

Oral Abstract Session: Best Of SIO

1. Phase I Dose-Escalation Trial of Trametes Versicolor in Women with Breast Cancer

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Introduction: Trametes versicolor, also known as Coriolus versicolor and commonly called Turkey Tail, is a medicinal mushroom hypothesized to improve immune function in women with breast cancer who have received standard treatment with surgery, chemotherapy and radiotherapy. Natural killer (NK) cell activity of peripheral blood lymphocytes in cancer patients has been associated with favorable prognosis following primary cancer treatment. Our group has previously shown that radiotherapy produces immune defects in breast cancer patients, especially in NK cell activity, an important component of the innate immune system.

Purpose: The purpose of this nine-week dose escalation trial of a mushroom called Trametes versicolor (Tv) was to determine the safety and dose limiting tolerability of oral administration of Tv and to evaluate the Tv dose-related immune response of women with breast cancer who have received chemotherapy and radiotherapy.

Methods: This phase I, two-center, dose escalation study sought to determine the maximum tolerated dose of T. versicolor when taken orally twice a day for six weeks by women with stage I, II or III breast cancer who completed surgery, chemotherapy and radiation therapy. Each Tv dose cohort had a minimum of three participants. Baseline NK cell activity, T/B/NK cell subsets and complete blood count with differential were measured before the start of radiotherapy and again immediately after radiotherapy. Measurements were also taken every two weeks during the six weeks of treatment, followed by three weeks of washout for a total of nine weeks in the post-radiation setting. The three dose cohorts of Tv included: 3, 6 and 9 gram daily Tv. All participants were monitored for adverse events (AE), immune function and fatigue throughout the 9-week clinical trial.

Results: Both 3 and 6 grams/day of T. versicolor oral ingestion were tolerable and produced no significant clinical or laboratory adverse events. In comparing the 3 and 6 gram dose cohorts, there was a significant dose-related increase in NK cell activity/NK cell that was associated with increasing dose of Tv. Tv enhanced NK cell activity in a dose dependent fashion with the higher 6 gram dose eliciting higher NK cell activity in the post radiotherapy-setting. However, Tv had no effects on

subset counts of T, B or NK cells, red blood cell compartments or other white blood cell compartments. The first 9 gram dose study participant completed the study and had no AEs.

Conclusion: Trametes versicolor is safe and tolerable at oral doses of 3 and 6 grams/day and enhances NK cell activity in a dose-dependent fashion. The potent immunological activity of this medical mushroom may offer an important immunotherapy for women with breast cancer in the post-radiotherapy setting when women are immunologically vulnerable to breast cancer relapse.

2. Effects of Healing Touch and Relaxation on Immunity and Mood in Cervical Cancer Patients During Chemoradiation

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Purpose: Patients receiving chemoradiation for cervical cancer are at risk for distress, chemoradiation-related side-effects, and immunosuppression. This prospective randomized clinical trial examined effects of a complementary biofield therapy, Healing Touch (HT), versus relaxation training (RT) and standard care (SC) for 1) supporting cellular immune function, 2) improving mood and quality of life (QOL), and 3) reducing treatment-associated toxicities and treatment delay in cervical cancer patients receiving chemoradiation.

Methods: Sixty women with stages IB1 to IVA cervical cancer were randomly assigned to receive SC or 4x/weekly individual sessions of either HT or RT. Sessions were conducted in the Clinical Research Center or Radiation Oncology Facility immediately following radiation during their 6-week chemoradiation treatment. Patients completed psychosocial assessments and blood sampling before chemoradiation at baseline, weeks 4 and 6. Five specific HT techniques, designed to promote calm and facilitate balancing of energy flow in the body, were used. The relaxation intervention was manualized and included passive progressive relaxation, autogenic relaxation, and imagery-based relaxation.

Results: Multilevel regression analyses using orthogonal contrasts tested for differences between treatment conditions over time. HT patients demonstrated a minimal decrease in natural killer (NK) cell activity over the course of treatment whereas NK cell activity of RT and SC patients declined markedly during radiation (group by time inter-

action: $p=0.018$). HT patients showed greater decreases in 2 different indicators of depressed mood (CESD depressed mood subscale and POMS depression scale) compared to RT and SC patients (group by time interactions: $p < 0.05$). Between group differences were not observed in QOL, treatment delay, or clinically-rated toxicities.

Conclusion: Intensively administered HT appears to have positive effects in preserving NK cell activity and reducing depressed mood during chemoradiation among advanced cervical cancer patients. Effects of HT on toxicities, treatment delay, QOL, and fatigue were not observed. Long-term clinical implications of findings are not known.

3. Outcome of Brief Counseling on Cancer-Related Fatigue Among Patients Undergoing Radiation Therapy

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Purpose: Cancer-related fatigue (CRF) is a major symptom burden that negatively affects quality of life among diverse groups of cancer patients. This study seeks to evaluate the outcome of a brief counseling program that is based on the National Cancer Institute (NCI) guidelines to manage CRF.

Methods: We conducted a prospective cohort study among patients undergoing radiation therapy (RT). All patients were given a 10 minute brief behavioral counseling session during the first two weeks of RT that was based on the NCI guidelines. Patients included those with stage I-III tumors for non-palliation with a Karnofsky score of 60 or better. The Brief Fatigue Inventory (BFI) and M.D. Anderson Symptom Inventory (MDASI) were administered at baseline and at the end of RT.

Results: Among the 93 patients who participated in the study, the mean age was 64.7 (SD 10.6); female/male (38/62%); white/non-white (70/30%); prostate/breast/others (47.8/29.4/22.8%); 79(85%) provided data for assessment at the end of RT. For patients who had received chemotherapy prior to RT or patients who received RT only, the BFI score showed non-significant absolute change (-0.2 and 0.7, respectively); however, among those patients who received concurrent chemotherapy, mean fatigue increased from 3.0 to 5.2, $p<0.001$. The change in BFI was also significantly correlated with MDASI change (correlation coefficient, 0.72, $p=0.001$). Counseling was perceived as useful and practical by 89% of participants. By the end of RT, 59% used exercise,

41.6% sought nutrition counseling, 72.7% prioritized daily activities, 74.4% napped during the day, 70.5% talked with other cancer patients, 27.3% practiced relaxation techniques, 22.1% took herbs/supplement, and 19.5% took medications.

Conclusion: Our data suggests that brief behavioral counseling based on the NCI guidelines is well accepted by RT patients and might be effective for preventing CRF in patients who do not receive concurrent chemotherapy. However, among those who receive concurrent chemotherapy, other types of interventions are required to prevent worsening fatigue. Randomized controlled clinical trials are needed to confirm these findings and to determine whether more tailored or integrative therapies are better than the existing guideline-based approach for CRF among those RT patients who receive concurrent chemotherapy.

4. Safety of High-Dose Vitamin D Supplementation in Women at High Risk for Breast Cancer

Julie Campbell, Columbia University Medical Center; Dawn Hershman, Columbia University Medical Center; Matthew Maurer, Columbia University Medical Center; Kevin Kalinsky, Columbia University Medical Center; Sheldon Feldman, Columbia University Medical Center

Purpose: Vitamin D has diverse biological effects on proliferation, differentiation, and apoptosis in multiple tissues, including the breast. Observational studies have demonstrated that serum 25-hydroxyvitamin D (25-OHD), an objective measure of vitamin D status, is inversely related to breast cancer risk, such that levels >40 ng/ml are associated with about a 40% reduction in breast cancer risk compared to women who are vitamin D deficient (25-OHD <20 ng/ml). Serum 25-OHD above 32 ng/ml is thought to be sufficient for bone health and vitamin D toxicity occurs with levels above 150 ng/ml. However, uncertainty remains about whether vitamin D supplementation will reduce breast cancer risk, the optimal dose of vitamin D, and the target level of serum 25-OHD. We examined the safety of high dose vitamin D and the effects on serum 25-OHD in women at high risk for breast cancer.

Methods: Women at high risk for breast cancer, defined as 5-year Gail risk score $\geq 1.67\%$, history of lobular or ductal carcinoma in situ (LCIS/DCIS), or BRCA1 or BRCA2 mutation carrier, were assigned to a 1-year intervention of cholecalciferol (vitamin D3) 20,000 IU (2 capsules) weekly or 30,000 IU (3 capsules) weekly. Additional eligibility criteria included baseline serum 25-OHD ≤ 32 ng/ml and no history of kidney stones. Participants were monitored for toxicity, particularly hypercalcemia and hypercalciuria, every 3 months during the

1-year intervention. They underwent a digital mammogram and random core biopsy (premenopausal women) or breast MRI (postmenopausal women) at baseline and 12 months, as well as serial blood collections at 0, 6, and 12 months. Serum 25-OHD was measured by Diasorin radioimmunoassay.

Results: From November 2007 to July 2010, 31 of 60 participants were enrolled and 13 have completed the 1-year intervention. Median age: 50 (37-70); Premenopausal/ postmenopausal: 19/12; White/Hispanic/Black/Asian: 15/14/1/1; Median body mass index: 25.2 kg/m² (20-38); Elevated Gail risk/LCIS/DCIS: 18/8/5; Mean baseline serum 25-OHD: 22 ng/ml (11-31). High-dose vitamin D supplementation resulted in a mean serum 25-OHD at 3 months of 52 ng/ml (24-83), at 6 months of 54 ng/ml (26-75), at 9 months of 53 ng/ml (40-61), and at 12 months of 57 ng/ml (48-71). No significant hypercalcemia (serum calcium >10.5 mg/dl) occurred. One woman withdrew from the study due to hypercalciuria (spot urine calcium/creatinine >0.37) and another dropped out due to worsening gastroesophageal reflux symptoms.

Conclusion: We have demonstrated that a 1-year intervention of high-dose vitamin D3 20,000 IU or 30,000 IU weekly is well-tolerated and able to increase serum 25-OHD above 40 ng/ml in all participants, without any episodes of hypervitaminosis D. The effects of high-dose vitamin D on mammographic density, tissue and serum-based biomarkers of breast cancer risk are currently being evaluated. Large-scale randomized controlled trials are necessary to determine the safety, efficacy, optimal dose and duration of vitamin D supplementation for breast cancer chemoprevention.

5. Sweet Gum Extract Inhibits the Proliferation of Prostate Cancer Through Dual Inhibition of PI3K/AKT and mTOR Pathways

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Purpose: Emerging evidence strongly suggests that activation of the PI3 kinase (PI3K)/Akt and mammalian target of rapamycin (mTOR) pathways promotes the development of prostate cancer. Dual inhibition of both pathways may provide a novel therapy for this disease. In an effort to identify novel dual mTOR/PI3kinase pathway inhibitors, we examined whether antiproliferative effect of Liquidambar styraciflua (sweet gum) was mediated through dual inhibition of these two pathways in prostate cancer cells.

Method: The anti-proliferative effect of sweet gum extract (LIS-100) was tested against human prostate cancer PC3, LNCaP (PTEN null), and DU145 (PTEN wildtype) cells. Cell cycle effect was evaluated with FACS analysis while autophagic cell death was examined by transmission electron microscopy. Western blotting or Functional Proteomic Array (RPPA) were used to determine the effects of LIS-100 on signal-transduction protein expression by prostate cancer cells. These pharmacologic observations were confirmed using siRNA to suppress mTOR expression or genetically elevating the expression of PTEN by plasmid transfection.

Results: Our preliminary study demonstrated that LIS-100 exerted stronger anti-proliferative effects on PC3 and LNCaP cells (IC₅₀ = 1.85 and 2.75 µg/ml, respectively) when compared to DU145 cells (only by 12.7%). LIS-100 inhibited proliferation of PC3 cells by arresting cells at the G2/M phase of the cell-cycle and inducing autophagic cell death in a concentration dependent manner. LIS-100 exerted nearly equal inhibitory activity of PI3K and mTOR (ED₅₀ = 5.5 and 4.25 µg/ml, respectively) in PC3 cells, but preferentially greater inhibition (by 3-fold) of mTOR than PI3K/Akt proteins in PC3 cells. The results from RPPA analysis confirmed that LIS-100 (2.5 to 5 µg/ml) not only markedly inhibited proteins associated with PI3K/Akt/mTOR pathways (e.g., Akt, p70S6K, S6, 4EBP1, GSK3, TSC2), but also suppressed upstream proteins (IGF1r and IRS-1) in the PI3-kinase cell-signaling pathway. Furthermore, the anti-proliferative effect of LIS-100 was reversed by 46% in mTOR siRNA-transfected PC3 cells compared to control oligo, confirming the involvement of mTOR in growth suppression. Similarly, the role of PTEN as a target of LIS-100 (5 µg/ml) elicited inhibition was confirmed by totally reversing its effects in the PTEN-transfected PC3 cells compared to controls. Even though the treatment of LIS-100 at 250 mg/kg lasted only for 7 days, the growth of PC3 tumors in the orthotopic mouse model was significantly inhibited by 51.8 ± 10.2% (p < 0.05). Immunohistologically, Ki67 proliferation marker staining of prostate tumor cells was markedly reduced in tumor bearing mice treated at 250 mg/kg compared to vehicle treatment. Lastly, phosphoprotein staining was noticeably reduced in the tissues treated with 250 mg/kg of LIS-100 comparing to controls samples, particularly those phosphoproteins associated with mTOR and angiogenesis pathways (e.g., p4EBP and MMP2).

Conclusion: Sweet gum extract has shown important potential to inhibit the proliferation of human prostate cancer cells through, at least partially, dual inhibition of PI3K/Akt and mTOR pathways.

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Oral Abstract Session: Qualitative Research

6. Development of a Natural Health Product Decision Aid for Managing Menopausal Symptoms After Breast Cancer Treatment: Needs Assessment Results

Lynda G. Balneaves, University of British Columbia; Alison S.A. Brazier, University of British Columbia; Leah Lambert, University of British Columbia; Dugald Seely, Canadian College of Naturopathic Medicine

Purpose: More than half of breast cancer survivors experience menopausal symptoms following cancer treatment. Many women look towards non-hormonal therapies to help manage symptoms, with natural health products (NHPs) being among the most commonly used treatment options. The use of NHPs is frequently unaddressed in cancer care settings because health professionals often lack the knowledge, time, and resources required to facilitate NHP decisions. Decision support interventions, such as decision aids, are needed as survivors report difficulties in making sense of conflicting information concerning NHPs. Consequently, women are at risk for making uninformed decisions which could result in serious side effects. In phase 1 of a 3-phase project aimed at developing and evaluating a computer-based, interactive NHP decision aid for managing menopausal symptoms after breast cancer treatment, a needs assessment of breast cancer survivors was conducted. The purpose of the needs assessment was to understand the types of therapies women consider or use to manage menopausal symptoms, as well as their need for information and support when making treatment decisions.

Methods: Several focus groups were conducted with breast cancer survivors recruited through two cancer agencies in Canada. Focus groups were 90 minutes in length, digitally recorded and transcribed verbatim. Women were asked how they make treatment decisions to manage menopausal symptoms; whether they experienced conflict related to making these decisions; their current knowledge about treatment options; and the support and resources they access or require to make these decisions. Inductive thematic analysis was used to analyze the data.

Results: Findings highlight that the menopausal symptoms many breast cancer survivors experience, and the challenges they face in finding safe and effective treatment options create a great deal of distress. Women consider many treatments options for managing menopausal symptoms

including pharmaceuticals (e.g., Effexor, lorazepam), NHPs (e.g., black cohosh, St. John's wort), other CAM therapies (e.g., mindfulness-based stress reduction, acupuncture), as well as lifestyle changes (e.g., exercise and diet). When making treatment decisions, women draw on multiple sources of information, including health professionals, the Internet, family and friends, and other survivors. Women report a lack of accessible and credible NHP information to inform their decision making, and experience difficulty in making these decisions. The difficulty is particularly acute due to the estrogen-sensitive nature of many of the women's breast cancers and their concerns about using a NHP that may increase the risk of recurrence (i.e., phytoestrogenic herbs). A number of women choose not to treat their symptoms, even when bothersome, or choose pharmaceutical drugs with unwanted side effects due to a lack of acceptable information regarding NHPs. Women indicate they want to receive condensed, summarized, and credible information on the most promising and safe complementary treatment options.

Conclusion: Specific feedback from the women regarding the treatment options that are of greatest interest to them, and their support needs for making these decisions will inform the content and structure of the NHP decision aid being developed. An overview of the decision aid will be presented.

7. Cancer Treatment Decision Making: Describing and Understanding Patients' Pathways of Care

Marja Verhoef, University of Calgary; Mary Koithan, University of Arizona; Andrea Mulkins, University of Calgary; Emily McKenzie, University of Calgary; Lynda Balneaves, University of British Columbia

Purpose: Cancer treatment decision-making is a complex process taking place over time, impacted by a wide range of variables, and consisting of a variety of treatments. This pilot study aims to describe treatment and care as pathways patients follow during their cancer trajectory.

Methods: We are following a cohort of individuals aged 18-75 with a first-time diagnosis of stage I-III breast or prostate cancer for up to one year. Patient characteristics, treatment decisions (conventional, complementary/alternative and self-care) and salient life events impacting on

treatment decisions are followed over time. Data are collected from medical charts, quantitative questionnaires, qualitative baseline interviews and monthly telephone interviews.

Results to date: Thirty-three participants have been recruited in Canada and the US. For some participants data collection is still in process. While analysis is ongoing, the data show that pathways of treatment and care develop at an early stage in the cancer care trajectory and are often enduring. Some individuals, however, expressed the possibility of exploring other pathways in the future if they did not receive the anticipated results in their chosen route. Examples of emerging pathways include: 1. Aggressive Conservative Path: These are often women with young children living at home who have chosen an aggressive conventional treatment plan, even if they used complementary/alternative (CAM) pre-diagnosis. Once the conventional regime is completed, individuals may begin to explore CAM therapies to help them regain their strength and wellness. 2. Reasoned Conventional Path: These individuals thoroughly assess conventional treatments presented by their physicians and have little interest in exploring CAM options. Often, they consult other patients who have already received the therapy under consideration. Post-treatment they are pragmatic, rarely think about the cancer, and generally do not consider using CAM. 3. Reasoned Integrative Path: These are individuals who believe in the benefits of both conventional and CAM treatment and focus on curing as well as healing. They conduct research in both areas and depend on a wide range of information (evidence) sources. 4. Reasoned Alternative Path: This group includes mostly men with prostate cancer who have made major life changes since their diagnosis preferring to explore natural therapies they believe will heal their bodies.

Factors that appear to influence the chosen pathways include: 1. motivation for treatment, 2. treatment cost, 3. pre-diagnosis life or family events, 4. philosophy of healing, 5. nature of relationship with health care providers, 6. satisfaction with cancer treatment, and, 7. beliefs (especially spiritual beliefs).

Conclusion: Data collected to date confirm the importance of looking at pathways of treatment and care and related treatment decision-making. To date, literature about treatment decisions and care pathways have been based on the choices captured in medical records rather than as explained within the context of patients' lives. Emerging data suggest that decision paths are much more complex and influenced by a host of variables previously unexplored. These findings confirm the need for a larger study in which participants are followed for longer periods of time.

8. "Time is on My Side": The CAM Decision-Making Process of Men Living with Prostate Cancer

Lynda G. Balneaves, University of British Columbia; Jennifer Bell, University of British Columbia; Tracy L.O. Truant, British Columbia Cancer Agency; Marja J. Verhoef, University of Calgary; Joyce Davison, Vancouver Hospital and Health Sciences Centre

Purpose: Individuals living with cancer, including men with prostate cancer, are increasingly turning towards complementary and alternative medicine (CAM) as part of their treatment and survivorship plan. CAM use is being reported by 18-72% of men, depending on the geographical location, stage of disease, treatment, and the definition of CAM used. While research has uncovered some of the motivations behind men's use of CAM during prostate cancer, little is known about their decision-making process. Such knowledge is essential in the development of gender appropriate and disease-specific CAM education and decision support interventions. The purpose of this study was: 1) to explore how men living with early-stage prostate cancer make decisions about CAM and 2) to develop a conceptual model of the overall decision-making process.

Methods: Using grounded theory qualitative methodology, a Purposeful sample of 20 men with early-stage disease was drawn in British Columbia. The men participated in in-depth interviews about their CAM decisions, the factors associated with the decision-making process, and the information sources they used to facilitate their decision. The interviews were transcribed verbatim and open, axial and selective coding and constant comparative analysis was used to identify overall core categories and the related themes.

Results: One overarching core category, "Time is on my side", was identified and was representative of the men's CAM decision-making process. The openness to consider CAM came as a result of the men perceiving themselves as "having the time" to consider CAM as a result of their early-stage of disease, from previous beliefs that pre-disposed them towards CAM therapies, and a desire for control over their illness and treatment options. The men approached the treatment decision from two perspectives: "Casting a wide net" and "Focusing one's treatment approach". Men who casted a wide net had limited past experience with CAM and moved through a whittling down process of seeking credible information, evaluating evidence, establishing trust and weighing risks versus benefits. Focusing one's treatment approach was seen in men who had previously used CAM, had an established relationship with a CAM practitioner and a strong

desire for control. These men tended to monitor the effects of CAM on their symptoms and disease, thus validating the selections they made.

Discussion: The findings of this study suggest that CAM use in men with early-stage prostate cancer is reflective of their previous experiences and autonomy in treatment decisions, as well as of their perception of prostate cancer as being a “slow moving” disease, permitting them time to explore their options. The “Time is on my Side” model provides guidance to health professionals and educators regarding the level and type of CAM information and decision support required by men living with prostate cancer. Specific education and decision support interventions that have been developed and are currently undergoing testing within a CAM research program to address these diverse needs will be discussed briefly.

9. My Living Story: Testing Life Review and Online Social Networks for People with Advanced Cancer

Meg Wise, University of Wisconsin-Madison; Lucille Marchand, University of Wisconsin-Madison

Purpose: Advanced cancer can engender considerable distress and an active search for meaning. A clinic-based life intervention reduced distress in hospice patients (Chochinov, 2002, 2005). We hypothesized that people earlier in the illness trajectory could also benefit from life review and that communication technologies could extend access and provide tools to enhance and share the story. Our NCI-funded randomized study is testing the effects of My Living Story (MLS) on distress and existential well-being for people living with advanced cancer. MLS consists of a life review interview by phone, delivery of an edited life story and a personalized online social network (called miLivingStory) with links to educational resources. We are also exploring satisfaction

with the life review process, social networking use patterns, and themes that emerge from the life stories.

Methods: (1) Study design: Randomized wait-list control. (2) Sample: 100 patients with hematological, Stage III or IV cancer, at least a six-month prognosis, must be willing and able to use the web. (3) Measures at 0, 2, and 4 months: FACIT-Sp (existential well-being), POMS-Bref (distress), demographics, cancer status, and prior computer experience. (4) Analysis: Descriptive statistics to analyze survey data and grounded theory to analyze life stories.

Results: To date, 68 people have been randomized to MLS or control and only 2 have dropped out (due to illness or death). Sample includes 50 women, 18 men; mean age 53 (range 35-80). About half have Stage IV cancer; 90% are on chronic chemotherapy; 53% use CAM. Scores at baseline are low for distress and high for existential well-being (1.2 and 2.8 on a 4-point Likert scale, respectively). 54% have at least a bachelor's degree; 40% work and 30% are retired; 39% already had their own social network. Of the 24 MLS 2-month post-tests, only half used their miLivingStory network; none reported it as very helpful. By contrast, all had participated in the life story interview, 75% rated it as helpful or very helpful. About 40% of wait list control participants have chosen to participate in the life story interview. Major themes emerging from the life stories suggest include: simplicity, forgiveness, gratitude, meaning and Purpose through relationships, legacy, and living in the present with integrity.

