65.5%, they evaluated outcomes by procedure type (gastrectomy or surgical bypass, exploratory laparotomy). Subset-analysis comparing total gastrectomy and subtotal gastrectomy responses indicated that similar palliation was achieved in all categories [19]. Good palliation for bleeding, defined as a patient not requiring a blood transfusion after the procedure until death or time of last follow-up, was described in 83% of patients receiving gastrectomy and 80% of patients receiving surgical bypass [13]. Choi [14] measured mean postoperative analgesic intake as a surrogate of relief of pain and stated that patients undergoing laparoscopic surgical bypass consumed less analgesic (430 mg) than those undergoing open surgical bypass (540 mg).

Miscellaneous measures of effective palliation included re-admission to hospital, hospital-free survival, hospitalization index, and ingestion index (Table 5). Reasons for re-admission to hospital for non-terminal events in 40% of patients after surgical bypass were nausea,

Table 3 Effective palliation: postoperative inpatient stay

Study	Outcome measured	Treatment group (*N*)	Outcome result
Lo [15]	Mean postoperative stay	BP (40)	13.3 days (5–44)
Choi [14]	Mean postoperative stay	OGJ (38)	12.5 ± 3.9 days
		LGJ (30)[a]	8.5 ± 2.9 days
Maetani [16]	Median hospital stay	BP (17)	28 days (19–38.5)
Stupart [20]	Mean hospital Stay	BP (67)	7 days
Maetani [16]	Possibility of discharge	BP (22)	77.30%

BP surgical bypass, *OGJ* open gastrojejunostomy, *LGJ* laparoscopic gastrojejunostomy

[a] Excluded surgical mortality

Table 4 Effective palliation: other physical indicators

Study	Outcome measured	Treatment group (*N*)	Outcome result
Choi [14]	Mean analgesic intake (NSAID)	OGJ (38)	540 ± 123.2 mg
		LGJ (30)	430 ± 58.2 mg
Samarasam [19]	Patients able to do normal activity after surgery	G (78)	83%
		BP or EL (21)	29%
	Patients experiencing vomiting post-op	G (78)	6%
		BP or EL (21)	52%
	Patients experiencing hematemesis post-op	G (78)	0%
		BP or EL (21)	14%
	Patients experiencing melena	G (78)	6%
		BP or EL (21)	52%

NSAID nonsteroidal anti-inflammatory drug, *OGJ* open gastrojejunostomy, *LGJ* laparoscopic gastrojejunostomy, *BP* surgical bypass, *EL* exploratory laparotomy

Table 5 Effective palliation: other indicators

Study	Outcome measured	Treatment group (*N*)	Outcome result
Lo [15]	Readmitted to hospital[a]	BP (51)	63%
Ouchi [18]	Hospital-free survival (>3 months)	G (64)	82.80%
		BP (15)	33.30%
		EL (16)	56.20%
Miyagaki [17]	Hospital index[b]	G (52)	0.311
	Ingestion index[c]	G (52)	0.871
Wang [12]	Median duration of palliation	TG (107)	4.9 months
		DG (150)	8.9 months
		BP (64)	3.6 months

N number of patients, *BP* surgical bypass, *G* gastrectomy, *EL* exploratory laparotomy

[a] Non-terminal admissions

[b] Hospital index: duration of hospital stay relative to overall survival

[c] Ingestion index: duration of period in which oral intake maintained relative to overall survival

occasional vomiting, loss of appetite, weakness, and bronchopneumonia [15]. Stupart et al. [20] noted that 13 patients required re-admission for bleeding after discharge from hospital. Hospital-free survival was lowest for surgical bypass patients and highest for gastrectomy patients [18]. Duration of palliation was measured by Wang et al. [12] and defined as the period of time post-procedure in which symptoms were relieved and during which parenteral fluid or nutritional therapy was not required.

Discussion

A wide range of useful, effective palliation outcomes was reported in the 9 studies included in this review, although none formally reported QOL. Time to oral intake was a commonly used indicator; results varied depending on the surgical procedure performed. Length of hospital stay was reported by 5 studies, with gastrojejunostomy associated with shorter hospital stays than gastrectomy, and laparoscopic gastrojejunostomy was associated with a shorter

stay than an open procedure. These reports of intervention effectiveness are important in terms of targeting symptom-specific relief and ensuring high success rates for relieving symptoms without incurring long hospitalization stays. Data on the palliative effectiveness of gastrojejunostomy procedures is important, given that a common complication of advanced gastric malignancy is gastric outlet obstruction (GOO) caused by either growth of the tumor or progression of metastatic disease. A recent prospective study involving patients with different primary cancers concluded that both stent placement and surgical bypass had a similar ability to relieve the symptoms of GOO; however, the predominant diagnosis in both treatment arms was pancreatic cancer [21]. Treatment of this particular complication in the advanced gastric cancer population needs to be addressed with further prospective studies.

