From research to practice: do users of an ear acupuncture service to manage breast cancer-related hot flushes & night sweats do as well as research participants?

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Introduction

Research participants often have better outcomes than patients receiving the same treatment in standard care settings. After conducting research into using a standardised ear acupuncture protocol to treat menopausal side-effects of adjuvant hormonal treatment for early breast cancer, we introduced an ear acupuncture service. As part of evaluating this service, we wanted to explore the following:

Key Question

- Do service users report poorer outcomes than research participants?

Methods

Participants

- Women age ≥35 years diagnosed with early breast cancer
- Without relapse or metastatic disease
- ≥ 6 months post active treatment (surgery, chemotherapy, radiotherapy)
- Taking adjuvant hormonal therapy ≥ 6 months
- Experiencing hot flushes and night sweats (HF&NS) ≥ 3 months
- Self-reporting an average of ≥ 4 HF&NS per 24-hour period.

Acupuncture protocol

- Standardised treatment once weekly, for 8 treatments
- Using the National Acupuncture Detoxification Association (NADA) ear acupuncture protocol
- Delivered in a small group setting, of up to 5 women per group
- Administered by:
  - 1 licensed acupuncturist (research study)
  - 3 NADA trained non-acupuncturists (service).

Measurement

- Hot Flush Diaries – measured HF&NS frequency and severity over a 2-week period
- Women’s Health Questionnaire (WHQ) – measured 9 domains of physical and emotional wellbeing associated with the menopause transition
- Problem Rating Score (PRS) – measured how bothersome women find their HF&NS.
- Measures were administered at:
  - Baseline (2 weeks prior to treatment)
  - End of treatment (EOT)
  - At 4 weeks after EOT (EOT+4)
  - At 18 weeks after EOT (EOT+18).

The NADA Protocol

This standardised protocol uses 5 acupuncture points on the surface of the ear. It is designed to be used in a group setting. In the UK, it can be delivered by licensed acupuncturists, and by non-acupuncturists who have been trained and who are annually assessed by NADA UK.

Results

Recruitment and Service Use

- 50 out of 54 recruited completed the research (R) treatments
- 47 completed EOT+ measures
- 45 completed EOT+4 and 38 completed EOT+18 measures
- Of 90 service users (S) not having treatment at time of analysis:
  - 8 had less than 4 HF&NS per 24-hour period
  - 17 did not complete EOT measures
  - Of 67 evaluable service users completing EOT measures:
    - 56 completed EOT+4 and EOT+18 data.

Comparing Hot Flush and Night Sweat Frequency

- The median number of HF&NS at baseline was:
  - 10.7 per day (std dev = 4.8) for R
  - 10.5 per day (std dev = 5.5) for S
- Reductions in frequency for both groups were significant at all time points
- There was no significant difference between groups at each time point.

Comparing Emotional and Physical Wellbeing

At EOT, the WHQ domains displayed below showed significant improvement for Research participants. Service users did not have significant improvement in Memory/Concentration. Overall, both groups showed similar scores at each time point, and similar levels of improvement.

Discussion

In this study, service users who completed treatment and returned EOT questionnaires recorded similar outcomes to research participants. This may be because both groups:

- Were from the same geographic area
- Had similar demographic characteristics
- Were subject to the same inclusion criteria
- Received similar levels of time and attention.

The main differences were the high number of service users who did not:

- Meet inclusion criteria (n=11, 8.2%), with <4 HF&NS per 24-hours at baseline
- Return EOT data (n=17, 18.9%):
  - 8 (8.9%) did not complete treatment (due to illness, recurrence, relocation)
  - 9 (10%) who completed treatment did not return EOT data.

Conclusion

It is possible for service users to do as well as research participants. Service providers may prioritise patient care over rigorous application of inclusion criteria and follow-up of data return.

Acknowledgements

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| ![Ear Acupuncture Image](image1) | ![Ear Acupuncture Image](image2) | ![Ear Acupuncture Image](image3) | ![Ear Acupuncture Image](image4) | ![Ear Acupuncture Image](image5) | ![Ear Acupuncture Image](image6) | ![Ear Acupuncture Image](image7) | ![Ear Acupuncture Image](image8) |
The Safety of Chinese Herbal Medicine and How it is Reported – Serious Safety Concerns or Mere Chinese Whispers?

Aims, Objectives and Rationale

It is our perception that the safety of Chinese herbal medicine is often unfairly reported in the media and medical journals. This led us to investigate one event concerning an adverse reaction to a Chinese herbal formula in 2010. We set out to:

- Look at how one high profile event concerning the safety of Chinese herbal medicine was conveyed, and identify any significant reporting bias.
- Determine whether this event gives cause for concern about the safety of Chinese herbal medicine in day-to-day practice in the United Kingdom.
- Develop a more thorough understanding of the complexity of the pathogenesis of aristolochic acid nephropathy (AAN) in order to acquire a balanced and less biased assessment of the contrasting evaluations in the scientific, medical and Chinese medicine journals and literature.
- We postulate that in developing and presenting this understanding, practitioners of Chinese medicine (prospective and practicing) might be better informed about adverse drug reactions (ADRs) and in turn, more equipped to respond to any subsequent issues concerning toxicity, regulation and the legislative process in the future.

Introduction and Context

Patricia Booth took Long Dan Xie Gan Wan for 5 ½ years and developed renal failure and urothelial carcinoma. The case went to court in 2010. The herbal formula contained Mu Tong. The pills were analysed and found to contain aristolochic acid since 1999 and a prescription only medicine since 1997.

The following events took place...

1997 --- Between 1997 and 2002 Patricia Booth took Long Dan Xie Gan Wan for her acne

2002 --- November: she stopped taking the remedy because she felt ill

2003 --- February: Tests showed she had chronic long-term kidney failure and she went on dialysis

2006 --- She developed cancer of the urinary tract and had major surgery to remove it

2008 --- She had a heart attack and survived

2010 --- She was on dialysis 3 times a week and waiting for a kidney transplant.

The verdict: Ying Wu was given a 2 year conditional discharge.

The judge stated that the case demonstrated the need for regulation of the profession.

The Formula

The pills were analysed and found to contain aristolochic acid which has been a banned substance since 1999 and a prescription only medicine since 1997.

