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ORIGINAL ARTICLE

Clinical outcomes of gastrointestinal stromal tumor in southern Thailand

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Abstract

AIM: To review a single institutional experience in clinical management of gastrointestinal stromal tumors (GIST) and analyze for factors determining treatment outcome.

METHODS: Clinicopathological data of patients with a diagnosis of GIST who were treated at our institute during November 2004 to September 2009 were retrospectively reviewed.

RESULTS: Ninety-nine cases were included in the analysis. Primary tumor sites were at the stomach in and small bowel in 44% and 33%, respectively. Thirty-one cases already had metastasis at presentation and the most common metastatic site was the liver. Sixty-four cases (65%) were in the high-risk category. Surgical treatment was performed in 77 cases (78%), 3 of whom received upfront targeted therapy. Complete resection was achieved in 56 cases (73% of operative cases) and of whom 27 developed local recurrence or distant metastasis at a median duration of 2 years. Imatinib was given as a primary therapy in unresectable cases (25 cases) and as an adjuvant in cases with residual tumor (21 cases). Targeted therapy gave partial response in 7 cases (15%), stable disease in 27 cases (57%) and progressive disease in 13 cases (28%). Four-year overall survival was 74% (95% CI: 61%-83%). Univariate survival analysis found that low-risk tumor, gastric site, complete resection and response to imatinib were associated with better survival.

CONCLUSION: The overall outcomes of GIST can be predicted by risk-categorization. Surgery alone may not be a curative treatment for GIST. Response to targeted therapy is a crucial survival determinant in these patients.

Key words: Gastrointestinal stromal tumor; Targeted therapy; Overall survival; Progress free survival; Progressive disease

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INTRODUCTION

Gastrointestinal stromal tumors (GISTs) are relatively uncommon mesenchymal neoplasms arising primarily in the wall of the stomach, small intestine, and colon, and other sites within the abdomen[1]. Although GIST comprises only 0.2% of all gastrointestinal tumors, it is the most common mesenchymal tumor, accounting for 80% of gastrointestinal tract sarcomas. Recent studies have found incidence rates of GISTs of 10-20, 7-15, and 14 cases/million per year in the United States[2], Europe[3], and Taiwan[4], respectively. The primary tumor is most commonly located in the stomach (50%-65%) or small intestine (25%-30%), however it has also been reported in the colon, esophagus and a number of extra-gastrointestinal sites[5-7].

Surgery is the mainstay treatment with a curative aim for localized GISTs without metastasis. Previous studies have found five-year disease free survival in primary GISTs in whom complete surgical resection could be achieved to be 65%[8,9], although another study found recurrent disease in a number of cases after complete surgical resection at a median time of 20 mo[9]. In primarily unresectable or metastatic disease, the current first line treatment is a tyrosine kinase inhibitor, imatinib mesylate. Such molecular targeted therapy gives a varying response rate depending on the tumor location, histological risk stratification and mutation status of the receptor tyrosine kinase *KIT*. In general, symptomatic GIST cases who were in the high risk group have shown poorer disease free survival rates even when complete surgical resection could be achieved[9-12]. Other than histopathological criteria, risk determinants for disease specific survival include non-gastric primary location, macroscopic residual tumor and tumor rupture. In unresectable cases, various studies have found that factors determining response were primarily biological characteristics, including a high mitotic index and *KIT* mutation status[13,14].

This study aimed to review the clinical presentations, pathological characteristics and treatment outcomes of GIST cases in a university hospital setting in Southern Thailand, analyzed for factors effecting treatment outcomes.

MATERIALS AND METHODS

The study was approved by the Institutional Ethic Committee of the Faculty of Medicine, Prince of Songkla University. A list of patients with the pathological diagnosis of GIST during November 2004 to September 2009 was obtained from the Department of Pathology and the Tumor Registry Unit of our institution, Songklanagarind Hospital. Details on sociodemographic and clinical data, pathological and laboratory findings, and treatment were retrieved from the hospital information system. A diagnosis of GIST was based on a histopathological appearance that was compatible with GIST (spindle or epithelioid cell type) and was confirmed by positive immunohistochemical staining for CD117. Patients who were referred to our institute after a diagnosis was made were included only if the pathological slides were available for review. Patients without adequate follow-up were excluded from this review.

The morphological characteristics of the tumors were evaluated according to the risk stratification criteria of the National Institutes of Health (NIH) consensus (Fletcher's criteria 2002)[10], which classifies GISTs into very low, low, intermediate, and high risk categories. Our treatment usually began with surgical removal of the tumor if possible. In cases with unresectable tumor or distant metastasis, treatment began with a daily dose of 400 milligrams of imatinib, a tyrosine kinase inhibitor. Response to the treatment was evaluated and assessed by a radiologist, beginning at 12 mo after treatment initiation, based on the Response Evaluation Criteria In Solid Tumors (RECIST) method[15]. Long-term treatment outcomes included overall survival (OS) and progress free survival (PFS) with recurrence, progressive disease and death set as sensors for the PFS analysis.

The mutation status of the tumors was analyzed in cases in which a specimen was available. For analysis, tumor DNA was extracted from formalin-fixed paraffin embedded tissue using a DNeasy Blood and Tissue Kit (Qiagen). The mutation study covered exons 9 and 11 of *KIT*. The studies used polymerase chain reaction and direct nucleotide sequencing method.

Descriptive statistics were used to describe the baseline characteristics and clinical information of each patient. Univariate survival analysis used the Log-rank test and a stepwise Cox proportional hazard analysis was used for multivariate survival analysis. The statistical significance of each variable was tested by a log-likelihood ratio of successive models at a P value < 0.05. All analysis was done using the Stata version 6.0 program (Stata Corporation, TX).

RESULTS

From November 2004 to September 2009, 100 patients were diagnosed with GIST. One patient was excluded due to being lost to follow up before receiving any treatment, leaving 99 cases in the analysis. Patients who were referred after initial diagnosis accounted for 51% of the total. Gender distribution was 55 male: 44 female or 1.25:1. The median age at diagnosis was 58 years (range 10-82 years). The only case of pediatric GIST was a girl who presented at the age of 10 years. Almost all patients (87%) were symptomatic and about half (57%) presented with an abdominal mass. Twenty-six patients (26%) came with gastrointestinal bleeding, 2 had gut obstruction and 2 had intestinal perforation.

The most common primary tumor sites were the stomach (43 cases, 44%) and small bowel (33 cases, 33%). The other sites were the rectum (5 cases), omentum (2 cases), retroperitoneal (3 cases) and unknown primary (13 cases). Thirty-one cases already had metastasis at presentation and the most common metastatic site was the liver.

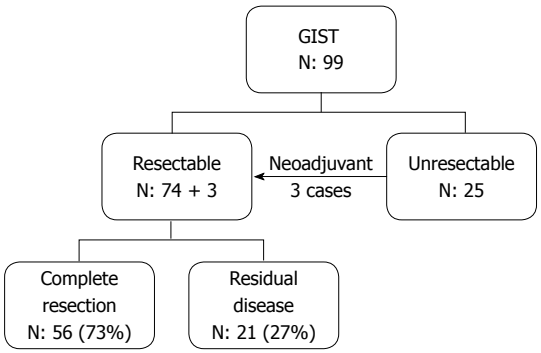

Figure 1 Categorization of 99 cases of gastrointestinal intestinal tumor according to their resectability. GIST: Gastrointestinal stromal tumor; N: Number.

