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ORIGINAL ARTICLE

Follow-up after surgery for gastric cancer: how to do it

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Abstract
There is no consensus on follow-up after gastric surgery for cancer, nor evidence that it improves outcomes. We investigated the impact of intensity of follow-up, comparing the regimens adopted by two centres, in Italy and in the UK. Patients who underwent surgery for gastric and junctional type-3 adenocarcinoma, between September 2009 and April 2013, at the Surgical Clinic, University of Brescia (Italy), and at the Department of Upper Gastrointestinal Surgery, University College London Hospital (UK), were identified. Patients' demographics, stage, recurrence rates, modality of detection and treatment were recorded. Overall survival and costs were compared between the two protocols. A total of 128 patients were included. Recurrence rates were similar ($p=0.349$), with more than 70% diagnosed during regular follow-up appointments in both centres. At univariate and multivariate analysis, stage I and treatment of recurrence were associated with a better survival. Patients treated for recurrence at the Italian centre showed an almost significant better survival ($p=0.052$). The intensive Italian surveillance protocol was associated with significant higher costs per year. Follow-up and early detection of recurrence did not affect survival in the analysed series, focused on periods in which chemotherapy was ineffective towards recurrence. However, intensive follow-up allowed a greater number of patients to receive a treatment for recurrence; this might prove useful in the next few years, when more effective chemotherapy combinations are expected to become available. The costs could be reduced by adopting a less intensive surveillance programme.

Keywords Follow-up · Gastric cancer · Gastric surgery · Surveillance

Introduction

Gastric cancer is the fourth most common cancer in the world, with the highest incidence rates in Japan and Eastern Asia. Despite a steady decline of the incidence over the last decades, the prognosis remains poor, with 5-years survival rates of 21.9% in Europe [1]. Recurrence usually occurs within 2 years of surgery [2–11].

Routine follow-up is practised worldwide, but its value after gastric cancer resection has not been established yet. At present, there are no randomised clinical trials (RCT) supporting follow-up. Several authors have investigated the survival benefit of early recurrence detection by intensive

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post-operative surveillance. Although some found that follow-up was successful in identifying asymptomatic recurrences, no improvement in overall survival (OS) was achieved [5, 10–16].

No standardised follow-up protocols are available [17–22]. Studies assessing the cost-effectiveness of follow-up in colorectal and breast cancers have been published [23, 24], but not on upper gastrointestinal (GI) malignancies. It is difficult to support intensive surveillance programmes, in which investigations are performed in asymptomatic patients with the aim of detecting early recurrence, at high cost to health services with low potential clinical benefit. On the other hand, investigating symptomatic patients provides treatment for benign complications or palliative therapy for recurrent disease [25].

We investigated the clinical and financial impact of follow-up after gastric cancer surgery, comparing an intensive surveillance program, adopted by an Italian centre, and a minimalist follow-up regimen, performed in a UK centre.

Methods

Patients and inclusion criteria

Patients who underwent surgery between September 2009 and April 2013, at the Surgical Clinic, University of Brescia Hospital (Italy, UBH), and at the Department of Upper GI Surgery, University College London Hospital (UK, UCLH) were identified.

Included were patients with histologically confirmed adenocarcinoma of the stomach and Siewert type-3 gastrooesophageal junction (GOJ). Patients with high-grade dysplasia and other histopathology, as well as those patients who underwent palliative treatment or abandoned surgery (due to intra-operative findings of metastatic or nonresectable disease), were excluded.

The demographic and clinical–pathologic variables recorded are shown in Table 1. Information regarding recurrence (pattern, timing and treatment) was also retrieved.

A minimal follow-up of 2 years was performed (data collection concluded on 30 April 2015).

Follow-up regimen

The intensive surveillance programme adopted by UBH (regimen A) included, besides the clinical examination, regular blood tests and imaging, according to type of cancer, risk of recurrence and post-operative year (Table 2), as suggested by the Italian Research Group for Gastric Cancer (IRGCC) [26].

