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Original article

Alleviating gastro-intestinal symptoms and concerns by integrating patient-tailored complementary medicine in supportive cancer care



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SUMMARY

Background & aims: Chemotherapy-induced gastrointestinal (GI) toxicities often impair quality-of-life (QOL) and require reduction of the chemotherapy dose intensity. We explored the effects of a complementary integrative medicine (CIM) therapeutic process, administered in conjunction with conventional supportive care, on GI-related symptoms and concerns in patients undergoing chemotherapy.

Patients and methods: We conducted a prospective, pragmatic study among patients undergoing chemotherapy referred by their healthcare providers to a CIM-trained integrative physician (IP) for consultation, followed by CIM treatments. Symptom severity and patient concerns were assessed at baseline and at an IP follow-up visit at 6-12 weeks, using the Edmonton Symptom Assessment Scale (ESAS) and the Measure Yourself Concerns and Wellbeing (MYCAW) questionnaires. Adherence to the integrative care (AIC) program was defined as attendance of ≥ 4 CIM treatments, with ≤ 30 days between sessions

Results: Of the 308 patients referred to the IP consultation, 275 (89.3%) expressed GI symptoms and concerns, 189 of whom attended the follow-up IP assessment. Of these, 144 (46%) were found to be adherent to the treatment plan (AIC group). Repeated measure analysis indicated a statistical interaction between baseline and follow-up scores, for ESAS (appetite, p=0.005; drowsiness, p=0.027; shortness of breath, p=0.027; and sleep, p=0.034) and for MYCAW outcomes. This when comparing the AIC to the non-AIC group responses.

Reduction of GI concerns (p=0.024) was greater among patients in the AIC group (MYCAW question-naire), with significantly less chemotherapy-related hospitalizations found in this group (p=0.008). The participation of a registered dietitian during CIM treatments led to greater reduction in nausea (from 4.24 to 1.85 vs. 2.73 to 1.36, respectively; p=0.017).

Conclusions: Integration of CIM with standard supportive care, especially in patients adhering to the CIM treatment regimen, may help reduce chemotherapy-induced GI symptoms and concerns, as well as QOL-related non-GI symptoms. Further research is needed in order to explore the effects of specific CIM modalities on GI symptoms and concerns during chemotherapy.

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1. Introduction

Supportive care for patients with cancer undergoing chemotherapy has improved significantly, largely the result of an enhanced awareness of the importance of quality-of-life (QOL)-related issues and improved symptom control, such as the newly available anti-emetic agents [1]. Yet the toxic effects of anti-cancer treatments continue to present a significant challenge to both

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patients and their healthcare providers. These include gastrointestinal (GI) concerns such as nausea, appetite and taste alteration, mouth sores, constipation, diarrhea, abdominal pain and treatment-related toxicities, bloating. Other such chemotherapy-related fatigue and peripheral neuropathy, as well as a wide range of emotional and physical issues, can all cause significant distress and exacerbate one another. Treatment-related symptoms often lead to the cessation or delay of treatment regimens, necessitating a reduction in dose density with reduced efficacy [2,3]. There is therefore a need to search out new treatment options which are both safe and effective in improving QOLrelated outcomes, which would allow for the completion of treatment regimens as planned.

The use of complementary and integrative medicine (CIM) in conjunction with chemotherapy is widespread, with many patients turning to these therapies for the relief of symptoms which are not addressed in conventional supportive care [4]. There is a large body of evidence supporting the benefits of a number of CIM modalities, including for the treatment of GI-related symptoms. For example, Chinese herbal medicine, acupuncture and acupressure have all been found to be effective in reducing chemotherapy-induced nausea and vomiting (CINV) [5-8]. In addition, mind-body medicine (e.g., hypnosis, yoga, guided imagery, progressive muscle relaxation training) have also been found to be of benefit for CINV [9-11], and xerostomia can be reduced by hypnosis [12] and acupuncture [13]; oral mucositis by nutritional supplements such as Carob (Ceratonia siliqua L.), Rhodiola algida, glutamine, and honey [14–17]; taste alteration following irradiation with zinc supplementation [18]; and diarrhea with probiotics and the Japanese Kampo medicinal herb Hangeshashin-to [19–21].