When the NIH risk criteria was used to categorize the cases, 65% of the patients were in the high risk group, with 17%, 12% and 6% in the intermediate, low and very low risk groups, respectively. On histopathology, 98% of cases were positive for CD117 immunohistochemistry, positive staining for CD34 was 79%, smooth muscle actin 30%, S100 24% and desmin 9%. Mutations of *KIT* were studied in 35 cases whose specimens were available. The study detected *KIT* mutations in 19 cases; 17 in exon11 and 2 in exon9.

Surgical treatment

The seventy-seven cases who underwent surgical treatment included 74 cases who had primary surgery and 3 cases who received upfront tyrosine kinase inhibitor therapy prior to their operation (Figure 1). Fifty-six cases in this group (73% of operative cases) achieved complete resection. About half of these 56 (29 cases) were in the high risk group according to the NIH risk classification. Seven of the patients who had a complete resection later developed local recurrence, and 14 distant metastases. Twenty of these 21 cases were in the high risk category and the median time to recurrence was 23.3 mo. In the 25 unresectable cases, 16 cases (64%) originally presented with metastasis, all of which were categorized as high risk according to the NIH risk classification. In the 9 of these cases without metastasis, the main reason for unresectability was structure involvement.

We achieved complete resection in the majority of gastric GIST cases (70%), the complete resection rate was 46% in extra-gastric tumors (Table 1).

Response to tyrosine kinase inhibitors

Tyrosine kinase inhibitor therapy was given to our patients when they had an unresectable tumor, residual disease, or recurrence after primary surgical resection. According to the RECIST, of the 47 patients who received tyrosine kinase inhibitor therapy, 7 cases (15%) had partial response, 27 cases (57%) had stable disease, and 13 cases (28%) had progressive disease. Of the 3 cases in which surgical exploration was performed after targeted therapy and the radiologic diagnosis scored stable disease or partial response, one achieved a complete pathological response (Figure 2). Adverse reactions were recorded in 18 cases (38%). The three most common adverse reactions were edema (6 cases, 13%), anemia (5 cases, 11%) and skin rash (3 cases, 6%)

Table 1 Resectability of gastrointestinal stromal tumor according to primary tumor sites *n* (%)

Primary sites	No. of cases	Complete resection	Residual disease	Unresectable
Stomach	43	30 (70)	9 (20)	4 (9)
Small bowel	33	20 (61)	6 (18)	7 (21)
Rectum	5	2 (40)	1 (20)	2 (40)
Extra-gastrointestinal	18	4 (22)	5 (28)	9 (50)

When the primary tumor site was considered, 4 cases (31%) of gastric GIST achieved a partial response, which was significantly higher than in the other sites ($P = 0.047$) (Table 2).

Survival analysis

Until the preparation of this manuscript in September 2011, the mean follow-up period was 49 mo. The four-year overall OS and PFS rates (Figure 3) were 74 % (95% CI: 61%-83%) and 72 % (95% CI: 59%-82%), respectively.

On univariate analysis, presence of liver metastasis, presence of residual disease or unresectability, high risk disease, non-gastric primary site, presence of liver metastasis and unresponsiveness to targeted therapy were factors that were significantly associated with poorer OS (Table 3). High risk disease, unresponsiveness to targeted therapy and gastric GIST had significantly poorer PFS. High risk categorization reduced 4-year PFS from 95% in other risk groups to 61 ($P < 0.01$). Gastric GIST had a 4-year PFS of 89%, compared to 63% in other primary sites ($P = 0.04$). On multivariate analysis, the NIH risk category was the only factor that most fit the Cox regression model at the hazard ratio of 6.12 (95% CI 1.4-26.4)

Considering cases who were primarily resectable, the 4-year recurrent free survival (RFS) was 76.5%. 4-year RFS in cases with high NIH risk (94.1%) was also significantly better than those in other risk categories (62.9%) ($P < 0.01$) (Figure 3C).

DISCUSSION

It has only been since around the year 2000 that the term GIST began to appear in pathological reports in our institute. The diagnosis became more common in the following years, possibly due to increasing awareness of this diagnosis of both the pathologists and the clinicians. In general, the tumor is defined as a mesenchymal neoplasm arising in the gastrointestinal tract and expressing KIT (CD117)[16]. The mainstay treatment for a GIST is surgical removal. The five-year survival rate after complete surgical resection was reported at 48%-79%[17]. In situations where complete resection is not possible, tyro-

