Workshop Outline

• Part 1
  – The Western Approach
    • Evaluation of Female and Male Infertility
      – Dr. Magarelli: Female Issues
      – Dr. Gilbert: Male Issues

• Part 2
  – Acupuncture
    • Clinical Pearls, Literature Review and Treatment Paradigms
      – Dr. Balk: Female Infertility
      – Dr. Gilbert: Male Infertility

• Part 3
  – State of the ART on IVF and TCM Treatments
    – Dr. Magarelli and Diane Cridennda, L.Ac.

• Panel Discussion & Q/A
Key Issue: Biologically Based

- What is your chances of getting pregnant by intercourse alone at age:
  - 15  20% per month
  - 30  10%
  - 40  3%
  - 45  << 1%

How age affects fertility in females:
Western View

Female Eggs: a limited resource!

7,000,000 eggs
Before delivery

2,000,000 eggs
Newborn

400,000 eggs
at Puberty

60,000/mo
10,000/mo

400,000 eggs
at Puberty

13 yo

Zero (0) eggs
at Menopause

50 yo

400 ovulations

1,000/month

Females Oocytes (eggs) & Time

Women's Age in Years

Eggs

20 25 30 35 40 45 50

0

50,000
100,000
150,000
200,000
250,000
300,000
350,000
400,000
450,000

1,000 eggs/month

200 300 400 500 600 700 800 900 1000

700,000
800,000
900,000
1,000,000
1,100,000
1,200,000
1,300,000
1,400,000
1,500,000

Workshop on Infertility & TCM
Females Oocytes (eggs) & Babies!

Key Concept

- Women make NO eggs during their lifetimes!

Physiology of Male Subfertility

Bruce R. Gilbert, MD, PhD, FAAMA
Associate Clinical Professor of Urology
Associate Clinical Professor of Male Reproductive Medicine
Weill Cornell Medical College

Pregnancy Odds each month

Women's Age in Years

Eggs
INFERTILITY - A Couple's Dilemma

Combination of Male and Female Factors

Testis Anatomy

Seminiferous Tubules and Sertoli Cells

Cross section of one of the 600 to 1200 seminiferous tubules present in the Human testis....
Hypothalmic-Pituitary-Gonadal Axis

Causes of Male Factor Subfertility

- Varicocele: 37%
- Idiopathic: 25%
- Testicular Failure: 9%
- Obstruction: 6%
- Cryptorchidism: 6%
- Volume: 5%
- Agglutination: 3%
- Viscosity: 3%
- Androgenization: 2%
- Sexual Dysfunction: 2%
- Ejaculatory Failure: 2%
- Endocrine: 1%

It takes a lot of motile sperm…

to fertilize an egg

Treatment of Male Factor Subfertility

Non Surgical Options
• Conservative Therapy (Dietary changes, lifestyle changes)
• Complementary Approaches (Acupuncture, Herbal)
• Medical Treatment (Nutritional, Antibiotic, Hormonal)
• Assisted Reproductive Technology (IUI, IVF/ICSI)

Treatment of Male Factor Subfertility

SURGICAL TREATMENT:
• Diagnostic and Therapeutic Procedures (biopsy, vasogram)
• Corrective Procedure (Varicocele Ligation)
• Reconstructive Procedures
• Microsurgical Vasovasostomy and Vasoepididymostomy
• Resection of Prostatic Obstruction
• Sperm Retrieval (Open/Perc)
  – Epididymal
  – Testicular
  – Seminal vesicle
Microsurgical Sperm Retrieval

• Epididymal
• Testicular

Part 2:
Acupuncture and Infertility
Clinical Pearls

Judith Balk, MD MPH
April 8, 2006
AAMA

Acupuncture and Fertility
TCM Clinical Pearls

From the book “Plain questions”

• “Sufficient kidney qi leads to normal menstrual function; dredging the Ren Channel and activating the Chong channel results in regular menstruation and thence to pregnancy.”

• As early as 259 AD, acupuncture formulae were given for infertility.

Commonly affected meridians

• Chong Mo
• Kidney
• Liver
• Spleen
• Conception Vessel

Acupuncture and Infertility

• Anovulation
• Polycystic ovary disease
• HPO axis dysfunction
• Poor uterine artery perfusion
• Adjunct to IVF
• Unexplained
Acupuncture in Normally Ovulating Women

- Acupuncture affects endocrine function

- Points: Ki-12, CV-3, CV-4, low freq stim
- LH-RH stimulation test with or w/o ap stim
- Greater increases in LH and FSH from LHRH with acupuncture than without


Loci of acupuncture stimulation

Can acupuncture help women to ovulate?