Conclusions: This is the first study to test the effects of integrating an expert-elicited life story with online social networking. Introducing a new online social network might not be feasible for people who already have one or for those who must learn to use it. Eliciting and delivering a life story appears to be helpful for people with advanced cancer. We will present selected vignettes representing the major life story themes.

Oral Abstract Session: Using Existing Infrastructure To Collect Data

10. Impact of Education on Practice Patterns and Attitudes of Oncologists Regarding Herbs and Supplements: A National Survey

Richard Lee, M.D. Anderson Cancer Center; Lorenzo Cohen, M.D. Anderson Cancer Center; Olufunmilayo Olopade, University of Chicago; Farr Curlin, University of Chicago

Purpose: Patients commonly ask their oncologists for advice regarding the use of herbs and supplements (HS) during treatment; however, the education of oncologists on this topic remains unclear. This study explored correlations between education on HS by US oncologists and their practice patterns and attitudes on the topic.

Methods: A national probability sample of 1,000 current ASCO members was contacted by mail and email to complete a survey regarding clinical approaches to HS use by cancer patients.

Results: A total response rate of 46% was obtained, 423 out of 927 delivered surveys. The majority of respondents were male (72%) and Caucasian (76%) with an average age of 48. Four out of ten oncologists (41%) reported any education about HS. The primary methods were by informal discussions (79%), lectures (71%), and CME event or conference (39%). The following levels of agreement was found when asked about specific statements: HS help with cancer treatment side effects (34%), HS benefit physical symptoms (38%), HS benefit psychological symptoms (53%), and HS are safe and have minimal side effects (41%). Only one-third (36%) of oncologists felt they knew enough about HS to answer their patients' questions. On average, oncologists talked to 41% of their patients about the use of HS and 67% stated either sometimes or often supporting the use of HS. The majority of oncologists (87%) had provided chemotherapy along with HS in the past year. For patients with a curable cancer, 81% of respondents would discourage the use of an unknown herb with chemotherapy, while only 37% would do so for an incurable patient. When asked about four clinical scenarios involving herbs (St. John's Wort, soy, Gingko biloba, and Kava kava), 56-84% were able to answer the questions correctly; however 55-79% of oncologists felt unsure about their answers. Reporting any education about HS was correlated with higher likelihood to initiate a discussion with patients about HS (OR 3.3, $p < 0.01$), being sure about their answers

regarding the four herbal clinical scenarios asked (OR 2.1, $p < 0.01$), and being able to answer patients' questions about HS (OR 3.5, $p < 0.01$) in multivariate analysis.

Conclusion: Most US oncologists have not received any education about HS and this is correlated with their self reported ability to answer patients' questions about herb and supplements. As indicated by this study, oncologists commonly provide chemotherapy to patients currently using HS, and thus more education needs to be provided to practicing oncologists about HS to ensure safe and effective cancer treatment.

11. Paediatric Oncologists' Attitudes Towards Complementary and Alternative Medicine in Germany

Alfred Laengler, Gemeinschaftskrankenhaus Herdecke; University Witten/Herdecke, Center for integrative medicine; Rieke Boeker, University of Marburg; Friedrich Edelhaeuser, University Witten/Herdecke, Center for integrative medicine; Genn Kameda, Gemeinschaftskrankenhaus Herdecke; Georg Seifert, Charite, Universitaetsmedizin, Berlin

Background: Complementary and alternative treatment- Methods (CAM) are gaining increasing importance both in general paediatrics and in paediatric oncology (PO). Various international studies have focused on medical oncologists as well as paediatricians attitudes towards CAM. In PO, however there has been no systematic research on paediatric oncologists' attitudes towards CAM till now. We are presenting the results of a survey of German paediatric oncologists on their attitudes towards CAM.

Methods: A semi-validated questionnaire was distributed to all medical members of the Association for PO in Germany (GPOH). Descriptive statistics were gathered and correlation coefficients were calculated.

Main Results: 177 physicians, among them 69 women and 108 men with a median PO-experience of 12 years, completed the survey for an overall response rate of 25%. Of the respondents 62% work in an university hospital; 66% are in the position of a registrar or head of department. Doctors' readiness to begin talks is influenced by their knowledge and their attitude towards CAM. In 39% of all cases a discussion about

using CAM is initiated only by patients or their parents. Eighty percent of all paediatricians say that CAM therapies should be used only after conventional medical treatment ended or if it failed. They are mainly concerned about potential harmful interactions with conventional medicine and additional costs for patients. Forty-nine percent of all respondents say that they have no knowledge of CAM, 36% gained their knowledge out of personal interest. More than 70% of the respondents stated, that they have an interest to integrate CAM as an integral part into the curriculum of medical schools as well as part of post-graduate continuous medical education.

Main Conclusions: Despite concerns over simultaneous use of CAM in conventional medical treatment, talking about CAM therapies is no routine procedure in patient-physician dialogue. Knowledge of CAM should be part of medical education.

12. A Descriptive Analysis of Participants in the Integrative Medicine Program at The University of Texas M.D. Anderson Cancer Center—Looking Back at a Decade of Service

Laura Fletcher, The University of Texas M.D. Anderson Cancer Center; Richard T. Lee, The University of Texas M.D. Anderson Cancer Center; Noel Salcedo, The University of Texas M.D. Anderson Cancer Center; Lorenzo Cohen, The University of Texas M.D. Anderson Cancer Center

Purpose: Results from a surveys conducted at The University of Texas M.D. Anderson Cancer Center indicate that between 50-80% of cancer patients are using some form of complementary/integrative medicine (CIM) therapy. The purpose of this retrospective review was to describe the characteristics of participants (patients and caregivers) of the Place...of wellness, the integrative center at M.D. Anderson since 1998.

Methods: Place of wellness participants complete an initial registration questionnaire which includes, demographics (age, gender, ethnicity), cancer diagnosis and stage, and previous use of CIM. Additionally, participation in programs and services is tracked. Individual participant data since the establishment of the Place of wellness in September, 1998 (N=22,445) was reviewed. Specific programs evaluated included acupuncture, energy modalities, expressive arts, hatha yoga, kundalini yoga, massage, meditation, movement, music therapy, nutrition, relaxation, tai chi, and Tibetan practices.

Results: The majority of the participants were women (71%), Caucasian (71%) and from Texas (57%) with mean age of 51.5 years. Fifty-one percent were patients and 21% were the spouse or significant other with the remain-

ing being family members or friends. The most common diagnoses were breast (15%), hematology (16%), gastrointestinal (10%), lung (7%), and genitourinary cancers (5%) with 26% considered unknown or diagnosis not provided. Eighty-one percent were in active treatment at the time of registration. Of those who responded to the inquiry about previous use of CIM (N=20470), 28% stated that they had used some form of CIM. The most commonly used therapies were massage (57%), prayer/meditation (41%), yoga (29%), chiropractic (28%), and herbs (24%). Over 60,804 total encounters were documented during the past decade. The most common programs utilized were massage (16,596); music therapy (6,780); yoga (5,838); acupuncture (4,803) only offered for the past 5 years; and energy modalities including qi gong, reiki, and healing touch (4,745). Participants commonly used these therapies only once. Ninety percent of participants using massage only had a maximum total of four sessions; similarly participants using energy modalities, yoga, and music therapy only had a maximum total of seven sessions. Only 10% of patients used more than ten acupuncture sessions.

Conclusion: Cancer patients and caregivers at M.D. Anderson have utilized many of the CIM therapies offered with acupuncture, energy modalities, yoga, massage, and music therapy being the most common. Surprisingly, approximately half of the participants were caregivers. Patients and caregivers may benefit from further education of the benefits of CIM and the role it can play in cancer care. Analysis of associations between patient characteristics and the CIM utilized is ongoing and this will likely be helpful to other centers establishing CIM programs.

13. The Urban Zen Initiative: A Pilot Study to Implement an Optimal Healing Environment on an Inpatient Oncology Floor

Benjamin Kligler, Beth Israel Medical Center, New York City; Peter Homel, Beth Israel Medical Center, New York City; Esther Sackett, Beth Israel Medical Center, New York City; Jeanne Kenney, Beth Israel Medical Center, New York City; Stewart Fleishman, Beth Israel Medical Center, New York City

Purpose: Studies have suggested that techniques such as relaxation and yoga can have widespread beneficial effects on patient outcomes such as pain, fatigue, mental health, spirituality, as well as on the physiological responses to radiation and chemotherapy. Many of the complementary medicine interventions in the literature have involved patients in a ambulatory care setting. This presentation describes the Urban Zen Initiative (UZI) at Beth Israel Medical Center and its impact on cancer patients in an inpatient hospital setting.

Methods: The clinical interventions which underlie the UZI were based on the concept of an “optimal healing environment,” and included remodeling the physical space; holistic nursing techniques; training for the nursing staff (relaxation therapies, imagery, aromatherapy protocol); and yoga therapists on the unit to work one-on-one with patients. Study groups consisted of 1) a control group of patients admitted to the oncology unit while the intervention was still in the planning phase, and 2) a treatment group of patients admitted after the UZI intervention was implemented. The primary goal of this intervention was to improve the quality of patients’ experience when admitted to the hospital for cancer care. Outcome measures (Profile of Mood States Brief Form and EQ-5D) were collected immediately after admission and immediately before discharge. In-person interviews were also conducted with a subset of patients immediately prior to their discharge.

Results: 89 patients were enrolled in the Pre UZI Phase sample and 74 in the Post Phase. Mean +/- SD age of the Pre group was 53 ± 17 and 54 ± 15 for the Post group ($p = 0.55$). 45 % of the Pre group was female compared to 51% of the Post group. The majority of both groups were being treated for malignancy. On the POMS, levels of Tension, Depression, Fatigue, and Mood Disturbance were significantly lower after implementation of UZI ($p = 0.009$; $p = 0.03$; $p = 0.03$; 0.008), while levels of Vigor were significantly higher ($p = 0.001$). On the EQ5D, mobility scores worsened during the pre UZI phase, but improved during the Post Phase ($p = 0.03$). Pain and discomfort decreased during both the pre and post UZI phase but the rate of improvement during the post phase was significantly greater ($p = 0.01$). Four major themes emerged in the qualitative analysis of the interview: 1) Fear and its antidotes: information/caring/connection; 2) “I want to be home”/ Impact of the Physical Environment; 3) Symptom control; and 4) Learning new things (“Surprise/Amazement”).

Conclusion: This study provides support for the impact of a “healing environment” intervention on the subjective experience of patients on an inpatient oncology unit. The data from the POMS and EQ5D analyses show that the intervention engendered lower levels of anxiety and stress than in the pre-UZI cohort. The qualitative data strongly supports the hypothesis that the yoga intervention and the presence of a quiet, healing physical space contributed to greater symptom control and overall well-being during the hospital stay.

14. Low Dietary Intake of Calcium Associated with Increased Risk of Fracture in Males Undergoing Treatment for Acute Lymphoblastic Leukemia

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Purpose: Bone fractures occur frequently in children undergoing treatment for acute lymphoblastic leukemia (ALL). Prospective studies suggest that high dietary calcium intake is associated with improved bone mineralization and reduced fracture risk in healthy children and adolescents. Preliminary results of a prospective multi-institution study investigating dietary micronutrient intake and treatment related toxicity in children receiving treatment for ALL are reported.

Methods: Assessment of dietary intake is incorporated within the ongoing DFCI ALL Consortium Protocol 05-001. Institutional review board approval was obtained by each participating center. Dietary intake is assessed in children ages 2-18 yrs using the pediatric Harvard Food Frequency Questionnaire. Associations between dietary intake and risk of fractures were analyzed for those participants for whom bone toxicity data were available using SPSSv17.

Results: Dietary intake at diagnosis and its association with bone toxicity was analyzed for 176 participants. Mean age was 6.6 yrs (SD 4.4) and 77 were female, 98 were male. Leukemia risk classification included 112 Standard Risk and 63 High Risk. Daily calcium intakes less than the Daily Recommended Intake (DRI) were observed in 42 (54%) females and 69 (70%) males at time of diagnosis of ALL. Fractures were subsequently observed in 11 females and 11 males. Among males only, calcium intake below the DRI at diagnosis was associated with an increased risk of fracture (OR 5.5; 95% CI 1.5, 20.7), even after adjusting for age or leukemia risk category. Risk of fracture further increased in males with intake <DRI for both vitamin D and calcium (OR 8.0; 95% CI 1.1, 55.1).

Conclusion: Males undergoing treatment for ALL with low intakes of calcium are at increased risk for developing fractures, independent of age and leukemia risk group. Dietary interventions aimed at improving intake of calcium and vitamin D during treatment for ALL requires further study.

15. The Prognostic Role of Quality of Life Assessment in Ovarian Cancer

Donald Braun, Cancer Treatment Centers of America; Diagnt Gupta, Cancer Treatment Centers of America; Edgar Staren, Cancer Treatment Centers of America

Purpose: There is accumulating evidence that quality of life (QoL) provides information on patient longevity independent of known prognostic factors. We investigated whether QoL functional domains and symptom items could provide prognostic information for ovarian cancer patients treated with integrative oncologic therapy.

Methods: 246 ovarian cancer patients treated at two single-system cancer centers between Jan 2001 and Dec 2008 were investigated. QoL was evaluated prior to initiation of treatment using EORTC-QLQ-C30 which incorporates a global, 5 functional and 9 symptom scales. Scores range from 0-100 with higher scores in the global and functional scales and lower scores in the symptom scales indicating better QoL. Patient survival was defined as the time interval between the date of first patient visit and the date of death from any cause/date of last contact. Univariate and multivariate Cox regression analyses were performed to evaluate the prognostic significance of QoL after controlling for the effects of age, tumor stage and prior treatment history.

Results: Mean age at presentation was 54.7 years. There were 40 analytic (newly diagnosed) and 206 non-analytic patients (recurrent disease). Stage of disease at diagnosis was I, 25; II, 20; III, 123; IV, 64; and 14 indeterminate. Median overall survival was 18.8 months (95% CI: 14.9-22.6). Mean global QoL scores were 58.3 and 57.6 for locoregional and metastatic disease ($p=0.83$) and 60.6 and 57.1 for analytic and non-analytic disease ($p=0.39$). On univariate analysis, QoL scales predictive of survival were physical ($p=0.003$), fatigue ($p=0.02$), nausea/vomiting ($p=0.01$), pain ($p=0.03$) and dyspnea ($p=0.001$). Upon multivariate analyses, only nausea/vomiting ($p=0.01$) and dyspnea ($p=0.02$) were predictive of survival independent of other QoL scales, age, stage, and treatment history. Prior treatment history also predicted worse survival ($p<0.001$).

Conclusion: Baseline QoL provides useful prognostic information in ovarian cancer as well as guidance for the inclusion of alternative treatment modalities to conventional cancer care. These findings demonstrate that QoL symptoms that are amenable to alternative therapies may aid decision-making in clinical practice and should be considered when designing clinical trials

Oral Abstract Session: Studies In Progress

16. The Development, Component Parts, and Models of Care of Integrative Oncology: A Scoping Review

Dugald Seely, The Canadian College of Naturopathic Medicine; Sarah Young, The Canadian College of Naturopathic Medicine; Laura Weeks, Ottawa Hospital Research Institute; Isabelle Gaboury, University of Calgary

Purpose: With a growing acceptance of and interest in integrative oncology care we systematically explored the literature for information on both facilitators and barriers to the development and sustainability of integrative oncology clinics internationally. As part of this process and to better understand commonalities and differences between integrative oncology centres we aimed to explore and document both components of, and dynamics of, care within these clinics.

Methods: We conducted a scoping review, which included searching eight electronic databases from inception to March 2010 for papers that included data on integrative oncology clinics. To be included in the review, papers had to describe: the addition of complementary care to conventional cancer care; a service for cancer patients and survivors; and original research or a description of the process of cancer care. Data was extracted according to six main concepts comprising 88 data elements. The main concepts included: 'description of the article', 'description of the clinic', 'components of care', 'clinic organizational structure and behaviour', 'patient interactions through the clinic', and 'measurable outcomes employed'.

Results: A broad screen of 828 records resulted in 96 manuscripts to review for potential inclusion, of which 34 were included in the scoping review. A total of 18 integrative clinics providing care to cancer patients and survivors were described. Approximately 60 percent of the centres (n=11) seek to conduct research, while the rest did not report on this aspect. Nearly 40% (n=7) of the centres provide conventional care on location in addition to complementary medicine whereas four (22%) provide only complementary care. All clinics espoused a philosophy of integrative care and the remaining 45 percent of the clinics (n=8) reported a process to enable collaboration with conventional practitioners. Compensation patterns, funding, organizational structure, patient demographics, practitioner accreditation and training and clinical outcomes were poorly reported overall. The data from the literature we were able to access suggest distinct

models for UK and USA based integrative cancer care. Clinics described within the UK are most often cancer support centres adjacent to conventional cancer clinics that provide free counseling, information resources, navigation services, and light touch therapies. The USA model often involves larger cancer centres within hospital and academic settings that combine conventional care and complementary therapies. Educational programs involving seminars, workshops, yoga, and relaxation classes are key components identified in the USA model.

Conclusion: The literature provides several examples of models of integrative oncology care and suggests that distinct models operate within the UK and USA. While we gained a general understanding of the components of such care there is a lack of information regarding facilitators and barriers to the development and sustainability of such clinics. We plan to follow up with the centres identified in this review to further explore these concepts.

17. Development of a Brief Yoga Intervention Implemented while Patients are Undergoing Chemotherapy for Recurrent Ovarian Cancer: The Journey

Stephanie Sohl, Wake Forest University Baptist Medical Center; Julie Schnur, Mount Sinai School of Medicine; Leslie Daly, Mount Sinai School of Medicine; Kathryn Suslov, Mount Sinai School of Medicine; Guy Montgomery, Mount Sinai School of Medicine

Purpose: The primary goal of any therapy for patients who have persistent or recurrent ovarian cancer is shifted from solely pursuing a cure to the control of symptoms and overall maximization of quality of life. Yoga interventions have been found to improve symptoms and quality of life in cancer patients. The present report presents feasibility data and a preliminary exploration of the immediate effects of a brief yoga intervention for patients undergoing chemotherapy for recurrent ovarian cancer.

Methods: Women undergoing chemotherapy for recurrent ovarian cancer were recruited. Qualitative interviews with this population prior to recruitment revealed an interest in yoga with resistance to making additional appointments or having lengthy sessions. Thus the Yoga Skills Training (YST) was designed to be 15-minutes in duration and implemented during patient visits. Participants were also given

questionnaire packets every three weeks, linked to the same chemotherapy appointments. VAS scales assessed relaxation and anxiety before and after each YST session. In addition, participants completed the Cancer Behavior Inventory (self-efficacy), the State Trait Anxiety Inventory, the Brief Pain Inventory, and the Functional Assessment of Cancer Therapy Fatigue at each time point.

Results: Of the 17 eligible patients, 7 participated in the present study (40%). Participants had a mean age of 61.7 years, were 100% White, 86% non Hispanic, and 43 % married. Non participants had a mean age of 69.9 years, were 70% White, 70% non Hispanic, and 60% were married. There was also attrition over time: Time 2 (n=4); Time 3 (n=3); Follow-up (n=3). Immediate effects of the YST revealed large effect sizes for changes in anxiety (d=1.20), relaxation (d=-0.98) and self-efficacy for coping with cancer (d=0.97). Graphs of longitudinal data indicated a reduction in anxiety over time and no clear trajectory for pain and fatigue.

Conclusion: Although increasing evidence supports the effectiveness of yoga, there are logistical challenges to engaging in this intervention for patients with recurrent ovarian cancer. Results showed immediate improvements in anxiety, relaxation, and self-efficacy, which may persist beyond the initial intervention. These large effects suggest that even a one-time intervention may be valuable. If YST is indeed found to be effective in future studies, the brevity of the intervention may facilitate the integration of yoga into the current health care system.

18. A Pilot Study of Gentle Yoga for Non-Small Cell Lung Cancer Patients

Judith Fouladbakhsh, Wayne State University; Davis Jean, Wayne State University; Kowalewski Kathleen, Wayne State University; Schultz Robert, Children's Hospital of Michigan; Szczesny Susan, Wayne State University

Purpose: Although more than 7 million U.S. cancer survivors use complementary and alternative medicine therapies, only a small percentage (4.1%) use yoga as a self-care practice. The emerging literature on yoga provides support for feasibility and effectiveness for cancer patients, although clinical trials are lacking among males and those affected by lung cancer. This study examined the feasibility of a yoga intervention for post treatment lung cancer patients living in the community. Specific aims include: 1. Explore the feasibility of a standardized yoga intervention with post-treatment non-small cell lung (NSCL) cancer patients, identifying factors that influence enrollment, attendance and adherence to a standardized yoga intervention program and home prac-

tice. 2. Obtain preliminary data of effects of yoga on dyspnea, sleep, distressed mood, and quality of life.

Methods: This quasi-experimental pilot study used a one-group repeated measures design that included: a 3-week pre-intervention phase, an 8-week intervention phase (45-minute weekly yoga classes with home practice) and a 3-week post intervention phase, with a 3 and 6-month follow-up. Adults (18 years of age and older) with Stage I-IIIa NSCL who had completed initial cancer treatment were eligible for enrollment. Analysis included descriptive statistics, repeated measures ANOVA models using SPSS 18.0 software, and analysis of salivary cortisol samples at the WSU College of Nursing Biophysiology Laboratory. Outcome measures include dyspnea score (VAS), pulse oximetry & spirometry values, sleep measures (PSQI), mood (POMS-brief) & QOL (SF-36). The CAM Healthcare Model (Fouladbakhsh & Stommel, 2007) guided the study.

Results: A pilot sample of Stage I-IIIa NSCL patients (N= 6 females; 3 males), ages 51-78, were recruited; despite advanced age and morbidity, 7 participants successfully completed the 14 week study with no untoward effects; attendance exceeded 95%. Six-month follow-up is in progress. Mild to moderate dyspnea was reported by 25-50% with 2 reporting concurrent COPD and emphysema; significant decreases (p<0.05) were noted in dyspnea and reports of tension following yoga sessions; no increased respiratory distress was noted throughout the study period. Improved sleep quality and decreased use of sleep medication (65% during intervention) were reported. All participants completed home practice logs indicating consistent use of the Study Home Practice Manual; 6 of 7 (1 unavailable) practicing at 3 month follow-up. Statistical (repeated-measures) and biological specimen analysis in progress.

Conclusions: Factors influencing enrollment in the yoga intervention have been identified. Patterns of improved sleep quality, decreased use of sleep medication and continuing yoga practice have been noted. Information obtained on the feasibility and outcomes of the yoga intervention will guide and support future research studies on yoga for non-small cell lung cancer patients and survivors.

19. Acupuncture for Chemotherapy-Induced Fatigue: A Randomized Controlled Trial

Gary Deng, Memorial Sloan-Kettering Cancer Center; Yi Chan, Memorial Sloan-Kettering Cancer Center; K. Simon Yeung, Memorial Sloan-Kettering Cancer Center; Andrew Vickers, Memorial Sloan-Kettering Cancer Center; Barrie Cassileth, Memorial Sloan-Kettering Cancer Center

Background: Many cancer patients develop fatigue during chemotherapy. Some continue to experience chronic fatigue after the completion of chemotherapy even when no medical etiology can be identified. Currently there is no reliable treatment chemotherapy induced chronic fatigue. In a previous single armed study, acupuncture appeared to reduce fatigue in this population of patients.

