

in patients with colorectal cancer and its relationship with QoL, particularly with chemotherapy described as one important stressor. Therefore the main aim of this study was to explore the relationship between stress and QoL in patients who received chemotherapy for the first time.

Material and Methods: The sample was integrated by 27 colorectal cancer patients; 13 women and 14 men, whose ages were between 24 and 70 years old. After medical oncologist consultation, where chemotherapy treatment was assigned for the first time, participants were recruited; those who accepted to participate in the study signed an informed consent form and were referred for a comprehensive assessment session.

The Perceived stress scale (PSS) utilized measures the level of stress control perceived, the Health Related Quality of Life Inventory (InCaViSa) measures QoL in chronic or acute diseases; The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) measures QoL in patients with cancer. All instruments have appropriate psychometric properties for Mexican population.

Results: According to PSS, 45% of patients showed low levels of stress, 48% moderate and 7% high levels of stress. A significant negative correlation was found with stress perception and physical performance, cognitive functioning, free time and daily life evaluated by InCaViSa scale. A significant positive correlation was found with stress perception and fatigue, pain, insomnia and financial difficulties scales. Finally, a significant negative correlation was found with physical, role, emotional, cognitive and social functioning and with the global QoL evaluated by EORTC QLQ-C30.

Conclusions: In general terms, higher levels of stress were observed when higher level of symptomatology and problems like fatigue, pain, insomnia and financial difficulties were reported, and also less functionality in physical, role, emotional, cognitive and social domains, including physical performance, free time and daily life, all of which translated in worst QoL in patients with colorectal cancer before receiving chemotherapy for first time.

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POSTER

Impact of Adjuvant Chemotherapy on Survival of Patients With Stage II Colon Cancer – Retrospective Study

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Background: Colorectal cancer (CRC) is the third most common malignant tumour. The stage of the tumour at time of resection is the most important prognostic factor. The issue of adjuvant treatment for stage II colon cancer patients using 5-FU-based therapy is less well defined. But, the clearly well established survival benefit for stage III colon cancer patients have led some physicians to recommend adjuvant chemotherapy for stage II colon cancer patients.

Materials and Methods: This retrospective study was conducted on all pathologically confirmed stage II colon cancer patients (273 patients) who received adjuvant chemotherapy in the Clinical Oncology Unit, Radiation Sciences Department, Medical Research Institute, Alexandria University between January 1995 to December 2004. The data including: Clinicopathological Parameters (Age, Sex, Family history, Tumour histology, Tumour grade, Tumour marker, Number of lymph nodes dissected, Vascular invasion and Bowel obstruction) Adjuvant Chemotherapy in the form of 5-FU+Ca leucovorin (Regimens of chemotherapy received either Mayo clinic or De Gramont regimen), Doses of chemotherapy and Number of cycles were registered.

Results: More dissected lymph nodes were accompanied by higher disease-free survival (DFS) and overall survival (OS) rates at 3 and 5 years respectively; but did not reach statistical significance. Patients who had symptoms duration less than 6 months (earlier presentation) had statistically significant higher OS at 3 years but not at 5 years. Symptoms duration showed no impact on DFS. There was no difference in DFS and OS in different systemic chemotherapy regimens. Patients who received 6 cycles had significant higher DFS when compared with patients who received less number of treatment cycles. Intestinal obstruction was accompanied by lower OS at 3 and 5 years and DFS at 3 years only. Vascular invasion had impact on both DFS and OS at 3 and 5 years. Higher level of CEA was accompanied by lower DFS and OS at 3 and 5 years. Patients who had poorly differentiated tumours had lower DFS when compared with patients who had well differentiated tumours. For all patients, DFS at 3 & 5 years were (72.9%) and (57.1%) respectively, while OS at 3 & 5 years were (86.1%) and (73.6%) respectively.

Conclusion: Although there was no improvement in OS, DFS was significantly better with adjuvant chemotherapy. Stage II colon cancer patients who have high risk features, including intestinal obstruction, vascular invasion, inadequate lymph node dissection or T4 disease seem to benefit from adjuvant systemic chemotherapy. The co-morbidities and likelihood of tolerating adjuvant systemic chemotherapy should be considered as well. Also, researchers must continue to search for other

therapies which might be more effective, shorter in duration and less toxic than those available today.

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POSTER

Hardly Any Excess Mortality for Long-term Colon Cancer Survivors in the Netherlands 1989–2008

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Background: With the marked increase in the number of long-term cancer survivors, there is an increasing need for more up-to-date analysis of survival for patients who have already survived a certain period of time. Standard survival curves at diagnosis of cancer are rather pessimistic, since they are also based on patients who die within the first few years. Conditional 5-year relative survival therefore serves better information about the current prognosis of survivors during follow-up. We determined conditional 5-year relative survival rates for colon cancer patients, according to age, gender, and tumour stage for each additional year survived up to 15 years after diagnosis.