- Sometimes!

- 34 patients with ovulatory dysfunction by history, ultrasound, BBT
- 35% marked and 48% slight improvement in ovulation
- Labs: bidirectional changes (towards normal) for FSH, LH, E2
Can acupuncture help women to ovulate?

- Point selection:
  - BL-23 and BL-18 to tonify the liver and kidneys
  - CV-3 and CV-4 to reinforce primordial qi and to regulate the flow of qi and blood
  - Sp-6 to regulate the three Yin channels
  - Extra points 16 and 19 to tonify liver and kidneys, regulate the Ren and Chong meridians, and nourish the uterus

- Technique: just enough to obtain de qi, then retained for 20-30 minutes
- 3/week for 3 months

Xiaoming M et al. Clinical studies on the mechanism for acupuncture stimulation of ovulation.

What about anovulation in PCOD?

- It works for some women: Lean, ↓ metabolic defects
- 24 women
- EA 2x/week x 2 wks, then q wk x 6-10 wks
- BL-23 → BI-28 @2 Hz x 30'
- Sp-6→Sp-9 @2 Hz x 30'
- MH-6, TH-5, GV-20 manual stim
- 9 women began to ovulate
- ↓ in LH/FSH, testosterone []

Polycystic Ovary Disease: Case Report

- 32 yo with primary infertility and PCOD x 6 years
- CV-4, CV-3, Extra-16, Sp-6
- Extra 16 is Uterus Pt., 4 cun ↓ umb, 3 cun lateral
- 5 daily treatments with high freq stim x 20
- Menstrual cycle d 9-13 for 2 cycles
- 1st cycle: no spontaneous bleed
- 2nd-4th cycles: regular menses
- 5th cycle: spontaneous full-term pregnancy


Induction of Ovulation

- On Cycle Day 10-12: CV-4, CV-3, Sp-6, Extra-16 for 30 minutes, low freq stim x 3 days
- 6/13 cycles with EA had ovulation
- EA ovulation induction works when there depression of sympathetic activity


Is ↓ sympathetic activity a marker of acupuncture working, or is the ↓ sympathetic activity the effective component?

<table>
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<tr>
<th>Changes of HST</th>
<th>Ovulation</th>
<th>No Ovulation</th>
<th>Total</th>
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<tbody>
<tr>
<td>Increased</td>
<td>5</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Decreased</td>
<td>1</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

*p<0.05 as estimated by X² test
Auricular acupuncture for oligomenorrhea or luteal insufficiency

- N=45 infertile women
- Results compared to hormone treatment
- Matched for age, BMI, tubal patency, etc
- One tx/week, each 30' x 3 months
- Points: gonadotropin, ovary, uterus, gestagen, kidney, H-P, spleen, omega, and secondary psychosomatic points

Auricular acupuncture

- No difference in pregnancy rates, but 7 in the acupuncture group also received hormones.
- Side effects only in hormone group
- 44% of those with menstrual irregularities remained infertile after acupuncture vs. 56% of controls
- Conclusion: A/P is alternative tx for female infertility due to hormone disorders.


Pulsatility Index

- Pulsatility Index greater than 3.0 at the time of embryo transfer may predict 35% of the failures to become pregnant (Steer et al. 1992)
- Acupuncture can significantly lower PI (Stener-Victorin et al. 1996)
Poor uterine artery perfusion

- Infertile, healthy women with PI ≥ 3.0
- A/P twice per week x 4 weeks, 30’ each
- Decreased sympathetic outflow
- Bl-23 → Bl-28 (100 Hz)
- Sp-6 → Bl-57 (2 Hz)
- One of the protocols in Paul’s study

Reduction in Pulsatility Index

<table>
<thead>
<tr>
<th>Pulsatility Index</th>
<th>Before acupuncture</th>
<th>Following 8 acupuncture treatments</th>
<th>14 days after cessation of acupuncture</th>
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<tbody>
<tr>
<td>0</td>
<td>3.26</td>
<td>2.65</td>
<td>2.08</td>
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Adjunct to IVF—embryo transfer