Purpose: The primary objective is to determine whether acupuncture reduces chronic fatigue after chemotherapy more effectively than placebo.

Methods: Prospective randomized sham-controlled trial with a power of 90% and an alpha of 5% to detect a 20% difference in post-treatment fatigue scores between the treatment group and the control group.

Results: Cancer patient without anemia or thyroid dysfunction who reported moderate to severe fatigue persisting for at least two months following completion of chemotherapy were randomized to receive true or sham acupuncture once weekly for six week. One hundred and one patients were enrolled and randomized to true (n=49) or sham (n=52) acupuncture. Patients randomized to the true acupuncture group were crossed over to receive true acupuncture in week 8. Brief Fatigue Inventory, Hospital Anxiety and Depression Scale and Functional Assessment of Cancer Treatment Scale were evaluated before, during and after the treatment period and will be reported.

20. Psychosocial Distress in Advanced Cancer Patients: An Overview of Psilocybin-Assisted Psychotherapy and the Ongoing New York University Phase II Pilot Study

Alexander Belser, M.Phil, Columbia University, Teachers College

Purpose: The primary objective of this double-blind, placebo-controlled pilot study is to assess the efficacy of psilocybin administration (4-phosphoryloxy-N,N-dimethyltryptamine), a serotonergic psychoactive agent, on psychosocial distress, with the specific primary outcome variable being anxiety associated with advanced, recurrent or poten-

tially life threatening cancer. Researchers at New York University School of Medicine and Bluestone Center for Clinical Research are conducting this Phase II pilot study investigating the effects of psilocybin on anxiety and psychosocial distress in advanced cancer patients. Psilocybin is a psychoactive agent found in a specific type of mushroom and used for centuries for religious and spiritual purposes. This study is separate but similar to a recently completed study at the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, and to an ongoing study at the Johns Hopkins University. A secondary objective of the study is to determine the feasibility of administering psilocybin to this patient population, with regards to the following issues: safety, patient recruitment, consent for treatment, and retention.

Methods: The study utilizes a randomized, double blind, placebo-controlled crossover design at 7 weeks and includes prospective follow-up of 6 months duration. The dose of psilocybin is 0.3mg/kg and the total subjects for the study is 32. Nine sessions of psychotherapy are conducted with two dedicated therapists, constituting a therapeutic dyad. Secondary outcome measures will look at the effect of psilocybin on symptoms of pain perception, depression, existential/psychospiritual distress, attitudes towards disease progression and death, quality of life, and spiritual/mystical states of consciousness. Stephen Ross, M.D., Director of the Division of Alcoholism and Drug Abuse at Bellevue Hospital, is the Principal Investigator of this project. Subject enrollment began in April, 2009.

Results: As this Phase II study is currently underway, we have collected preliminary data; relevant outcomes from our sister studies at UCLA and Johns Hopkins will be addressed. We will present an overview of the study design and hope to foster collaboration between professionals dedicated to studying and facilitating cancer treatment and researchers using this novel compound and therapy modality.

Conclusion: It is hypothesized that a one time experience with psilocybin will occasion dramatic shifts in consciousness and meaningful spiritual experiences that will lead to short-term and long-term improvement in anxiety, depression, and pain associated with advanced cancer.

Oral Abstract Session: Basic Science Research

21. Helleborus Niger Induces Apoptosis Via an Anti-Mitochondrial Mode of Action in Neuroblastoma Cells

Patrick Jesse, Department of Pediatric Oncology/ Hematology, Charité Universitätsmedizin Berlin; Catharina Delebinski, Department of Pediatric Oncology/ Hematology, Charité Universitätsmedizin Berlin; Günter Henze, Department of Pediatric Oncology/ Hematology, Charité Universitätsmedizin Berlin; Georg Seifert, Department of Pediatric Oncology/ Hematology, Charité Universitätsmedizin Berlin

Purpose: Helleborus niger, also known as Christmas Rose, belongs to the family of Ranunculaceae, a family of flowering plants with about 2500 different species. Helleborus niger (HN) as a homeopathic remedy is used in anthroposophic-extended cancer therapy in the adjuvant treatment of different malignancies. Until now, only limited preclinical and clinical data are available. We recently reported on apoptosis-inducing activities of HN in different hematological malignancies and primary cells of patients with childhood ALL and AML. In this new study, we evaluated the effect of HN in the neuroblastoma cell line NXS2. Neuroblastoma is the most common solid extracranial tumor in childhood and is associated with overall poor survival in high-risk patients and recurrent relapse, so that new treatment alternatives are needed to improve outcome.

Methods: In vitro effects of an aqueous root extract of HN were evaluated on the neuroblastoma cell line NXS2 by measuring LDH release, Annexin/PI staining, transition of the mitochondrial membrane potential and Western Blot analysis.

Results: To exclude an unspecific, necrotic damage to the cell surface LDH release was measured after 4 hours of incubation with HN. Measurements revealed a very low LDH release, thus cell viability was over 90% in all concentrations used. After 24 and 48 hours Annexin/PI staining showed a dose- and time- dependent distinction into early and late apoptotic cells, identifying apoptosis as major cause of cell death. In Western Blot analysis an activation of Caspase-3, the main executioner caspase of apoptosis, could be found after 36h incubation with the extract. A dose-dependent breakdown of the mitochondrial membrane potential was determined after 24 and 48 hours, revealing that an anti-mitochondrial mode of action is responsible for HN induced cell death. In this line, activation of caspase-9 was determined via Western Blot analysis, identifying an involvement of the intrinsic apoptosis pathway in HN induced apoptosis.

Conclusion: For the first time we were able to show, that an extract of Helleborus niger induces apoptosis in the neuroblastoma cell line NXS2. Apoptosis is executed via an anti-mitochondrial mode of action associated with a breakdown of the mitochondrial membrane potential and caspase-9 activation. Dose- and time-dependent experiments showed strongest apoptotic effects after 48 hours, revealing that rather late than early apoptotic- pathways may play a role in HN induced cell death. First results in a SCID/CB17 mouse model revealed a good tolerability of HN in vivo. Trials of HN in SCID/CB17 neuroblastoma and leukemia mouse models are currently ongoing with results expected soon.

22. Cellular Location and Expression of Na, K-ATPase Alpha3 Subunits Affect the Anti-Proliferative Activity of Oleandrin

Peiyang Yang, The University of Texas, M. D. Anderson Cancer Center; Imad Shureqi, The University of Texas, M. D. Anderson Cancer Center; Carrie Cartwright, The University of Texas, M. D. Anderson Cancer Center; Crandell Addington, Phoenix Biotechnology Inc; Robert Newman, The University of Texas, M. D. Anderson Cancer Center

Background: We have previously reported that the differential anti-proliferative effect of a lipid soluble cardiac glycoside, oleandrin and the clinical product PBI-05204 that contains oleandrin, on human and mouse pancreatic cancer cells was correlated with expression of Na, K-ATPase alpha3 isoform (Yang, P., Molecular Cancer Therapeutics, 8: 2318, 2009) in those cells. In the current study, we investigated the role of the relative distribution and expression of Na, K-ATPase alpha3 isoform in oleandrin elicited anticancer activity in human colon cancer.

Methods: The anti-proliferative effect of oleandrin on undifferentiated and differentiated human colon cancer CaCO2 cells was measured by BrdU staining. The location and distribution of Na, K-ATPase alpha3 isoform in human tissues or cells were determined by immunohistochemistry and fluorescence staining. The expression of ERK and pERK protein was evaluated by western blotting technique.

Results: It has been reported that the Na,K-ATPase alpha3 isoform is primarily located in the plasma membrane of neurons, however, the distribution of alpha3 isoform in tumor tissues has yet to be examined. The results of immunohistochemical staining suggested that the alpha3 isoform

was predominantly located in the cytoplasmic membrane in normal (non-malignant) lung and colon tissues. In contrast, the location of this enzyme isoform in malignant lung and colon tumor tissues was shifted to a peri-nuclear location. The level of alpha3 isoform in the nucleus was only 25% of that in the cytoplasm in normal lung tissues, whereas the nuclear concentration of this isoform was almost 4-fold higher than that of cytoplasmic location in paired lung tumor tissues. Intriguingly, distribution of alpha3 isoform was also shifted from a peri-nuclear position in the undifferentiated wild-type human colon cancer CaCO2 cells to a cytoplasmic membrane location in differentiated CaCO2 cells as assessed by fluorescence alpha3 staining. Transmission electron microscopic examination indicated that oleandrin (5-10 nM) caused undifferentiated CaCO2 cells to undergo autophagic cell death as evidenced by the presence of autophagosomes and increased numbers of vacuoles, but no such phenomena occurred in oleandrin treated differentiated CaCO2 cells. Furthermore, oleandrin exerted relatively strong anti-proliferative activity in undifferentiated CaCO2 cells (IC50, 6.25 nM), whereas less than 20% inhibition of cell proliferation in differentiated CaCO2 cells even with use of as high as 25 nM concentration of oleandrin. Noticeably, oleandrin altered the phosphorylation of ERK in undifferentiated CaCO2 cells, but not in differentiated CaCO2 cells.

Conclusion: Taken together, these preliminary data suggest that the location of Na,K-ATPase alpha3 isoform was altered in human tumor tissues or cells in comparison to that in normal tissue or well differentiated cancer cells. The alteration of the cellular location of this particular isoform appears to affect the anti-proliferative activity of oleandrin and products such as PBI-05204 that contain this lipid soluble cardiac glycoside.

23. An Extract from Toad Skin, Huachansu, Strongly Enhances Radiosensitivity of Human Lung Cancer Cell Lines

Li Wang, University of Texas M.D Anderson Cancer Center; Luka Milas, University of Texas M.D Anderson Cancer Center; Uma Raju, University of Texas M.D Anderson Cancer Center; David Molkentine, University of Texas M.D Anderson Cancer Center; Peiyang Yang, University of Texas M.D Anderson Cancer Center

Purpose: Huachansu (HCS), an extract from dried toad (*Bufo gargarizans* or *B. melanostictus*) skin, contains biologically active substances including steroidal cardiac glycosides and indole alkaloids. It possesses antitumor activity and is well tolerated by cancer patients. The present study examined whether HCS enhances radiosensitivity of cancer cells.

Methods and results: Three human lung cancer cell lines, H460 and A549 (p53 wild type), and H1299 (p53 null) were used. They exhibited dose-dependent cytostatic and/or cytotoxic responses to 24 h treatment with HCS, with an IC50 of approximately 20 mg/ml assayed by cell viability. IC50 dose was used in subsequent experiments in combination with IR. Treatment endpoint was clonogenic cell survival determined 12-14 days after irradiation with 2-6 Gy, with or without HCS. Cells were treated with HCS for 24 h before IR or was added immediately post exposure for 24 h. A 24 h pretreatment, but not post IR treatment, strongly enhanced radiosensitivity of H460 and A549 cells, with enhancement factors of 1.91 and 1.94, respectively, at 50% survival. Neither HCS treatment scheme affected radiosensitivity of H1299 cells. HCS pretreatment of H460 and A549 cells significantly prolonged the presence of radiation-induced double-strand breaks detected on the basis of γ H2AX foci at 30 min, 4, 16 or 24h after 2 Gy IR. This suggests that inhibition of DNA repair may be an underlying mechanism of HCS-induced enhanced radiosensitivity. In addition, H460 and to lesser degree A549 cells treated with HCS were more susceptible to radiation-induced apoptosis. For example, the percentage of apoptotic cells (TUNEL) in H460 exposed both to HCS and 4 Gy (measured 24 h after IR) was $43.4 \pm 1.1\%$, a value significantly higher than additive values of $5.2 \pm 1.2\%$ (HCS treatment alone), $10.5 \pm 2.7\%$ (IR alone). The percentage of apoptotic cells in untreated control was $4.2 \pm 0.9\%$. This finding was supported molecularly by increased expression of cleaved caspase-3 and decreased expression of Bcl-2 analyzed by Western blot. Thus, increased susceptibility of cells to radiation-induced apoptosis is another mechanism underlying HCS-induced enhancement of cell radiosensitivity. Additional experiments showed that treatment of H460 and A549 cells with HCS induced no significant changes in cell cycle distribution to affect radiosensitivity.

Conclusion: In conclusion, our findings demonstrated that HCS strongly enhanced radiosensitivity of human lung cancer cell lines and that major underlying mechanisms included inhibition of DNA damage repair and increase in radiation-induced apoptosis. The observed radiosensitizing effect seems to be related to p53 status as only the p53 wt cell lines responded. These data suggest that HCS may have potential to improve the efficacy of radiotherapy.

24. Effect of Coenzyme Q10 on Doxorubicin Cytotoxicity in Breast Cancer Cell Cultures

Jacquelyn Shaw, Herbert Irving Comprehensive Cancer Center, Columbia University; Ying Ka Ingar Lau, Herbert Irving Comprehensive Cancer Center, Columbia University; Heather Greenlee, Department of Epidemiology, Herbert Irving Comprehensive Cancer Center, Columbia University; Matthew Maurer, Department of Medicine, Herbert Irving Comprehensive Cancer Center, Columbia University

Purpose: Doxorubicin is a standard adjuvant therapy for early-stage breast cancer and is the most important drug for the treatment of diffuse large B-cell lymphoma. In both cases, it significantly improves disease-free and overall survival. However, 3-20% of patients develop chronic cardiomyopathic changes and congestive heart failure due to doxorubicin therapy. Doxorubicin-induced cardiotoxicity is thought to be due to increased generation of reactive oxygen species (ROS) within cardiac myocyte mitochondria. Coenzyme Q10 (CoQ10) is a lipid-soluble antioxidant that may protect against mitochondrial ROS, and thus prevent doxorubicin-induced cardiotoxicity. Despite the potential benefits of CoQ10 in preventing cardiotoxicity, it is unknown if CoQ10 diminishes the desired pro-oxidant antineoplastic effects of doxorubicin therapy. This study examines the cellular uptake and effects of CoQ10 on doxorubicin cytotoxicity in breast cancer cell cultures.

Methods: Breast cancer cell line MDA-MB-468 was tested for its ability to uptake exogenous CoQ10 over a dose range of 0.09uM to 9uM. In humans, the standard supplementation dose raises plasma CoQ10 levels from 0.5uM to 2uM; breast cancer patients have a typical plasma level 0.9uM. MDA-MB-468 cells were treated with CoQ10 for 48 hours, then washed and homogenized. Homogenate CoQ10 concentration was determined using High Performance Liquid Chromatography (HPLC) and normalized using a protein quantification assay. To determine if CoQ10 affects doxorubicin cytotoxicity, breast cancer cell lines MDA-MB-468 and BT549 were treated with doxorubicin at each cell line's IC50 concentration (MDA-MB-468 IC50 determined to be 36.9nM and BT549 IC50 determined to be 211.6nM) and a dose range of 0.09uM to 9uM of CoQ10 for 72 hours. A proliferation assay determined the percent growth inhibition of each drug therapy combination, including that of CoQ10 as a single agent.

Results: We demonstrated that CoQ10 concentration increases exponentially as higher exogenous concentrations are administered to cells. Adding 0.09uM of CoQ10 increased the amount detected from 30.7ug CoQ10 per ug

protein (when no CoQ10 was added) to 53.2ug CoQ10. Adding 0.9uM and 9uM CoQ10 increased detected levels even higher to 140.5ug and 1,468ug CoQ10 per ug protein, respectively. We also demonstrated that CoQ10 does not significantly inhibit the growth inhibition effect of doxorubicin, nor does CoQ10 alone significantly inhibit cell growth, even at high concentrations. When treated with only doxorubicin, MDA-MB-468 growth inhibition was 53.6%. This inhibition did not change significantly when any concentration of CoQ10 was added. The growth inhibition of doxorubicin alone for BT549 cell line of 36.6% was also not significantly altered by CoQ10 additions. When added alone, up to 180uM of CoQ10 did not inhibit cellular growth in either cell line.

Conclusion: These results indicate that CoQ10 in vitro does not have large negative effects on doxorubicin's cytotoxicity. Because intracellular levels of CoQ10 were not determined, further studies are recommended to confirm intracellular and mitochondrial levels of CoQ10 with increased dosage. In vivo studies and clinical trials are needed to determine whether CoQ10 minimizes doxorubicin's effectiveness as a cancer therapy agent.

25. Resveratrol, a Natural Product (NP), Synergizes with Mitomycin C for Potent Antitumor Activity Against Human Metastatic Colon Cancers

Derek Johnson, Cancer Treatment Centers of America; Komen Brown, Cancer Treatment Centers of America; Adriana Rosales, Cancer Treatment Centers of America; Timothy Birdsall, Cancer Treatment Centers of America; Edgar Staren, Cancer Treatment Centers of America

Purpose: A substantial challenge in the practice of integrative cancer treatment is to identify active combinations of natural products (NPs) that can collaborate with conventional treatment modalities to achieve enhanced tumor control. This approach is especially attractive for tumors that survive initial treatment and metastasize. But it has been difficult to prove efficacy of combining NPs with conventional treatment such as chemotherapy due in large part to the challenges inherent in conducting controlled clinical trials with combination regimens. These challenges provide a rationale for translational research studies to characterize effects of NPs on tumor processes. The current study replicated the clinical situation of peritoneal carcinomatosis in that it investigated the activity of resveratrol (RV), a phytoalexin from the skin of grapes, to modulate tumor proliferation and gene expression in human metastatic colorectal cancers derived from surgical specimens that were subjected to treatment with Mitomycin C (MMC), the chemotherapy agent given by

hyperthermic intraperitoneal chemotherapy (HIPEC) post surgical de-bulking in our center.

Methods: Tumor proliferation was assessed with a standard MTS assay using the ATCC cell line, T84 as well as single cell suspensions prepared from three metastatic colon cancer surgical specimens (stomach metastasis (SM), ovary metastasis (OM) and peritoneal carcinomatosis (PC). Synergies between RV and MMC were further investigated using commercial qRT-PCR gene array kits.

Results: Resveratrol produced a dose-dependent inhibition of proliferation of the T84 cell line ranging from 2.5% (2.5ug/mL) through 58% (5ug/mL). Dose dependent inhibition of proliferation was also observed with cells from human metastatic colon cancer specimens with inhibition ranging from 7.8% (2.5ug/mL) to as much as 54% (5ug/mL). The effects of RV were found to collaborate with pharmacologically relevant concentrations of MMC. Thus, 58.8%, 50% and 87.7%

inhibition of T84 cell proliferation was observed with RV, MMC and RV+MMC, respectively. The corresponding values for surgical specimens were SM: 58.8%, 50%, and 87.7%, respectively; OM: 43.2%, 69.5%, and 78.1%, respectively; and PC: 11%, 27.1% and 40.5%, respectively. Additional effects of RV on colon cancer lines were observed when assaying gene expression. In OM, the combination of RV and MMC showed higher up-regulation of many pro-apoptotic genes than were observed with RV or MMC alone. Among the genes up-regulated by RV, MMC, and RV+MMC were FAS (3.8, 4.4, 7.6, respectively), CASP8 (15, 1.2, 3.1), CASP10 (5.4, 2.9, 12.5), CARD6 (3, 3.5, 4.5), and TNFRSF10B (2.3, 3.5, 7.2).

Conclusion: That the effects of RV can collaborate with chemotherapeutic agents commonly used in the treatment of metastatic colon cancer patients suggests that combination regimens of this NP with cancer chemotherapy may be valuable in patients for both adjuvant therapy and for maintenance of remission.

Oral Abstract Session: Natural Products Research

26. Active Hexose Correlated Compound (AHCC) Reduces a Variety of Anticancer Drug-Induced Side Effects in Mice

Koji Wakame, Amino UP Chemical., Co; Daisuke Nakamoto, Amino UP Chemical., Co; Hiroshi Nishioka, Amino UP Chemical., Co; Hajime Fujii, Amino UP Chemical., Co

Purpose: AHCC is widely used in Japan, the United States, Europe, Korea, China and Thailand. AHCC has a unique α -1,4 glucan structure, in contrast to the β -1,4 glucan structure in most medicinal mushrooms. Many physicians report striking benefits in their cancer patients when AHCC is used as part of a complementary medicine regimen. The previous studies also found that AHCC improves quality of life and reduces anticancer drug-related side effects in patients receiving cancer chemotherapy. In vivo study, AHCC has been reported to strengthen the anticancer effect of cisplatin (CDDP) and ameliorate its side effects in female BALB/cA mice inoculated with Colon-26 tumor cells. In this study, we investigated to scientifically prove the ameliorative effect of AHCC for various kinds of side effects caused by anticancer drugs.

Methods: The role of AHCC (360 ~ 1,000 mg/kg, p.o) in alleviating negative effects of several anticancer drugs was explored in non-tumor-bearing mice (five-week old, male ddY) receiving monotherapy with paclitaxel (TAX) or gemcitabine (GEM), or multi-drug chemotherapy with TAX plus CDDP, 5-fluorouracil (5FU) plus irinotecan (CPT), CDDP plus 5FU, or doxorubicin (DXR) plus cyclophosphamide (CY). Outcomes with and without AHCC supplementation were compared to controls. We investigated bone marrow cell viability and liver function in mice given TAX, and measured white blood cell (WBC) count, bone marrow cell viability and kidney function in mice given multiple anticancer drugs. Further, in GEM-treated mice, we evaluated WBC count, hemoglobin content and bone marrow cell viability as well as colony forming unit-granulocyte macrophage (CFU-GM) and burst forming unit-erythroid (BFU-E).

Results: The multi-drug treatments significantly reduced bone marrow cell viability and leukocyte count in all groups; these myelosuppressive effects were generally alleviated by AHCC. Hepatotoxicity and nephrotoxicity caused by the treatments including TAX and/or CDDP were also significantly improved by AHCC. The death rate was 20 to 30 percent in all treatment groups except TAX plus CDDP, and

supplementation with AHCC greatly reduced or eliminated mortality. AHCC improved the GEM-induced reduction of WBC count, hemoglobin content and bone marrow cell viability, and recovered the viability of hematopoietic progenitor cells of leukocytes and erythrocytes in the colony forming assays of CFU-GM and BFU-E.

Conclusions: These results support the concept that AHCC can be beneficial for cancer patients receiving chemotherapy. If these results are extended to humans, AHCC might contribute to improved quality of life and well-being of cancer patients undergoing chemotherapy.

27. Efficacy and Safety of Allergen Removed Rhus verniciflua Stokes Extract in Patients with Advanced Hepatocellular Carcinoma

Yee-hong Jung, East West Neo Medical Center, Kyunghee University; Wan-kyu Eo, East West Neo Medical Center, Kyunghee University; Se-hyun Kim, Graduate School of East West Medical Science, Kyunghee University; Won-cheol Choi, East West Neo Medical Center, Kyunghee University; Soo-kyung Lee, East West Neo Medical Center, Kyunghee University

Purpose: Hepatocellular carcinoma (HCC) is one of poor prognostic cancer in Asia-Pacific region. Especially in advanced HCC, there is limited treatment option. Rhus verniciflua Stokes (RVS), a plant grown in East Asia, has been studied in vitro and in vivo anti-tumor effects. The clinical usage of RVS was limited because of its allergenic component, urushiol. We could get the allergen removed RVS extract (aRVS) through the processes of standardization and quality control. In order to investigate the efficacy and safety of aRVS on HCC, we conducted a retrospective cohort study on advanced HCC patients treated with aRVS.