Long Dan Xie Gan Wan
(Gentiana Longdancan Decoction to Drain the Liver)

Long Dan Cao --- Radix Gentianae Lactacea
Huang Qin --- Radix Scutellariae Baicalensis
Zhi Zi --- Fructus Gardeniae Jasminoidis
Chai Hu --- Radix Bupleuri
Mu Tong --- contains AA
Che Qian Zi --- Akebia Quinata
Zu Xie --- Rhizoma Alismatis Orientalis
Sheng Di Huang --- Radix Rehmanniae glutinosae
Dang Gui --- Radix Angelicae Sinensis
Gan Cao --- Radix Glycyrrhizae Ulamensis

"Spot Treatment Gave Woman Cancer, Court Told".

Should Aristolochic Acids Carry All the Blame?

- Dharmendra11 argues that, “Ultimately, all herbs are toxic at some dosage level, and that all herbs contain ingredients that can be shown to be carcinogenic or mutagenic in a laboratory test.” Moreover, in email correspondence with Dr. Debbie Shaw (government adviser on toxicity and herbal medicines), this argument was refuted; she argued that there is now sufficient clinical evidence regarding the toxicity of AAS.
- Blackwell22 and Maciocia12 argue that in the 1993 Belgium incident, the potential drug-herb interactions were never investigated. Dr. Shaw has subsequently contested this argument, stating that possible ADRs of the associated pharmaceuticals was tested and no association was found, ruling out therefore, the possibility of “inhibition”. Nevertheless, the assignation of the term of “Chinese Herbs Nephropathy” appears somewhat spurious.

How Does this Affect the Practice of Chinese Herbal Medicine?

The following have been banned:10(p2):

- Plants containing aristolochic acid cause cancer of the renal, pelvic, and of the ureter.

“Traditional Chinese Practitioner Breaches Medicine Act”

History of Aristolochic Acids:

<table>
<thead>
<tr>
<th>Year</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1960</td>
<td>Shown to have carcinogenic and mutagenic properties</td>
</tr>
<tr>
<td>1975</td>
<td>Shown to have pharmaceutical properties</td>
</tr>
<tr>
<td>1993</td>
<td>Over 100 cases of irreversible nephropathy in Belgium dimming clinic that used Chinese herbs mixed with pharmaceutical preparations</td>
</tr>
<tr>
<td>1997</td>
<td>Became a prescription only medicine</td>
</tr>
<tr>
<td>1999</td>
<td>Became a banned substance</td>
</tr>
<tr>
<td>2002</td>
<td>Herbal remedies containing aristolochia shown to be carcinogenic</td>
</tr>
<tr>
<td>2012</td>
<td>The International Agency for Research on Cancer concluded that, Plants containing aristolochic acid cause cancer of the renal, pelvic, and of the ureter.</td>
</tr>
</tbody>
</table>

"Chinese Herbal Pills Gave Woman Cancer Court Hears"...
Aristolochia Species

Those plants belonging to family Aristolochiaceae: Frequently found in CHM to include:

<table>
<thead>
<tr>
<th>Botanical Name</th>
<th>Part Used</th>
<th>Pin Yin</th>
<th>Classical Categorisation and action</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Aristolochia fangchi</em></td>
<td>Root</td>
<td>Guang Fang Ji</td>
<td>Originally categorized in the herbs that drain dampness. Now categorized as an &quot;Obstructive Substance&quot; in CHM. It dispels wind-dampness, stops pain, clears heat &amp; promotes urination. Used for wind-damp and heat to disperse urine &amp; reduce oedema</td>
</tr>
<tr>
<td><em>Aristolochia macrophylla</em></td>
<td>Stem</td>
<td>Guan Mu Tong</td>
<td>Originally placed in the &quot;herbs that drain dampness category&quot; but now categorized as an &quot;Obstructive Substance&quot; in CHM. Useful to clear heart fire and promote urination in damp-heat li patterns. Promotes lactation</td>
</tr>
<tr>
<td><em>Aristolochia contorta</em></td>
<td>Fruit</td>
<td>Ma Du Ling</td>
<td>Also categorized as an &quot;Obstructive Substance&quot; in CHM. Useful to clear heart fire and promote urination in damp-heat li patterns. Promotes lactation</td>
</tr>
<tr>
<td><em>Aristolochia debilis</em></td>
<td>Fruit</td>
<td>Ma Du Ling</td>
<td>Used for wind-damp and to promote urine &amp; reduce oedema</td>
</tr>
</tbody>
</table>

It is clear that exponents of Chinese herbal medicine assign different members of the Aristolochia species to same pinyin nomenclature. This reflects a practice of substituting one herb from within a given species with another. For example, the fruit of *A. contorta* and *A. debilis* may be substituted for one another and acclimated the name Ma Du Ling, while the herb part of *A. contorta* and *A. debilis* is traded as Tian Xian Tang.19-22

Aristolochic Acids and Aristolactams:

Aristolochic acids are the toxic components of Aristolochia Species. In terms of CHM the two most commonly discussed variants are Aristolochic Acid I (AA-I) and Aristolochic Acid II, (AA-II) but it is the former (AA-I) that appears to be associated with the development of AAN23.

Aristolactams can be found occurring naturally in Aristolochia species but their presence within humans is generally the product of the detoxification of AA. Aristolactams I is metabolite of Aristolochic Acid I, which subsequently and upon activation, forms DNA-adducts. These in turn induce mutations and can lead to the evolution of urothelial carcinoma.24

**Epidemiological Evidence**

Aristolochic Acid Nephropathy and Balkan Endemic Nephropathy

Independent research undertaken to determine the underlying aetiological causes Aristolochic Acid Nephropathy (AAN) and the Balkan Endemic Nephropathy (BEN) yielded some profound similarities. Epidemiological evidence, including the clinical presentation of patients and histological findings, strongly support the view that AAN and BEN share the same aetiological factor, namely AA. This proposition has been substantiated by clear evidence that patients suffering from both conditions, and who in addition have developed urothelial carcinoma, also present with AA-AI adducts in kidney tissue. It has been postulated that patients from the Balkan cohort may have been subjected to AA ingestion by way consumption of bread, produced from locally grown wheat that had grown and consumed in fields with Aristolochia clomats. This strongly supports the hypothesis that herbs or plants containing AA are the aetiological factors in the development of gross anatomical, histological and genetic renal abnormalities.19,26