Methods: Patients diagnosed in the Netherlands with colon cancer stage I–III in 1989–2008 aged 15–89 years were selected from the Netherlands Cancer Registry. Conditional 5-year relative survival was computed for every additional year survived up to 15 years. Period analysis with follow-up period 2004–2009 was used.

Results: There was hardly any excess mortality (conditional 5-year relative survival >95%) 1–4 years after diagnosis for stage I patients and 4–7 years after diagnosis for stage II patients, with patients aged 45–74 years reaching this point later compared to the younger and elderly patients. For stage III patients, hardly any excess mortality was observed 5 years after diagnosis for those aged 75–89 years, but remained elevated up to 13 years after diagnosis for those aged 15–44 years. Initial differences in relative survival at diagnosis between age and stage groups largely disappeared with number of years survived.

Conclusion: The prognosis for colon cancer survivors improved with each additional year survived. In the first years after diagnosis conditional survival improved largely for all colon cancer patients, especially for stage III patients. There was hardly any excess mortality for colon cancer patients stage I–III at some point within 15 years after diagnosis, being later for more advanced stage. Quantitative insight into conditional survival for cancer patients is useful for caregivers to help planning optimal cancer surveillance and inform patients about their prognosis.

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POSTER

Incidence of Major Surgeries in Patients With Metastatic Colorectal Cancer

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Background: As surgical procedures may potentially interfere with anticancer drug therapy for metastatic colorectal cancer (mCRC), the objective of this study was to examine the proportion of patients with mCRC who underwent major surgeries.

Methods: Using a large U.S. medical claims database from a nationally commercially-insured population, patients with diagnosed mCRC between January 2004 and March 2010 were identified. The first metastasis diagnosis date served as the index date. Patients were followed from the index date to death, disenrollment, or end of the study period (March 31, 2010), whichever occurred first. Major surgery was defined according to the list of major surgeries developed by the National Committee for Quality Assurance (NCQA) using Current Procedural Terminology (CPT) procedure codes. Major surgeries were examined by anatomic locations: 1) colon or rectum; 2) liver or lung; and 3) all other anatomic sites. Major surgeries on colon or rectum were assessed separately, since they likely include a high percentage of interventions to remove primary tumours. The proportion of major surgeries was descriptively analyzed.

Results: The study sample included 4,768 mCRC patients who met the study inclusion and exclusion criteria between January 2004 and March 2010. Mean age was 60.0 years old and 45.9% of patients were female. Mean length of follow-up observation period was over one year (414 days). Overall, 42.3% of patients had at least one major surgery on anatomic

sites other than colon/rectum after mCRC diagnosis. By anatomic locations, 17.6% of patients had major surgeries on liver or lung (13.4% on liver and 4.9% on lung); and 32.3% had major surgeries on all other anatomic sites. Major surgeries on colon or rectum occurred in 35.9% of patients (32.9% on colon and 4.1% on rectum).

Conclusions: Major surgeries are highly prevalent in patients with mCRC from this commercially insured population after mCRC diagnosis. This might have implications for anticancer drug therapy in mCRC patients.

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POSTER

Electric Stimulation of Anal Sphincter as a Treatment Option for Fecal Incontinence After Ultra-low Coloanal Anastomosis With or Without Intersphincteric Resection

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Background: Progress in combined treatment makes possible sphincter saving treatment for patients with low rectal tumour. Many clinics report about good oncological outcome. But functional results after ultra low coloanal anastomosis (CAA) with or without intersphincteric resection (ISR) sometimes disappointing. The purpose of this study was to prospectively investigate patients with fecal incontinence after ultra low CAA with or without ISR and evaluate the efficacy of electromyostimulation (EMS) as a treatment option.

Patients and Methods: 36 patients were treated for fecal incontinence. All patients had low rectal cancer and received preoperative chemoradiotherapy following by proctectomy with or without ISR with hand-sewn CAA. For electromyostimulation we use Neurotrac ETS device in "incontinence" mode.

Technics: Bipolar probe introduced into anus. Each session lasts 20 minutes. Usually started with 20–30 mA to maximal amplitude up to 80 mA. Total number of sessions was 10. Success was evaluated by anometry, water infusion test, Wexner scale and FIQL score.

Results: Mean squeeze pressure increased significantly after stimulation from 1.52 to 2.4. Mean score by Wexner scale improve from 16.6 to 8.3. Mean index according Wexner scale for hard and liquid stool and flatus incontinence improve from "2.96", "3.59" and "3.44" to "1.14", "1.92" and "1.55" respectively. Naturally, group without ISR showed better results. Mean FIQL score increase from 1.49 to 3.27.

Conclusion: Preliminary results for EMS have shown that patients achieved higher maximum voluntary squeeze pressures, and showed a marked improvement in their continence. Given the advantage of ambulatory use and non-invasive approach the EMS seems promising in terms of achieving improved fecal continence and quality of life in selected patients.