Methods: We investigated advanced HCC patients who had locally advanced disease and extrahepatic metastases. The inclusion criteria were administration of RVS extract more than once from June 2006 to December 2008, the performance status of ECOG 0 to 2, and class A or B of Child-Pugh score. Thirty-five advanced HCC patients were analyzed. The primary outcome was overall survival and the secondary outcomes were adverse events and tumor response. The overall survival was analyzed with the Kaplan-Meier Curve and the Log rank test. The safety and adverse event were assessed with the CTCAE version 4.0. The response rate was assessed by the RECIST criteria. The prognostic factor was assessed with

the Cox proportional hazards model. The statistical analysis was performed with the SPSS 13.0 for windows.

Results: Among 35 patients, 24 patients had extrahaptic metastases, 16 patients had portal vein thrombosis, 6 patients were in the class B of Child-Pugh score, and 34 patients were in BCLC stage C. Out of 22 patients with available ECOG performance status record, 8 patients were in ECOG 2. Before initiation of aRVS, 25 patients underwent transcatheter arterial chemoembolization (TACE). Nine patients were treated with systemic chemotherapy. The median time to initiation of aRVS was 5.4 months since diagnosis of advanced HCC.

The median overall survival was 6.4 months and 1-year survival rate was 20.0%. The median overall survival in patients with Child-Pugh class B was 5.1 months. Only 16 patients were able to assess response rate. Five patients had stable disease, and 11 patients had progressive disease. No patients had a response. Adverse events were observed in 5 patients, and it includes dyspepsia, epistaxis, and gastric ulcer. Hematologic toxicities were not found. Independent prognostic factors were the serum AFP concentration over 400ng/mL (hazard ratio, 6.61; 95% CI, 1.58 to 27.70; P=0.010) and the Child-Pugh class B (hazard ratio, 3.99; 95% CI, 1.04 to 15.32; P=0.044).

Conclusion: Considering the fact that the majority of patients were previously treated with local treatment or systemic chemotherapy, the median overall survival of 6.4 months in advanced HCC patients deems promising. In conclusion, aRVS is effective for the treatment of advanced HCC in patients from Korea, and is well tolerated. aRVS seems to be an appropriate option for the treatment of advanced HCC, including Child-Pugh class B.

28. Effect of Chinese Herbal Medicine JDXZF on Hand-Foot Skin Reaction Associated with the Multi-Targeted Kinase Inhibitors Treatment

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Purpose: Multi-targeted Kinase Inhibitors (MKIs) play an important role in cancer therapy. Hand-Foot Skin Reaction (HFSR) is one of the major dose-limiting toxicities, which can impact quality of life (QOL) and may lead to MKIs dose modification or interruption. Chinese herbal medicine JDXZF (including Herba dictamni cortex, etc.) is an empirical formula for reducing cutaneous toxicities induced by

MKIs. It is designed to observe the effect of JDXZF on hand-foot skin reaction associated with the multi-targeted kinase inhibitors treatment.

Methods: Entry Criteria: Diagnosis of cancer, with HFS/HFSR grade ≥ 1 (NCI-CTCAE version 3.0) after molecular targeted therapy. Age: 18 to 85. Able to participate in study procedures. No history of hand and foot skin diseases. No concurrent other treatment for HFS/HFSR. Patients are randomized to 1 of 2 treatment arms. Patients orally took Chinese herbal extract JDXZF (Arm I) or no special treatment (Arm II). JDXZF granules 10g was dissolved in 200mL of hot water and orally taken, twice daily for 7 days as one treatment cycle. Pts were assessed before and after treatment, including a physical examination. Evaluation criteria, CR as symptoms disappear completely, PR as grade for HFSR decreases more than 1 level, Total response rate as CR+PR.

Results: 61 pts have been enrolled, all of them are Asian, 24 male and 37 female. Total response rate was 80.5% (29/36) in Arm I, CR 38.9% (14/36), PR 41.7% (15/36), 36% in the Arm II, CR 8% (2/25), PR 28% (7/25), JDXZF is effective on the treatment of slight moderate rash and severe skin itch caused by EGFRIs.

Conclusions: The preliminary study has shown Chinese herbal medicine JDXZF is effective for relieving pain and helpful for the skin lesion on treating MKIs-induced HFSR. JDXZO is an advanced Chinese herbal extract ointment based on JDXZF for easy use and acceptable. No side effect such as allergy or infection related to JDXZO was found. The objective of the coming clinical trial is to evaluate the efficacy and safety of JDXZO external treatment on HFS/HFSR and designed by department of oncology, Guang An Men Hospital. This coming project will be supported by Unitech Medical, Inc. USA.

29. Development and Implementation of a Randomized Trial of Manuka Honey for Radiation Esophagitis

Lawrence Berk, Moffitt Cancer Center; Shannon Fogh, University of California, San Francisco; Kyoungwha Bae, Radiation Therapy Oncology Group Statistical Center; Deborah Bruner, University of Pennsylvania School of Nursing; Lisa Kachnic, Boston Medical Center

Purpose: Honey has a long history of use for wound healing, first documented in the Ancient Egyptian Smith Papyrus from the seventeenth century B.C. Recently honey has proven active in three small overseas trials for the prevention of oropharyngeal mucositis during head and neck irradiation. It was hypothesized honey would also be active for

esophagitis during radiation therapy. Therefore a randomized Phase II study was designed to test this hypothesis. This abstract describes the process and challenges of nutraceutical and botanical clinical trial design.

Method: A concept was developed within the Radiation Therapy Oncology Group (RTOG) Symptom Management Committee, part of the RTOG Community Clinical Oncology Program (CCOP), an international cooperative research group focused on radiation therapy. The literature was reviewed to justify the trial and determine the best trial design and which honey to use. A concept was developed and reviewed within the RTOG prior to submission to the NCI Symptom Management and Health Related Quality of Life Steering Committee (SC). It was then sent to the SC for evaluation and approval. After concept approval, the protocol was finalized and submitted to the NCI's Division of Cancer Prevention, the funding organization of CCOP symptom management trials.

Results: A thorough review of the literature of wound healing and mucositis confirmed the in-vitro and in-vivo activity of honey for the prevention and treatment of mucositis. Manuka honey was identified as the best researched and most consistent honey available. The organization overseeing the quality assurance of Manuka honey, the Active Manuka Honey Association (AMHA) of New Zealand, was contacted and agreed to assist in the trial. The AMHA is supplying low-peroxide Manuka honey which will be sterilized in a gamma-irradiator. It will undergo independent testing for the standardizing factor (UMF) and for bacterial and fungal contamination. All honey will be from one pooled batch. The trial was originally designed to be a Phase II placebo controlled trial investigating Manuka honey. However, an acceptable placebo, equivalent in taste and texture to honey is difficult to manufacture and the protocol was rewritten as a comparison of honey and local standard of care. The AMHA offered to supply a Manuka honey lozenge as well as liquid honey. This allows better identification of the locus of activity of the honey. Therefore, the trial was redesigned as a three arm trial of liquid honey, the equivalent amount of liquid honey in lozenge form and local standard of care. The trial is expected to open this fall. It took approximately 1 year from initial concept development to submission of the full protocol.

Conclusion: Development of this Manuka honey study highlights many of the hurdles in designing and implementing large clinical trials of nutraceuticals and botanicals, including justifying the trial's hypothesis, obtaining an appropriate supply of the product, defining the quality assurance for the product to insure its purity and safety, and identifying a funding mechanism for trial implementation.

This project is supported by CCOP grant U 10 CA37422 by the National Cancer Institute (NCI).

30. Efficacy of Moxibustion on Cancer Pain; A Randomized, Single-Blinded, Placebo-Controlled Pilot Study

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Background and Purpose: Moxibustion has been widely used in Oriental Medicine to ameliorate various types of pain. This pilot study was designed to evaluate if moxibustion could improve cancer pain in metastatic cancer patients.

Study design and Method: The study design was prospective, randomized, single-blinded, and placebo-controlled trial. 16 patients were recruited from December 2009 to July 2010 and all of them met the inclusion criteria. They were randomized to either moxibustion group or sham moxibustion group, and were treated once a day for seven consecutive days. Five moxibustion points were selected for both group from the area where the cancer was causing pain and five moxa cones were applied to each point. In the moxibustion group, moxa was left in place until heat was delivered to the skin and removed when less than 0.5cm remained unburnt, while in the sham group moxa was removed before the heat reached the skin at more than 1cm was left unburnt. We assessed the effects of moxibustion on the BPI (Brief Pain Inventory) total score, the BPI pain intensity, the BPI pain interference, quality of life using the FACT-G (Functional Assessment of Cancer Therapy; General). Daily intake of opioids for seven consecutive days was recorded. The blinding credibility was also tested and adverse effects were observed.

Results: A total of 16 patients were enrolled in the trial, and two patients were lost during the study period. One was lost due to increasing amounts of ascites, and the other patient was lost due to abruptly increased pain caused by the aggravation of their pancreatic cancer, therefore 14 of 16 patients completed the trial. The results of pain scores as measured by using the BPI are shown in Table 1. The difference value in the change of the BPI total score between groups was statistically significant (intervention vs control: -0.97 ± 0.97 vs 0.39 ± 0.56 , $p=0.014$). The difference in the BPI pain intensity score and the BPI pain interference scores also showed sig-

nificant improvements (the BPI pain intensity, experimental vs control: -0.82 ± 0.86 vs 0.54 ± 0.83 , $p=0.027$, the BPI pain interference, experimental vs control: -1.12 ± 1.23 vs 0.24 ± 0.56 , $p=0.037$). Those statistical improvements remained unchanged when adjusted to the difference values of opioid consumption. Results of the FACT-G showed no significant improvement. There was no statistically significant difference of opioid consumption between groups. The blinding was credible ($p=0.559$) and no serious adverse effects including a burn was reported.

Conclusion: Moxibustion provided in this pilot study reduced cancer pain in metastatic cancer patients. Further researches are needed to warrant this result.

Oral Abstract Session: Research In Mind-Body Approaches

31. Clinical Outcomes from Yoga and Massage in a Comprehensive Cancer Center

Sarah Rausch, Moffitt Cancer Center and Research Institute; Elayne Paine, Moffitt; Jonatha Wright, Moffitt; Sharen Patel, Moffitt; Bari Ruck, Moffitt

Purpose: Integrative therapies are increasingly being used by cancer patients as supportive therapy to enhance comfort and help manage symptoms and side effects of cancer and its treatment.

Methods: At Moffitt Cancer Center, a Comprehensive Cancer Center in Tampa, Florida, US, over 1,000 cancer patients have been seen since January 1, 2010 for yoga, massage, or Qigong. All of these patients have reported symptom severity before and after each integrative service they received, using 0-10 rating scales of pain, fatigue, nausea, anxiety, emotional distress, physical distress, and overall QOL.

Results: Symptom scores were reduced on all measures by approximately 45%. Massage reduced pain by approximately 48%, fatigue and physical distress were reduced by 43% and all other measures reduced by at least 35%. Yoga and Qigong reduced pain by 44%, fatigue and anxiety were reduced by 45% and all other measures reduced by at least 39%.

Conclusions: These data indicate that a various Integrative Medicine services are extremely helpful to cancer patients in reducing significant clinical symptoms associated with cancer and its treatment. Cancer centers should consider integrative therapies as to help manage these symptoms.

32. Impact of Yoga on Functional Outcomes in Breast Cancer Survivors with Aromatase Inhibitor-Associated Arthralgias

Mary Lou Galantino, Richard Stockton College of New Jersey and University of Pennsylvania; Laurie Greene, Richard Stockton College of New Jersey; Benjamin Archetto, Richard Stockton College of New Jersey; Melissa Baumgartner, Richard Stockton College of New Jersey; Paula Hassell, Richard Stockton College of New Jersey

Purpose: Arthralgia affects postmenopausal breast cancer survivors (BCS) receiving aromatase inhibitors (AI) which may result in reduced function and long term well-being. While there is evidence for yoga to improve subjective

report of Quality of Life (QOL) in various cancer populations, no studies reported objective functional improvement associated with yoga. This study aims to establish the feasibility of studying the impact of yoga on objective functional outcomes for AI-associated arthralgia (AIAA).

Methods: Postmenopausal women with stage I-III breast cancer who reported AIAA were enrolled in a single arm feasibility trial. Yoga was provided twice a week for 8 weeks and participants were instructed to do a home-based yoga program. An Iyengar yoga program was specifically developed with emphasis on postures, breathing and meditation while attending the safety concerns for individuals with musculoskeletal pain. Certified instructors led the yoga sessions for 1.5 hours with a 15 minute check-in period to assess progress and function. The Sit and Reach (SR), and Functional Reach (FR) were evaluated by trained physical therapists and served as the primary outcomes. Self-reported Patient Specific Functional Scale (PSFS) and FACT-B were secondary outcomes. Paired-t tests were used for analysis.

Results: Among the 10 BCS with AIAA, mean age 58 (SD 6.23), 9 were Caucasian, 1 African American and 90% provided data for assessment at the end of the yoga intervention. From baseline to the end of intervention, participants had significant improvement in flexibility measured by SR (22.90 to 30.10) and in balance measured by FR (25.36 to 39.19), both $p < .01$. The PSFS also improved from 4.55 to 7.21, as well as QOL measured by FACT-B (89.33 to 106.05), both $p < 0.05$. No adverse events nor development or worsening of lymphedema was observed. Eighty percent of participants adhered to the home based program of 15 minutes 3 times per week.

Conclusion: Preliminary data suggests that yoga may improve flexibility and balance in breast cancer survivors who experience AIAA. A randomized controlled trial is needed to establish the definitive efficacy of yoga for objective functional improvement in BCS with AIAA.

33. Eudaimonic Well-Being is Associated with Decreased Inflammation and Increased Cortisol Variability in Fatigued Breast Cancer Survivors

Shamini Jain, Samuelli Institute; Shauna Shapiro, Santa Clara University; John Ives, Samuelli Institute; Paul Mills, University of California San Diego

Purpose: Recent research indicates that well-being may be related to positive health outcomes in cancer patients, but mechanisms by which well-being confers enhanced health are unclear.

Method: We examined the relationship between eudaimonic well-being (Well-Being Scale, Ryff), as well as fatigue (MFSI-sf), positive and negative affect (CESD), and quality of life (FACT-B) with resting inflammatory markers and diurnal cortisol variability in 60 breast cancer survivors with persistent fatigue (Stages I-IIIa, mean age = 52). Plasma levels of inflammatory markers sIL-6R, neopterin, and IL-1Ra were assayed via ELISA. Diurnal cortisol variability was assessed via slope calculations of salivary cortisol collected at four timepoints (wake, 12pm, 5pm, and 9pm) over a two day period. Demographic and disease characteristics were entered as covariates if significantly associated ($p < .05$) with dependent variables.

Results: Analyses revealed that eudaimonic well-being was associated with decreased inflammation and increased cortisol variability. Specifically, hierarchical linear regression (controlling for covariates HER-2 status and cancer stage) revealed that higher scores in Autonomy predicted decreased cortisol slope (standardized beta = $-.286$, $p = .016$, adjusted R-square = $.15$). In addition, regression analyses (controlling for covariate HER-2 status) revealed that higher scores in Positive Relationships were associated with lower IL-6r levels (standardized beta = $-.27$, $p = .004$, adjusted R-square = $.16$). Fatigue, positive and negative affect, and quality of life were not associated with dependent variables.

Conclusion: Results replicate previous findings for a non-cancer population, and suggest that aspects of eudaimonic well-being are uniquely associated with decreases in inflammation and increases in cortisol variability in fatigued breast cancer survivors. There is a need to further examine eudaimonic well-being as a potential protective factor in cancer patients and survivors.

34. Impact of Integrative Medicine on Immediate Pain and Anxiety Scores in Oncology In-Patients at Abbott Northwestern Hospital

Jeffery Dusek, Abbott Northwestern Hospital; Lori Knutson, Abbott Northwestern Hospital; Gregory Plotnokiff, Abbott Northwestern Hospital; Mimi Lindell, Abbott Northwestern Hospital; Jan Boettcher, Abbott Northwestern Hospital

Purpose: National surveys indicate that complementary and alternative medicine (CAM) are currently used by 15% of American hospitals and are used by a high proportion of

oncology patients. The term Integrative Medicine (IM) is used to signify the use of massage, acupuncture and mind-body therapies in conventional hospital or clinic settings. The Purpose of this study is to describe the population of oncology patients receiving IM in a large, tertiary care hospital and to assess pain and anxiety scores before and immediately after the IM intervention.

Methods: The setting for this study of IM is the Penny George Institute for Health and Healing at Abbott Northwestern Hospital. The George Institute is uniquely suited for this work as it is the nation's largest inpatient IM program serving over 19,000 unique patients since 2004. An EPIC based flowsheet for IM was developed by the George Institute staff. The new flowsheet imbeds the IM intake form, IM assessments and clinical outcomes directly within the patient's electronic health record. These data are now accessible to providers of direct patient care (e.g., physicians, nurses) in real time. As part of the flowsheet, IM practitioners record patient's prior use of IM therapies as well as obtain a pre-treatment pain, anxiety and nausea score on a 10 point scale. The same outcomes are asked immediately upon completion of the IM visit.

Results: Using the new flowsheet, we conducted a retrospective study (July 2009 to March 2010) of 300 unique oncology patients who were referred for and received IM while in the hospital. IM included massage, mindbody, acupuncture or various combinations of these therapies. Results from the 1st visit per patient indicate that 64% patients received massage only, 13% received massage/mindbody/acupuncture combined, 10% had combined mindbody/massage, 5% were presented with mindbody therapies only, 4% had acupuncture only, and 2% were exposed to either a combined mindbody/acupuncture or acupuncture/massage therapy. The percentage of women receiving treatment was 61%, the average age for patients was 55.8 (15.5 sd) years. Preliminary analyses indicate a significant reduction in pain scores from pre-score average of 4.64 to a post score mean of 2.59 (~44% reduction) and reduced anxiety from a mean of 3.27 to 1.67 (~49% reduction). In addition to these outcomes, results from predictive modeling analyses will be presented as well.

Conclusion: With this new improvement, the electronic health record can serve as a means to truly integrate IM within a conventional care system. Acute changes in pain and anxiety were observed with additional studies planned to examine the duration of pain relief over several hours after IM. Predictors of which patients respond to which therapies are vital for documenting improvement in patient centered outcomes and quality and could enable the growth of IM across the country in this era of healthcare reform.

35. “Cuidar al Que Cuida” (CQC) (“Caring for the Caregiver”): Integrative Medicine (IM) Education Can Reduce Burnout in Caregivers

M. Laura Nasi, ASOI (Iberoamerican Association of Integrative Oncology_www.as-oi.org) & FUNDALEU (Foundation for Fight Against Leukemia); Pablo Mountford, ASOI & FUNDALEU; Mariana Garcia Mata, ASOI & FUNDALEU; Lourdes Lucas, ASOI & FUNDALEU; Ana Carella, ASOI & FUNDALEU

Purpose: We hypothesized that by having health care givers attend an introductory course on the holistic view of the human being and having them experience personally the benefits of the IM approaches, would benefit their own well being as well as the introduction of IM approach to their patients and the increase in referrals.

Methods: 2 groups of health care professionals were selected by the Human Resources department (HR) of Fundaleu: Selection was based on the strategic position of the people in the team as well as on the HR perception of need for an intervention for burnout. By demand of the HR, participants were divided into 2 groups: medical and directive staff in one, and non-medical (nursing, administrative, laboratory) on the other. The CQC course consisted of 6 sessions, 1 to 1.5 hours long, once a week, for 6 consecutive weeks. Each session consisted in a theoretical and a practical section. Practice sections included meditations, guided visualization, music-therapy exercise, auto-massage exercise and behavioral education. On session 1, all participants completed a MBI (Maslach Burnout Inventory) as well as a Mindfulness questionnaire. Attendees also completed a self awareness habits questionnaire. The MBI was repeated during session 6. An evaluation will be performed at 3 months. Evaluation included both quantitative and qualitative (testimonial) data. Sessions were coordinated by one MD and one or 2 therapists.

Results: The non-medical staff had an attendance of 90% where the medical-directive group had an attendance of only 55%. Evaluation of the non-medical group pre and post CQC showed improvement of the emotional exhaustion (40% higher mean scores to 20%), worsening of depersonalization (increase from 20% to 30% of higher mean scores) and no change in personal accomplishment (30% and 30% higher mean scores). The medical-directive staff could not be evaluated as assistance was below that required for group evaluation. A 3-month evaluation will evaluate the longer term impact as well as the impact on patient referral. Qualitative analysis showed overall satisfaction. Participants testified the course had enabled them to make beneficial habit changes

both at work and at home. The main recommendation was to prolong the course or establish maintenance sessions.

Discussion: Favorable outcome was already seen with a short 6-week intervention in the non-medical group. The lack of improvement in depersonalization or personal accomplishment may be due to the short duration of the intervention or due to the fact that evaluation was performed immediately after the conclusion of the intervention. The 3-month evaluation will be useful to detect whether improvements are seen at a longer interval.

Conclusion: A 6 week intervention of “Caring for the Caregiver” for the medical-directive and non-medical staff at an academic institution helped to improve emotional exhaustion and quality of life in the group. Longer follow-up as well as a longer intervention may be needed to see more significant changes. The 3-month evaluation will be available for presentation at the SIO 2010 Conference.

36. Narrative Intervention with Oncology Professionals: Stress and Burnout Reduction through an Interdisciplinary Group Process

Nicole Saint-Louis, Hospital of the University of Pennsylvania

Purpose: The increased prevalence of cancer diagnoses ensures that oncology healthcare professionals will be faced with more challenges than ever before in their work with cancer patients, especially in hospital environments. The literature demonstrates that professional caregivers are at risk for burnout (BO), compassion fatigue/secondary traumatic stress (CF/STS), job stress and job satisfaction and have minimal forums for which they can share their experiences. In an environment of ever-shrinking resources, it is imperative to use innovative methods to help the professionals cope with the day-to-day challenges of caring for terminally ill individuals. This exploratory mixed-methods study investigated the efficacy of a narrative intervention group with oncology professionals.

Methods: Forty oncology health care providers from three inpatient oncology units completed the Health Consultants’ Job Stress & Job Satisfaction Questionnaire (HCJJSQ), the Professional Quality of Life Scale: Compassion Satisfaction, Burnout and Fatigue Scale Version IV (ProQOL-CSF-R-IV), and the Maslach Burnout Inventory-Human Services Survey (MBI-HSS) with subscales of emotional exhaustion (EE), depersonalization (DP) and personal accomplishment (PA), pre- and post-intervention along with post-session evaluations with three Likert questions and three open-ended questions in addition to ten in-depth interviews.

Results: Statistically significant decreases were found in BO, CF/STS, EE, DP, and job stress with significant increases in job satisfaction from the first month to the fourth month. Professionals discussed the rigors of their work and their impressions of the narrative oncology groups reporting overall positive experiences with specific appreciation for shared perspectives and finding comfort within the narrative exchange.

Conclusion: Professionals on inpatient oncology units benefit from structured groups such as narrative oncology reporting greater team affiliation, and comfort within the shared perspectives of their colleagues. Policy and educational implications are also discussed.