Surveillance at UCLH (regimen B) was mainly based on clinical examination. Patients were initially seen 3 weeks

Table 1 Demographic and clinico-pathological characteristics of the two populations

	UBH—cohort A (75 patients)		UCLH—cohort B (53 patients)		*p*
	n	%	*n*	%	
Age (years)	68		67		0.10
Gender					
Male	49	65	29	55	0.22
Female	26	35	24	45	
Histotype					
Intestinal	39	52	25	47	0.55
Diffuse	26	35	23	44	
Mixed	10	13	5	9	
Lympho-vascular invasion					
Present	61	81	30	57	**0.002**
Absent	14	19	23	43	
Stage					
I	14	18	17	32	**0.01**
II	24	32	20	38	
III	35	47	11	21	
IV	2	3	5	9	
Type of surgery					
Sub-total gastrectomy	37	50	30	57	0.11
Total gastrectomy	25	33	22	41	
Extended total gastrectomy	9	12	0	-	
Completion of gastrectomy	4	5	1	2	
Lymphadenectomy					
D1	4	5	9	17	**0.03**
D2	71	95	44	83	
Radicality					
R0	64	85	45	85	0.09
R1	4	15	8	15	
Perioperative treatment					
Neo-adjuvant	11	15	34	64	**< 0.00001**
Adjuvant	25	33	32	60	**0.002**
Recurrence (rate)	32	43	17	32	0.349
Pattern of recurrence					
Loco-regional	8	25	4	24	0.62
Distant	6	19	6	35	
Combined	5	15	2	12	
Peritoneal	13	41	5	29	
Modality of detection					
During follow-up appointment	25	78	12	71	0.55
GP referral or patient auto-presentation outside regular follow-up	7	22	5	29	
Clinical presentation					
Symptomatic	10	31	11	65	**0.02**
Asymptomatic	22	69	6	35	
Type of treatment					
Curative intent	3	9	1	6	0.57
Symptomatic/palliative intent	12	37	9	53	
No treatment	17	53	7	41	

Bold values are the statistically significant values which resulted in differences between the 2 cohorts

Table 1 (continued)

UBH University Brescia Hospital, *UCLH* University College London Hospital

after surgery, then every 3 months during the first year, every six in the second year and yearly thereafter. A computed tomography (CT) was usually performed within 2 years of surgery.

In both centres, the length of follow-up was between 5 and 10 years.

Statistical analysis

All statistical analyses were performed by Statistical Package for the Social Sciences (SPSS) version 23 software. *P* values < 0.05 were considered to be statistically significant. Post-operative in-hospital deaths and unrelated mortality were not included in the survival analysis.

Descriptive analysis was performed with contingency table and the two cohorts were compared in terms of clinical characteristics by Chi squared test.

The survival curves were generated by Kaplan–Meier and were compared using the log-rank test. Overall survival was defined as the time from surgery until death for any causes or last follow-up. Disease-free survival (DFS) was defined as the time from surgery to recurrence, the latter considered as radiological or histopathological documentation of relapse.

Univariate analysis was performed with Kaplan–Meier and log-rank test; demographics (age, gender, centre) and disease-specific variables (histotype, lymphovascular invasion, stage, type of surgery, lymphoadenectomy, R status and peri-operative treatments) were tested in all patients. Recurrence-specific variables (pattern, symptoms, modality of detection and treatment) were considered only for patients with documented relapse.

Variables demonstrated to be significant at univariate analysis were tested at multivariate analysis, using the Cox proportional hazard model.

Financial analysis

We compared the estimated cost for a single-patient follow-up, according to the two regimens. In addition to the surgical outpatient appointment (OPA), we considered costs of the investigations included in the follow-up protocols: blood tests (included tumour markers, TM), chest X-ray (CXR), abdominal ultrasound (US), computed tomography (CT), 18F-fluoro-deoxy-D-glucose positron emission tomography (PET) and upper GI endoscopy (OGD). Tariffs were calculated in euros (cost for each investigation shown in Table 3).

Investigations performed outside the standard surveillance programme were not included.

Table 3 Cost of the principal components of surveillance

Investigations	Italian tariff (€)[a]	UK tariff (€)[b]
Surgical OPA follow-up	17.90	110
CXR	15.49	42.65
Abdominal US	71.79	59.10
CT chest + abdomen, with contrast	312.47	145.85
PET	1081.86	564.10
MRI abdomen	252.14	250.40
ODG + biopsies	77.59	507.70

Blood tests included full blood count, iron, vitamin B12, liver and kidney function tests, C-reactive protein and tumour markers (CEA, carcinoembryonic antigen; CA 19.9, cancer antigen 19.9)

CXR chest X-ray, *US* ultrasound, *CT* computed tomography, *PET* positron emission tomography, *MRI* magnetic resonance image, *OGD* oesophagogastroduodenoscopy

[a]Tariff for the Lombardy Region Ambulatory Services of 2013 revised in 2015

[b]http://www.england.nhs.uk/resources/pay-syst/tariff-guide/

Table 2 Follow-up schedule according to regimen A (University Brescia Hospital)