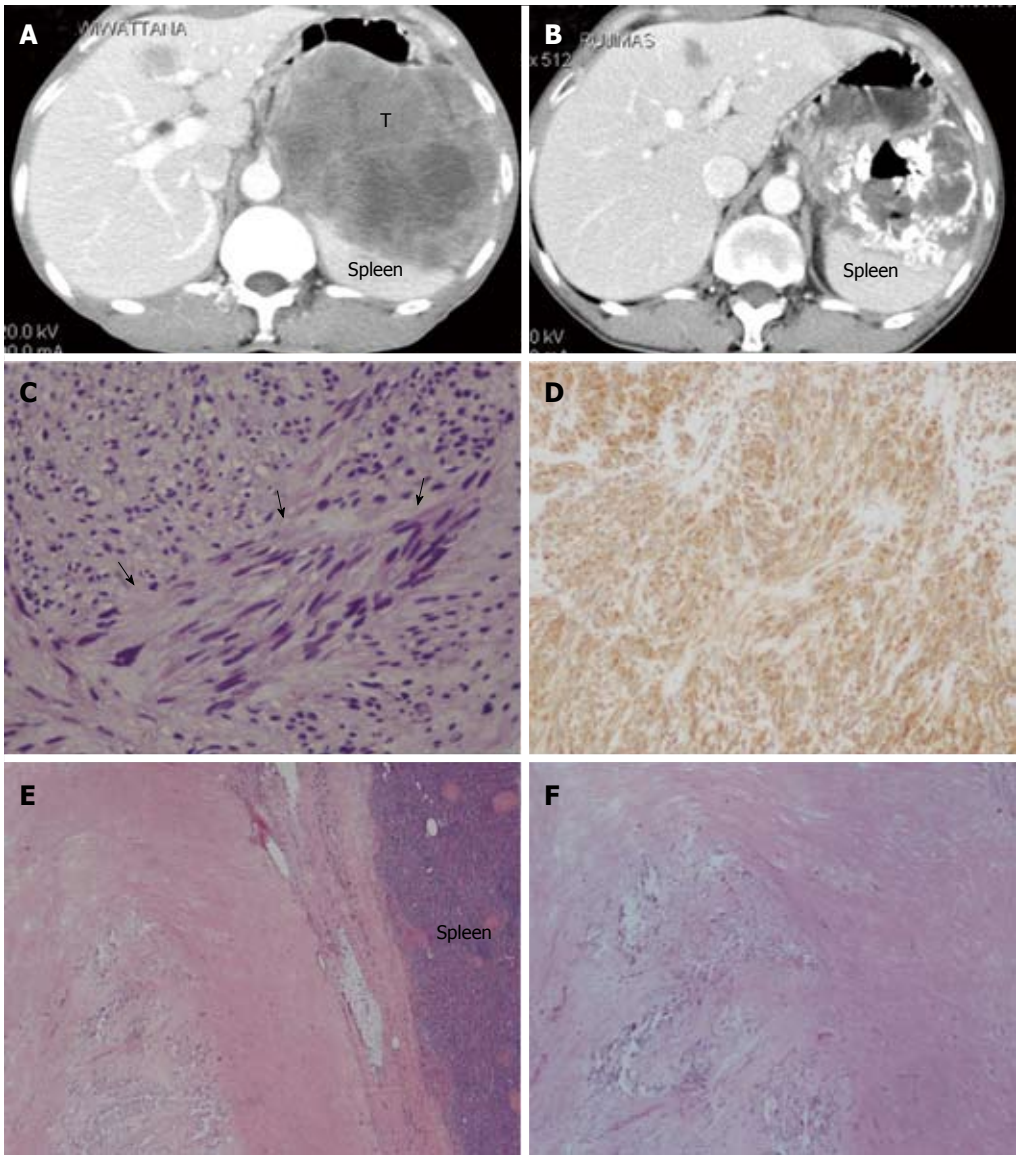

Figure 2 Abdominal computerized tomography and histopathological pictures of a 68-year-old male patient who presented with abdominal mass. A: Computerized tomography (CT) shows a large enhancing solid mass (T), measuring 11.2 cm × 11.9 cm × 10.7 cm, occupying the left upper quadrant between the stomach and the spleen. A liver nodule is also visible in segment Ⅳ; B: Forty months following the beginning of imatinib therapy, a follow-up CT showed partial tumor response; C, D: Image-guided tissue biopsy revealed a spindle cell tumor (arrows) that marked CD117. The mitotic cell count was 2 cells/50 high power fields; E, F: Following an en bloc resection including a total removal of the stomach together with the spleen and a wedge resection of hepatic metastasis, the pathological tissue showed only a stromal hyalinization and dystrophic calcification with a scanty number of differentiated spindle cells that marked S-100, but not CD117.

Table 2 Response to targeted therapy according to site of primary tumor *n* (%)

	PR[1]	SD	PD
All 47 cases	7 (15)	27 (57)[2]	13 (28)
Stomach (13 cases)	4 (31)	7 (54)	2 (15)
Small bowel (19 cases)	1 (5)	10 (53)	8 (42)
Rectum (2 cases)	-	2 (100)	-
Extra-gastrointestinal (13 cases)	2 (15)	8 (62)	3 (23)

[1]Response as evaluated by the response evaluation criteria in solid tumors method; [2]One case in this group had complete histopathological response. SD: Stable disease; PD: Progressive disease; PR: Partial response.

sine kinase targeted therapy is the current treatment of choice.

In our study, a majority of our patients were symptomatic cases that belonged to the high risk category. At presentation, 25% of the cases were considered unresectable, either due to anatomical difficulty or presence of distant metastasis. Surgery was performed in 78% and complete resection was achieved in 73% in cases who underwent surgical exploration. However, we found that 48% of the patients who achieved complete tumor removal developed local recurrence or distant metastasis at a median duration of 2 years. This figure was consistent with previous studies that also experienced a medium-term recurrence after the surgical treatment alone[18-20]. Our analysis showed that almost all these failure cases were in the original high risk category, according to the NIH criteria, which raises a question concerning the role

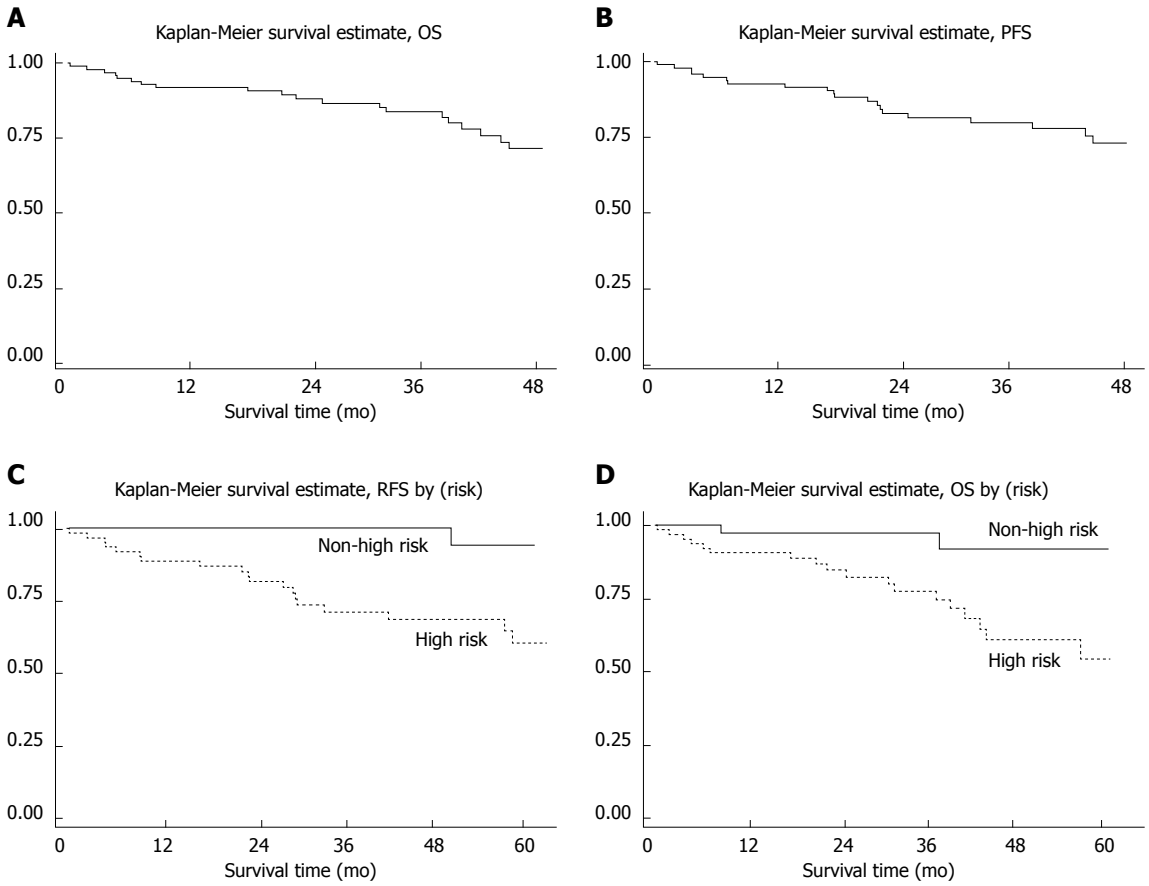

Figure 3 Kaplan-Meier survival probability curves. Kaplan-Meier survival probability curves showing overall survival (OS) (A) progress free survival (PFS) (B), significant difference in the recurrent free survival (RFS) after surgery in primary resectable cases, comparing between the cases in the high risk group according to the National Institute of Health risk categorization, and the cases in the other risk groups (C) and significant difference in the OS (D).