**Other Chinese Herbs purported to contain AA’s**

A comparative study on the AA content of *Xin Xun* root and aerial portion demonstrated that levels of AAI in the root of *Xin Xun* was negligible whilst levels in the aerial portion were higher. 0.1270.021 mg/kg (aerial) to 0.0867.06 mg/kg (root). The study also demonstrated that alcoholic (methanolic) extracts contained more AAI than water extracts. The authors recommended that the herb be administered by way of water decoction. An earlier study undertook by L.t. et al., reported that AA content of nine Asian species varied from 3.31 mg/kg – 3376.9 mg/kg in alcoholic extracts.14,27,28

RCHM VOLUNTARY RESTRICTIONS AND CAUTIONS:

Due the presence of Aristolochic Acid in Asanum species the RCHM has issued a voluntary ban on the use of *XIN XIN* (Asanum species)

**The Scientific Evidence**

**AAN Pathogenesis**

Formation of Aristolactams Aristolochic Acid (AA) metabolized in the liver to form aristolactams. This reflects a practice of substituting one herb from within a given species with another. For example, the fruit of *A. contorta* and *A. debilis* may be substituted for one another and acclimated the name Ma Du Ling, while the herb part of *A. contorta* and *A. debilis* is traded as Tian Xian Tang.19-22

African American nephropathy and Balkan endemic nephropathy

**Consumption of Chinese herbal medicine may include herbs with an Aristolochic Acid component.**

For example, Dian Li Gao Tang.19-22

Aristolochic acid nephropathy: A worldwide problem


**Formation of Aristolactams**

Aristolochic Acid (AA) metabolized in the liver to form aristolactams. Aristolactams I is metabolite of Aristolochic Acid I, which subsequently and upon activation, forms DNA-adducts. These in turn induce mutations and can lead to the evolution of urothelial carcinoma.24

**Executive of exocytosis and neutrophil adhesion from Aristolactams.**

AA I metabolite (AAI) is oxidized to a carcinogenic metabolite. This metabolite is toxic to both normal and neoplastic cells. It can cause cellular damage in the stroma and lumen of the kidney tubule and can cause mutagenesis. 

**Possible role of Aristolactams in the histology of renal nodules.**

This is a consistent theme in rat models of AAN. A cellular model demonstrated that aristolactams stimulated cell proliferation and increased cell growth. This is consistent with the presence of renal nodules in humans with AAN. Thus, it is possible that aristolactams may play a role in the histology of renal nodules.

**Formation of DNA Adducts**

Aristolochic Acid (AA) metabolized in the liver to form aristolactams. Aristolactams I is metabolite of Aristolochic Acid I, which subsequently and upon activation, forms DNA-adducts. These adducts seemingly lie dormant within urothelial cells and subsequently can undergo an irreversible DNA restoration, forming the formation of DNA adducts on an 8-Bromo-7-deazauridine (8-BrdU) substrate.

**Retroformation**

The metabolite, aristolactam component derived from Aristolochic Acid and its environmental toxicities and drugs or in the way of the metabolic detoxification. Used for wind-damp and to promote urine & reduce oedema

**In the Liver**

Biotransformation of AA by cytochrome P450 enzymes (aristolochic acid I phase I metabolism). AA is metabolized by cytochrome enzymes to a metabolite (aristolochic acid I phase II metabolism).

**In the Kidney**

Biotransformation of AA by cytochrome P450 enzymes (aristolochic acid I phase I metabolism) and then to a metabolite (aristolochic acid I phase II metabolism). Concerns for AA: A. Aristolochic Acid I metabolite formation. B. Aristolochic Acid I phase II metabolism (AAI metabolism).

**Retroformation**

The metabolite, aristolactam component derived from Aristolochic Acid and its environmental toxicities and drugs or in the way of the metabolic detoxification. Used for wind-damp and to promote urine & reduce oedema

**In the Liver**

Biotransformation of AA by cytochrome P450 enzymes (aristolochic acid I phase II metabolism). AA is metabolized by cytochrome enzymes to a metabolite (aristolochic acid I phase II metabolism).

**In the Kidney**


**Retroformation**

The metabolite, aristolactam component derived from Aristolochic Acid and its environmental toxicities and drugs or in the way of the metabolic detoxification. Used for wind-damp and to promote urine & reduce oedema

**In the Liver**

Biotransformation of AA by cytochrome P450 enzymes (aristolochic acid I phase III metabolism). AA is metabolized by cytochrome enzymes to a metabolite (aristolochic acid I phase III metabolism).

**In the Kidney**

Biotransformation of AA by cytochrome P450 enzymes (aristolochic acid I phase III metabolism) and then to a metabolite (aristolochic acid I phase IV metabolism). Concerns for AA: A4: Aristolochic Acid I metabolite formation. A5: Aristolochic Acid I phase II metabolism (AAI metabolism).

**Retroformation**

The metabolite, aristolactam component derived from Aristolochic Acid and its environmental toxicities and drugs or in the way of the metabolic detoxification. Used for wind-damp and to promote urine & reduce oedema

**In the Liver**

Biotransformation of AA by cytochrome P450 enzymes (aristolochic acid I phase IV metabolism). AA is metabolized by cytochrome enzymes to a metabolite (aristolochic acid I phase IV metabolism).

**In the Kidney**

Biotransformation of AA by cytochrome P450 enzymes (aristolochic acid I phase IV metabolism) and then to a metabolite (aristolochic acid I phase V metabolism). Concerns for AA: A6: Aristolochic Acid I metabolite formation. A7: Aristolochic Acid I phase II metabolism (AAI metabolism).

**Retroformation**

The metabolite, aristolactam component derived from Aristolochic Acid and its environmental toxicities and drugs or in the way of the metabolic detoxification. Used for wind-damp and to promote urine & reduce oedema

**In the Liver**

Biotransformation of AA by cytochrome P450 enzymes (aristolochic acid I phase V metabolism). AA is metabolized by cytochrome enzymes to a metabolite (aristolochic acid I phase V metabolism).