Months	3	6	9	12	15	18	21	24	27	30	33	36	42	48	54	60
Clinical examination	b, c, d	a, b, c, d	b, c, d	a, b, c, d	b, c	a, b, c, d	b, c	a, b, c, d	c	a, b, c, d	c	a, b, c, d	a, b, c	a, b, c, d	a, b, c	a, b, c, d
Blood tests	b, c, d	a, b, c, d	b, c, d	a, b, c, d	b, c	a, b, c, d	b, c	a, b, c, d	c	a, b, c, d	c	a, b, c, d	a, b, c	a, b, c, d	a, b, c	a, b, c, d
US		a, b	d	a		a, b, d		a		a, b, d		a	a, b, c	a	a, b, c	a, b
CXR	d		d	a		d		a		d		a				
CT		c, d		b, c, d		c		b, c, d		c		b, c, d		b, c, d		c, d
OGD			d	a, b, c		d		a, b, c		d		a, b, c		d		a, b, c, d

US ultrasound, *CXR* chest X-ray, *CT* computed tomography, *OGD* oesophagogastroduodenoscopy, *GOJ* gastrooesophageal junction

[a]Low-risk gastric cancer

[b]Moderate-risk gastric cancer

[c]High-risk gastric cancer

[d]Oesophageal and GOJ cancer

Results

A total of 144 patients were identified. Of these, 128 met the inclusion criteria: 75 from UBH (cohort/regimen A) and 53 from UCLH (cohort/regimen B).

The demographic and clinico-pathological characteristics are summarised in Table 1.

The mean age was similar in the two populations (67 vs 68 years, $p = 0.10$). The commonest histotype, intestinal adenocarcinoma. lymphovascular invasion (LVI), was present in more than 80% of patients in group A ($p = 0.002$), relating also to an higher rate of patients presenting with advanced disease within this group (50%, $p = 0.01$). A complete resection (R0) was achieved in 85% of patients, in both centres. No significative differences were found in the surgical approach, the most common performed procedure being a sub-total gastrectomy. A D2 lymphoadenectomy was performed among the majority of patients in both cohorts. Perioperative treatment was mainly received by patients in group B ($p < 0.00001$ and 0.002, respectively, for neoadjuvant and adjuvant therapy). Recurrence rates were similar between the two centres ($p = 0.349$), most of which were diagnosed within 2 years of surgery. The pattern of recurrence was similar, with the peritoneal type highly represented among UBH patients (41%). More than 70% of relapses were diagnosed during regular follow-up appointments in both regimens. Symptoms suggesting recurrence were more common among patients belonging to group B ($p = 0.02$).

53 and 41% of patients, respectively, at UBH and UCLH, did not receive any treatment for recurrence. When given, treatment was mainly palliative in both centres. A curative surgical approach was performed only in four cases: three patients belonging to cohort A and one to cohort B.

From the survival analysis, post-operative in-hospital deaths and unrelated mortality (9 patients from regimen A, 7 from regimen B) and patients with Stage IV disease were excluded.

At univariate analysis, the variables associated with a better OS were: absence of LVI ($p = 0.011$), stage I ($p < 0.001$) and treatment of recurrence ($p < 0.001$).

At multivariate analysis, the variables confirmed as independent prognostic factors for better OS were: stage I ($p < 0.044$, HR 6.0, 95% CI 0.6–55.8) and treatment of recurrence ($p = 0.004$, HR 0.3, 95% CI 0.1–0.6).

No significant differences were found in stage-specific OS and DFS between the two centres (results not shown). As revealed by the multivariate analysis, treatment of recurrence was associated with better OS in both centres. This was particularly evident within cohort A patients (Fig. 1), in which the difference between treated and nontreated recurrences was statistically significative (OS of 39.6 vs 14.09 months, respectively; $p = 0.002$).