Table 3 Univariate survival analysis of factors associated with survival in 99 cases of gastrointestinal stromal tumors

	Four-year OS (%)	*P* value
OS (99 cases)	72.4	
Primary tumor site		0.02
Stomach	86.5	
Non-stomach	64.5	
Risk category[1]		< 0.01
Non-high risk (35 cases)	92	
High risk (64 cases)	60.9	
Liver metastasis at diagnosis		< 0.01
Absent (72 cases)	86.3	
Present (27 cases)	44.6	
Residual disease after surgery		0.04
Absent (56 cases)	84.1	
Present (21 cases)	61.5	
Response to targeted therapy		0.03
CR + PR (8 cases)	88.9	
SD + PD (40 cases)	64.2	

[1]Risk categorization according to the United States National Institute of Health consensus 2002. OS: Overall survival; SD: Stable disease; PD: Progressive disease; CR: Complete response; PR: Partial response.

of postoperative adjuvant treatment in the high risk patient. Two recent studies have suggested that adjuvant imatinib therapy may improve RFS after the resection of a primary gastrointestinal stromal tumor[21-23], although these studies had only a limited follow-up duration, thus the findings are still not confirmed.

The GIST is not a chemosensitive tumor. Nevertheless, small molecule targeting the specific tyrosine kinase is an effective adjuvant treatment and is a prototype of targeted therapy in human neoplasms. Imatinib mesylate is a compound known to be active against BCR-ABL, KIT receptors and platelet-derived growth factor receptor-α[23]. Imatinib clearly has a role in unresectable GISTs and also resectable GISTs with residual disease after surgery. A number of studies examining the efficacy of imatinib in advanced GISTs found that it gave 5% complete response, 45%-65% partial response and 18%-32% stable disease[24-26]. The 15% partial response and 56% stable disease rates in our patients were relatively low. However, the 4-year OS of 74% in our patients was compatible with other major studies in the post-imatinib era[19,27,28]. We had 3 patients in whom upfront imatinib converted the tumor from unresectable to removable. As mentioned earlier, one of these cases had pathologically complete remission and 2 cases had tumor shrinkage, to an extent that then allowed their complete removal, suggesting a positive role for this drug in preoperative down-staging of GISTs. In addition, our study

found that gastric GISTs responded to the treatment better than other sites, which may explain the better prognosis of GISTs in this location[29]. A recent multi-institutional trial suggested that extension of imatinib treatment duration to 36 mo significantly improved RFS for operable GISTs[30].

On survival analysis, the study found associations between certain clinical parameters and survival, including gastric site, risk categorization and treatment factors. An excellent outcome could be expected if complete resection could be achieved. Up to 95% 3-year OS was observed in cases with complete tumor removal. In cases that could not have their tumor removed in the first place, disease control depended solely on the response to targeted therapy. Unresectable cases which imatinib failed to control the tumor growth had an average 3-year OS of less than 60%, compared to 80% in those who achieved at least stable disease status. Although the resectability and targeted therapy response were crucial outcome determinants, analysis of the whole series showed that the NIH risk categorization was an independent factor that predicted survival probability in our patients. On average, patients who were not in the high-risk group had more than 90% survival probability. This could be partly at least explained by noting that high risk patients were less likely to have a complete tumor removal, as tumor size is one parameter that determines risk in the NIH risk consensus.

In conclusion, our study examined the treatment outcomes of GISTs over a 5-year period in a teaching hospital in southern Thailand. The study found that the outcomes were mainly determined by tumor resectability and response to targeted therapy and that NIH risk categorization could predict the overall prognosis.

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COMMENTS

Background

Gastrointestinal stromal tumors (GISTs) are relatively uncommon mesenchymal neoplasms arising primarily in the wall of the stomach, small intestine, and colon, and other sites within the abdomen. Surgery is the mainstay treatment with a curative aim for localized GISTs without metastasis. In primarily unresectable or metastatic disease, the current first line treatment is a tyrosine kinase inhibitor, imatinib mesylate. Such molecular targeted therapy gives a varying response rate depending on the tumor location, histological risk stratification and mutation status of the receptor tyrosine kinase KIT.

Research frontiers

This study aimed to review the clinical presentations, pathological characteristics and treatment outcomes of GIST cases in a university hospital setting in Southern Thailand, analyzed for factors effecting treatment outcomes.

Applications

On survival analysis, the study found associations between certain clinical parameters and survival, including gastric site, risk categorization and treatment factors. An excellent outcome could be expected if complete resection could be achieved. Up to 95% 3-year overall survival (OS) was observed in cases with complete tumor removal. In cases that could not have their tumor removed in the first place, disease control depended solely on the response to targeted therapy. Although the resectability and targeted therapy response were crucial outcome determinants, analysis of the whole series showed that the NIH risk categorization was an independent factor that predicted survival probability in our patients.

Terminology

GIST is one of the most common mesenchymal tumors of the gastrointestinal tract (1%-3% of all gastrointestinal malignancies). They are defined as tumors whose behavior is driven by mutations in the *Kit* gene or *PDGFRA* gene, and may or may not stain positively for Kit.

Peer review

This is a retrospective study of GISTs in a single institution in Thailand. Despite the lack of novelty, the manuscript was scientifically well written. It is important to share clinical data on GISTs worldwide and to clarify nation-specific trends of this rare disease. Thus, the reviewer thinks this case series study from Thailand is valuable and potentially worth publishing.

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BRIEF ARTICLE

Omission of breakfast and risk of gastric cancer in Mexico

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Abstract

AIM: To investigate factors associated with gastric cancer (GC) in the Mexican population using a validated questionnaire.

METHODS: We designed and validated in Spanish a Questionnaire to Find Factors Associated with Diseases of the Digestive Tract using GC as a model. A cross-sectional study using 49 subjects, with confirmed histopathological GC diagnosis, and 162 individuals without GC participated. Odds ratio and 95% CIs were estimated in univariate and multivariate analysis adjusted for possible confounding factors. In order to match age groups, a multivariate sub-analysis was performed in subjects ⩾ 39 years of age and in females and males separately.

RESULTS: In the univariate analysis, we found an association between GC and education to primary level or below, low socioeconomic status, the use of dental prostheses, omission of breakfast, consumption of very hot food and drink, addition of salt to prepared foods, consumption of salt-preserved foods and the pattern of alcohol consumption. We found protection against GC associated with the use of mouthwash, food refrigeration and regular consumption of fruit and vegetables. In the multivariate sub-analysis with subjects of ⩾ 39 years, the omission of breakfast was identified as a risk factor for GC.