Poster Session Presentations

37. Use of Dietary Supplements Among Children with Cancer in Guatemala

Elena J. Ladas, Division of Pediatric Oncology, Columbia University Medical Center, New York; Federico Guillermo Antillon Klussmann, Unidad Nacional de Oncologia Pediatrica, Guatemala City; Silvia Rivas, Unidad Nacional de Oncologia Pediatrica, Guatemala City; Deborah Hughes Ndao, Division of Pediatric Oncology, Columbia University Medical Center, New York; Doree Damoulakis, Division of Pediatric Oncology, Columbia University Medical Center, New York

Purpose: International surveys demonstrate children with cancer are significant consumers of traditional and complementary/alternative medicine (TCAM). Dietary supplements are often the most common type of TCAM in use with conventional treatment. Utilization of dietary supplements and its consequent impact on the decision for conventional treatment and survival among children with cancer in Guatemala have yet to be explored.

Methods: Institutional review board approval was obtained for a survey of TCAM use and its associations in children with cancer at the Unidad Nacional de Oncologia Pediatrica, Guatemala. A random, cross-sectional sample of 78 parents was interviewed in person from May 2008-February 2010 after obtaining consent. Demographic data, dietary supplements used, and referral and communication about use were collected.

Results: Median age 10 years (1-18). Gender: 49 male/29 female. Diagnoses include leukemia (60%), lymphoma (18%), solid tumors (13%), and other (9%). 24% were Mayan, 86% attended religious services regularly, and 62% lived >2 hours from the clinic. 52 (67%) patients reported dietary supplementation use. 46% used herbal supplements, 31% juicing, 28% addition of specific fruit/vegetable, and 5% snake/scorpion venom. Reasons for dietary supplementation were to provide immune support (34%), overall strength/wellbeing (30%), improve hemoglobin (15%), cure (11%), nutrition (3%), weight gain/loss of appetite (3%), gastrointestinal relief (2%), and relaxation (2%). Quilete (20%), alfafa (14%), noni (10%), bulls tea (6%), and macuy (8%) were the most common types of herbal supplements used. The majority of dietary supplements were described as very effective (68%) and were referred by family/community members (55%). 49% of all reported dietary supplements were not disclosed to their physician.

Conclusion: Use of dietary supplements was quite common among this sample of pediatric oncology patients. As there are concerns about the potential for adverse interactions, educational and research initiatives on the safety and efficacy of dietary supplements are needed.

38. Prevalence of Complementary Medicine Use in a Phase I Clinical Trials Program: The M. D. Anderson Cancer Center Experience

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Purpose: A key endpoint of early cancer clinical trials is the assessment of toxicities and their possible association with new experimental drugs. We therefore evaluated the concurrent use of complementary and alternative medicine (CAM) in patients with advanced malignancies seen in a dedicated Phase I clinic.

Patients and Methods: An investigator-designed survey was anonymously completed by patients seen in the Phase I Clinic. Pharmacologic CAM included any oral, topical or intravenous agent, including vitamins, dietary supplements, and herbal products. Non-pharmacologic CAM included prayer, meditation, hypnosis, massage, and acupuncture.

Results: Of the 404 patients approached about completing the CAM survey, 394 (98%) agreed to respond and 309 (76%) surveys were returned. Of those 309 patients, 162 (52%) used one or more CAM. Of the 162 CAM users, 77% utilized pharmacologic CAM, 71% used non-pharmacologic CAM, and 48% used both modalities. The most frequent CAM used were vitamins (70%), prayer (57%), and herbal products (26%). CAM utilization was not significantly associated with race, age, level of education, employment or income level, but was used more by women than men ($p < 0.01$). There was no statistically significant association between the use of CAM and quality of life as perceived by patients. Of the CAM users, 43% of patients had been using CAM for >5 years. Only 5% reported having side effects from using CAM, while 23% did not fully disclose their CAM use to their physicians.

Conclusion: CAM usage is common in patients with advanced malignancies seen in a Phase I clinic.

39. Use of Acupuncture and Traditional Oriental Medicine by Male Patients with Genitourinary Cancers at an Academic Medical Center

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Purpose: To examine the use of acupuncture and related traditional oriental medicine (TOM) practices in men with genitourinary cancers.

Methods: We conducted a retrospective review of men with genitourinary cancers seen by a single practitioner of acupuncture and oriental medicine in an academic medical center from 10/2009-07/2010. Patients were identified by examination of a computerized appointment database and all patients with the primary ICD-9 code of the following cancers were screened; 185-malignant neoplasm of the prostate, 186-malignant neoplasm of the testis, 187-malignant neoplasm of the penis, 188-malignant neoplasm of the bladder, 189-malignant neoplasm of the kidney. Data from consecutive patients were analyzed and demographics, disease characteristics, acupuncture, TOM and related complementary procedures were noted.

Results: Of the 25.9 weeks screened, 28 patients were found and 25 of 28 [89.3%] were evaluable. The reason for non-evaluation was due to missing data. The average age was 71.9 [Range 56-90]. The primary cancer diagnoses were as follows: 23/25 [96%] prostate cancer, 1/25 bladder cancer, 1/25 [4%] renal cell carcinoma. 3/25 [12%] had a history of other cancers including 1:1:1 (renal cell, thyroid, lung respectively). The most predominate chief complaint was flushing (hot flashes) 5/25 [20%], followed by urinary frequency 4/25 (16%), low back pain 4/25 (16%), and insomnia 4/25 (16%). Other reported chief complaints included fatigue, abdominal/pelvic pain, foot pain and neck pain. Almost two-thirds of the men 18/25 (72%) were concurrently receiving urologic medications including phosphodiesterase inhibitors, 5-alpha reductatase inhibitors, anti-muscarinics, leutinizing-hormone releasing hormone analogs, anti-androgens, and/or immunotherapy (Bacillus Calmette-Guerin (BCG)). 10/25 (40%) also reported various co-morbid cardiovascular conditions and of those, 3/25 were currently receiving anti-coagulation therapy. The average INR of the three patients receiving anti-coagulation therapy was 1.12 (SD 0.08). All patients 25/25 received full body acupuncture and the average number of visits received by each patient was 14.8 (SD 4.21). Other TOM and complementary interventions included auricular acupuncture 8/25 [32%], scalp acupuncture 1/25 [4%], herbal medicine 8/25 [32%], diet/lifestyle 17/25 [68%], qi gong 5/25

[20%], guided imagery 3/25 [12%], mindfulness based stress reduction 1/25 [4%]. There were no reported side effects with regard to any acupuncture needle injury including hematoma or any other reported adverse events.

Conclusions: Men with genitourinary cancers receiving acupuncture and related TOM modalities had both urologic complaints likely related to their primary cancer diagnosis and other quality of life (QOL) complaints such as insomnia, fatigue, and musculoskeletal pain. Men receiving acupuncture and TOM therapies were also commonly receiving urologic medications and had a variety of co-morbid conditions including second cancers. This analysis demonstrates that a multidisciplinary approach to treating patients with genitourinary cancers may be valuable with regard to amelioration of common and bothersome QOL symptoms and that acupuncture, TOM and other complementary interventions are likely safe.

40. Vitamin D Status in Minnesota Healthcare Employees with a History of Breast, Colon or Prostate Cancer

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Purpose: Vitamin D appears to have clinically significant anti-cancer activity including inhibition of breast, colon and prostate cancer cell proliferation, stimulation of apoptosis and inhibition of tumor angiogenesis, invasion, and metastasis. Several studies document that breast and colorectal cancer mortality rates are inversely related to serum 25(OH)D status. Large retrospective studies document that mean levels ≥ 40 ng/ml after diagnosis are associated with significant reductions in overall mortality. The purpose of this study is to understand vitamin D intake and status in Minnesota health care employees with a history of breast, colon or prostate cancer.

Methods: Serum 25(OH)D levels (DiaSorin, Stillwater, MN) and extensive health questionnaires were obtained from 10,646 employees throughout Minnesota and western Wisconsin in February through March, 2010 as part of an annual, "BeFit Wellness Rewards" employee health campaign.

Results: Of the 10,646 participants, 227 (2.1%) reported a history of breast, colon or prostate cancer. Demographics are as follows: 93% were women, 96% were white, 48% identified their role as Professional/Management and the mean age was 52.4 (10.6 SD). The mean body mass index (BMI) was 28.4 (6.2 SD) with 35% of the sample having a BMI >30 . Intake of

no vitamin D was reported by 73 participants (31%). Of those reporting any vitamin D intake, less than half took more than a multivitamin daily. Vitamin D status was positively related to reported intake ($p < .0001$) and inversely related to BMI ($p < .0008$). The mean value was 31.9 ng/ml (14.25 SD) (range 4 to 87 ng/ml). Twelve participants (5.3%) demonstrated levels < 10 ng/ml. The mean values by intake: none, 23.2 ng/ml; "don't know" 29.2 ng/ml; up to 400 IUs/day, 32.6 ng/ml; 401-1000 IUs, 32.4 ng/ml; 1001-2000 IUs, 40.6 ng/ml; $> 2,000$ IUs, 43.2 ng/ml. Standard deviations ranged from a low of 10.6 to a high of 14.6. The mean values by BMI: less than 25, 35 ng/ml; 25-29.9, 34.3 ng/ml; 30-34.9, 27.6 ng/ml and > 35 , 25.7 ng/ml. Standard deviations ranged from 11.4 to 15.0. For persons with a BMI < 30 , mean serum 25(OH)D levels ≥ 40 ng/ml were achieved at reported intakes of > 1000 IUs of D3 per day. For persons with a BMI > 30 , mean serum 25(OH)D levels ≥ 40 ng/ml were achieved at reported intakes of $> 3,000$ IUs a day.

Conclusion: In this presumably well-treated and potentially well-informed population of health care employees with a history of breast, colon or prostate cancer, most demonstrated serum levels of 25(OH)D far below the 40 ng/ml mean associated with a significant reduction in mortality. This data demonstrates that current federal recommendations for vitamin D3 supplementation (200-400 IU daily) are insufficient for most Minnesotan health care employees with a history of these cancers. This data supports maintenance dosing of 2,000 IUs a day of vitamin D3 for persons with a BMI < 30 and 4,000 IUs a day for persons with a BMI > 30 . Due to documented differences in metabolism and the relatively large standard deviations for each mean serum value, effective replenishment and maintenance dosing strategies will require serial serum 25(OH)D measurements.

41. Complementary and Alternative Medicine and the Development of Self in Chronic Diseases: A Prospective, Multi-Centre Observational Survey in the Narayanganj District of Bangladesh

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Purpose: Modern lifestyle has contributed to serious increases in chronic diseases like cancers & tumors, hypertension, heart diseases, and diabetes mellitus; as well as debilitating diseases like rheumatoid arthritis. Currently, most medications or therapies for treatment of the above diseases have serious side-effects, which sometimes can be more life-

threatening than the disease itself. It is important, therefore, to turn to plant sources for discovery of novel yet safe compounds, which has less or no side-effects to treat the above diseases. The present survey was carried out amongst the traditional health practitioners in the Narayanganj district of Bangladesh to collect information on plants used by them to treat the above diseases.

Methods: Information was collected through a series of interviews with traditional health practitioners, rural and urban people. Field notes were recorded on the plants and their uses; following the methodology of Bhat et al. (1990) and Martin (1995). The identified plant specimens were stored at the Bangladesh National Herbarium; under the first author's collector series.

Results: The following plants or plant parts were found to be used as remedy for cancers & tumors: *Achyranthes aspera* (L.), *Catharanthus roseus* (L.) G.Don, *Morinda citrifolia* (L.), *Linum usitatissimum* (L.), *Aegle marmelos* (L.) Corr.Serr., *Glycosmis pentaphylla* (Retz.) DC., *Derris indica* (Lam.) Bennet, *Randia dumetorum* (Retz.) Poir., *Ficus racemosa* (L.), *Ocimum tenuiflorum* (L.), *Melia azadirachta* (L.), *Polygonum persicaria* (L.), *Abrus precatorius* (L.), *Cyrtandra cupulata* Ridl., *Myristica fragrans* Houtt., and *Nigella sativa* (L.). Plants used for treatment of hypertension included *Maranta arundinacea* (L.), *Bacopa monnieri* (L.) Pennell, *Tinospora cordifolia* (Thunb.) Miers, *Citrus aurantifolia* (Christm.) Swingle, *Plantago ovata* Forssk., *Momordica charantia* Descourt., *Cocos nucifera* (L.), *Allium sativum* (L.), and *Mangifera indica* (L.). Plants used to treat heart diseases were *Ocimum gratissimum* (L.), *Terminalia arjuna* (Roxb.) W. & A., *Cicer arietinum* (L.), *Aphanamixis polystachya* (Wall.) R.N. Parker, *Borassus flabellifer* (L.), and *Swertia chirata* Buch.-Hams. ex Wall.. Anti-diabetes mellitus plants included *Abroma mollis* DC., *Lepidagathis hyalina* Nees, *Citrus maxima* Merr., *Andrographis paniculata* (Burm.f.) Wall. ex Nees, *Syzygium cumini* (L.) Skeels., *Tamarindus indica* (L.), *Coccinia grandis* (L.) Voigt, *Aloe vera* (L.) Burm.f., *Momordica charantia* Descourt., *Feronia elephantum* Corr^{ma}, *Carica papaya* (L.), *Withania somnifera* (L.) Dunal, and *Embllica officinalis* Gaertn.. Plants used as remedy for rheumatoid arthritis included *Datura metel* (L.), *Achyranthes aspera* (L.), *Ricinus communis* (L.), *Piper betle* (L.), *Calotropis gigantea* (L.) W.T.Aiton, *Basella alba* (L.), *Musa sapientum* (L.), *Nigella sativa* (L.), *Aconitum napellus* (L.), *Ipomoea aquatica* Forssk., *Santalum album* (L.), *Brassica napus* (L.), *Lasia spinosa* (L.) Thwaites, *Curcuma longa* (L.), and *Boerhaavia diffusa* (L.).

Conclusion: A survey of the scientific literature revealed that preliminary studies conducted on some of the above-plants justify their use to treat specific ailments as practiced

by the traditional health practitioners. Other plants need to be scientifically studied towards obtaining new and safer medicines for treatment of diseases like cancers & tumors, hypertension, heart diseases, and diabetes mellitus; as well as debilitating diseases like rheumatoid arthritis, which affect a large portion of the world's population and have become the foremost chronic diseases in modern times.

42. Traditional Chinese Medicine in Oncology. Preliminary Results from a Three-Year Pharmacoepidemiology Survey in Italy.

Alfredo Vannacci, Florence University; Francesco Lapi, Florence University; Eugenia Gallo, Florence University; Alessandra Pugi, Florence University; Ersilia Lucenteforte, Florence University

Purpose: While acupuncture is the best-known Chinese medical treatment in the West, herbal medicine is traditionally one of the more important treatment modalities used in Traditional Chinese Medicine (TCM), both in oncological and non-oncological fields. Treatment of oncological patients with TCM is usually based on a combination of acupuncture, herbal medicine and dietary therapy. Many studies were performed to assess the possible role of acupuncture in supporting oncological patients (mainly for the treatment of chemo/radiotherapy side effects), but little is known on the use of the other TCM modalities. Additionally, while acupuncture is substantially safe, several concerns may be raised regarding the safety of Chinese Herbal Medicines (CHM). In fact CHMs are composed of several different herbs tailored to the individual patient, and although massive databases of genomic, proteomic and chemical data are now available to study and identify the structure of active compounds from herbal drugs, still little is known on pharmacognosy and pharmacogenomics of most CHMs.

Methods: Here we report preliminary results of a three-year research aimed to assess pharmacoepidemiology of CHM in Italy, conducted by means of a Prescription Event Monitoring (PEM) survey. Phases of the research include: 1. Realization of a National Registry for CHM practitioners. 2. Epidemiological survey on the prevalence of use of CHM. 3. Short-, medium- and long-term evaluation of the efficacy and safety of CHMs in the frame of the PEM Survey. 4. Pharmacological researches aimed at describing pharmacodynamic, pharmacokinetic and pharmacogenetic issues of main CHMs.

Results and Conclusion: Results of the first half year of the project will be reported in the current communication, with particular regard to the set up of a national registry of CHM qualified practitioners, and to preliminary results of

the epidemiological survey on the prevalence of CHM use Italy with particular reference to the treatment of oncological patients. Research supported by a Young Researchers' grant from Italian Ministry of Health.

43. Oncology Acupuncture Trials and Trends from 1997 to 2010, Search Results from American Society of Clinical Oncology (ASCO) Database

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Background: ASCO is the most influential clinical oncology professional organization in the United States and in the world. With its 27,000 members, ASCO represents mainstream medicine in oncology. Oncology acupuncture is a recently emerged clinical intervention for managing cancer-related symptoms and is seen as a form of "complementary and alternative medicine". By reviewing oncology acupuncture trial abstracts accepted by ASCO, one could begin to evaluate the emergence of oncology acupuncture with mainstream oncology care.

Methods: The ASCO abstract database (<http://www.asco.org/ASCOv2/Meetings/Abstracts>) was independently searched by two authors in June 2010. All ASCO meetings and prior meetings were selected. "Acupuncture" or "electroacupuncture" were used as the search terms. The obtained abstracts and their relevance to oncology acupuncture were reviewed. Abstracts were included in the final analysis if they were of a clinical study of acupuncture. Abstracts were excluded if they were determined to be unrelated to oncology acupuncture or referenced in a CAM survey without clinical content. The following data were extracted for the final analysis: publication year, symptoms studied, cancer population, type of clinical study, number of participants, and study outcomes.

Results: The initial search yielded a total of 95 abstracts containing the search terms. Seventy-two articles were excluded for their irrelevance to our study aim. The remaining 23 abstracts, which were published from 1997 to 2010, were included for the final analysis. The peak period of publication was the 2009 ASCO annual meeting, with a total of 7 studies published. Among those 23 abstracts, five (22%) studies reported survey results of acupuncture use in cancer patients and one (4%) study was a retrospective chart review. Seventeen (74%) studies were prospective clinical trials. Within these clinical trials, nine (53%) studies were randomized controlled trials (RCT), with a median N=36, range: 17-128; and 8 (47%) were single arm trials, with a median

N=22, range: 4-50. Breast cancer (43%) was the most studied population in all included publications, followed by prostate cancer (13%), colorectal cancer (9%) and head and neck cancer (9%). Hot flashes (38%) were the most studied symptom, followed by chemotherapy-induced nausea and vomiting (19%), neuropathic symptoms (13%) and cancer pain (13%). Among these clinical trials, fourteen (82%) studies reported favorable outcomes, one (6%) with negative outcomes, and the remaining two (12%) studies were ongoing trials.

Conclusions: Oncology acupuncture is being more reported by the mainstream medical community, such as ASCO. Although current clinical trials are still limited by small sample sizes and early phase exploration, oncology acupuncture shows recent promise in the management of symptoms of cancer and its related treatment. Conducting well-designed clinical studies with scientific rigor is the best avenue to provide scientific evidence for oncology acupuncture.

44. Vitamin D Testing, Serum Levels and Supplementation in Memorial Sloan-Kettering Cancer Center (MSKCC) Patients

Kathleen Wesa, Memorial Sloan-Kettering Cancer Center; K. Simon Yeung, Memorial Sloan-Kettering Cancer Center; Barrie Cassileth, Memorial Sloan-Kettering Cancer Center

Purpose: The importance of vitamin D in cancer has achieved national attention. Vitamin D deficiency is associated with worse outcomes in patients with breast, colorectal and lung cancer and an increased risk of colorectal cancer in multiple large epidemiological and observational studies involving 16,000-38,000 patients. An RCT using calcium ± vitamin D or placebo in 1179 post-menopausal patients showed decreased cancer incidence with vitamin D levels approximating 40 ng/ml. A recent major epidemiologic review of 10 prospective cohort trials involving over 368,000 patients found no association between vitamin D levels and cancer incidence in uncommon cancers- endometrial, esophageal, gastric, kidney, non-Hodgkin lymphoma and ovarian cancer. However, a twofold increase in pancreatic cancer incidence was found with vitamin D levels >40 ng/ml. Clarification through additional research is needed. As a first step towards analyzing vitamin D levels with survival we assessed vitamin D tests ordered at MSKCC regarding test frequency, vitamin D values obtained and vitamin D supplementation administered.

Methods: 25-hydroxy vitamin D level is the standard marker for body stores of vitamin D. We searched the MSKCC clinical database for all such values requested at MSKCC from January 1, 2003 through June 30, 2010, and obtained data on

specific cancer diagnosis, survival status, age, race, gender, BMI and vitamin D prescriptions dispensed at MSKCC.

Results: 12,817 unique individuals for whom 25-hydroxy vitamin D level had been requested were identified; preliminary analyses are reported here. (1) Patterns of vitamin D testing: There was an exponential increase in the number of vitamin D tests ordered over time. In 2003, an average of 33 vitamin D tests were requested monthly, increased thereafter, and essentially have doubled since 2005, with over 1,300 tests ordered each month in 2010. (2) Vitamin D administration: Increased numbers of vitamin D prescriptions were filled; the majority of patients received vitamin D2, although calcitriol was also administered. (3) Vitamin D levels in patients: The vast majority of patients were found to be deficient as defined by serum levels <30 ng/ml. Vitamin D levels will be compared against survival data, cancer type and demographic data in future analyses.

Conclusions: Vitamin D testing is increasingly popular, with an exponential increase in tests ordered. The majority of patients were found to be vitamin D deficient. The increase in vitamin D prescriptions dispensed suggested general awareness of such deficiencies as well as an attempt to correct them. The interpretation of vitamin D test results and translating the vitamin D values into appropriate clinical practice to optimize bone density, improve survival and decrease the risk of secondary cancers is an increasingly complex task. Different vitamin D recommendations may be required for cancer prevention, for optimizing bone health, and for patients with specific cancer diagnoses. It remains to be determined whether vitamin D supplementation for vitamin D deficient cancer patients will improve outcomes.

45. Integrative Approach with Complementary Medicine to Cancer Patients in the Hospital Campo di Marte (Lucca, Italy)

Elio Rossi, Tuscany Network for Integrative Medicine; Bartoli Paola, Tuscany Network for Integrative Medicine; Di Stefano Mariella, Tuscany Network for Integrative Medicine; Pellegrini Manuela, Local Health Unit 2 Lucca ; Baldini Editta, Local Health Unit 2 Lucca

Introduction: The incidence of CAM use after the cancer diagnosis among the Tuscan cancer patients was 17%. The most widely used forms were herbal medicine (52%), homeopathy (30%) and acupuncture (13%). Use was higher in the urban area and among women, breast cancer patients, and persons with a higher education (Johannessen H. 2008). That's why we decided to establish an Outpatient Clinic for integrative medicine applied to oncology.

Aim: The aim is to give citizens qualified and evidence-based information about the use of Complementary Medicine and the principles of the correct nutrition of cancer patients; to address patients to the treatment by acupuncture, homeopathy and herbal medicine in order to decrease the adverse effects of radiation therapy, chemotherapy and hormonal therapies and improve their quality of life. The aim of the study is to evaluate the effect of homeopathic treatment in decreasing the adverse reactions of chemotherapy, radiation therapy and anticancer drugs in cancer patients and improve their quality of life.