**In the Kidney**

Biotransformation of AA by cytochrome P450 enzymes (aristolochic acid I phase V metabolism) and then to a metabolite (aristolochic acid I phase VI metabolism). Concerns for AA: A8: Aristolochic Acid I metabolite formation. A9: Aristolochic Acid I phase II metabolism (AAI metabolism).

**Retroformation**

The metabolite, aristolactam component derived from Aristolochic Acid and its environmental toxicities and drugs or in the way of the metabolic detoxification. Used for wind-damp and to promote urine & reduce oedema

**In the Liver**

Biotransformation of AA by cytochrome P450 enzymes (aristolochic acid I phase VI metabolism). AA is metabolized by cytochrome enzymes to a metabolite (aristolochic acid I phase VI metabolism).

**In the Kidney**

China and Taiwan.

A retrospective follow-up study undertaken by Chinese researchers in Taiwan of a random sample of nearly 200,000 people, concluded that a prescription of more than 30g of Mutong and 60g of Fangchi was associated with an increased risk of developing chronic kidney disease (CKD). Ruling out other confounding factors such as age, sex, hypertension and diabetes, and the use of non-steroidal anti-inflammatory drugs and paracetamol, the researchers demonstrated a dose dependent relationship between consumption of these herbs and the incidence of CKD.

In a separate paper the same researchers demonstrated that a dose response relationship between the ingestion of more than 60g of Mutong (equivalent to 150mg of Aristolochic Acid) and the development of urinary tract carcinoma.

A longitudinal study undertaken in China between 1997 and 2006 (involving 300 patients with a AAN diagnosis), demonstrated that taking a high dose of AA-containing medication (AAGM) frequently induced irreversible non-oliguric acute tubular necrosis and subsequent progressive renal failure. Long-term ingestion of AAGM, either intermittently or continuously, resulted inpd chronic interstitial tubular nephropathy whilst short-term consumption of a low dose resulted in abrupt tubular dysfunction. Interestingly, the researchers also suggested that the accumulation and high concentration of AAG in the kidney is one of the main deciding factors for the rapid progression of renal dysfunction in AAN patients and this may in part be due to mechanisms that prevent the repair of tubular epithelial cells and therefore tissue.

What Other Relevant Issues Does This Case Give Rise To?

- **Nomenclature** - Mu Tong can have a number of herbal substitutions that will still be assigned and prescribed with the same Pin Yin nomenclature. One of these herbs is a species of Aristolochia, which is toxic; some of the other substitutions are harmless. There have been cases where pin yin names are very similar and have been confused with one another, with disastrous consequences.

- **Product Quality** - Although not directly related to this case, it is a common cause for safety concerns. Herbs can be contaminated with heavy or toxic metals, or can be adulterated for economic reasons. However, according to a letter that the Register of Chinese Herbal Medicine (RCMH) sent out to its members in 2012, personal communication with Emma Farrant, there have been no reported cases of contamination of Chinese herbs with heavy or toxic metals in the last 10 years.

- **Regulation = Safety**. After interviews with Michael McIntyre (Chair of the European Herbal and Traditional Medicine Practitioners Association) and Emma Farrant (Chief Executive Officer of the Register of Chinese Herbal Medicine RCMH), it became apparent that without regulation, a similar occurrence to the Patricia Booth incident might easily happen again. The judge who ruled on the case suggested that regulation of the profession was needed.

- **A better-informed profession**. The education (first entry or continuing professional development) of practitioners of Chinese herbal medicine needs to instil a comprehensive understanding of adverse drug reactions (ADR) and the implication of a ‘Delayed’ or ‘End-of-use’ ADR and in turn, the need to monitor patient progress or by contrast, deterioration.

This will need to sail safer, as practiced by Libby: thus, understanding the mechanism underlying drug interactions is useful, not only in preventing drug toxicity or adverse effects, but also in devising safer therapies for disease.

- **Conclusion** - The actual case of Patricia Booth was fairly reported; all relevant information was presented clearly and the claims that were made regarding toxicity appeared to have some factual basis. However, it would seem that it is common practice for both the general press and medical literature to indiscriminately assign the attributes of a one Chinese herb to the collective practice of Chinese medicine; rather than naming the specific nephrotoxic herb, the headlines use generic terms such as, Chinese herbal medicine. This raises questions about racial bias or possible agendas that seek to undermine an alternative tradition. The high profile that this story received in the media, compared to what we actually know about the adverse reactions to pharmaceutical medications in general, appeared somewhat unfair. By contrast, according to McCarthy, there were 26,000 times more fatalities from medical misadventure and pharmaceutical drugs, than from herbal medicine. This is obviously not proportionally reported in the press. There are definite safety issues when using Chinese herbal medicine, but with more stringent regulation these concerns would be greatly reduced, and certainly in this case, Patricia Booth would not have suffered kidney failure and cancer.

The evidence accrued from the vast array of research that has been undertaken to determine the underlying pathological process behind nephropathy, (including interstitial fibrosis, chronic kidney disease and urothelial carcinoma), strongly confirm that the most consistent culprit in this event is Aristolochic Acid. Epidemiological evidence and an ever-increasing prevalence of AAN events worldwide, that are independent of other concomitant ADR’s, environmental sources or biological predisposition, currently provide incontrovertible evidence for a justified removal of herbal medicines containing the substance.

Whilst far too many people have suffered as a result of inadvertent consumption of this nephrotoxic and carcinogenic substance, practitioners of Chinese herbal medicine might learn from the accrued evidence in the hope that comparable events are avoided in the future.