CONCLUSION: Our study suggests an association between the omission of breakfast and the failure to refrigerate food with GC in the Mexican population.

Key words: Gastric cancer; Questionnaire; Risk factors; Omission of breakfast

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INTRODUCTION

It has been estimated that, since 1990, gastric cancer (GC)

has become the second most common form of cancer in the world, even though its incidence has decreased gradually in recent decades, especially in those countries with greatest resources[1]. Since 1980, the rate of mortality of GC in Mexico has shown an increasing trend, albeit with no significant changes, and it remains the second most common cause of death by cancer[2]. According to the latest report of the Histopathological Register of Malignant Tumors in Mexico, GC is the third most common cancer in men and the fifth in women[3]. In Mexico, there are few reports detailing the survival of patients with GC, and the stages at which they are diagnosed: two studies carried out in third-level reference hospitals indicate that 2%[4] and 3%[5] of cases are diagnosed in early stages, while Japan and the United States report 33.7% and 17.1%, respectively[6]. The evidence suggests that the factor which determines patient survival is the stage at which the disease is diagnosed. Sanitary intervention should begin at the stage at which the disease is diagnosed, and it is reasonable to expect greater GC patient survival if the cancer is detected at an early stage. In Mexico, unfortunately, the scarcity of data concerning the incidence by stages and prevalence of GC makes it difficult to justify programs of early detection.

It is currently accepted that GC is a process involving multiple factors, from environmental to genetic, the interaction of which influences the development and progression of the disease. The established GC risk factors are diverse, but they can be grouped. Nutritional factors: high consumption of salt, smoked food, hot spicy dishes, nitrite-rich food or water, high carbohydrate and fat ingestion, and low consumption of milk, fruit, fresh vegetables, selenium, vitamins A, C and E[7]. Also high consumption levels of tobacco and alcohol, although these GC risks remain controversial[8]. Bacterial and viral infections such as: *Helicobacter pylori* (*H. pylori*)[9], mycoplasma[10] and Epstein-Barr viral infections[11]. Precursor conditions: for example chronic atrophic gastritis[12], Barrett's esophagus[13], intestinal metaplasia[14], dysplasia[15] and Ménétrier's disease[16]; Accumulation of genetic changes including: p53[17], E-cadherin[18], c-myc[19] and microsatellite alterations[20]. Certain dietary habits in Mexico have been linked to the development of GC, such as the consumption of salt, processed meats and vegetables[21], alcoholic beverages[22], capsaicin[23], polyphenols, nitrates and nitrites[24].

Due to the fact that GC is preceded by a long period of latency, it is possible to perform interventions during this stage which allow the prevention of manifestation of the disease[25]. In this context, we have designed and validated a Questionnaire to Find Factors Associated with Diseases of the Digestive Tract (QUFA-DT©), utilizing GC as a model. We propose that the QUFA-DT© could be a valuable instrument for future selection of Mexican patients to undergo gastroendoscopy for the early diagnosis of GC.

MATERIALS AND METHODS

Characteristics of the study

This was a cross-sectional analytical study approved by the ethics committee (official minute JE/035/07) of the "Dr. Miguel Dorantes Mesa", third-level reference Hospital of the Health Services of Veracruz State, Mexico. The study complied fully with the principles of the Declaration of Helsinki of the World Medical Association, 2002.

Subjects involved

Patients with a confirmed histopathological diagnosis of GC, as reported in the Hospital records of 2008 and 2009, were invited to participate with informed consent. Sixty-five patients, all advanced GC cases, were identified within the hospital records, of whom 16 had already died. Among the blood bank donors at the same Hospital, 162 apparently healthy individuals were selected, i.e. individuals free of any chronic pathology, who had no clinical history of cancer. Relatives of the GC patients who participated in the study were excluded. Blood bank donors were recruited from May 2009 to January 2010.

Data collection

A rapid application instrument called QUFA-DT© was designed and validated in Spanish. This instrument gathers sociodemographic information regarding lifestyle, clinical history, factors associated with the development of tumors of the mouth, stomach, colon and rectum. The development of the QUFA-DT© took place in the following steps: (1) systematic review of the literature in English and Spanish; (2) production of the instrument; (3) evaluation by a panel of six experts; (4) application with a sample of 49 people with GC, and 162 without GC; and (5) statistical analysis.

Statistical analysis

In the univariate analysis, proportions and means were compared by χ^2 and Student's t test, respectively. Risks were estimated by odds ratio (OR) and 95% CI. Multivariate analysis was carried out by logistic regression adjusted by the conditional forward method. The dependent variable was GC diagnosis, while covariates were age, sex, use of mouthwash, use of dental prosthesis, food refrigeration, omission of breakfast, consumption of very hot food or drinks, addition of salt to prepared food and consumption of highly salted foods. In order to match age groups, a multivariate sub-analysis was performed in subjects $\geqslant$ 39 years of age and in females and males separately. In this case, the dependent variable was GC diagnosis and the covariates were omission of breakfast, dental prosthesis use and food refrigeration. Statistical significance was considered to be $P \leqslant 0.05$. Analyses were performed using SPSS software version 18 and Epidat version 3.1.

Table 1 General characteristics of the subjects, *n* (%)

	Total (*n* = 211)	With GC (*n* = 49)	Without GC (*n* = 162)
Sex			
Male	152 (72.0)	23 (46.9)	129 (79.6)
Female	59 (28.0)	26 (53.1)	3 (20.4)
Age (yr)[1]	40.2 ± 16.1	62.1 ± 10.7	33.5 ± 10.7
Minimum	18	39	18
Maximum	83	83	64
Histopathological classification			
Diffuse adenocarcinoma	–	26 (53.1)	–
Intestinal adenocarcinoma	–	21 (42.8)	–
Lymphoma	–	2 (4.1)	–
Marital status			
Single	56 (26.5)	6 (12.2)	50 (30.9)
Married	90 (42.7)	27 (55.1)	63 (38.9)
Living with a partner	46 (21.8)	5 (10.2)	41 (25.9)
Divorced	8 (3.8)	1 (2.0)	7 (4.3)
Widowed	11 (5.2)	10 (20.4)	1 (0.6)
Education level			
No formal education	26 (12.3)	14 (28.6)	12 (7.4)
Primary	66 (31.3)	26 (53.1)	40 (24.7)
Secondary	49 (23.2)	4 (8.2)	45 (27.8)
Bachelors	23 (10.9)	0 (0.0)	23 (14.2)
Professional technical	1 (0.5)	0 (0.0)	1 (0.6)
Graduate	45 (21.3)	5 (10.2)	40 (24.7)
Postgraduate	1 (0.5)	0 (0.0)	1 (0.6)
Place of work[2]			
Without employment	51 (24.2)	27 (55.1)	24 (14.8)
Rural	57 (27.0)	12 (24.5)	45 (27.8)
Urban	103 (48.8)	10 (20.4)	93 (57.4)
Socioeconomic status[3]			
Low	134 (63.5)	42 (85.7)	92 (56.8)
Medium	67 (31.8)	4 (8.2)	63 (38.9)
High	10 (4.7)	3 (6.1)	7 (4.3)

[1]mean ± SD; [2]Rural: working outside the town; urban: working in the town; [3]Monthly household income: low ≤ $376 USD; medium $377 to $979 USD; high ≥ $980 USD. GC: Gastric cancer.

