Abstract 12 - BEST OF SIO

IN VIVO ASSESSMENT OF THE THERAPEUTIC EFFECTS OF LYOPHILIZED LEECH SALIVA EXTRACT FROM (Huridinaria manillensis) ON DIFFERENT TUMOR XENOGRAFT MODELS IN NUDE MICE

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BACKGROUND: Ancient traditional physicians from many countries used leeching to treat a wide range of diseases for thousands of years. A large number of peptides and proteins have been identified and characterized in leech saliva extract (LSE), including anti-thrombotic agents, cancer metastasis inhibitors and anti-microbials. Currently, leech therapy is established as an important tool in microsurgery and reconstructive operations having demonstrated superior clinical outcomes for the optimal salvage of grafted tissues.

METHODS: In the current study, we have determined the in vivo toxicity and efficacy of LSE from (Huridinaria manillensis). For the toxicity study, we used 5 groups of CD1 mice, 3 mice per group, which were subcutaneously injected with vehicle or 1, 5, 10 and 20 mg/kg of LSE twice weekly for 4 weeks. After 4 weeks, we collected blood samples for CBC as well as liver and kidney function tests. In addition, liver, spleen, kidney, lung and brain tissues were collected for further toxicological analysis (ongoing). To evaluate the in vivo efficacy of LSE in the PC3 tumor model, we used 4 groups of male nude mice, six mice per group, which were subcutaneously injected with 0.5 mg/kg or 1 mg/kg LSE, docetaxel (15 mg/kg) as a positive control or vehicle, respectively. Currently, we are determining the effect of LSE on the LNCaP xenograft mouse model (ongoing study).

RESULTS: The data demonstrate that LSE is safe when administered up to 20 mg/kg with no toxicity. There is a significant decrease in the growth of PC3 xenografts with either docetaxel or LSE (1 mg/kg) treatment compared to the vehicle-treated control mice. There was no significant difference between the anti-tumor activity of docetaxel and LSE (1 mg/kg). There was a significant decrease in the body weight of docetaxel-treated mice while there was no change in the body weight of LSE-treated mice.

CONCLUSIONS: To our knowledge this is the first report of LSE as a safe biological agent with significant anti-tumor activity in the PC3 prostate cancer xenograft model with no apparent side effects.

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BASELINE RESPONSE EXPECTANCY: A POTENTIAL TOOL FOR PERSONALIZED ACUPUNCTURE THERAPY

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BACKGROUND: Randomized trials of acupuncture have been limited by impressive responses in the sham arm. We sought to evaluate the relationship between baseline response expectancy, a key component of the placebo effect, with pain reduction in real and sham acupuncture.

METHODS: We analyzed data from a randomized controlled trial using electro-acupuncture (EA) and sham electro-acupuncture (SA). The trial was conducted among 67 women with stage I-III breast cancer who experienced joint pain attributable to aromatase inhibitors. Pain was measured using the Brief Pain Inventory (BPI) at Baseline and Week 8 (End of intervention). The Acupuncture Expectancy Scale (AES), a validated instrument was used to measure Baseline expectancy. In this scale, a higher score indicates a greater degree of expectancy. We built a linear regression model to evaluate the association of percent BPI severity reduction with baseline AES, by treatment group.

RESULTS: In the SA group each point increase in baseline AES was associated with a greater percent BPI reduction (regression coefficient 7.9, p=0.007). In the EA group, by contrast, there was no association between Baseline AES and percent BPI reduction (p=0.89). Regardless of AES score, the average BPI severity reduction in the EA group was always greater than 30%. Patients with a low score on the AES had better pain reduction with EA than SA. As Baseline AES rose, the difference between EA and SA diminished and SA eventually surpassed EA.

CONCLUSIONS: The relationship between expectancy and treatment response is distinct between real and sham acupuncture. While patients receiving EA had a clinically significant improvement in pain regardless of expectancy, patients receiving SA only gained a benefit if they expected one. Patients with high Baseline expectancy may gain equivalent benefit from a less aggressive form of acupuncture such as superficial needling with minimal manipulation.

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EFFECT OF TRADITIONAL CHINESE MEDICINE ON THE RECURRENCE AND METASTASIS OF STAGE II AND III COLORECTAL CANCER AFTER RADICAL OPERATION: A PROSPECTIVE, MULTICENTER COHORT STUDY* (THE 5-YEAR FOLLOW-UP RESULTS)

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BACKGROUND: Chinese medicine has been widely used in patients with postoperative colorectal cancer in China. However, their effectiveness and safety have not been well understood based on scientific evidence. The objective of this study is to evaluate the effectiveness of Chinese medicine on recurrence and metastasis of stage II and III colorectal cancer after radical operation.

METHODS: Post-radical operation stage II and III colorectal carcinoma patients treated between April 1, 2007 and February 28, 2009 were included in this study. Information on the cases was gathered from eight hospitals in China. A prospective multicenter cohort study was performed. All patients received comprehensive treatment with Western medicines, and follow-up visits were conducted according to
NCCN Guidelines. The exposure factor was defined as whether the patient used traditional Chinese medicine. Data gathering and statistical analysis were conducted by the Evidence-based Medicine Center of Beijing University of Chinese Medicine.