Thus, understanding the mechanism underlying drug interactions is useful, not only in preventing drug toxicity or adverse effects, but also in devising safer therapies for disease.
**TEXTUAL RESEARCH ON INTENT IN ACUPUNCTURE AND Moxibustion: THE GREAT COMpendium (1601)**

Richard Bertschinger

Old Teacher Mulberry says: Few folk are aware of the 'secrets of the stars', this rule alone divides the very best and worst doctors...

tienxing, mijue shaoren zhi, zhifa zhuanfen, qianhou shi 天星秘少人知，此法兮分前后者。The Rhyme 'Secrets of the Stars'

ODES, SONGS AND RHYMES HAVE BEEN USED BY PHYSICIANS IN CHINA FOR CENTURIES AS A MEANS OF MEMORISING AND PASSING ON METHODS OF PRACTICE AND DIAGNOSIS, MORAL ATTITUDES, EFFECTIVE POINTS, DIAGNOSTIC TIPS AND RULES OF THUMB. THIS RESEARCH INTO THEIR TEXTS, FROM THE SONG, YUAN AND MING OFFERS A RICH INSIGHT INTO THE LIFE AND THOUGHT OF SOME REMARKABLY SKILLED PHYSICIANS, AS WELL AS PRACTICAL INDICATIONS FOR TREATMENT. WE SEE INTO THE DEPTHS OF THEIR VIEW AND TRADITION, BETTER ABLE TO UNDERSTAND THEIR BRAODTH OF DIAGNOSTIC SKILLS AND TREATMENT PLANNING, AND AS A RESULT MAY GREATLY IMPROVE THE NEED OF AN UNDERSTANDING OF GREAT INTENT WITHIN OUR OWN PRACTICE.

THE ACUPUNCTURE AND MOXIBUSTION: THE GREAT COMPENDIUM (1601), BY THE LATE MING PHYSICIAN YANG JIZHOU CONTAINS ODES AND RHYMES COMPOSED BY TRADITIONAL ACUPUNCTURISTS FROM THE PREVIOUS FEW CENTURIES. Ming ‘digests’ that were precursors to Yang Jizhou’s compilation include – the Spiritual Response Bible (1425); Gatherings of Outstanding Acupuncturists (1529); Acupuncture and Moxibustion in its Great Entiry (1439); Lifesense in All Things (c.1440); A First Introduction to Medicine (1575); A System of Medicine Ancient and Modern, among others.

IN CONCLUSION: THESE RHYMES TOUCH UPON FIVE MAIN AREAS:
1. THE NEED FOR A TEACHER,
2. A STUDY OF THE OLD,
3. THE NEED TO PRESERVE, LEARN ARTISTRY, SENSITIVITY AND GENTLENESS,
4. AN UNDERSTANDING OF YIN AND YANG...
5. AND LASTLY, A SETTLED AND SOLID HEART, OPEN TO THE GREAT INTENT.


from the crazy Taoist acupuncturist Ma Danyang:

治病如神灵，泽如流波露，北斗降真机，金锁数开阖。至仁可传授，匪人莫用说。

healing a disease is like magic – a torrent whirling as wind-driven snow - the Northern Dipper sends down its true workings, the Golden Lock teaches us to snap it open! one truly clever can pass this on, the unfaithful have only restless talk.

Ma Danyang’s Song on the Twelve Points Shining Bright as the Starry Sky and able to heal all the Many Diseases

an example of the acu-points in cosmic view:

From Building Guest up to the Yin Valley, HIDing the Horizontal Bone - Great Glory at the mountain’s foot.

For even though Heaven and earth are vast, they take non of the sun and moon, their discernment akin to the full array of stars which represent the mind of old, the stillness as whirling snow.

The golden needle and still at the Dark Gate.

Ode to the Whole Body’s Points Shining Bright as the Starry Sky and able to heal all the Many Diseases

as Old Teacher Mulberry says:

夫医乃人之司命，非玄士而莫为：针乃理之渊微，须至人之指教。

A physician is a man working as the arbiter of human destiny – If we are not determined there is nothing we can do!

A needle follows the principle of depth through subtilty - And we must be taught by the very best of men.

Ode to the One Hundred Symptoms

to touch upon the mystery of the Art and relieve suffering:

The Neijing Suwen chapter On the Natural Behaviour of Those of Ancient Times says: ‘… and then there were those wise people of old - their model lay in the skies and earth, their images the sun and moon, their discernment akin to the full array of stars which reveal the time; they acted in accordance with Yin and Yang, and recognised the distinction between the four seasons…’ Ming physician Li Zhongzi (1642) adds: ‘These wise people were essentially those who followed the path of healing. They modeled themselves upon the principle of the skies and earth, and acted in accordance with Yin and Yang in order to apply the arts of needle, medicinal herbs and stone probe. One who can use these tools will bring harmony to the body. Then they will be somebody indeed!’ In Chinese literature the images of the sun (mand moon) represent the enlightened self ‘心’. Li Zhongzi: ‘But the great lights once seen, the smaller lights once and for all would be extinguished.’

The Neo-taoist Wang bi states: ‘For even though Heaven and earth are vast, they take non-being as their pivot - and though Kings and sages are great, they take humbleness as their master.

The message of these Odes and rhymes is clear – to possess a humility along with great power. This is the intent expressed in this poems. A great intent which sweeps up and along all small intents – this is the province of the great-heart.

Introduction to The Great Intent: Acupuncture Odes, Songs and Rhymes

what were the Odes all about?

James Liu (1962) describes a Fu or Ode ‘not as a verse form but as a literary genre’. They are ‘descriptions or expositions, usually lengthy and elaborate, in verse or in prose, on given subjects’. He also quotes the ancient poet Sima Xiangru ‘the mind of the writer of Odes can be achieved from within but cannot be conveyed in words’. Thus the Odes were to ‘evoke the Muse’; as vehicles for the transmission of an oral tradition, they are intrinsic to the great craft of acupuncture doctoring.

Introduction to The Golden Needle (1951)

stillness as ground central, a philosopher speaks:

‘Stillness is it, which has to be our lord – to be without desire and thus still. Stillness is the goal for human kind! Then the sage ‘is one in virtue with Heaven and earth, one in light with the sun and moon, one in order with the four seasons, and one in finding good or ill-fortune with the gods and spirits.’

Chou Tung 1017-1073 commenting on the Taiji Diagram.