Methods: The patient sets up a consultation visit calling to the phone number of CUP, or he's addressed by the Cancer Department of Lucca (CORD) to the info-point. In the clinic he/she will meet a medical doctor, specialised in oncology and expert in nutrition and complementary medicine, who listens to his/her problems and advise him/her about nutrition and complementary medicine. The indications to complementary treatments include the application of simple pre-defined protocols to decrease some of side effects of cancer therapies (i.e. acupuncture and/or homeopathy in chemotherapy/radiation therapy), the indication of therapeutic sessions of acupuncture/homeopathy to decrease side effects during anti-hormonal treatments (weight increase, water retention, problems of amenorrhea or menopause) and improve the quality of life.

Results: In the preliminary stage of activities, 11 patients have been visited (1 male and 10 female); the average age is 49.2 years; 6 patients were affected by breast cancer, 2 by ovarian cancer, 2 by rectal cancer, 1 by osteosarcoma, and 1 by chondrosarcoma. All the patients received homeopathic treatment: in 2 cases to relieve the adverse effects of radiation therapy, in 2 cases those of chemotherapy, in 2 to decrease secondary symptoms of menopause induced by hormone therapy. In 2 cases we tried to improve the symptoms of terminal stage patients who later deceased. In 3 cases we tried to improve the symptoms and quality of life of patients. The most used remedies were *Nux vomica* (symptoms from chemotherapy) *Radium bromatum* and *Belladonna* (symptoms from radiation therapy) and *Lachesis* and *Sepia* in artificial menopausal syndrome. The first results seem positive; however 2 patients among 11, in terminal stage, are dead.

Conclusions: Preliminary data about the effects of homeopathic treatment seem to confirm its usefulness. Statistically evaluated data will be available next months.

46. Integrative Tumor Board: A Case Report and Discussion From East-West Cancer Center

Hwa Seung Yoo, East-West Cancer Center

Aim: To introduce the application of wheel balance cancer therapy (WBCT) in cancer treatment through an intensive study of a representative patient.

Method: A 59-year-old, female patient who was a secondhand smoker and who carried no significant medical and family history was diagnosed with T1N0M1 (stage 4) lung adenocarcinoma. Immunohistochemistry was positive for thyroid transcription factor-1, CK7, cyclin D1, p53, and Ki-67 on both lung biopsy specimens. An open lobectomy with mediastinal nodal dissection followed. The patient was transferred to East-West Cancer Center (EWCC) suffering from exertional dyspnea (NYHA [New York Heart Association] grade 2) with thoracic pain and pain in both upper limbs because of the decreased ventilatory capacity and reduced exercise capacity after a pulmonary resection. She also complained of emotional stress. EWCC provided WBCT, a multimodality alternative protocol based on the theory of traditional oriental medicine. Physicians regularly monitored whether metastasis or recurrence existed through blood and radiation tests. Observations and dialogues with the patient were used to record the changes in symptoms such as thoracic pain, dyspnea, anxiety, and fear. Results. Treatments at EWCC led to a disease-free survival of 28 months without adjuvant chemotherapy. Neither metastasis nor recurrence occurred during this period. Exertional dyspnea recovered to NYHA grade 1. Other physical and psychological symptoms were alleviated.

Conclusion: This report suggests that WBCT may have the potential for extending life expectancy, controlling symptoms, and improving quality of life in cancer patients.

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47. Integrated and Individualized Lifestyle Intervention for the Patients with Cancer and Obesity

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Purpose: The incidence of obesity has increased during recent decades and made a drastic change of cancer populations in Japan. Among changes in the physiological function of adipose tissue, decreased level of adiponectin, fat specific anti-inflammatory protein, is a possible mechanism involved in carcinogenesis and cancer progression (Cancer Research 2010). We have recently started a weight management clinic to perform integrated intervention to the lifestyle-related cancer patients. In the present study, we isolate adipocyte precursors obtained from patient's fat tissue, which we call Metabolic Stem Cells (MSC) to establish individualized intervention (Hormone and Metabolic Research, 2010).

Methods: Integrated lifestyle intervention including diet & exercise program, psycho-oncology, acupuncture and aromatherapy, etc. was performed for the weight control of lifestyle-related cancer patients. Meanwhile MSC were prepared from fat tissues collected at the operation. They were differentiated in cultures into mature adipocytes and treated with drug or supplementation medium every 48 hours to assess 80 candidate agents in a 96 well plate.

Results: Increased plasma levels of adiponectin (8.95 ± 6.04 to 10.7 ± 6.85 $\mu\text{g/ml}$) were observed among patients whose BMI (26.7 ± 1.99 to 25.9 ± 1.68 kg/m^2) and visceral fat area (138.8 ± 41.0 to 137 ± 42.9 cm^2) were decreased with integrated lifestyle interventions. After three months, individualized drug or supplementation was prescribed based on their MSC profile for ameliorating hypoadiponectinemia.

Conclusion: Integrated intervention for the weight control was preferably performed for the patient to combat with obesity related cancer. For the individualized intervention, MSC system can become a way for the scientific tool to pretest and screen candidates to maintain ameliorating fat metabolic profile.

48. Integrative Oncology for Breast Cancer Patients: Introduction of an Expert-Based Model

Gustav Dobos, University Duisburg-Essen; Petra Voiss, Kliniken Essen-Mitte; Ilka Schwidde, Kliniken Essen-Mitte; Anna Paul, University Duisburg-Essen; Felix Joyonto Saha, University Duisburg-Essen

Breast cancer is one of the most frequent forms of cancer in the Western world. Although conventional therapies are standardized by guidelines, up to 30% of the decisions for chemotherapy are questionable. On the other side, treatment methods of Complementary and Alternative Medicine (CAM) are generally ignored by oncologists, in spite of its promising evidence.

The cooperation between the Departments of Senology and Department of Complementary and Integrative Medicine at Kliniken Essen-Mitte has established a new concept of Integrative Oncology based on an expert panel. It permanently reviews current scientific literature for mainstream-, as well CAM-therapies, so a state of the art knowledge for the best treatment decisions for breast cancer patients can be guaranteed. In this model, breast surgeons, physicians with specialization in CAM-therapies and mind-body instructors work together closely.

In this talk, the CAM-components of the model of Integrative Oncology for breast cancer patients will be introduced. The focus for CAM-therapies is the strengthening of self-healing capacity of the body, as well as the treatment of side effects of chemotherapy, such as: xerostomia, bone marrow depression, polyneuropathy, gastrointestinal disorders, pain of muscle and joints, depression and fatigue. A broad range of treatments such as nutrition, exercise, training in mindfulness and relaxation (relaxation response) as well as acupuncture, Chinese herbal treatment, qigong, massage therapy, substitution of vitamin D and the importance of social support will be discussed. Supportive CAM-treatments of patients are useful before, during and after chemotherapy. Based on current scientific evidence and the situation of individual patients, recommendations on different integrative treatments are developed. The concept of Integrative Oncology for breast cancer patients will be discussed.

49. Integrative Physical Therapy For Cancer: Using Principles of Ayurveda and Yoga in Traditional Physical Therapy

Nicanor Cotiangco, Riverside Medical Center Kankakee IL

Purpose: Almost all research in Integrative Oncology is focused on cures and reducing the effects of treatment. None looks at the patients life prior to the diagnosis. By using the Ayurvedic assessment tool, patient and healthcare provider will be able to look at the basic health status of the patient and determine areas that can be improved. This empowers the patient to be actively involved in their cancer recovery.

Method: Ayurvedic assessment of primary functions of the body both lifestyle and diet and teaching patients to relearn basic skills such as active relaxation, breathing, breathing movement coordination.

Result: Regardless of the "dosha" the patient had prior to diagnosis of cancer, most patients feel empowered with the awareness of the areas of their life that needs improvement.

Conclusion: Helping patients look at their lives and identify areas that they can improve and learning the skills to do so makes patients actively involved in their cancer recovery. The sense of empowerment comes from being able to focus on what they can do instead of a quick fix cure to the problem.

50. CAM in Japan Versus the US: From the Patient/Advocate Perspective

Ann Fonfa, The Annie Appleseed Project

Purpose: The patient/advocate perspective is often heard in the United States. Groups have formed around just about every type of cancer and many are grassroots whose conferences or events include CAM information. As everyone acknowledges, this is a patient-driven movement. Japan is in contrast to the United States in that the patient advocacy movement is just beginning to get respect there. African movements have a long way to go.

Methods: At the request of a Japanese corporate sponsor I traveled to Japan in July 2010. While their main goal was to have me meet and speak to a group of doctors already using integrative approaches, I wanted to meet with patients and advocates. Interestingly I met a Japanese breast cancer survivor at a meeting in Washington, DC earlier in the year and was able to arrange to see her in Tokyo. She led me to other patients. Social media like Facebook helped me find people with all types of cancer, living in Japan.

Results: The poster will present viewpoints prevalent among US patient advocates in contrast to those of the Japanese patient advocates, and some from other countries. Almost every country has its own burgeoning patient advocacy movement that is more or less involved in decision-making. Here in the US, patient advocates sit on FDA Advisory committees, work on grant reviews at the Department of Defense and at the state level, and are welcomed at national scientific conferences like the San Antonio Breast Cancer Symposium, American Society for Clinical Oncology, American Association for Cancer Research, and of course, the Society for Integrative Oncology. The patient advocate voice is different from that of a practitioner of any kind—he or she brings their personal work histories to the table—not just their cancer experience. Often this is a completely different set of experiences than the solely scientific one. This is true in Japan as well. Patient advocates have been writing articles and commenting on scientific press statements. One survivor recently got national publicity for her critical comments on a recently published article.

Patient advocacy in Africa is rooted in trying to find treatment options within the continent for patients. Most coun-

tries have very few clinics, very far apart—mostly in or near the larger cities. They generally do not have much respect for “traditional medical systems” and often strongly reflect conventional views.

Conclusion: As in the United States, the most organized patient advocacy groups are formed around breast cancer. There is a strong and growing patient advocate movement worldwide.

51. Quantitative Analysis for Cancer-Induced Cachexia

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Purpose: Medical literature estimates up to 20% of cancer deaths are attributable to the cancer-wasting syndrome known as cachexia. The current state of therapeutic options for cancer-induced cachexia (CIC) is dismal and multiple medical therapies are under investigation. Our goal is to perform a quantitative analysis of the degree to which patients are experiencing CIC.

Methods: Planned enrollment is 15 patients with Stage III - IV head and neck cancer in a pilot study to evaluate biomarkers for CIC. Patients receive eight weeks of concurrent chemo-radiation therapy consistent with the standard of care. Serum markers for known operative mechanisms in cachexia are measured: TNF alpha, C reactive protein (CRP), and interleukins 1, 6, 8 (IL-6, IL-1, IL-8). Blood is drawn at baseline (0 weeks), 4 weeks, end of radiation treatment (8 weeks) and at one month follow-up (12 weeks).

Dual-energy x-ray absorptiometry (DEXA) scans are performed for each patient at 0 and at 12 weeks to analyze body composition and provide data on muscle proteolysis and lipolysis. Patients keep 3-day food journals at 0, 4, 8 and 12 weeks to measure nutrient intake. Each patient's functional status and physical activity will be analyzed using standard activities of daily living and basic physical performance indices. Indirect calorimetry measurements measure body weight, body mass index (BMI), intracellular and extracellular water, and energy expenditure.

Through collaboration with the Department of Oncology at the University of Alberta in Canada, further analysis of the

serum is completed to identify phospholipid content of cell membranes.

Results: Two patients have completed the pilot study, both with stage IVA cancers of the oral cavity and pharynx. Patient A lost 5.5 kg of weight from baseline through his week 12 follow up appointment, with a 8.3% increase in fat mass and corresponding 8.3% decrease in fat free mass. Notably, patient A had a resting energy expenditure (REE) of 2099 Kcal/day or %126 of predicted, consistent with a hyper-metabolic rate. Final DEXA reading showed 49.8kg of lean body mass (65.2%). Patient B lost 12.6kg from baseline through his 12 week follow up appointment, with minimal loss of fat mass (0.9%). REE was 1782 Kcal/day or 101% of predicted REE with a normo-metabolic rate. Final DEXA reading showed 51.3kg of lean body mass (70%). Serum cytokine analysis and phospholipid data are pending at the time of submission.

Conclusions: Our results thus far are consistent with prior studies showing cachectic cancer patients to range from hypo to hyper-metabolic. Each of the two patients demonstrates opposing metabolic effects likely due to the acute phase inflammatory response to tumor. Patient A is hypermetabolic, with an increase of 8.3% in fat mass at the expense of lean body mass. Patient B demonstrates an even larger weight loss of 12.6kg but remains normo-metabolic with a minimal fat loss of 0.9%. His weight loss is primarily lean body mass, likely muscle proteolysis secondary to tumor. Our preliminary results demonstrate the complexity of CIC and the need for multi-modality intervention.

52. Integrating a Narrative Medicine Telephone Interview with Online Life Review Resources for Cancer Patients

Lucille Marchand, University of Wisconsin-Madison; Meg Wise, University of Wisconsin-Madison

Purpose: Cancer engenders considerable pain—and existential pain is a far greater source of distress than physical pain. Life review helps, but requires energy and skill. Chochinov (JAMA, 2002) found that eliciting hospice patients' life story via a taped interview and giving them a copy of their story reduced patient distress. We hypothesized that patients earlier in the illness trajectory of cancer could benefit from an integration of Chochinov's intervention and online life review resources (eHealth). Our purpose was to develop and test feasibility of: 1) physician-led dignity-enhancing telephone interview, 2) delivery of the life story manuscript, and 3) access to miStory, a self-directed educational website for enhancing the original life story.

Method: Patients, recruited via physician invitation at the University of Wisconsin Carbone Comprehensive Cancer Center, signed an IRB-approved consent form, tested the intervention for 3 months, and provided feedback via an exit interview. Grounded theory was used to analyze the original and final stories and exit interviews.

Results: Eleven patients enrolled; mean age 67 (43-85); 6 Stage I (1 dropped), 5 Stage IV. Everyone valued telling and receiving their story. Higher death salience yielded more extensive and reflective narrative revisions. Story themes included overcoming adversity, life is a gift, people as priority, and I am a better person because of cancer. People with no prior computer experience did not choose to use the electronic tools for enhancing their story. Older users with some computer experience required significant technical support. Computer savvy people used miStory, but requested capabilities for uploading their enhanced story and for social networking. Bereaved caregivers contacted us several months after the study to share the importance of the story in the patient/family illness experience.

Conclusion: Eliciting and delivering a life story can “jump start” a reflective life review process. eHealth can extend access to resources to enhance and share the life story. A randomized follow-up study is now under way to test whether this intervention with an enhanced web interface can improve existential well-being, family support and generativity of adults with advanced cancer.

53. Identifying, Enhancing and Applying Psychosocial Assets in Advanced Cancer

Meg Wise, University of Wisconsin-Madison; Lucille Marchand, University of Wisconsin-Madison

Purpose: Research has shown that cancer can enhance people's strength and lead to resilience and a sense of thriving. The aim of this pilot study was to learn how advanced cancer patients and their caregivers identified, amplified and applied their assets to cope with advanced cancer.

Methods: In-depth semi-structured interviews with advanced patients and their spousal caregivers asked people to reflect on their lives since diagnosis, what accounted for their positive coping, what they would advise someone just starting the advanced cancer journey, and how they thought they would be remembered. Grounded theory was used to analyze the transcribed interviews.

Results: The sample included 11 patients (7 advanced lung cancer; 4 advanced colorectal cancer) and 7 spousal caregiv-

ers of the advanced lung cancer patients. The mean age was 67 (range 31-83). The most salient pre-cancer assets included a healthy marriage, overcoming other life challenges, and a sense of adventure and life purpose (with or without religion). Despite considerable sadness and loss, participants acknowledged at least one area of life that had improved (e.g., relationships, gratitude). Three broad coping strategies emerged: (1) Enlisting and Enhancing One's Assets (e.g., relationships, mastery, humor); (2) Holding Paradoxes (e.g., both accepting and defying their poor prognosis); and (3) Reframing Time (e.g., life review, legacy, being present, and clarifying goals).

Conclusion: Focusing on the cancer experience elicited a life review. When asked, "What accounts for coping with your cancer as well as you have?" people responded with vivid vignettes and rich illness narratives. Although not the intention of the study, the interview itself functioned as a useful intervention. Participants thanked the interviewer for the opportunity to talk and reflect deeply—often for the first time—on their cancer experience. Many asked for a copy of their interview transcript. Thus, this study suggested the value of an interview-elicited illness narrative focused on coping and assets or strengths and informed our subsequent efforts to develop a narrative intervention.

54. Preliminary Study of Group Problem-Solving Therapy for Japanese Cancer Patients in Palliative Care Setting.

Kei Hirai, Osaka University; Naoko Wada, Osaka University; Naoko Kanai, Toyonaka Hospital; Naoshi Ito, Osaka University; Hiroko Motooka, Kansai University of Welfare Sciences

Background: Comprehensive care including psychological support for advanced and metastatic cancer patients are needed in palliative care setting. We preliminary developed a support program using group problem-solving therapy. Problem-solving therapy is a brief and structured intervention that focuses on skill training based on problem solving model (D'Zurilla & Goldfried, 1971). Previous study (Nezu et. al, 2003) reported the effectiveness of problem-solving therapy not only for common mental disorders but also for cancer patients' psychological distress. Moreover Japanese preliminary clinical findings suggested that the effectiveness of the treatment for alleviating psychological distress in Japanese cancer patients (Akechi et. al, 2008). However we have no experience of group problem-solving therapy in palliative care setting.

Purpose: The purpose of this study was to evaluate the feasibility and acceptability of group problem-solving therapy for psychological distress in Japanese cancer patients.

Methods: 10 cancer patients, aged between 56 and 75 years, participated in the program. Each group was composed of 4, 3, and 4 patients. The primary outcome was the drop-out rate. In addition we asked the participants to assess their degree of expectation and satisfaction in from 1 to 5 point. The Hospital Anxiety and Depression Scale (HADS) was the secondary outcome. Data were collected at a pre-, post- and a 3-month follow-up.

Results: Two of the participants drop-outed(the drop-out rate was 20%). The means of their degree of expectation at pre-program was 3.9 ± 0.35 . The means of their degree of satisfaction were 4.3 ± 0.46 at post-program and 4.0 ± 0.7 at 3-month follow-up. Additionally the means of the HADS scores were 12.1 ± 8.2 at pre-program, 10 ± 6.4 at post-program and 14.5 ± 10.1 at 3-month follow-up.

Conclusion: Our preliminary experience suggests the acceptability and feasibility of adapting group problem-solving therapy for Japanese cancer patients in palliative care setting. Further research is required to examine the effectiveness of group problem-solving therapy for emotional disorders in cancer patients.

55. The Seven Levels of Healing®: Update on Implementation in the Rocky Mountain Cancer Centers Network

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Purpose: The Seven Levels of Healing® is a comprehensive integrative oncology education and support program designed to help patients and loved ones coherently address the mental, emotional, and spiritual as well as physical issues encountered on the cancer journey. Since completion of a pilot project at the Rocky Mountain Cancer Centers (RMCC) in Boulder, CO in 2008, implementation of the Program has expanded to three additional sites in the RMCC Network in Colorado. We report on the results to date of implementing this Program in a community cancer center network, and provide assessments about the Program's usefulness, impact, and benefits for participants.

Methods: Between August 2007 and July 2010, The Seven Levels of Healing® program was offered at a total of four sites in RMCC Network (Boulder, Colorado Springs, Denver, and Longmont), to anyone touched by cancer, including patients, relatives, friends, and health professionals. Specially trained

RMCC staff facilitated the seven-week Program's weekly two-hour sessions. Potential participants attended a two-hour Introductory Session prior to enrolling. Feedback forms were collected at the end of each session and upon Program completion. The Seven Levels of Healing are: Level 1: Education and Information—provides vital information about conventional cancer diagnosis and treatment. Level 2: Connection with Others—focuses on the need for and benefits of a strong support network. Level 3: The Body as Garden—explores the safe and effective use of evidence-based CAM. Level 4: Emotional Healing—addresses the important emotional issues often encountered on the cancer journey. Level 5: The Nature of Mind,—explores how thoughts and beliefs, and the meanings given to events, influence one's experience of cancer, and life. Level 6: Life Assessment—guides participants to discover the deepest purpose of their lives and their most important goals. Level 7: The Nature of Spirit—explores the spiritual dimensions of life and healing.

Results: 417 individuals participated in one of 38 seven-week Programs: 308 women, 109 men; ages 27-87 (average=55; median=56). Participants included 272 patients (189 in active treatment; 83 treatment completed), 109 relatives, 17 friends, and 16 healthcare professionals. Combined "very useful" or "extremely useful" ratings for each Level session were: Level 1=79%, Level 2=85%, Level 3=82%, Level 4=84%, Level 5=77%, Level 6=90%, Level 7=92%. Upon completion of the seven-week Programs, 92% of respondents (n=310) rated their overall experience as "excellent" or "outstanding." When asked if they would refer others to the Program, 88% of participants stated they would do so "strongly" or "enthusiastically." Participants also consistently reported multiple benefits derived from the Program, including numerous positive impacts on their sense of physical, mental, emotional, or spiritual well-being.

Conclusion: These findings demonstrate the feasibility of implementing The Seven Levels of Healing® program in a network of community cancer centers, with a strong, positive response from a highly diverse group of participants. The Program is now in its third year, and implementation in additional RMCC centers is underway. Future goals include expanded research on its impact, costs, and benefits for physicians and staff, as well as for participants.

56. A Need for Change: Implications from an Analysis of Participants in a CAM Education Program

Lynda G. Balneaves, University of British Columbia; Antony Porcino, University of British Columbia; Eric Wong, University of British Columbia; Marja Verhoef, University of Calgary; Tracy L.O. Truant, BC Cancer Agency

Purpose: Cancer patients, support persons, and health care providers (HCPs) struggle with making decisions about complementary and alternative medicine (CAM), even though up to 80% of Canadians with cancer use CAM. The Complementary Medicine Education and Outcomes (CAMEO) research program opened at the British Columbia Cancer Agency (BCCA) in April 2008 to address the CAM information and decision support needs within the BCCA. CAMEO does so by providing a variety of programs, including information support (phone and email consultations), education sessions and courses, and 1:1 counseling. This presentation provides an analysis of the type of individuals contacting CAMEO, their information and decision support needs, and the interventions provided.

Methods: All participants contacting the CAMEO program are logged into a database that captures demographic variables (i.e., type of participant, type of cancer, type of health care professional (HCP)), the reason for contacting CAMEO, the CAM information/support requested, and the intervention provided. Descriptive statistics were used to summarize key demographic characteristics and services provided. Content analysis was used to examine the reasons for contacting the CAMEO program.

Results: Of the 464 participants included in the database to date, 60.1% are patients, 20.3% support persons, 17.9% HCPs, and 1.7% CAM practitioners. The reasons for contacting CAMEO include: 1) Questions about CAM therapies; 2) Finding and evaluating CAM information; 3) Working with CAM practitioners; and 4) Requesting other information. The first three categories, specific to CAM therapy information, represent 38.1% of all initial contact, the fourth category the remaining 61.9%. Questions about CAM Therapies includes general queries about CAM treatment options, and specific queries about CAM therapies, lifestyle recommendations, or the safety of combining CAM with conventional treatments. Finding and Evaluating CAM Information includes questions about identifying and accessing credible information, and evaluating the scientific merit of information. Working with CAM Practitioners includes requests for referrals and information on finding practitioners. It also includes questions on how to manage contradictory information obtained from CAM practitioners and conventional HCPs. Requesting Other Information captures pragmatic reasons for contacting CAMEO. These include registering for research projects and courses, general questions about CAMEO, and requests for collaboration from CAM therapy providers. Many consultations initially focus on registering for courses or general CAMEO information but develop into requests for specific CAM information or decision-making support. With regards to interventions provided, 41.2% of all participants received

information via email or phone; 53.4% of patients/support persons and 22.9% of HCPs attended a group education course; 5.0% of patients were recruited to 1:1 counseling; and 13.3% of patients received referrals to a BCCA HCP.