RESULTS

With a response rate of 100%, a total of 211 subjects were included in this study. The general characteristics of the study population are shown in Table 1.

All subjects were interviewed face to face by two qualified interviewers, with the majority completing the QUFA-DT© in less than 20 min. Possible factors associated with GC are detailed in Table 2, where it can be seen that associations exist between the development of GC and schooling to primary level or below, low socioeconomic status, use of dental prostheses, omission of breakfast, consumption of very hot food and drinks, consumption of salt-preserved foods and pattern of alcohol consumption.

In contrast, protection against GC was found to be associated with the use of mouthwash, food refrigeration and regular consumption of fruit and vegetables. No associations were found between development of GC and the habitual use of tobacco, or the consumption of alcohol and of capsaicin, in comparison to abstinence.

In the multivariate analysis, we found in the adjusted model that only the omission of breakfast ($P = 0.004$), use of dental prosthesis ($P = 0.017$), and lack of food refrigeration ($P = 0.005$) were associated with GC (Table 3). In contrast, in the multivariate sub-analysis with subjects ⩾ 39 years of age, omission of breakfast was identified as the sole risk factor for GC in women (OR, 7.0, 95% CI = 1.45-33.80), men (OR, 5.25, 95% CI = 1.02-27.0) and in general (OR, 6.06, 95% CI = 1.74-21.14).

DISCUSSION

Although GC is the second leading cause of cancer death in Mexico[2], there are no data with which to support programs of prevention, detection and control of this disease. Information is scarce regarding factors associated with GC in the population of Mexico[21-24] and there is a lack of validated instruments to identify such risks. This study proposes an instrument called QUFA-DT© which can be used in the search for factors associated with this disease.

The results of the multivariate analysis of factors potentially associated with GC suggest an increased risk of GC development in people with a primary or lower educational level and low socioeconomic status, which is consistent with the results of previous studies[26,27]. While we found that regular consumption of alcohol, but not tobacco, has an association with GC risk, we believe that this data is inconclusive. It is clear that international reports regarding both of these factors in relation to GC are still controversial[8,28].

The use of a dental prosthesis was identified as a risk factor for GC in the adjusted multivariate model. However, this result can be treated with caution given that age may act as a confounding factor; in our study, patients with GC had a higher mean age than those free of the disease, and this higher mean age could reasonably be expected to imply a greater probability of requiring such prosthesis. To our knowledge, there have been no reports concerning the association of this variable with GC, although it has been reported for oral cancer[29]. Further testing is therefore required to confirm this association.

In the multivariate adjusted model, we also found an association between GC and the lack of food refrigeration, which again is consistent with the findings of previous studies[30,31]. Interestingly, in countries with a documented decrease in GC, this has been attributed in part to the use of refrigeration for preserving food[31,32]. Unfortunately, a considerable percentage of households in Veracruz do not have adequate conditions for food hygiene: only 68.2% have refrigerators, 73.5% have piped water and 50.5% have drains connected to a public network[33]. It is striking that the percentage of households with a television set (85.9%) is higher than that of households with refrigerators (68.2%)[33] and that 20% of houses still have dirt floors[33]. These socioeconomic data for our state, Veracruz, acquire major relevance in explaining the reasons why those patients skipped break-

Table 2 Association between sociodemographic characteristics, habits, diet and pathological history of gastric cancer, *n* (%)

	With GC (49)[1]	Without GC (162)[1]	OR (95% CI)	*P* value
Education level				
Higher than primary	9 (18.4)	110 (67.9)	1	
Primary or below	40 (81.6)	52 (32.1)	9.40 (4.25-20.81)	< 0.0001
Socioeconomic level				
Medium-high	7 (14.3)	70 (43.2)	1	
Low	42 (85.7)	92 (56.8)	4.57 (1.93-10.77)	0.0002
Use of tobacco[2]				
Non-smoker	27 (55.1)	87 (53.7)	1	
Smoker-ex-smoker	22 (44.9)	75 (46.3)	0.95 (0.50-1.80)	0.99
Pattern of tobacco consumption[3]				
Occasional	15 (30.6)	54 (33.3)	1	
Habitual	7 (14.3)	22 (13.6)	1.15 (0.41-3.19)	0.49
Consumption of alcohol[4]				
Non-consumer	20 (40.8)	57 (35.2)	1	
Consumer-ex-consumer	29 (59.2)	105 (64.8)	0.79 (0.41-1.51)	0.47
Pattern of alcohol consumption[5]				
Occasional	21 (72.4)	101 (96.2)	1	
Habitual	8 (27.6)	4 (3.8)	9.62 (2.65-34.90)	0.0001
Use of mouthwash				
No	46 (93.9)	127 (78.4)	1	
Yes	3 (6.1)	35 (21.6)	0.24 (0.07-0.81)	0.014
Use of dental prosthesis				
No	31 (63.3)	158 (97.5)	1	
Yes	18 (36.7)	4 (2.5)	22.94 (7.26-72.42)	< 0.0001
Refrigeration of food				
Yes	24 (49.0)	137 (84.6)	1	
No	25 (51.0)	25 (15.4)	5.71 (2.82-11.54)	< 0.0001
Omission of breakfast				
No	14 (28.6)	137 (84.6)	1	
Yes	35 (71.4)	25 (15.4)	13.70 (6.46-29.07)	< 0.0001
Consumption of very hot food or drinks				
No	43 (87.8)	159 (98.1)	1	
Yes	6 (12.2)	3 (1.9)	7.40 (1.78-30.79)	0.006
Addition of salt to prepared food[6]				
No	32 (65.3)	138 (85.2)	1	
Yes	17 (34.7)	24 (14.8)	3.05 (1.47-6.34)	0.002
Consumption of fruit[7]				
Rare	29 (59.2)	64 (39.5)	1	
Frequent	20 (40.8)	98 (60.5)	0.45 (0.23-0.86)	0.015
Consumption of vegetables[7]				
Rare	31 (63.3)	69 (42.6)	1	
Frequent	18 (36.7)	93 (57.4)	0.43 (0.22-0.88)	0.011
Consumption of salt-preserved foods				
No	29 (59.2)	129 (79.6)	1	
Yes	20 (40.8)	33 (20.4)	2.70 (1.36-5.35)	0.004
Consumption of capsaicin				
No	11 (22.4)	26 (16.0)	1	
Yes	38 (77.6)	136 (84.0)	0.66 (0.30-1.46)	0.30
Family history of gastric cancer				
No	44 (89.8)	159 (98.1)	1	
Yes	5 (10.2)	3 (1.9)	6.02 (1.39-26.19)	0.018