The growing awareness of the conventional medical establishment regarding the potential benefits of CIM in supportive care has led to the establishment of a number of integrative medicine programs within leading U.S. cancer centers [22,23], as well as in other Western countries [24]. CIM consultations and subsequent treatments play an integral role at these centers, and are geared toward improving QOL while ensuring safety (i.e., side effects, negative interactions with anti-cancer therapies, etc.). The integrative oncology environment is characterized by a patient-centered, biopsycho-social-spiritual approach which guides a multiple-modality treatment plan tailored to the patient's specific concerns. This integrative approach requires the cooperation of other supportive care-healthcare practitioners, including nutritional consultants and psycho-oncologists.

The goal of the present study was to explore the impact of an integrative oncology program, in which CIM treatments are provided in addition to conventional supportive care therapies, on chemotherapy-induced GI-related toxicities and patients' concerns, as well as other QOL-related outcomes. For this purpose we chose a pragmatic methodological approach, reflecting the real-world clinical setting of the CIM program which serves as an integral part of a public conventional-care oncology service.

2. Methods

2.1. Study design and location

The study was designed as a prospective pragmatic trial, examining patients' preferences and the impact of a CIM intervention on chemotherapy-induced GI toxicity, as well as other QOL-related outcomes. The study took place at the Integrative Oncology Program (IOP) at the Haifa and Western Galilee Oncology Service of Clalit Healthcare services. The IOP approach is patient-centered, addressing concerns regarding QOL-related outcomes during chemotherapy and advanced disease [25].

Patients age 18 years and older who were undergoing chemotherapy in the outpatient oncology service at the Lin and Zebulon Medical Centers in northern Israel (between July 2009 and July 2012) were eligible for study inclusion. Chemotherapy regimens were either adjuvant or neo-adjuvant protocols for local disease, or else palliative for advanced disease. Patients presenting to the study centers were referred by their oncologists, nurse oncologists, or psycho-oncologists to the integrative physician (IP) for consultation. Referrals were based on a structured list of specific QOL-related concerns, including gastro-intestinal symptoms such as nausea and vomiting, mouth sores and gingivitis, alteration of taste, reduced appetite, weight change, dietary concerns, constipation, diarrhea, abdominal pain/flatulence/bloating, and heartburn. Non-GI-related concerns included fatigue, pain and emotional distress.

2.2. Assessment of patients' QOL and gastro-intestinal concerns

The initial (baseline) IP consultation lasts approximately an hour. IPs are medical doctors with extensive training in CIM treatment modalities, as well as in conventional supportive cancer care. A follow-up visit to the IP is scheduled at 6 and 12 weeks following the initial consultation.

At the initial IP consultation, treatment-related symptoms and QOL-related outcomes are evaluated using the Edmonton Symptom Assessment Scale (ESAS), a Likert-like study tool scoring 10 symptoms, of which two are related to GI concerns (nausea and appetite) and the remainder either general (fatigue, depression, anxiety, drowsiness, feeling of well-being, and sleep) or specific non-GI-related symptoms (pain, shortness of breath). The severity of symptoms is self-scored by patients, and ranges from 0 (no symptoms) to 10 (worst possible symptoms) [26]. Baseline and follow-up ESAS scores are also analyzed following categorization to one of the following 4 groups: 0, no symptoms; 1–3, mildly severe symptoms; 4–6, moderately severe symptoms; and 7–10, severe symptoms.

At the same time, GI-related and other concerns are evaluated using the Measure Yourself Concerns and Wellbeing (MYCAW) tool. The MYCAW is a Likert-like questionnaire in which patients are asked to list their two most important concerns, which are then scored from 0 (of no concern) to 6 (of greatest concern). In addition to addressing their symptoms, patients are also asked to score their general feeling of well-being (0, as good as it could be; 6, as bad as it could be), followed by two open-ended questions regarding "other issues related to your health" and "what has been the most important issue for you?" [27].

GI concerns are considered to be significant if they fulfill one or more of the following criteria: 1. the presence of nausea or a lack of appetite, with an ESAS score of ≥ 4 ; 2. a score of ≥ 3 on the MYCAW questionnaire for one or two of the following GI-related concerns: nausea/vomiting; mouth sores and/or pain; heartburn; abdominal flatulence and/or pain; diarrhea or constipation; reduced appetite; weight change; or 3. an expressed interest in nutritional counseling. Patients for whom the referring healthcare provider listed a GI-related concern as an indication for the referral were included as well.

2.3. CIM treatments

At the end of the initial IP consultation the goals of treatment are established and a treatment plan is designed in accordance with the patient's expectations and main concerns. The IP presents the patients an updated in-depth explanation regarding the level of research-based evidence on the efficacy and safety of the CIM treatment options. CIM treatments are provided by qualified and experienced practitioners, with the following therapeutic

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