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POSTER

Vitamin E Supplementation Against Oxaliplatin Induced Peripheral Neuropathy

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Background: Chemotherapy induced peripheral neuropathy (CIPN) is a common and dose-limiting side effect of anticancer drugs. Typically, the clinical presentation reflects an axonal peripheral neuropathy with glove-and-stocking distribution sensory loss, combined with features suggestive of nerve hyperexcitability such as paresthesia, dysesthesia and pain. These symptoms may be disabling, adversely affecting activities of daily living and thereby quality of life. We assessed the efficacy and safety of vitamin E supplementation to evaluate the reduction in intensity of oxaliplatin-induced peripheral neuropathy.

Materials and Methods: We have observed 80 patients (average 66 yrs) with no history of peripheral neuropathy due to any cause (diabetes, alcohol, toxins) affected by colon cancer (stage III) and undergoing oxaliplatin-based chemotherapy. In our sample 40 patients were scheduled to receive vitamin E at dose of 400 mg/die at the occurrence of neuropathy until the end of the treatment (group 1), meanwhile the other 40 patients did not take vitamin E (group 2). Neurologic clinical examination and nerve conduction study were performed for each patient at the start of symptoms and at the end of chemotherapy using NCI-CTC for grading the severity of neuropathy. The concentration of calcium and magnesium were evaluated before every course of chemotherapy.

Results: All the patients who received vitamin E (group 1) showed a significant reduction in intensity of neuropathy. We have found a significant reduction of sural sensory nerve action potential (SNAP) amplitude and a reduction of speed of nerve conduction in group 2 compared to the group 1 ($p < 0.001$).

Conclusions: CIPN is a limiting side effect for patients undergoing oxaliplatin based therapy. Evaluate a treatment without side effect, not expensive, easy to recruit is important to ensure a good quality of life, to keep the dose dense of chemotherapy, to avoid therapy dose reduction due to the neuropathy. Vitamin E might prevent and/or lessen the side effects to CIPN.

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POSTER

Systemic Inflammatory Response in Predicting Survival in Patients With Operable Colorectal Cancer

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Background: Several inflammatory response materials could be biomarkers for prediction of prognosis of cancer patients; elevated C-reactive protein (CRP), increased white cell, neutrophil, platelet, and decreased albumin. The Glasgow Prognostic Score (GPS) combines circulating CRP and albumin level, the neutrophil/lymphocyte ratio (NLR), and the platelet/lymphocyte ratio (PLR) has been introduced for prognostic scoring system in colorectal cancer (CRC). Thus, in this study, we attempted to identify an more adequate prognostic model related with systemic inflammatory response for CRC.

Methods: Between Mar 2005 and Dec 2008, 200 patients who underwent curative resection for colorectal cancer were enrolled in this study. Systemic inflammatory parameters (CRP, albumin, neutrophil, lymphocyte, and platelet count) were checked for making 3 scoring systems. Based on clinical survival data, we then compared PFS and OS with GPS, NLR, and PLR.

Results: Male to female was 123:77. Median age of the patients was 64 years (range, 26–83 years). Median follow-up duration was 27.2 months (range 7.8–52.7 months). 36 patients were observed disease progression or death. 19 patients were passed away during follow-up duration. 3 year PFS and OS were 72% and 86%, respectively. Numbers of GPS 0, 1, and 2 patients were 154 (77%), 44 (22%), and 2 (1%), respectively. Survival analysis according to GPS, PFS and OS could not be able to show the prognostic significance ($P = 0.313$ and $P = 0.263$). Cut-off value of NLR and PLR were determined 3 and 180 by ROC curve. Both of NLR and PLR were observed as a good prognostic biomarker of PFS and OS ($P = 0.009$ and $P < 0.001$ in PFS, $P = 0.006$ and $P = 0.001$ in OS).

Conclusions: Although GPS, NLR, and PLR were introduced as prognostic scoring systems for operable CRC, PLR which is constructed of platelet/lymphocyte count may represent a useful prognostic index for the prediction of PFS and OS in operable CRC.

Oral Presentations (Mon, 26 Sep, 14:45–16:30) Gastrointestinal Malignancies – Noncolorectal Cancer

6500

ORAL

Second Interim Results of the GIDEON (Global Investigation of Therapeutic DEcisions in HCC and of Its Treatment With Sorafenib) Study – Barcelona-Clinic Liver Cancer (BCLC) Stage Subgroup Analysis

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Background: GIDEON is an ongoing, global, prospective, non-interventional study of HCC patients (pts) receiving sorafenib (Sor) in real-life practice. Its aim is to evaluate Sor safety and efficacy in diverse settings and pt subgroups. The predefined subgroup analysis by the BCLC is presented.

Material and Methods: Demographics, medical/disease/treatment history are recorded. At follow-up visits Sor dose, concomitant treatment, liver function, adverse events (AEs) and efficacy are recorded. From Jan 2009 to April 2011, over 3000 pts have been enrolled from 39 countries, achieving study target enrollment. Per protocol, the 2nd interim analysis (IA) was planned when ~1500 treated pts were followed ≥ 4 months.