Chinese Acupuncture Combined with Antidepressant Medication for Hospitalized Depression Patients: A Pragmatic Randomized Controlled Trial

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Background
Depression is predicted to become the second leading contributor to disease all over the world by 2020, affecting at least 350 million people. Almost one million lives are lost yearly due to suicide which translates to 3000 suicide deaths every day (WHO, 2012). Antidepressants are one of the major treatments, represented by selective serotonin reuptake inhibitors (SSRIs), but they are still unsatisfactory as there are great number of unresponsive patients, undesirable side effects and delayed efficacy (Arroll et al., 2005). Acupuncture has been involved in the treatment and research of depression for more than 20 years (Meng et al, 2002). The application of acupuncture for the treatment of depression is increasing (Barnes et al., 2007) and in general has achieved significant clinical efficacy but is still questioned by some western researchers (Pilkington et al, 2010; Smith et al, 2010).

This pragmatic randomised controlled trial (RCT) aims to assess the effectiveness of acupuncture, combined with antidepressants, for the treatment of hospitalized depression patients with depression.

Methodology
The key points of the TG were GV24, GV20, GV14 and GV4 for all TG patients with Dao-qi acupuncture technique, plus additional acu-points individually.

86 patients with depression were recruited to the study from the in-patient Department of Medical Psychology via a consultant at the out-patient Department of Nanjing Brain Hospital (NBH) in 2006. After screening for the Hamilton Depression Rating Scale (HDRS) and the International Classification of Diseases Version 9 (ICD-9), finally there were 71 patients completed the study.

Patients were randomized into either acupuncture treatment group (TG) or a control group (CG) with random assignment of 2:1 respectively.

Baseline assessment measures were taken before patients were randomized and allocated to the groups (W0) with the test of HDRS scales and factor scales, repeated post-intervention at one week after W0, two weeks W2, four weeks W4 and six weeks W6 thereafter.

All the patients were prescribed one of the SSRIs and health care. TG patients were combined with acupuncture intervention by one senior acupuncturist.

The key points of the TG were GV24, GV20, GV14 and GV4 for all TG patients with Dao-qi acupuncture technique, plus additional acu-points individually.

Results
There were significant differences in HDRS and factor scales between the acupuncture TG and CG. The TG had a marked improvement in emotion, sleep and body anxiety from the first week. After six weeks’ treatment, there were significant differences in HDRS scale and factor scales of emotion and body anxiety between the TG and CG and no significant differences in factor scales of sleep and cognitive handicap.

Intervention of acupuncture manifested improved the level of depression compared with SSRIs only

Discussion

Antidepressants, as a sample of Selective Serotonin Reuptake Inhibitors (SSRIs), is the major medication for the treatment of depression and it is regarded as successful (Mann, 2005).

This pragmatic RCT efficacy trial compared the CG with conventional antidepressants and the treatment group with antidepressants combined with acupuncture; there was no non-treatment group. This kind of pragmatic trial could benefit public health service guidance (Foster, 2007).

The placebo or sham acupuncture control study may help to identify the effects of different acupuncture interventions but not the effectiveness of acupuncture as a whole therapy (Molassiotis et al, 2012).

In addition, the design of acupuncture combined with medication versus medication only could not be blind (Smith et al, 2010).

Acupuncture combined with antidepressants appeared to speed the clinical effect, particularly the emotion, sleeping, body anxiety and total scales, even from the first week of treatment. Arguably, the positive effects will continue beyond the six weeks trial.

The limitations of this study are the small sample size of population and the lack of long term follow-up investigation. In addition, further research could be designed with fewer doses of antidepressant medicine, plus acupuncture versus normal dose of antidepressants only.

Conclusion
Acupuncture combined with SSRIs can quickly improve the condition of depression and most of the other complaints surpass the intervention of SSRIs only. This improvement in patients continued throughout the six weeks of management. Intervention of acupuncture has positively contributed to the treatment of depression. Further studies of large sample trials and less doses of medication is warranted. No adverse events were reported.

References

Table 1. Baseline Demographic and Clinical Characteristics of Trial Groups

<table>
<thead>
<tr>
<th>Sex (M/F)</th>
<th>Age (years)</th>
<th>Baseline Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>(%)</td>
<td>(%)</td>
<td>(%)</td>
</tr>
<tr>
<td>TG (n=45)</td>
<td>22 (49.1)</td>
<td>9 (20.0)</td>
</tr>
<tr>
<td>CG (n=26)</td>
<td>13 (50.0)</td>
<td>6 (23.1)</td>
</tr>
</tbody>
</table>

HDRS Total scale
HDRS Factor Scale
E: Emotion
A: Anxious
S: Sleep
H: Body Anxiety
C: Cognitive Handicap

Figure 1. HDRS Total scale and factor scales after treatment

Figure 2. HDRS Total scale and factor scales at baseline
Lifestyle and self-care advice within traditional acupuncture: developing an appropriate outcome measure.

Dr Charlotte Paterson, Russ Chapman, Rosemary Norton, Jane Robinson, Richard Bertschinger, Alison Lindsay (South West Acupuncture Research Group).

BACKGROUND
Our previous work established that self-care talk and advice is an integral part of traditional acupuncture1. Before we can evaluate the effectiveness of such advice we need to identify an appropriate outcome measure.

A. PILOTING AN 'OFF THE SHELF' QUESTIONNAIRE
Our preferred option was to find an 'off the shelf' questionnaire and validate it for use in traditional acupuncture.

We searched the literature for a questionnaire that had good face validity and identified the Health Education Impact Questionnaire (heiQ™)2. We piloted the heiQ™ in 33 new patients - details in the box below.

Details of the heiQ™ pilot
Five practitioners trying to recruit all new fee-paying patients for heiQ™ self-completion at their first and fourth consultation. Completed questionnaires were posted for central analysis and practitioners logged their experiences and patient comments.

Over 15 weeks, 33 new patients were seen, 21(64%) patients recruited, 16 (48%) initial questionnaires returned, 10 (30%) initial questionnaires were complete. 13 (39%) follow-up questionnaires were received, 8 (24%) of which were complete.

LESSONS FROM THE PILOT
1. The questionnaire was not appropriate for traditional acupuncture:
   • practitioners and patients feeling 'irritated' by the questionnaire content and lack of 'fit' with acupuncture practice.
2. Administration by practitioners at 1st consultation was often not feasible:
   • potential interference with establishing a therapeutic relationship
   • practical issues such as time
   • patients presenting in too distressed a condition

B. DESIGNING A NEW QUESTIONNAIRE
The process of piloting the heiQ™ had taught us that a questionnaire would only be acceptable to patients and practitioners if it reflected their experience of traditional acupuncture.