Conclusion: The CAMEO program is increasingly being contacted for information provision and decision support by a variety of individuals with a range of information needs, demonstrating its relevance and viability. The findings of this analysis will inform existing and future CAMEO interventions. In addition, the findings are important in identifying how interventions should be prioritized and made available as a crucial and much-needed part of standard care within conventional cancer care settings.

57. The Effect of Reflexology in Cancer Patients with Pain in Palliative Care

Marcia Molinaro, National Cancer Institute; Pedro Fernandes, National Cancer Institute; Neli Muraki, National Cancer Institute

Purpose: The concept of Total Pain is a syndrome associated with physical, social, psychological and spiritual factors. Reflexology is the physical act of applying pressure to the feet and hand with specific thumb or finger techniques, based on a system of zones and reflex areas that reflect an image of the body on the feet and hands with a premise that such work effects a physical change to the body. The purpose of this study is to assess the effect of Reflexology in cancer patients with pain in Palliative Care.

Method: Randomised control trial, approved by Ethics Committee and Research, Protocol 82/09, with adult cancer inpatients of National Cancer Institute of Brazil, at Palliative Care Unit. The criteria of inclusion were: Visual Analogue Scale (VAS) between 4 and 7 in order to classify the pain, the Karnofsky Performance Scale (KPS) more than 40%, which allows patients to be classified as to their functional impairment. The intervention group received reflexology and the group control received superficial touch, both on the foot.

Results: 17 patients have been attended, 8 patients belong to the Reflexology Group and 9 belong to the Superficial Touch. The mean of age was 52.47 years. 11 patients were female and 6 male. The Karnofsky Performance Status: 11 had 40%, 4 had 50% and 2 patients had 60% of KPS. The location of pain reported: 4 reported pain in the head, 3 in the lumbar spine, 2 in the thoracic spine, 2 in the sacral spine, 2 in legs and four in other locations. The mean of pain before the Reflexology intervention was VAS 6.23, and after the Reflexology intervention was VAS 3.00.

Conclusion: It was noticed that Reflexology is efficient in the pain control, and patients reported other benefits, like: reduction of nausea and anxiety and feel safe and calm. This research is not finished yet, and we are working on that.

58. Yoga for Pain in Pediatric Hematology-Oncology Patients

Karen Moody, Children's Hospital at Montefiore; Majorie Vadhais, Children's Hospital at Montefiore; Ruth Santizo, Children's Hospital at Montefiore; Bess Abrahams, Children's Hospital at Montefiore; Jeremy Ader, Children's Hospital at Montefiore

Purpose: The purpose of this report is to describe the effectiveness of an initial yoga session in pediatric hematology-oncology patients presenting with pain.

Methods: Pediatric patients with sickle cell or cancer from the pediatric in-patient unit and outpatient day hospital were offered one-on-one bedside yoga by a certified yoga instructor, as part of the supportive care offered to this population at the Children's Hospital at Montefiore (CHAM). Yoga is a mind-body practice designed to achieve greater self-awareness, self-control, and overall well-being through a combination of meditation, breathing, relaxation exercises, and physical postures. At CHAM, the Integrative Medicine and Palliative Care Team developed a yoga intervention for children with cancer and sickle cell disease. Each yoga session was created using approaches from two therapeutic modalities: Integrated Movement Therapy™ and restorative yoga techniques. We reviewed the charts retrospectively of all 108 patients who received yoga interventions from December 2007 to June 2010. We extracted demographic characteristics, primary diagnosis, pain scores and qualitative direct personal quotes documented in the charts. This report describes those patients who presented with baseline pain scores >0 and for whom a post-yoga pain score was recorded. Patients who fell asleep after their yoga session, and thus had no documented post-yoga pain scores were excluded. We chose to collect data exclusively for the patients' initial yoga sessions in order to assess if yoga could be effective as a one-time intervention and for ease of comparison across participants. Patients reported their level of pain before and after the initial yoga session using the 10-point Wong-Baker FACES pain rating scale, a scale that has been shown to be valid and reliable with ill children. Pain scores before and after yoga were compared with a Student's t-test for paired samples.

Results: There were a total of 20 patients who presented for their first yoga session with a complaint of pain (score >0). Sixty five percent of the participants were female and the aver-

age was 15.25 years with a range of 6-20 years. The most common ethnicities represented were Black or African American (70%), multiracial (10%), and White (5%). The most common diagnoses were sickle cell disease with vaso-occlusive pain crisis (65%), sarcoma (20%), and leukemia (15%). The average baseline pain score was 6.90 (SD±2.25), with a range from 1 to 10. Right after participating in the initial yoga session, this score was reduced to 5.48 (SD±2.81) with a range of 0 to 10. The mean reduction in pain scores was 1.43 (SD±1.62), $p < .001$. Sample quotes included: "My body feels more relaxed; I liked that." and "I forgot all about the pain".

Conclusions: Our data offer preliminary support for the effectiveness of a single yoga session as an intervention among pediatric hematology-oncology patients for pain. The average reduction of pain by more than 1 point suggests significant clinical benefit. Quotes suggest that the yoga session was helpful in our population. These promising results suggest that the use of yoga as an intervention for pain in pediatric patients needs further research.

59. Development of a Viniyoga Protocol for Lung Cancer Patients

Judith Fouladbakhsh, Wayne State University; Sharma Vijai, American Viniyoga Institute; Flynn Tracy, Independent Yoga Teacher; Kraftsow Gary, American Viniyoga Institute

Purpose: This project aimed to develop a standardized yoga intervention protocol based on the American Viniyoga tradition for use in research with lung cancer patients. Protocol development is recognized as essential to yoga research, given the increasing prevalence and interest in yoga for wellness and symptom management and the need for consistency across studies.

Methods: Experts in Viniyoga were recruited to participate in the protocol development and included: Gary Kraftsow, the Director of the American Viniyoga Institute and author of the text "Yoga for Wellness" with previous protocol development expertise and participation in NIH funded studies; Dr. Vijai Sharma, a doctorally prepared psychologist and Registered Yoga Therapist with expertise in respiratory illness (COPD and emphysema); 3) Tracy Flynn, experienced Viniyoga teacher and study interventionist, and 4) the study investigator (longstanding yoga practitioner, healthcare provider, nurse faculty and CAM researcher). Meetings were held to establish a series of 8 45-minute classes with specific body postures (asanas), breathing exercises (pranayama) and calming meditative practices based on scientific rationale for the specific study population with recognition of illness and symptom concerns.

Results: The Viniyoga intervention protocol has been developed and implemented in a pilot research study (N=9) with post-treatment non small cell lung cancer patients, stages I-IIIa in a community-based setting. A series of 8 classes has been conducted using the protocol with male and female lung cancer patients ranging in age from 51 to 78; manuals for home-based practice and teacher-guided audiotapes have been developed and provided to study participants. Each 45-minute yoga class included a series of poses (asanas), breathing exercises, and meditation practices with specific focus on maximizing respiratory function, and recognizing potential limitations due to participant age and co-morbidity. Seven of nine study participants were successful in completing the study intervention of 8 week classes (1 withdrew, 1 died of other health problems prior to the intervention). No respiratory distress, dizziness or fatigue was noted during the 8 yoga sessions; Modifications for poses (chair vs mat) included in the protocol were used for eldest participants (78 & 74 yrs) as needed; classes fit 45 minute study time frame and home practice was reported at 100%. Qualitative data indicate positive responses to class sessions (e.g. "relaxing yet energizing"; "calming" etc).

Conclusions: This project has resulted in the development and implementation of a standardized yoga protocol based the Viniyoga tradition and on sound rationale from a panel of yoga and healthcare experts for the target population. The protocol worked effectively as an intervention for the pilot study and will be used in a larger study with cancer patients.

60. Preliminary Study to Develop the Instrument of Pattern Identification for Jing-ji and Zheng-chong

In Chul Jung, Daejeon University

Purpose: This study was performed to develop a standard instrument of pattern identification for Jing-ji and Zheng-chong.

Methods: The advisory committee on this study was organized by 15 neuropsychiatry professors of oriental medical colleges. The items and structure of the instrument were based on a review of published literature. We took consultation 2 times from the advisory committee and we took additional advices via e-mail.

Results: 1. We divided the symptoms and signs of Jing-ji and Zheng-chong into 9 pattern identification: heart deficiency with timidity(心膽虛怯), heart qi deficiency(心氣虛), heart blood deficiency(心血虛), heart yang inactivity(心陽不振), heart blood stasis(心血瘀阻), phlegm turbidity obstruct-

ing(痰濁阻滯), yin deficiency with effulgent fire(陰虛火旺), water qi intimidating the heart(水氣凌心), dual deficiency of the heart and spleen(心脾兩虛). 2. We got the mean weights that reflect standard deviation to each symptom of 9 pattern identification which had been scored on a 100-point scale. 3. We designed the Korean instrument of the pattern identification for Jing-ji and Zheng-chong. It was composed of 17 questions in question-and-answer form.

Conclusions: Instrument of pattern identification for Jing-ji and Zheng-chong was developed through experts' discussion. If the validity and reliability of this instrument is confirmed through additional clinical trial, the instrument of pattern identification for Jing-ji and Zheng-chong is expected to be applied to the subsequent research. Also we expect that this instrument will be applied to oriental medical diagnosis of anxiety in cancer patients.

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61. The Effects of Moxibustion on the Heart Rate Variability(HRV) in Cancer Patients

Hwa Seung Yoo, East-West Cancer Center, Daejeon University; Ok Hee Kim, Daejeon University; Rina Yu, Daejeon University

Objectives: We investigated the effects of moxibustion on autonomic nervous system with the Heart Rate Variability(HRV) in cancer patients, as well as we tried to observe how moxibustion on the balance of the autonomic nervous system.

Methods: We investigated the effects of moxibustion on autonomic nervous system with the Heart Rate Variability(HRV) in cancer patients, as well as we tried to observe how moxibustion on the balance of the autonomic nervous system. 10 patients with various cancers hospitalized in East-West Cancer Center volunteered. Their heart rate variabilities were checked before moxibustion. Indirect moxibustion was done at RN4, RN6 and PC6. HRV was checked by Max Pulse.

Results: Sympathetic nerve level became lower after moxibustion.

Conclusions: The results suggest that moxibustion in cancer patients tend to activate the autonomic nervous system.

62. Discrepancy of the Preference for Herbal Medicines in Cancer Patients with Psycho-Oncology Condition: A Survey on Thyroid Cancer Patients in South Korea

Dal-Seok Oh, Korea Institute of Oriental Medicine; Young-Suk Jo, Chungnam National University Hospital; Jong-Woo Kim, Kyung Hee University East-West Neo Medical Center; Bo-Ra Gwon, Korea Institute of Oriental Medicine; Nosoo Kim, Korea Institute of Oriental Medicine

Purpose: Anxiety, depression, or anger are not only the matter at the moment of being diagnosed as cancer (CA), it can but affect the disease progress, and health related quality of life (HRQoL) in CA patients (Pts). The objective of this survey was to investigate the supportive care on psycho-oncology (PO) reduction, the preference of herbal medicine and functional health food among the thyroid CA Pts in South Korea through rendering face-to-face interview surveys.

Methods: Inclusion criteria were thyroid CA Pts who felt PO condition including stress from the event of CA diagnosis within 5 years, and who were willing to be an interviewee. Groups were divided as severe (≥ 60 in stress index) PO condition group, mild to moderate condition group. Interviewers were pre-trained according to the interview protocol. This survey was conducted at endocrinology unit of internal medicine not in Oriental hospital but in Western hospital in order to reduce the selection bias of the interviewees from March through June, 2010. Total estimated population was about 90 thyroid CA Pts per group.

Results: About one third CA Pts have used self-supportive care intermittently, which was mainly passive ones, such as self-exercise, weekly mountain climbing. Their need on PO care was higher (65%) than expected, but, self-exercise was selected as the first choice. The general preference was higher in herbal medicines than in functional food by 1.9 folds. In the specific choice of active palliative care methods, on the contrary, the latter was preferable to the former by 1.5 folds.

Conclusion: The concept of active PO care was not apparently prevailed among the CA Pts with PO condition. Herbal medicine is less known for its therapeutic properties to the CA Pts with the specific PO needs due to the inappropriate claims. Further prospective clinical studies are needed to investigate the psycho-somatic effect of the botanicals on CA biomarkers or HRQoL.

63. Ear Acupuncture for Treatment of Cephalea as Side Effect of Antiemetic Post-Chemotherapy

Luigi Gori, Regional Center of Phytotherapy—Tuscany Sanitary Service; Vittorio Mascherini, Regional Center of Phytotherapy—Tuscany Sanitary Service; Alfredo Vannacci, University of Florence, Florence; Fabio Firenzuoli, Regional Center of Phytotherapy—Tuscany Sanitary Service

Cephalea represents one of the most costly diseases because of its very high prevalence, and in cancer patients can be particularly disabling. Antiemetic drugs like Ondansetron, Granisetron, Tropisetron, Dolasetron can have as common side effect cephalea with an incidence between 3 and 24%. We treated 18 consecutive patients with ear acupuncture for cephalea due to post chemotherapy antiemetic treatments. Were excluded patients in which cephalea could be secondary to metastases, surgical treatment or other causes not related to antiemetic therapy. Patients (median age 62 y.o., range 51-82 y.o.; female: male ratio 2.3:1) underwent 6 treatments in alternate days as outpatients. We enrolled patients who were non responders to common synthetic drugs treatments and reporting more than 3 episodes weekly after chemotherapy. They were evaluated on the base of the VAS scale, duration, frequency of episodes and use of drugs before and after treatment. Patients showed a median improvement of 32% on VAS, and reduction in frequency and median duration of episodes. 4 patients were considered non responders. There were no adverse events. Ear acupuncture can be considered safe and probably an be efficacious in the treatment of cephalea.

64. Effects of Allergen Removed Bee Venom Phamacopuncture on Chemotherapy-Induced Peripheral Neuropathy - A Pilot Study

Jae-Woo Park, East-West Cancer Center, Dunsan Oriental Hospital, Daejeon University; Ju-Hyun Jeon, Pain and Spine Center, Dunsan Oriental Hospital, Daejeon University; Stephen Sagar, McMaster University; Raimond Wong, McMaster University; Hwa Seung Yoo, East-West Cancer Center, Dunsan Oriental Hospital, Daejeon University

Objective: This study aimed to evaluate the clinical effect and safety of Allergen Removed Bee Venom Phamacopuncture (ARBVP) on chemotherapy-induced peripheral neuropathy (CIPN).

Method: Five patients who visited East West Cancer Center (EWCC) with CIPN were treated with ARBVP 3 times per week for one week. The selected acupuncture points are Ba Xie or Ba Feng. Each point was injected with 0.1 ml of

ARBVP. Total amount of ARBVP per one treatment was 0.4 or 0.8 ml. To evaluate the efficacy of ARBVP treatment, visual analog system (VAS), WHO CIPN grade and FACT-G (Health related quality of life) were compared before and after each treatment.

Results: After treatment, VAS score was significantly decreased ($P < 0.05$). Physical score in FACT-G was also significantly increased ($P < 0.05$). But WHO CIPN grade score and total FACT-G score showed no statistical difference (WHO CIPN grade: $P = 0.051$, FACT-G: $P = 0.25$). There were no adverse events.

Conclusion: This study suggests that ARBVP can be a potential candidate to relieve CIPN without side effects. Further clinical studies are required.

65. Effects of Vanadium Water on Cancer-Related Fatigue of Non Advanced Cancer Patients: Randomised Double Blinded Control Trial

Hong-Mei Zheng, East-West Cancer Center, Dunsan Oriental Hospital, Daejeon University; Dong-Hee Kim, Daejeon University; Suk-Hoon Lee, Chungnam National University; Yoo-Kyoung Park, Kyung Hee University; Hwa-Seung Yoo, East-West Cancer Center, Dunsan Oriental Hospital, Daejeon University

Objective: Evaluation of efficacy and safety of vanadium water (VW) on cancer-related fatigue of non-advanced cancer patients.

Methods: Experimental Group Administration Method: Participants administered three 500 ml/bottle bottles of Jeju Island's VW, which contains 40.2 μ L of vanadium, three times a day (morning, afternoon, evening) for 4 weeks (28 days) without any additional treatments for fatigue improvement. Control Group Administration Method: Participants administered three 500 ml/bottle bottles of ordinary water three times a day (morning, afternoon, evening) for 4 weeks (28 days) without any additional treatments for fatigue improvement.

Results: After 4 weeks of VW consumption, comparison of more than 30% reduced RPFS (Revised Piper Fatigue Scale) total score and base score through Fisher's Exact Test resulted statistical borderline significance ($p = 0.0799$) and result of t-test of comparison between two groups' RPFS total score and fatigue cognitive/mood changes resulted statistical significance ($p = 0.0112$). In detail, only 36.4% of control group ($N = 11$) showed improvement while 77.8% of treatment group ($N = 9$) showed fatigue improvement and com-

parison of thyroid hormone level changes between groups for safety evaluation didn't indicate any significant differences.

Conclusion: Daily consumption of 1.5 L of vanadium water for 4 weeks showed improvement of non-advanced cancer patients' fatigue.

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66. Zyflamend Inhibits the Expression and Function of Androgen Receptor and Acts Synergistically with Bicalutimide to Inhibit Prostate Cancer Cell Growth

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Background: Interference of androgen receptor (AR) signaling is a target for prostate cancer chemoprevention and treatment. We hypothesize that Zyflamend (ZYF) assert its anti-cancer effect by disrupting AR signaling. We also hypothesize that it may act synergistically with the anti-androgen bicalutimide to inhibit CaP cell growth.

Methods: Western blotting, ELISA and reporter assays were done to test ZYF on AR signaling. Semi-quantitative RT-PCR and AR half-life were also examined. Potential synergism between ZYF and bicalutimide were tested via cytotoxicity, colony formation assays, flow cytometry and Western blotting in the human CAP line, LNCaP.

Results: ZYF reduced AR protein, mRNA and protein stability levels in LNCaPs. Nkx3.1 and PSA were also reduced at the mRNA level. PSA promoter activity and secretion were lower after treatment of cells with ZYF. DHT induction of cell proliferation and AR responsiveness revealed reduction of AR, Nkx3.1 and PSA protein were demonstrated with ZYF treatment. Co-treatment with bicalutimide reducing cell growth, induced apoptosis and reduced Bcl-2 and BclxL, caspase-3 and PARP. Co-treatment also reduced Nkx3.1 and PSA protein.

Conclusions: These data indicate that ZYF suppresses cell growth mediated by AR signaling, and suggests that the co-treatment with the anti-androgen bicalutimide and ZYF may be a promising approach for cancer therapy and may demonstrate the mechanism of action of Zyflamend.

67. Zyflamend Mediates Therapeutic Induction of Autophagy to Apoptosis in Melanoma Cells

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Purpose: Melanoma is the most aggressive form of skin cancer. The rising incidence of melanoma and its poor prognosis in advanced stages are compelling reasons to identify novel therapeutic agents. While isolated dietary components such as lycopene, resveratrol, and isothiocyanate compounds have been shown to provide at least limited protection against cancer development, the use of whole herbs and herbal extracts for the prevention and treatment of cancer has not been fully studied and remains of great interest. Botanical supplements, specifically dietary botanicals, possessing anti-inflammatory, immunomodulatory and antioxidant properties are among the most promising group of compounds. In recent years, many researchers have studied the anti-proliferative effects of active constituents of natural products on the proliferation of malignant cells, and as a result the anti-inflammatory and anti-proliferative activities of many plant extracts has long been considered as supplemental therapeutics for cancer. Zyflamend®, a unique multi-herbal extract preparation, is a promising anti-inflammatory agent which has also been suggested to regulate multiple pathways in cancer progression, and data further suggests that Zyflamend contains ingredients that can suppress tumor cell proliferation, invasion, angiogenesis, and metastasis through regulation of inflammatory pathways. Therefore, we hypothesized that this multi-herbal preparation might inhibit melanoma proliferation by regulating multiple key anti-melanoma pathways in these cells.

Methods: To test this hypothesis, we studied the effect of Zyflamend on human melanoma tumor cell proliferation, migration, cell cycle regulation, direct cytotoxicity, apoptosis by Annexin V and autophagy by Transmission Electron Microscopy (TEM) Analysis.

Results: Here, we present that Zyflamend, as a multi-herbal agent "cocktail", inhibits melanoma growth by regulating the autophagy-apoptosis switch. Most significantly, the response to Zyflamend actually initiates caspase 9 cleavage, presumably due to sequestration of mitochondria in autophagosomes, and thus activates the intrinsic caspase cascade and apoptosis.

Conclusion: Our study highlights the importance of the use of whole herbs and concentrated herbal extracts, for the regulation of melanoma cell growth and Zylflamend in particular represents a particularly effective as well as potent candidate for consideration for an integrative oncologic approach to melanoma treatment.

68. Toxicological Study on Hang-Am-Plus in Mice

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Object: The major aim of this study was to define the toxicity of Hang-Am-Plus(HAP) in mice in short term and long term period.

Method: Subsequently, HAP was tested in an oral 1-week single oral dose toxicity test in male ICR mice and 5-week repeated toxicity study. Dose levels of single oral dose toxicity test are 0, 0.2, 1, 5 and 25 g/kg/day and those of repeated toxicity study are 0, 0.04, 0.2, 1 and 2 g/kg/day. We assayed their blood and urine and observed their morphology. Then we compared each numerical data by using Mann-Whitney U-test and ANOVA test.

Results: In single oral dose toxicity test, we observed a significantly lower value of RBC in mice of the S2-HAP, S3-HAP, S4-HAP, S5-HAP. And a significantly lower value of Hb, HCT, MCH in mice of the S4-HAP, S5-HAP groups were shown. In repeated dose toxicity study, there were no mortalities, no significant differences in every factor during the dosing period.

Conclusion: The no-observed adverse effect level (NOAEL) for the 8-week study with SB was considered to be over 2 g/kg/day.

69. The All-New Generation of the Fermented Wheat Germ Extract

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The fermented wheat germ extract, which is manufactured in Europe and the United States, has been the subject of several experiments and clinical studies in the field of cancer and autoimmunity. The extract primarily inhibits enzymes specifically associated with glucose metabolism in cancer

cells and the Warburg effect: lactate dehydrogenase, hexokinase, glucose-6-phosphate dehydrogenase and transketolase. It has no such effects on healthy cells. Drawbacks for using the previous product containing the extract were as follows: 1. the presence of a significant amount of maltodextrin, needed as a technological additive in the fermentation liquid for spray-drying; and 2. the product contained a large amount of fructose—because of organoleptic reasons. Thus, the weight of a single dose of the product was large. Additionally, instant properties of the product were also poor. It had an unpleasant smell and taste which hindered its widespread use.

Recently, an all-new generation of the fermented wheat germ extract has been developed. This product contains the freeze-dried concentrate of the pure fermentation liquid without maltodextrin or other added sugar. The new product preserves or exceeds the efficacy of the previous product, it is highly soluble in water and has pleasant organoleptic properties.