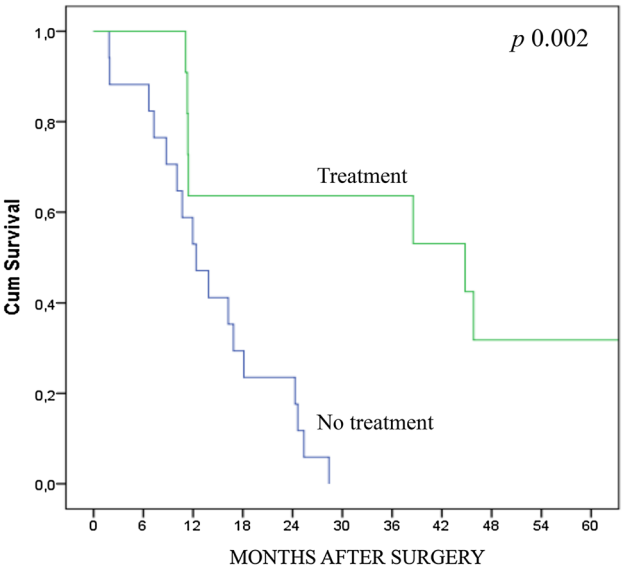

Fig. 1 Survival curves of patients with GC at University Brescia Hospital: comparison between treated and nontreated recurrences. Mean OS 39.5 vs 14 months, in treated and nontreated recurrences, respectively; $p = 0.002$

When compared, patients who received treatment for recurrence at UBH showed an almost significant better OS compared to those in UCLH (Fig. 2).

According to the surveillance protocol adopted by UBH, the cost of a single patient's follow-up varies from a minimum of €309.80 to a maximum of €1140.80 per year, depending on the risk of recurrence and time after surgery.

If a type B regimen would be used, the annual cost would be €94.10, €348.30 and €22.50, respectively, for the first, second and third year following surgery.

Discussion

Recurrence is a common problem after gastric cancer resection. Rates vary between 27 and 53% and over 80% occur within the first 2 years of surgery [2–4, 6, 9, 10, 15, 28].

Treatment options for recurrence are limited and rarely curative. For the majority of patients, systemic palliative chemotherapy (with or without radiotherapy) is the mainstay, ensuring the best quality of life and symptom control. Palliative surgery is used only if appropriate.

The primary aim of surveillance is to detect recurrence or metachronous primary cancers at an early and asymptomatic stage, when further curative treatments might still be possible, with a view to improving survival [4, 10, 27]. Equally important is the evaluation of patients' general condition, to detect and treat any benign complications or nutritional disorders.

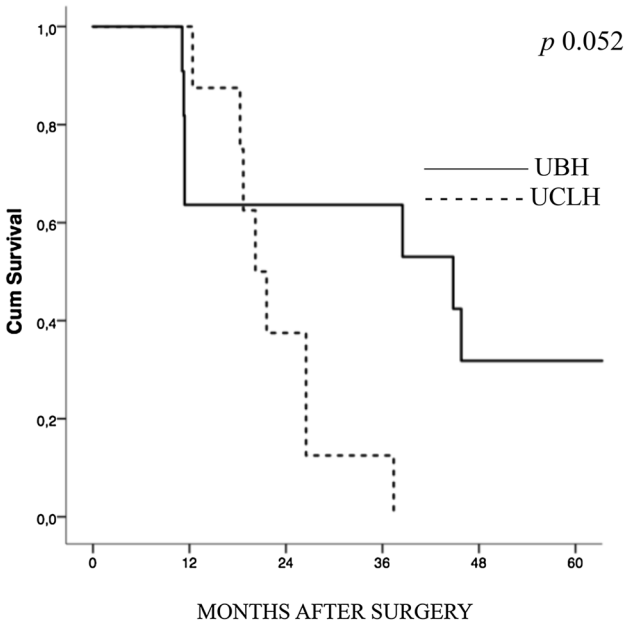

Fig. 2 Survival curves of patients with treated GC recurrence: comparison between the two centres. Mean OS 22.7 vs 9.6 months, in cohort A and B, respectively; $p = 0.052$. BS, University Brescia Hospital (cohort A); UK, University College London Hospital (cohort B)

Although the debate on the effectiveness, necessity and appropriateness of follow-up is common to many malignancies, it is particularly hot in the case of gastric cancer, due to a clear discrepancy between what emerges from the literature ("follow-up is needless") and the clinical policy of high volume centres with good quality standards ("follow-up should be done").

There are no RCTs supporting the effectiveness of follow-up for gastric cancer and no studies demonstrating a survival advantage of early recurrence detection through intensive follow-up.

All the available guidelines admit that routine follow-up does not affect survival outcomes, but should be used for treating symptoms derived from benign complications of surgical treatment, assessing nutritional status, providing psycho-social support and collecting data for research purposes [29].

In 2012, a Web roundtable entitled "Follow up. Diagnosis and management of late complications" was proposed and chaired by the Italian Research Group for Gastric Cancer (IRGGC). This roundtable registered a very high interest, with over 300 talks from all over the world, highlighting not only a discrepancy in the intensity of care provided by different health-care systems, but also a cultural dichotomy on the "patient–physician relationship" (western surgeons compared to "engineers whose patients ask them to repair their car" vs eastern surgeons, seen as "gurus who are asked to heal a person").