The self-care and traditional acupuncture questionnaire
We constructed this new questionnaire on the basis of the self-care categories from our previous qualitative work1:

Categories of self-help
• diet and eating practices
• Over-the-counter medications, herbs, supplements
• physical activity & back care
• rest and relaxation
• practice of therapies (including Chi Gong instruction)
• protection from the elements (e.g. keeping warm)
• Other

NEXT STEPS
We have begun a first pilot of the questionnaire with acupuncture patients. It is in both paper and electronic formats. A larger validation study will then be required.

If you would like to join us in that study (or lead it) you would be most welcome, please contact us.

ACKNOWLEDGEMENTS
Thanks to all the patients who helped with the pilot study.
We are grateful for a small grant from the British Acupuncture Council. (mostly we are self-funded: we do research because it is interesting and fun.)

FURTHER INFORMATION
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What effect does acupuncture have on cortisol levels? 
A Systematic Review

Mel Koppelman: MSc, MBAcC
Northern College of Acupuncture

BACKGROUND
Cortisol is a biological marker of stress and has been measured in acupuncture research covering a wide variety of clinical areas. As of yet, a systematic review of this literature has not been performed.

AIMS
- To identify as many existing studies as possible that have used change in cortisol levels as an outcome measure for assessing the effectiveness of acupuncture
- To synthesize the results of these studies to highlight key trends
- Where appropriate, to pool and quantitatively analyse the data from these studies

RESULTS
Nineteen trials involving 1,269 people were included. Seven trials involving 663 people measured cortisol before and after a single treatment. Compared to controls, an overall standardized mean difference of -0.51 was observed (95% CI -1.15 to 0.13), with acupuncture reducing cortisol levels more than controls, and this effect was not significant. Two trials involving 29 people measured mean daily cortisol output over five weeks of treatment. An overall standardized mean difference of 0.93 was observed (CI -1.83 to 3.70), with controls reducing cortisol more than acupuncture, and this effect was not significant.

METHODS
Search methods: Embase, Medline, AMED, CAMBase, CENTRAL, CINAHL, PsychNFO, ElectroAcupuncture and reference lists of articles were searched. Key researchers in the field were also contacted.

Selection criteria: RCTs comparing acupuncture to sham acupuncture, waitlist, or other treatment that measured cortisol at least once before and after the intervention.

Data collection: Trial quality was independently assessed and data was extracted into EPPi Reviewer and Excel.

DISCUSSION
The present review, in addition to identifying trends in the outcomes of the included research, undertook a thorough assessment of the quality of the included studies. Generally, the quality of the research was quite low, particularly in regards to the methodology around measuring cortisol.

The cortisol methodology quality assessment tool, developed from Nicolson and Hansen, is the first of its kind in the acupuncture research literature. Going forward, it would be helpful to have this tool validated, assessing which items are most important to study design and which, if any, of the items are superfluous. It has the potential to be useful to reviewers in their assessment of the quality of these studies. Moreover, the present study has highlighted the need for more high quality RCTs in this clinical area, and this tool could provide much needed guidance to researchers undertaking the primary studies, helping to increase the quality of their methods and the validity of their results.

CONCLUSION
While cortisol has been used as an outcome measure in many acupuncture trials since the 1970’s, this review is the first to comprehensively synthesize this data. The 19 studies from the 17 included reports cover a wide-range of clinical applications. On the whole, this literature suffers from poor quality, particularly concerning best practices for measuring cortisol levels and as such, it is difficult to draw meaningful conclusions about acupuncture’s effects on cortisol levels.

REFERENCES
A. Why EEG & EBR?
- Encephalography (EEG) records electrical activity on the scalp, and is useful for investigating rapidly changing cortical brain states.
- Eyeblink rate (EBR) is a marker for central dopamine function, and is also inversely correlated with parasympathetic activity.

B. OUR RESEARCH QUESTIONS
1. How do the EEG & EBR respond to stimulation at different acupuncture points?
2. How do the EEG & EBR respond to different modalities of acupuncture?
3. How do the EEG & EBR respond to electrical stimulation at different frequencies?
4. In particular, does stimulation drive the EEG or blinking at 10 Hz more than 2.5 Hz?

C. OUR PROTOCOL
(All interventions in balanced order)

Pilots 1-3
Points: LI4 to LI4 (LI4²), ST36², Left or Right LI4 to ST36
Parameters: 2.5 Hz or 10 Hz (256 μs)
Modalities: manual (MA), electro (EA), transcutaneous (TEAS)

Pilot 4
Left or Right ear (shenmen, concha), 2.5 Hz or 10 Hz, TEAS

D. OUR RESULTS
EEG (Pilot 1, N=7)
- Stimulation on the Right resulted in greater relative spectral power than on the Left.
- Stimulation of ST36² resulted in greater relative spectral power than at LI4².

EBR (Acupoint results)
Pilot 2 (N=12)
- Mean EBR was higher during stimulation on the Left than on the Right, but only after 10 minutes of stimulation.
- Mean EBR was higher during ST36² than LI4² stimulation (for MA and EA).

Pilot 3 (N=4)
- Mean EBR was higher during stimulation on the Left than on the Right during first MA and EA treatments in each session, but lower during second MA and EA (and both TEAS) treatments.
- Mean EBR was higher during LI4² than ST36² stimulation during first treatments in each session, but lower during second treatments (MA, EA, TEAS).

Pilot 4 (N=1)
- Mean EBR was higher during TEAS on the Left than on the Right ear.

EBR (Modality results)
Pilot 2
- EBR increased more with EA than MA.
- EBR increased more with 20 minutes than 5 minutes of EA.

Pilot 3
- EBR during EA usually increased compared to during prior MA.
- EBR decreased again after EA.
- EBR is usually greater for TEAS than MA.

E. OUR CONCLUSIONS
- EEG and EBR respond differently to MA, EA and TEAS at different acupoints.
- EEG and EBR changes are sometimes parallel, sometimes opposite.
- *Dosage/order effects suggest that EA has a greater effect on dopaminergic function or arousal than MA.
- Blink may be facilitated more by 10 Hz than by 2.5 Hz TEAS.