HPLC fingerprint chromatography spectra of the previous (spray-dried) and the new generation (lyophilized) products were similar. However, biological assays demonstrated improved efficacy for the lyophilized form. IC50 values for the new generation product, tested on several cancer cell lines, were similar or smaller than those for the previous product. In an experimental murine sarcoma model the lyophilizate showed significantly better tumor inhibition and overall survival than the spray-dried one. These results confirm prior research showing the heat labile nature of some of the molecules found in the fermented wheat germ extract. It is recommended that the lyophilized form be used exclusively in future research and for other uses.

70. Qualitative and Quantitative Gas-Chromatography-Mass-Spectrometry Analysis of Ephedrine on Traditional Chinese Medicine based Ephedra sinica (Ma Huang) Preparations Containing Versus Ephedra Decoction and Infuse.

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In Italy 15 millions of patients (15% -25 % of all patients) refer to complementary and alternative medicine (CAM). In accord with TCM theory, ephedra (*Ephedra sinica*, Ma Huang) is prescribed as traditional decoction for treatment

of respiratory diseases and other illnesses; as traditional remedy and preparation is considered safe. While ephedra containing dietary supplements were widely used in Europe and United States to promote weight and energy enhancement, but cases of sudden death, stroke, cardiovascular accident, hepatotoxicity and other side effects have been reported, so that in many countries has been banned or strictly regulated. Some cancer patients use ephedra used following the patterns of Chinese traditional medicine as treatment of fatigue and respiratory distress.

We performed gas-chromatography-mass-spectrometry analysis on traditional decoctions and infuse of ephedra to evaluate different concentrations of ephedrine and its derivatives. We prepared five types of concoctions; the first three of them in accord with traditional Chinese Materia Medica: 1) Ma Huang (decoction of ephedra), 2) Ma Huang Tang (MA HUANG and GUI ZHI (ramulus cinnamomi), XING REN (semen pruni armeniaca), ZHI GAN CAO (radix glycyrrhizae uralensis and honey), 3) Shan Han Lun (decoction MA HUANG with MA HUANG TANG) 4) ephedra infuse 5) ephedra decoction.

Results: Ephedra with other herbs concoctions, prepared on the base of traditional Chinese medicine contain a greater concentration of ephedrine than simple Ephedra infuse and decoction, so remain a dangerous treatment especially for cancer patients.

71. Immunostimulation of Natural Killer (NK) Cells by North American Ginseng in Adult and Juvenile Mice: Short Term Exposure Produces Long Term Effects.

Sandra Miller, McGill University; Lianping Ti, McGill University

Purpose: Cells mediating spontaneous cytolytic activity against tumor cells belong to the innate, non-adaptive immune system and are referred to as natural killer (NK) cells. Pre-weaned and newly weaned mice show little or no NK cell activity - the latter developing at puberty. We have shown that the cytokine, Interleukin-2 (IL-2) is capable of stimulating new NK cell production in both adult and juvenile mice. An agent capable of augmenting IL-2 production is a proprietary extract of ginseng, CVT-E002 (AFEXA Life Sciences, Inc.). We, thus, hypothesized that young adult and juvenile mice, fed CVT-E002 in their chow daily for 4 weeks, would show increased absolute numbers of NK cells - but would this effect be transient or sustainable?

Methods: Young adult C3H mice (8-9 wk) were given dietary CVT-E002 (80mg/6gm chow/day). Four wk later

(age: 12-13 wk), one group was euthanized and the bone marrow (BM), spleen and blood were assayed for their NK cell content. A second group was returned to untreated chow for the following 8 wk and then euthanized (age: 20-21 wk). Another group (C3H, juvenile) was given graded doses (to account for growth) of CVT-E002 at weaning (age: 4 wk) for 6 wk, then returned to untreated chow for the following 8 wk, and euthanized at age 18 wk. For all groups, identical controls consisted of mice given untreated chow throughout. For every mouse (CVT-E002-fed and control), the BM, spleen and blood, after extraction, were prepared by our standard laboratory methods to reveal the absolute numbers (BM, spleen), or relative (%) numbers (blood), of NK cells.

Results: (i) NK cells in the BM, spleen and blood were significantly elevated ($p < 0.005$:BM; $p < 0.0001$:spleen; $p < 0.0001$:blood) in young adult mice (8-9 wk) when assessed immediately after 4 wk of dietary CVT-E002 (age: 12-13 wk); (ii) when CVT-E002 was withdrawn at 4 wk and the mice were placed on regular diet for the following 8 wk (age: 20-21 wk), the spleen and blood still contained significantly more NK cells vs control ($p < 0.01$:spleen; $p < 0.05$:blood) with the BM having only slightly elevated NK cells vs control; (iii) for newly weaned, 4 wk old mice fed CVT-E002 for 6 wk followed by 8 wk on regular chow, all 3 organs had significantly ($p < 0.05$ - $p < 0.01$) more NK cells at sampling (age: 18 wk) than did corresponding controls in spite of the fact that these mice had not been exposed to CVT-E002 for the last half of their lives.

Conclusion: The maintenance of super-normal levels of NK cells, initially, and long after withdrawal of CVT-E002, is believed to be due to the latter's influence on the NK cell-governing BM and/or splenic stromal cell microenvironments. Irrespective of mechanism, however, the concept of providing this ginseng derivative as a food additive to boost immunity in adult or juvenile mammals could have profound prophylactic effect.

72. The Potential Role of TCM Differentiation in Pancreatic Cancer Growth

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Purpose: To evaluate the specific effect of TCM differentiation on pancreatic tumor growth and to uncover the potential function of "treatment based on differentiation" ("BianZhengLunZhi" in Chinese) in pancreatic cancer.

Methods: We established subcutaneous tumor models of pancreatic cancer with different differentiation including Damp heat ("Shi-Re" in Chinese) differentiation, Spleen deficiency ("Pi-Xu" in Chinese) differentiation, Blood Stasis

("Xue-Yu" in Chinese) differentiation in 48 C57/BL mice. Two days after TCM differentiation model established, panc02 cells were injected into the right subaxillary of all mice, 2x10⁶ cells for each. The effect of each TCM syndrome on subcutaneous transplanted tumor were evaluated. Tissue samples of subcutaneous transplanted tumors from Non-differentiation group and the differentiation groups in which tumor growth was slowest or fastest were selected for the continuing study.

The expression changes of CCR5, CXCR4, CCL3, CCL4, CCL5, CXCL12 mRNA in pancreatic carcinoma subcutaneous tumor with different differentiation were detected by semi-quantitative PCR. The protein level of CCR5, CXCR4, CD34 were observed by immunohistochemical staining. CCL3, CCL4, CCL5 which are ligands of CCR5 and SDF-1 present in subcutaneous transplanted tumor were determined using a sandwich ELISA kit (Duoset; R&D Systems). Seventy-two C57/BL mice were randomly divided into eight groups. We duplicated models of Shi-Re, Pi-Xu and Xue-Yu. Two days after TCM differentiation model established, panc02 cells were injected into the right subaxillary of all mice, 2x10⁶ cells for each. The effect of each TCM syndrome on subcutaneous transplanted tumor were evaluated and the response of TCM formula which was based on classic TCM theory "BianZhengLunZhi" on subcutaneous transplanted tumor with corresponding DIFFERENTIATION were also studied.

Results: The rates of pancreatic cancer subcutaneous transplanted tumor models with different differentiation are 100%. Tumor growth in Shi-Re group was slower than that in control group. Remarkably, tumors in Shi-Re group have a lower expression of CCR5, CCL4 and CCL5 than those in Non-differentiation group and Pi-Xu group. The volume of tumors in differentiation group did not decrease after administration of corresponding formula.

Conclusion: The study indicated that during the progression of pancreatic cancer the presence of TCM differentiation might be a protective reaction of the balance between body and the existence of tumor which was mediated by the expression of CCR5, CCL4 and CCL5. BianZhengLunZhi in pancreatic cancer might have no function, even might destroy the protective balance, which is remain largely unclear and need to be further studies.

73. Vitamin A and Lung Cancer: A Systematic Review

Heidi Fritz, The Canadian College of Naturopathic Medicine; Dugald Seely, The Canadian College of Naturopathic Medicine; Deborah Kennedy, The Canadian College of Naturopathic Medicine; Fergusson Dean, Ottawa Hospital Research Institute; Stephen Sagar, Juravinsky Cancer Centre

Purpose: Despite antiproliferative activity of vitamin A and use in cancer, there is no comprehensive synthesis of its safety and efficacy for patients with lung cancer. We conducted a systematic review of vitamin A and related retinoids for the treatment and prevention of lung cancer as well as assessing for possible interactions with conventional cancer therapy.

Methods: We searched seven electronic databases from inception to July 2009 for clinical, observational, and preclinical evidence pertaining to the safety and efficacy of vitamin A for lung cancer. We searched Pubmed and EMBASE from inception to July 2009 for evidence pertaining to potential interactions between vitamin A and chemotherapy or radiation therapy. Identified as potentially harmful and as a precursor to retinol, we also assessed the impact of beta-carotene on lung cancer prevention and treatment.

Results: 233 studies met inclusion criteria. Five RCTs tested Vitamin A or retinoids in the treatment of lung cancer, three assessed for primary prevention, and three for secondary prevention. Twenty-six phase I/ II, 32 observational and 67 preclinical studies were also included. Ninety-two studies were related to interactions. Although some results suggested a possible benefit, we found insufficient evidence to support the use of vitamin A or related retinoids for the treatment and prevention of lung cancer. Certain retinoids were associated with significant toxicity. Beta-carotene, with or without vitamin A, is associated with significantly increased risk of lung cancer in smokers.

Conclusion: There is a lack of evidence to support the use of Vitamin A or retinoids for the treatment and prevention of lung cancer. Beta-carotene should not be used in smokers. Retinoids deserve further study for their effects in other cancer types.

74. Selenium and Lung Cancer: A Systematic Review

Heidi Fritz, The Canadian College of Naturopathic Medicine; Deborah Kennedy, The Canadian College of Naturopathic Medicine; Rochelle Fernandes, The Canadian College of Naturopathic Medicine; Dugald Seely, The Canadian College of Naturopathic Medicine

Purpose: Selenium is a natural health product widely used in the treatment and prevention of lung cancer. Large chemoprevention trials have yielded conflicting results. We conducted a comprehensive systematic review of the safety and efficacy of selenium for the treatment and prevention of lung cancer, including an assessment of potential interactions with conventional therapies.

Methods: We searched Pubmed, EMBASE, CINAHL, Cochrane, AltHealth Watch, and the National Library of Science and Technology, from inception until August 2009, for human, observational, and preclinical evidence pertaining to the safety and efficacy of selenium for lung cancer. We searched Pubmed and EMBASE for evidence pertaining to potential interactions between selenium and chemotherapy or radiation therapy.

Results: Of 2748 records screened, 75 articles met the inclusion criteria. Of these, seven reported on a combination of three randomized controlled trials (RCTs) and two surrogate studies, 27 were observational studies, and 39 were preclinical studies. Of the RCTs, two related to primary prevention, one was related to treatment, and two investigated surrogate endpoints related to lung cancer treatment or prevention. There appears to be modification of effect by baseline selenium status, such that there may be potential benefit from selenium supplementation in populations with low baseline status, but increased risk of cancer and diabetes associated with supplementation in populations with higher baseline status.

Conclusion: Evidence is conflicting regarding safety and efficacy of selenium for lung cancer treatment and prevention. There remain unresolved questions around appropriate dose, form of selenium, and optimal selenium levels in humans.

75. Green Tea and Lung Cancer: A Systematic Review

Heidi Fritz, The Canadian College of Naturopathic Medicine; Deborah Kennedy, The Canadian College of Naturopathic Medicine; Fernandes Rochelle, The Canadian College of Naturopathic Medicine; Dugald Seely, The Canadian College of Naturopathic Medicine

Purpose: Green tea is a beverage widely used by lung cancer patients and the public at large for its purported anticancer properties. We conducted a comprehensive systematic review of the safety and efficacy of green tea for the treatment and prevention of lung cancer, including an assessment of potential interactions with conventional therapies.

Methods: We searched Pubmed, EMBASE, CINAHL, Cochrane, AltHealth Watch, and the National Library of Science and Technology, from inception to February 2010 for human, observational, and preclinical evidence pertaining to the safety and efficacy of green tea for lung cancer. We searched Pubmed and EMBASE for evidence pertaining to potential interactions between green tea and chemotherapy or radiation therapy.

Results: Of 1056 records screened, 66 articles met the inclusion criteria. Of these, two were Phase I trials, three were reports of one surrogate study, 14 were observational studies, and 47 were preclinical studies. The maximum tolerated dose ranged from 3 to 4.2 g/m² per day, and this was better tolerated in divided doses. Seven of 14 observational studies showed a significant protective effect associated with higher levels of green tea intake.

Conclusion: There is insufficient evidence around the efficacy of green tea for the treatment and prevention of lung cancer. Green tea appears to be safe at doses purported to have anticancer activity, up to 1500 mL per day. Further human intervention trials are necessary to explore the potential benefits of green tea or extracts of this natural health product for use in lung cancer treatment and prevention.

76. Fish Oils for Lung Cancer: A Systematic Review

Heidi Fritz, The Canadian College of Naturopathic Medicine; Kennedy Deborah, The Canadian College of Naturopathic Medicine; Rochelle Fernandes, University of Toronto; Dugald Seely, The Canadian College of Naturopathic Medicine

Purpose: Fish oil/omega-3 fatty acid supplements are among the most common natural health products (NHPs) used by cancer patients, but there is no synthesis of current knowledge for use in lung cancer. We conducted a systematic review of the safety and efficacy of fish oil/ eicosapentanoic acid (EPA) for the treatment and prevention of lung cancer.

Methods: We searched six electronic databases from inception to May 2010 for clinical, observational, and preclinical evidence pertaining to the safety and efficacy of fish oil/ EPA for lung cancer. We searched Pubmed and EMBASE for evidence pertaining to potential interactions between green tea and chemotherapy or radiation therapy.

Results: Of 636 records, 50 studies were included for full review and analysis. Six RCTs and two phase II trials were included for the treatment of cachexia in lung cancer patients, and one phase II trial was included for treatment of lung cancer. Eleven observational and 30 preclinical studies were included. Modest clinical benefit from use of fish oil and/ or EPA was seen on parameters associated with cachexia, notably weight loss, appetite, and physical function. There were also modest improvements seen in quality of life. One study found significant benefit on survival with high dose fish oil using 18g per day. Results obtained with combinational therapy were more promising than those associated with prognostic monotherapy. The recommended dose is $\geq 2g$ EPA

per day. There were no serious adverse events associated with use of fish oil in the studies reviewed.

Conclusions: Fish oil/EPA appears safe and may be effective in the treatment of cachexia and related symptoms. Use of EPA as part of a multifaceted approach to the treatment of cachexia may be advantageous in clinical settings.

77. Vitamin D and Lung Cancer: A Systematic Review

Heidi Fritz, The Canadian College of Naturopathic Medicine; Deborah Kennedy, The Canadian College of Naturopathic Medicine; Rochelle Fernandes, University of Toronto; Dugald Seely, The Canadian College of Naturopathic Medicine

Purpose: Much attention has been given to the prevalence of vitamin D insufficiency and its general anticancer effects, however there has been no synthesis of current knowledge for use in lung cancer. We reviewed the safety and efficacy of vitamin D for the treatment and prevention of lung cancer.

Methods: We searched six electronic databases from inception to April 2010 for clinical, observational, and pre-clinical evidence pertaining to vitamin D and lung cancer. We searched Pubmed and EMBASE for evidence pertaining to potential interactions between green tea and chemotherapy or radiation therapy.

Results: Of 1760 records, 29 studies were included for full review and analysis. One was an RCT for prevention of lung cancer, and three were uncontrolled Phase I and II trials for treatment of lung cancer. Twelve observational and 13 pre-clinical studies were included. Although preliminary results have been promising, there is a lack of clinical evidence on vitamin D for lung cancer. One RCT found decreased incidence of lung cancer in parallel with rates of other cancers among the vitamin D treated arm compared to placebo, but the total number of cases was insufficient to draw statistically significant conclusions. Calcitriol up to 38 µg three days per week in combination with paclitaxel therapy has not been associated with significant hypercalcemia or adverse effects.

Conclusions: There is a lack of existing human level evidence for vitamin D and lung cancer. Vitamin D deserves further study for its anticancer effects in lung cancer patients and those at risk of lung cancer. In the meantime, repletion therapy with appropriate monitoring is indicated in those with vitamin D insufficiency.

78. The Effect of Massage in Cancer Patients with Pain

Marcia Molinaro, National Cancer Institute; Pedro Fernandes, National Cancer Institute; Neli Muraki, National Cancer Institute

Purpose: Pain is a frequent symptom in cancer patient and Massage can be a complementary therapy to relief the suffering and reduce the pain. The purpose of this work is presenting a review about the benefits of massage in cancer patients with pain in palliative care. The method used was a review searching the following databases: Pubmed and Lilacs, and with the publication date from 1998/08/08 to 2008/08/08. The keywords used was: massage, neoplasm and pain. The criterias of inclusion were: original articles, interventionals studies, randomised or not. The languages selected for the research were: Portuguese, English, Spanish and French. The period of ten years for researching was necessary due of scarcity of articles.

Results: This strategy obtained 57 abstracts wich were read, and only 9 obeyed the criterias of selection. The types of massage found were: massotherapy, reflexology, soft massage, aromatherapy massage, foot massage and Swedish massage. The Visual Analogue Scale was the most used scale for measuring the pain. All the articles were in English language. 4 articles were about massage in patients with metastasis, and 3 studies the patients were at hospices. No article approached children or adolescents.

Conclusion: All the studies concluded that massage improved pain control, and also described others benefits as reductions of nausea, depression, nausea and anxiety. The studies showed that massage improves quality of life of cancer patients. This review was a the first step to a project of research at National Cancer Institute of Brazil.

79. The Chiropractic Care of Patients with Cancer: A Systematic Review of the Literature

Joel Alcantara, International Chiropractic Pediatric Association; Joey Alcantara, Private Practice of Chiropractic, Calgary, AB, Canada; Junjoe Alcantara, Private Practice of Chiropractic, San Jose, CA

Purpose: Deaths from cancer worldwide have been projected to continue rising, with an estimated 12 million deaths by 2030. More than 30% can be prevented. Chiropractic is the largest, and most regulated CAM profession. To investigate the nature of the chiropractic care provided to this patient population, we performed a systematic review of the literature.

Methods: The following electronic databases were searched: MANTIS [1965-2010]; ICL [1984-2010]; Pubmed [1966-2010]; Medline [1965-2010] EMBASE [1974-2010], AMED [1975-2010], CINAHL Plus [1965-2010], Alt-Health Watch [1965-2010] and PsychINFO [1965-2010]. Key words used were “cancer” and “neoplasm” in Boolean combination with “chiropractic” along with related words when appropriate. Eligibility criteria was: (1) the study was a primary investigation/report published in peer-reviewed English language journals; and (2) part or all of the study population involved patients with cancer.

Results: Our systematic review revealed 21 commentaries, 2 survey studies, 2 literature reviews, 2 case series and 60 case reports. The vast majority of the case reports/series are diagnostic in nature and confirm the risk factors for cancer patients such as a history of cancer, and failure to respond to conservative chiropractic care and continued clinical deterioration. The literature also highlight the use of imaging studies in the diagnosis of cancer that includes aneurysmal bone cyst, astrocytoma, metastasis from breast cancer, carcinoma, chordoma, chondroblastoma, chondrosarcoma, enchondroma, ependymoma, Ewing Sarcoma, fibrosarcoma, ganglioneuroma, hemangioma, leukemia, lipoblastomatosis, lung cancer metastasis, lymphoma, meningioma, mesothelioma, neuroma, neurofibromatosis type I, osteochondroma, osteoid osteoma, osteosarcoma, Pancoast tumor, pancreatic cancer, pheochromocytoma, prostate cancer, Schwannoma and teratoma. Despite the chiropractor’s role in pain management and accentuating the quality of life of cancer patients through diet and nutritional support, our findings do not support this given the lack of documentation of the practice activities of chiropractors in the care of such patients.

Conclusion: We recommend future research in this field to characterize the nature of the supportive care provided by chiropractors to reducing pain and suffering and improve overall quality of life of cancer patients.

80. Herbal-Synthetic Drugs Synergies

Fabio Firenzuoli, Regional Center of Phytotherapy—Tuscany Sanitary Service; Luigi Gori, Regional Center of Phytotherapy—Tuscany Sanitary Service; Alfredo Vannacci, University of Florence, Florence; Eugenia Gallo, University of Florence, Florence; Vittorio Mascherini, Regional Center of Phytotherapy—Tuscany Sanitary Service

Herbal interactions are a very important issue of clinical phytotherapy, it is well known they can give rise to higher toxicity than a synthetic drug or lower efficacy. These interactions if well known can be useful for interesting integrations with synthetic drugs a) Natural synergies in the same herbal drug;

Hypericum perforatum extract has better antidepressant activity when the phytocomplex contain hypericin, hyperforin and flavonoids, if administered as single substance has less efficacy. The extract of Salix alba works better when besides salicylate glycosides (inhibitors of cyclooxygenase) contain polyphenols that protect gastric mucosa b) Supernatural synergies when herbal extracts are used to improve the efficacy of a synthetic drug: citroflavonoids, sylimarin, piperine, liquorice, and others can be used to improve the bioavailability of a synthetic drug or a herbal extract. Liquorice can be used to protect the stomach and reduce the use of corticosteroids in patients suffering of rheumatoid arthritis; piperine improve many times the bioavailability of curcumin; grapefruit juice can improve the bioavailability of many synthetic drugs like very expensive anticancer drug, and could be used to reduce the cost of such therapies. c) Unnatural synergies: we found some herbal drugs have immediate and inexplicable efficacy for some disease, so in collaboration with our department of chemical analysis and public authorities we demonstrated that some herbal extract were adulterated with synthetic drugs: nimesulide in a remedy based on extracts of Harpagophytum procumbens and Tanacetum parthenium as antiinflammatory; or reserpine in an extract of olive leaf as hypotensive. When a patient reports inexplicable and exaggerated efficacy of an herbal drug, adulteration with a synthetic drug should always be suspected.

81. Psycho-Oncology: Cancer, Stress and Inflammation

Daniel Weber, ‘Panaxea Medicine’ and ‘Charles Sturt University’ and ‘World Federation of Chinese Medical Societies’; Janelle Wheat, Charles Sturt University; Geoff Curry, Charles Sturt University and Macquarie University; Hongsheng Lin, Guang’anmen Hospital, China Academy of TCM; Jie Li, Tumour Lab of Guang’anmen Hospital, China Academy of TCM

The connection between cancer and the psyche is one of long debate. Does attitude impact on cancer initiation and progression or is there no relationship? While the debate seems irresolvable as to the nature of this relationship another factor, which is central to both cancer and stress has had less discussion. Cancer and chronic inflammation has been of interest since the time of Virchow and authors no less credible than Angus Dalglish have written on the subject. Meanwhile, Yekta Dowlati reports that a significantly higher concentration of the pro-inflammatory cytokines TNF- α and IL-6 are found in depressed subjects. Is chronic inflammation the link that needs investigating in this relationship between cancer and stress? Is this the factor, which brings psychological distress and cancer into a clear causative relationship? This report is to establish this link as well as offer specific botanical interventions to treat the inflammatory state.