[1]Total may vary due to lost values; [2]Smoker: Consumes cigarettes currently or consumed prior to diagnosis of gastric cancer (GC); Ex-smoker: Has not consumed cigarettes for at least one year before the interview or on diagnosis of GC; non-smoker: does not consume cigarettes; [3]Occasional: Only smokes on special occasions which occur infrequently; habitual: Smokes one or more times per week; [4]Consumer: Consumes alcohol at the time of the interview or prior to diagnosis with GC; Ex-consumer: Has not consumed alcohol for at least one year before the interview or on diagnosis of GC; Non-consumer: Does not consume alcohol; [5]Occasional: Only consumes alcohol on special occasions which occur infrequently; Habitual: Consumes alcohol one or more times per week; [6]Addition of salt to prepared foods, during the course of meals; [7]Rare: Consumption of less than seven portions per week; Frequent: Consumption of seven or more portions per week.

fast (see below). The need to keep foods refrigerated in our state is accentuated by the climatic conditions. The average annual temperature, excluding the mountainous areas of "Cofre de Perote" and "Pico de Orizaba", ranges between 25-27 ℃, with maximum temperatures in the warmest month between 33-35 ℃ and minimum

Table 3 Association of the variables included in the multivariate analysis

	Non-adjusted model			Adjusted model		
	OR	95% CI	*P* value	OR	95% CI	*P* value
Use of dental prosthesis	9.44	1.26-70.78	0.029	9.68	1.51-61.97	0.017
Use of mouthwash	0.10	0.01-1.01	0.051	-	-	-
Omission of breakfast	6.65	1.94-22.79	0.003	5.21	1.70-16.00	0.004
Non-refrigeration of foods	4.18	0.99-17.60	0.051	6.58	1.78-24.32	0.005
Consumption of very hot food and drinks	11.81	0.86-162.85	0.065	-	-	-
Addition of salt to prepared food	2.29	0.56-9.49	0.25	-	-	-
Consumption of salt-preserved foods	4.75	1.14-19.73	0.032	-	-	-

Multivariate analysis conducted using logistic regression adjusted, by the forward conditional method, for the following variables: use of mouthwash, consumption of very hot food and drinks, addition of salt to prepared food and consumption of salt-preserved foods.

temperatures in the coldest month between 14-20 ℃[34], while cumulative annual rainfall is ⩾ 1000 mm[34]. We believe that, due to social and climatic conditions, for a significant percentage of households in Veracruz it is difficult to follow the recommendations of the World Health Organization (WHO) for the safe handling of food. As proposed by the WHO, the five keys to safer food are: keep food at safe temperatures; refrigerate cooked and perishable food preferable below 5 ℃; use safe water and raw materials; cook food thoroughly; separate raw and food cooked and keep hands, utensils and surfaces clean[35].

In the univariate analysis, the consumption of very hot food or drinks, or of foods preserved in salt, and the addition of salt to prepared foods were associated with GC, however, no such association was observed in the adjusted multivariate analysis. Consumption of foods preserved in salt and the addition of salt to prepared foods have been reported as risk factors for GC[36], however, further investigations are needed to determine the association between these variables and the development of GC. On the other hand, we found an association between protection against GC and the regular consumption of fruit and vegetables, consistent with the findings of previous studies[7,30].

We found that the omission of breakfast has a strong association with GC, which is evident in the adjusted model and in the sub-analysis by gender in subjects aged ⩾ 39 years. This finding appears to have a precedent in reports that claim that irregular eating is associated with GC[30,37]. It was also reported in these studies that overeating and eating quickly are factors associated with GC[30,37]. We believe that the reasons why those patients skipped breakfast are probably associated with their low socioeconomic status and level of education. Unfortunately, in our country a considerable percentage of Mexicans have lived for generations under conditions of poverty. In our experience, validation of the questionnaire was a very complex labor, since a considerable percentage of those patients surveyed found it difficult to understand questions, apparently simple to us. Others were surprised when we explained to them some of the common factors associated with the development of GC. We hypothesize that the omission of breakfast causes alteration of the natural stomach environment which may promote a precursor condition and/or susceptibility to bacterial or viral infections. As is known, irregular eating, especially skipping breakfast, has been associated with gastric ulcer development[38] and a history of gastric ulcer has been linked to Epstein-Barr virus-associated GC[39]. Interestingly, skipping breakfast correlates with Epstein-Barr virus-associated GC in male patients[39]. Additionally, the consumption of strong alcoholic beverages before breakfast has been associated with risk of GC[40]. While, Western-style breakfast has been associated with protection against GC[41].

The human stomach is a specialized organ which produces a highly acid secretion, gastric acid, which beyond its physiological role in digestion, is one of the body's major non-specific defense mechanisms against infection[42]. Food intake is the strongest physiological stimulus to the secretion of gastric acid. It has been postulated that elderly patients are prone to develop severe bacterial infections due to their natural reduction in gastric acid secretion[42]. Malnutrition predisposes to gastritis and reduced acid secretion[42]. Interestingly, transgenic mice with impaired secretion of gastric acid develop intestinal metaplasia[43,44], a precursor condition of GC[14]. In humans, a series of changes have been identified with respect to the mechanism of gastric carcinogenesis due to *H. pylori* infection: superficial gastritis, atrophic gastritis, intestinal metaplasia and carcinoma[45]. In this context, is probable that omission of breakfast, in combination with other risk factors, alters the secretion patterns of the stomach giving favorable conditions for colonization of pathogens, such as *H. pylori* or Epstein-Barr virus, which could promote gastric carcinogenesis.

In Veracruz State, it is necessary to implement programs of constant dissemination of healthy eating habits, comprising information on nutrition, portion size, regularity and speed of food consumption emphasizing the importance of not skipping breakfast. Such public health interventions could assist the prevention not only of GC, but other chronic degenerative diseases. For the planning and execution of these sanitary interventions it is mandatory to consider that in our state only 40%

of the population has access to public or private medical services[33] and this results in the poor demand for preventative public services and hence the lack of a preventive culture in our population[46]. As reported, clinical studies in humans have consistently found that dietary patterns characterized by a regular breakfast intake may improve risk factors for chronic disease[47]. Moreover, in children, not eating breakfast contributes to dietary inadequacies that are not compensated for at other meals[48,49]. In adolescence, a good quality breakfast has been associated with better mental health[50].

Our study had certain limitations, such as possible memory bias that can change over time, and the relatively small sample size. However, we believe that its strengths are the proposal of an instrument in Spanish to search for factors associated with GC, and the type of analysis employed, which allowed adjustment for potential confounding factors.

In conclusion, our study suggests an association between the omission of breakfast and the failure to refrigerate food, with GC in the Mexican population. We propose an instrument of rapid application in order to identify factors associated with GC; this instrument could be of great value to public health.

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COMMENTS

Background

In Mexico gastric cancer (GC) is the third most common cancer in men and the fifth in women. Its prognosis is difficult as it is commonly diagnosed at an advanced stage. In tertiary level hospitals in this country only 2%-3% of GC are diagnosed in the early stages, and unfortunately there are no programs for early detection of GC. As is known, the factor which determines patient survival is the stage at which GC is diagnosed; thus sanitary intervention should begin at that stage and it is reasonable to expect greater GC patient survival if the cancer is detected an early stage.