D. OUR RESULTS
EEG (Pilot 1, N=7)
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Pilot 3
- EBR during EA usually increased compared to during prior MA.
- EBR decreased again after EA.
- EBR is usually greater for TEAS than MA.

F. WHERE NEXT?
These findings need to be replicated and extended:
- Are results similar at other acupuncture points?
- What are the effects of interventions such as laser acupuncture?
- Does the yinyang model help to explain our results?
- Does baseline EBR indicate responsiveness to acupuncture?
- Does acupuncture have a ‘balancing’ effect on EBR?
A Pilot Study to Investigate the Impact of Auricular Acupuncture on Appetite

Authors: Ann Bradford, Veronica Tuffrey, Marie Polley

University of Westminster
Faculty of Science and Technology

Background:
- Weight and obesity issues are an increasing problem both in the UK and worldwide, leading to increased health risks.
- 62.8% of UK adult population classified as overweight or obese (BM 25+ kg/m²) in 2010.
- Contributing factors: availability of ‘calorie dense’ foods and eating in the absence of hunger, decline in physical activity.
- Appetite, food choice and food intake influenced by sensory (what we eat) and metabolic factors (how much we eat).

‘Investigations using acupuncture for weight loss’[3,9,10,11] suggest that it increases feelings of satiety through raised serotonin levels[2].

Studies investigating auricular acupuncture effectiveness on feelings of satiety may result in the formulation of cost effective treatment approaches.

Objective:
- To investigate changes in reported feelings of hunger and satiety in fasted subjects after an auricular acupuncture intervention.
- To inform the design of further studies into auricular acupuncture.

Design:
- Randomised, ‘no-treatment’ control, pilot study.
- Forty participants randomised to fasted control and fasted intervention groups (n=20 per group).

Intervention:
- All participants fasted for 12 hours prior to the beginning of the study period.
- Unilateral 5-point auricular acupuncture intervention for the active group (the control group having equal time with a 15 minute intervention).
- Needles inserted and left in situ for 15 minutes (ear used for intervention selected on ‘handedness’; right handed participants had needles inserted in right ear, left handed participants had needles inserted into left ear).

Main outcome measures: Self-reported feelings of hunger using Visual Analogue Scales (VAS) administered every 30 mins over the 2 hour study period (including a baseline scale on arrival before commencement of the study).

Visual Analogue Scales:
- These scales assess self-reported feelings of hunger, nausea and fullness, at the time-point at which it is administered.
- Questions ‘anchored’ by terms ‘None’/ ‘Not at all’ to ‘Extremely’/ ‘Very much’.
- As much as I have ever felt/A large amount at either end of a 100 mm line. It is marked by the participants at the interval that best represents how they feel[12,13]; the VAS ‘score’ is determined by measuring from the left hand end of the line to the point marked.

Visual Analogue Scale questions:
1. How hungry do you feel right now?
2. How sick do you feel right now?
3. How full do you feel right now?
4. How much do you think you could eat right now?
5. How much do you think you could eat right now?
6. How do you feel right now?
7. How much do you think you could eat right now?
8. How full do you feel right now?

Participant screening:
- Short medical questionnaire designed to screen out those with diabetes, pregnant or breast-feeding women, those taking morning medication with food, or who never ate breakfast.
- The SCOFF questionnaire[14] was used to help screen out those with an eating disorder or unhealthy attitude to food. Given to all volunteers to ensure a healthy attitude to food and a stable weight in the previous 3 months.

Points selection:
- A combination of points used in previous studies[15,16,17], affecting both the gut (and hunger) and others considered as having a more calming/sedative effect[17,18].
- The ‘sedative’ points have two possible modes of action:
  - Increase release of neurotransmitters[19]
  - Trigger endorphin increase[20].

Both of these actions, by improving mood and increasing a sense of well being may contribute to helping control appetite.

Visualization:

References

Acknowledgements
- This study was funded by Westminster University Research and Development Fund.
- Grateful thanks to the study participants and to Nadine Parry (audit assistant) for their assistance and support.

Keywords: Auricular acupuncture, obesity, appetite, satiety

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Appendix: Table of acupuncture points administered

Figure 1: Visual Analogue Scale results for hunger.
Figure 2: Visual Analogue Scale results for nausea.
Figure 3: Visual Analogue Scale results for fullness.
Figure 4: Visual Analogue Scale results for perception of how much you could eat.
Figure 5: Visual Analogue Scale results for perception of how much you think you could eat.

Study sequence:

Initial screening

Fasting

Randomised

Consent

VAS x 4 (every 30 mins)

‘timed interview’ control

Intervention

Baseline VAS

Results:
The first interval scale, 30 minutes into the study, indicated most difference between the two groups for 3 of the 5 questions asked (fig.1, fig.3, fig.4); here the decrease in feelings of hunger, the increase in feelings of unpleasantness of food and the amount they felt they could eat were most obvious. In question 4 (fig.4) the intervention group did not vary much from baseline in the amount they thought they could eat, however the control group had an increase in the amount they thought they could eat.

Discussion:
The changes in feelings of hunger between the two groups could be ascribed to the participants in the intervention group being aware they were having needles, however there was no overall effect seen and the intervention group did not feel sick or nauseous or have changes in all aspects of the VAS, indicating a more specific effect than that arising from just the needle insertion procedure.

This study indicates that ear acupuncture may have acute effects on appetite and also of preserving feelings of satiety. The needle retention time in this pilot study was 15 minutes, but retaining the needles for a longer period of time, or using a device that can prolong stimulation of the auricular points may lead to a more pronounced or prolonged effect.

Conclusion:
Results indicate a trend towards a reduction in feelings of appetite and possible preservation of feelings of satiety in the intervention (acupuncture) group and this was most evident 30 minutes after the acupuncture intervention. The findings suggest that feelings of appetite and satiety may be able to be modified and indicate the need for larger studies.

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A Pilot Study to Investigate the Impact of Auricular Acupuncture on Appetite

Visual Analogue Scale results Figs. 1-5

Fig.1

Fig.2

Fig.3

Fig.4

Fig.5

Study sequence:

Initial screening

Fasting

Randomised

Consent

VAS x 4 (every 30 mins)

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