The debate within the roundtable caught the attention of the Scientific Committee of the 10th IGCC (held in Verona in 2013), which decided to dedicate part of the conference to this topic by holding a Consensus Conference entitled "Rational and limits of oncological follow-up after gastrectomy for cancer". In preparation for that, a "restricted" working group (established in December 2012) performed a literature review and formulated seven unsolved issues, sharing a few statements for each of them. Their work was then proposed to a list of international experts (including surgeons, oncologists, gastroenterologists, statisticians and methodologists), to involve them in an "enlarged" working group. Of these experts, 48 agreed to participate, with a wide geographical distribution (including highly developed, "emerging" and low-economy countries), thus representing different health cultures worldwide. After 6 months of mainly Web-based discussion, six final points were produced and presented during the Consensus Conference on June 17 in Verona. A final statement for each issue was approved by vote and published as the core of the "Charter Scaligero" [30]. The first statement in particular declares that "there is no evidence that routine follow-up after curative treatment for gastric cancer (R0 resection, with or without adjuvant therapy) is associated with improved long term survival. However, routine follow-up should be offered to all patients for the following reasons: oncological (detection and management of cancer recurrence), gastroenterologic (endoscopic surveillance and management of postgastrectomy symptoms), research (collection of data on treatment toxicity, time to and site of recurrence, survival, and cost-benefit analyses), and pastoral (psychological and emotional support). Followup should include lifetime monitoring of the nutritional sequelae of gastrectomy, including, but not limited to, adequate vitamin B12, iron, and calcium replacement".

Our aim was to investigate the usefulness of an intensive surveillance programme, comparing outcomes and financial costs between the regimen adopted by an Italian centre, based on an intensive schedule tailored to patients' own risk of recurrence (according to the IRGGC guidelines), and a UK centre, performing mainly clinical examinations (symptoms and signs determining intensity of follow-up).

The two cohorts showed similar anthropomorphic characteristics, with comparable average age and male/female ratio.

As expected, Stage I was associated with better OS, at both uni- and multivariate analysis.

Scheduled follow-up detected more than 70% of recurrences in both regimens, notwithstanding their differences. However, no survival benefit was found, as stage-specific OS and DFS were similar between the two cohorts.

Treatment of recurrence was related to a better OS, at both uni- and multivariate analysis. Poor clinical condition, extensive metastatic disease and tumour burden could

be partially related to the worse OS in patient who did not receive treatment for recurrence. Vice versa, a better OS in those who received treatment might be associated with localised recurrence and/or better clinical condition. This was particularly evident within the Italian cohort, in which three patients received surgical treatment, with a potential curative intent.

Patient with recurrence treated at UBH indeed had a better OS compared to those at UCLH, despite that it did not reach statistical significance ($p = 0.052$). One of the reasons for this could be that four patients (12.5%) were still alive at the time the study was terminated (two of which underwent surgical resection).

It is evident that the cost of an intensive surveillance programme (like regimen A) is significantly higher compared to that of a minimal protocol (as per regimen B), especially in the long term. This is mainly because investigations are regularly performed in all patients and not only when clinically indicated.

The potential savings for a single-patient follow-up in adopting protocol B (instead of A) vary between a minimum of €53 to a maximum of €1.046 per year.

Conclusions

Despite its limitations (retrospective design, relatively small number of patients, lack of information regarding type of peri-operative treatment), the results of the present study support the IGCA expert consensus, by demonstrating that an intensive follow-up schedule allows a greater number of patients to receive treatment for recurrence.

Although it did not reach statistical significance, the different OS between the groups of patients who received treatment for recurrence in the two centres (Fig. 2) confirmed that a therapeutic attempt (especially if with potentially curative intent) should always be considered. In the next few years, it is reasonable to believe that the availability of more effective chemotherapy agents would translate this advantage also into a survival benefit.

To reduce the costs of the follow-up without impacting the quality of life and care provided, it is worth considering a less intensive schedule with a limited number of regular investigations. We suggest a follow-up, based mainly on clinical examination and focused on patient's symptoms, to be performed every 3 months during the first year and every 6 months on the second post-operative year, associated with blood tests and a CT scan at 12 and 24 months. Further investigations outside this schedule should be tailored on each patient and justified by clinical suspicion of recurrent disease. Limiting hospital attention to the first 2 years after surgery and relying on the long term follow-up with general practitioners and community physicians are also advised.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Research involving human participants and/or animals This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent For this type of study formal consent is not required.

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