RESULTS: The subjects included 312 Chinese patients (175 males and 137 females aged 58.05±12.75 years). Based on the invasion sites, 167 patients had colon cancer and 145 had rectal cancer. There were 166 and 59 patients who presented high and low exposure factors, respectively, whereas 87 were considered non-exposed. The loss ratio was 3.8%. TNM stratified analysis used in univariate analysis revealed that the age, gender, and invasion sites did not influence recurrence and metastasis. Kaplan Meier curves showed that the disease-free survival of the high exposure group significantly differed from those of the non-exposure groups (P=0.017). Meanwhile, the overall survival of the high exposure group significantly differed from those of the non-exposure groups (P=0.017). Multivariate analysis indicated that for OS both chemotherapy and high-exposure Chinese medicine were favorable independent prognostic factors (p=0.017, p=0.018).

CONCLUSIONS: Long-course, high-exposure TCM treatment can improve the prognostic effects of stage II and III colorectal cancer. Hence, TCM treatment can reduce the rate of recurrence and metastasis, and extend the duration of a recurrence- and metastasis-free status and overall survival. The rate of recurrence and metastasis of stage II and III post-radical operation colorectal cancer patients can be reduced by one year with consistent treatment with syndrome differentiation TCM based on routine treatment of Western medicine.

Abstract 116 – BEST OF SIO

DEMOGRAPHIC PREDICTORS OF USE AND SAFETY OF ACUPUNCTURE IN CHILDREN AND ADOLESCENTS UNDERGOING TREATMENT FOR CANCER

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BACKGROUND: The use of acupuncture has been reported in a number of studies performed among children with cancer; however, demographic predictors associated with the acceptance of acupuncture are unknown. We present the results of a prospective study that evaluated predictors of use and safety of acupuncture in children and adolescents undergoing cancer treatment.

METHODS: Eligible participants (N=90) were acupuncture-naive children and adolescents with cancer who were receiving treatment for cancer at Columbia University Medical Center. Upon consent, participants completed the Memorial Symptom Assessment Scale (MSAS) every 3 weeks and were offered acupuncture. Reasons for use and acute (<24 hours) and delayed (>24 hours) side-effects were collected after each acupuncture treatment. Frequencies and Chi Square analysis were performed with SAS 9.3.

RESULTS: A total of 252 sessions of acupuncture were delivered over the study period. Over half (54%) of participants requested acupuncture. Median age was 14 years (range 1-23), with older age significantly associated with use of acupuncture use (p=0.0001). Acupuncture was more often delivered to patients diagnosed with leukemia or lymphoma (p=0.044). Demographic variables associated with use of acupuncture included: ethnicity of the patient (p=0.0002), mother (p=0.0003) and father (p=0.0003); religion of patient's mother (p=0.00001) and father (p=0.00002); regular attendance of religious services (p=0.0045); and household income (p=0.0005). Acupuncture was requested most often for persistent symptoms and usually requested later compared to early in treatment. Most commonly, acupuncture was requested for the management of gastrointestinal-related conditions. Controlling for repeated observations, there was no increase in acute or delayed side effects related to acupuncture treatment in patients with and without thrombocytopenia (p=0.189) or neutropenia (p=0.497).

CONCLUSIONS: Acupuncture is widely accepted and safe among children undergoing treatment for cancer. Socio-demographic variables and persistent symptom burden predict the use of acupuncture, suggesting target populations for the delivery and scientific evaluation of acupuncture in pediatric oncology.

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EVALUATION OF ACTIVE HEXOSE CORRELATED COMPOUND (AHCC) FOR THE ERADICATION OF HPV INFECTIONS IN WOMEN

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BACKGROUND: HPV DNA has been detected in over 99% of cervical cancer patients. There is currently no effective medicine or supplement for eradication of HPV infections. We previously completed preclinical in vitro and in vivo mouse data that suggested AHCC will eradicate high risk (HR) HPV infections attributed to the modulation of the expression and signaling of IFN/β/ and may have a role in the prevention of HPV-related malignancies. The primary objective of this pilot study is to determine if AHCC is effective to eradicate cervical HR HPV infections.

METHODS: Women over the age of 30 that were HR HPV positive, otherwise healthy, and met the remaining eligibility criteria, were enrolled in the study to evaluate the effectiveness of AHCC 3 g by mouth once daily. Once a month patients received for a Cervista HPV HR Test (Hologic, Inc., Bedford, MA) and a 2 mL research blood sample was obtained to monitor immune markers. AHCC was continued 4 weeks beyond first negative Cervista test and then it was stopped. Patients continued in the study off treatment for another 4 weeks followed by a Cervista test to confirm eradication of HPV. Patients that had persistent HR HPV infection after 12 weeks of treatment were considered a treatment failure.

RESULTS: A total of ten HR HPV+ women have been enrolled on study. There has been one patient that was declared treatment failure. Three have achieved a negative HR HPV test result and a remaining six patients are still in the study. All patients will complete study by October 2014. Final study results will be presented at the meeting.

CONCLUSIONS: Preliminary results from this pilot study are consistent with our preclinical findings that AHCC appears to be effective for eradication of HPV infections. Further investigation in a formal phase II randomized placebo-controlled study is planned.