Research frontiers

In Mexico, unfortunately, the scarcity of data concerning factors associated with GC and prevalence of this disease makes it difficult to justify and develop programs of early detection. Application of questionnaires to identify subjects with exposure to GC risk factors is an important tool since it has been estimated that most GC cases are related to lifestyle and environmental factors, with a minor proportion attributed to genetic defects. Thus the authos developed and validated a Spanish questionnaire to find exposure to factors associated with GC in the Mexican population and we found that omission of breakfast and the failure to refrigerate food are associated with GC.

Innovations and breakthroughs

To the authos' knowledge this is the first study conducted in Mexico that identifies the omission of breakfast as a factor associated with GC.

Applications

Knowledge of factors associated with the evolution of GC and the development of an instrument to identify such factors is very useful for public health, especially in a country lacking a screening program for early detection of GC.

Terminology

The authors investigate factors associated with the development of GC in the Mexican population using a questionnaire. They found that omission of breakfast and failure to refrigerate food are factors associated with GC. They propose a questionnaire as an instrument for future selection of Mexican patients to undergo gastroendoscopy for early diagnosis of GC.

Peer review

It is a very interesting manuscript and suggested to be accepted as it is.

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Events Calendar 2012

January 14-17, 2012
10th Oncology Controversies and Advances Update
Steamboat Springs,
CO, United States

January 19-21, 2012
EASL Monothematic Conference: IMLI - Immune Mediated Liver Injury
Birmingham, United Kingdom

January 19-21, 2012
American Society of Clinical Oncology 2012 Gastrointestinal Cancers Symposium
San Francisco, CA, United States

January 19-21, 2012
2012 Gastrointestinal Cancers Symposium
San Francisco, CA, United States

January 20-21, 2012
American Gastroenterological Association Clinical Congress of Gastroenterology and Hepatology
Miami Beach, FL, United States

February 2-4, 2012
2012 Genitourinary Cancers Symposium
San Francisco, CA, United States

February 6-8, 2012
Pediatric Cancer Translational Genomics
Phoenix, AZ, United States

February 8–10, 2012
The 84th Annual Meeting of Japanese Gastric Cancer Association
Osaka, Japan

February 10-11, 2012
Cancer Survivorship for Clinicians
Seattle, WA, United States

February 14-17, 2012
ASCO Multidisciplinary Cancer Management Course
Eldoret, Kenya

February 20-24, 2012
Word Conference on Colorectal Cancer
FL, United States

February 22-23, 2012
National Cancer Institute Annual Biospecimen Research Network Symposium: "Advancing Cancer Research Through Biospecimen Science"
Bethesda, MD, United States

February 22-25, 2012
30th German Cancer Congress
Berlin, Germany

February 24, 2012
ASCO-German Cancer Society Joint Symposium, German Cancer Congress
Berlin, Germany

February 24-27, 2012
Canadian Digestive Diseases Week 2012
Montreal, Canada

March 7-8, 2012
First International Gulf Joint Conference: Management of colon, breast, and lung cancer (Joint Symposium)
Dammam, Saudi Arabia

March 9-10, 2012
ESMO Conference on Sarcoma and GIST
Milan, Italy

March 10-11, 2012
Colorectal Polyps and Cancers: A Multidisciplinary Approach
Scottsdale, AZ, United States

March 17-21, 2012
Methods in Cancer Research Workshop (Advanced Cancer Course)
Al Asha, Saudi Arabia

March 22-24, 2012
The 1st St.Gallen EORTC Gastrointestinal Cancer Conference
St.Gallen, Switzerland

April 13-15, 2012
Asian Oncology Summit 2012
Singapore, Singapore

April 15-17, 2012
European Multidisciplinary Colorectal Cancer Congress 2012
Prague, Czech

April 18-20, 2012
The International Liver Congress 2012
Barcelona, Spain

April 19-21, 2012
Internal Medicine 2012
New Orleans, LA, United States

April 20–21, 2012
OOTR 8th Annual Conference - Organisation for Oncology and Translational Research
Kyoto, Japan

April 28, 2012
Issues in Pediatric Oncology
Kiev, Ukraine

May 19-22, 2012
Digestive Disease Week 2012
San Diego, CA, United States

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Pancreatic Cancer: Progress and Challenges
Lake Tahoe, NV, United States

June 27-30, 2012
ESMO 14th World Congress on Gastrointestinal Cancer 2012
International Convention Center Of Barcelona,
Barcelona, Italy

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10th World Congress of the International Hepato-Pancreato-Biliary Association
Paris, France

July 5-7, 2012
International Research Conference on Liver Cancer
Heidelberg, Germany

July 6-8, 2012
The 3rd Asia – Pacific Primary Liver Cancer Expert Meeting "A Bridge to a Consensus on HCC Management"
Shanghai, China

September 1-4, 2012
OESO 11th World Conference
Como, Italy

September 14-16, 2012
ILCA 2012 - Sixth Annual Conference of the International Liver Cancer Association
Berlin, Germany

September 21-22, 2012
Research Symposium, Inflammation and Cancer
Houston, TX, United States

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GENERAL INFORMATION

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3 **Tian D**, Araki H, Stahl E, Bergelson J, Kreitman M. Signature of balancing selection in Arabidopsis. *Proc Natl Acad Sci USA* 2006; In press

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5 **Vallancien G**, Emberton M, Harving N, van Moorselaar RJ; Alf-One Study Group. Sexual dysfunction in 1, 274 European men suffering from lower urinary tract symptoms. *J Urol* 2003; **169**: 2257-2261 [PMID: 12771764 DOI:10.1097/01.ju.0000067940.76090.73]

No author given

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Patent (list all authors)

16 **Pagedas AC**, inventor; Ancel Surgical R&D Inc., assignee. Flexible endoscopic grasping and cutting device and positioning tool assembly. United States patent US 20020103498. 2002 Aug 1

Statistical data

Write as mean ± SD or mean ± SE.

Statistical expression

Express *t* test as *t* (in italics), *F* test as *F* (in italics), chi square test as χ^2 (in Greek), related coefficient as *r* (in italics), degree of freedom as υ (in Greek), sample number as *n* (in italics), and probability as *P* (in italics).

Units

Use SI units. For example: body mass, m (B) = 78 kg; blood pressure, p (B) = 16.2/12.3 kPa; incubation time, t (incubation) = 96 h, blood glucose concentration, c (glucose) 6.4 ± 2.1 mmol/L; blood CEA mass concentration, p (CEA) = 8.6 24.5 μg/L; CO_2 volume fraction, 50 mL/L CO_2, not 5% CO_2; likewise for 40 g/L formaldehyde, not 10% formalin; and mass fraction, 8 ng/g, *etc*. Arabic numerals such as 23, 243, 641 should be read 23243641.

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Italics

Quantities: *t* time or temperature, *c* concentration, *A* area, *l* length, *m* mass, *V* volume.
Genotypes: *gyrA*, *arg* 1, *c myc*, *c fos*, *etc*.
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