Addressing QOL endpoints in the non-curative, advanced gastric cancer patient population is difficult due to the lack of prospective research using validated QOL measurement tools. QOL has been defined as being patient-centered, measuring functionality with respect to daily living as well as patient satisfaction with those achievements and the overall subjective sense of well-being [22]. All of the studies summarized in this review retrospectively assessed various outcomes which attempted to objectively measure QOL and instead measured effective palliation of symptoms. The concept of objectively measuring QOL from the perspective of the physician using surrogate endpoints has been shown to underestimate both the occurrence of symptoms and the severity of those symptoms [22]. Furthermore, bias by indication is likely, due to the fact that many determinants such as the overall health of the patient, severity of disease burden, and severity of symptoms, factor into the management decision-making process and may be related to the outcomes achieved. In retrospective data, those factors and the decision-making process are not measurable or evaluable. Although these studies add to the understanding of the effectiveness of surgical treatment strategies for their ability to control symptoms, prospective comparisons of these interventions investigating QOL in the advanced gastric cancer population are critical.

Measurement tools

None of the QOL evaluations performed in the set of patients summarized by this review centered on the use of standard, validated measurement tools. Although these approaches are still an important contribution given the paucity of the literature, in the future valid measurements using tools that exist to measure QOL are necessary. Valid and reliable methods of assessing QOL specific to the gastric cancer population have progressed slowly. In the past 10 years, tools developed include the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire STO22 (EORTC QOL-SO22) (stomach cancer-specific instrument for clinical trials published in 2001) and the Functional Assessment of Cancer Therapy-Gastric Quality of Life Instrument (FAC-gc) (validated in 2010) [23, 24]. The Dysfunction after Upper Gastrointestinal Surgery for Cancer (DAUG S32), developed to assess QOL after cancer-related surgery, has also been validated and applies to the gastric cancer population [25]. A few of the studies included in this review were conducted prior to the development of validated tools in this field.

Trials evaluating the effectiveness of chemotherapeutic agents in advanced gastric cancer patients now incorporate QOL outcome measures [26]. Similarly, new trials aimed at evaluating adjuvant therapies, chemotherapy, or chemoradiation for gastric cancer have also included QOL outcomes in their assessments [27]. Studies of curative gastric cancer interventions include QOL outcome measures as well, such as the Spitzer QOL index, the Korean translations of the EORTC QLQ-C30 and QLQ-STO22, and the DAUGS32 scoring system [28–32]. Prospective surgical studies addressing reconstructive technique, extent of surgery, and operative technique have also evaluated QOL as an important endpoint when comparing the effectiveness of competing surgical therapy options [28–32]. A recent review of validated QOL tools in surgical trials for gastric cancer concluded that overall, few trials exist and the quality of their reporting is low [33]. A gap in the gastric cancer literature is evident–with a lack of QOL data pertaining to the surgical management of both curative and advanced gastric cancer patients. This gap is especially important for the non-curative population, for whom benefits and harms are poorly captured by traditional measures of mortality, morbidity, and survival.

Trials aiming to prospectively address management options for the advanced gastric cancer population should use one of these validated tools, as they provide reliable, patient-centered results and allow for easy comparison between studies. Currently, two randomized controlled trials are actively comparing gastrectomy with metastectomy plus systemic therapy versus systemic therapy alone in non-curative gastric cancer [34, 35]. The GYMSSA (GastrectomY and Metastectomy plus Systemic therapy vs. Systemic therapy Alone) and REGATTA (REductive Gastrectomy for Advanced Tumor in Two Asian countries) trials are examples of clinical scenarios warranting investigation in the non-curative gastric cancer population [34, 35]. Quality of life endpoints are included in the trial protocol for GYMSSA and will be measured using validated QOL tools (FACT-Ga, EORTC QLQ-STO22, SROTC QLQ-C30) [34]. Unfortunately, the primary and

secondary objectives for the REGATTA trial are survival, progression-free survival, and adverse events, and the collection of QOL endpoints is not mentioned in the protocol [35]. The comparison of surgery versus stent placement for the relief of malignant GOO in patients with non-curative gastric cancer could be another clinical scenario for comparison. Jeurnink et al. [36] attempted a randomized controlled trial for surgery versus stent in patients with malignant GOO, and QOL was measured using the European Organization for Research and Treatment of Cancer QLQ-C30, the EuroQol-5D, the EuroQol-visual analogue scale (VAS), and the European Organization for Research and Treatment of Cancer QLQ-PAN26; however, <10% of patients had gastric cancer. Possible barriers to the uptake of validated tools in randomized trials, such as lack of knowledge of their existence or lack of emphasis on the importance of QOL outcomes in patients with advanced disease also need to be investigated and addressed.

Conclusion

In many cases, gastric cancer presents at a late stage, when cure is not possible and optimal palliation must be tailored to the individual patient. Few prospective studies examine the impact of palliative operations on QOL as perceived by the patient and measured using validated tools. Randomized controlled trials or prospectively designed studies using validated tools are needed to evaluate palliative management strategies and determine the best treatment algorithm for this population.

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