- N=160: acupuncture versus no acupuncture
  - 29 before and after ET
  - Clinical pregnancy in 42.5% vs 29.3%
  - Pre-ET: MH-6, Sp-8, Lin-3, GV-20, St-29
  - Post-ET: St-36, Sp-6, Sp-10, Li-4
  - Ear: Shen-men, Zhigong, Neifenmi, Naodian
  - Part of Paul’s study

Adjunct to IVF

- Hypothesis: acupuncture that enhances the HPO axis and relaxes the uterus may improve pregnancy rates in IVF.
- At least one prior unsuccessful IVF cycle
- AP vs sham AP (toothpicks & guide tubes), eye pillows, heat lamp to abd
- If no pregnancy, crossed over to other arm

Quintero et al. A randomized, controlled, double-blind, crossover study evaluating acupuncture as an adjunct to IVF. Fertil Steril 2004;81 (supp 3):11-12

Adjunct to IVF

- 17/49 eligible subjects enrolled
- 4 ongoing pregnancies after first cycle, 2 per arm
- 4 in ap had chem pregnancy, 1 in sham arm
- After unsuccessful subjects crossed-over for 2nd cycle, 2 pregnancies in ap, 1 in sham
- 70% PR in ap group vs 30% in sham
- No difference in ongoing PR

Quintero et al. A randomized, controlled, double-blind, crossover study evaluating acupuncture as an adjunct to IVF. Fertil Steril 2004;81 (supp 3):11-12

Adjunct to IVF

- 7 subjects completed both arms of the study
- Used less gonadotropins in ap group
- 2 cycle cancellations, both in sham group
- None of the 5 patients with endometriosis had a viable pregnancy, nor 1 patient with Asherman’s
- Points chosen for different components of IVF cycle, at 4 points during IVF cycle.

Quintero et al. A randomized, controlled, double-blind, crossover study evaluating acupuncture as an adjunct to IVF. Fertil Steril 2004;81 (supp 3):11-12
Adjunct to IVF

1. Stimulate the HPO axis: Day 1-7: SP-6, ST-36, SP-9, ST-20, ST-29, CV-4, CV-6, LI-4. Tonification on all x 40’

2. Target the ovary: Day 10 to retrieval: BL-40, BL-57, BL-23, BL-25, GB-21, GB-20: Neutral on BL-23 and BL-25; Sedation on others; 40’

3. Uterine relaxation, increase uterine blood flow: Retrieval to transfer: SP-10, LI-4, LI-11, LIV-3, ST-28, ST-29, ST-25; Sedation on SP-10; Neutral on others; 45’

4. Within 48 hours after transfer: GV-20, REN-12, REN-6, ST-36, LI-11, add ear seed on left ear Shenmen and Endocrine; Tonification on all: 45’

Brandon Horn, JD, L.Ac. Eastern Center for Complementary Medicine, PC

Implantation Rates

Reduction in Gonadotropin Use

1. Quintero et al. A Randomized, Double-Blind, Controlled Cross-Over Study Evaluating Acupuncture as an Adjunct to In-Vitro Fertilization. Fertility and Sterility. Vol: 81, Supplement 3, April, 2004

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Evidence Based Medicine
Comparing Ongoing Pregnancy Rates\textsuperscript{1,3}
- Central Group
- Acupuncture Group

0% 10% 20% 30% 40% 50%

1. Quintero et al. A Randomized, Double-Blind, Controlled Cross-Over Study Evaluating Acupuncture as an Adjunct to In-Vitro Fertilization: Fertility and Sterility Vol: 81, Supplement 3, April, 2004

Point selection of presented studies

<table>
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<tr>
<th>Study</th>
<th>LI-4</th>
<th>S-V</th>
<th>Bl</th>
<th>XIAO</th>
<th>GB-20</th>
<th>GB-34</th>
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Acupuncture energetics Chong Mo Endocrine Protocols

- Ovaries: Signal program\:
  - Yang Ming
    - CV-2, CV-4, St-36, St-39, St-40, St-43, St-44
  - Shao Yang
    - CV-2, CV-4, GB-30, GB-34, GB-39

- Uterus: Signal program\:
  - Shao Yang
    - Liv-14, GB-20

- HPO (ant pit): Signal program\:
  - Shao Yang
    - LIV-14, GB-20, GB-34, GB-39
TCM diagnosis

- Kidney Yin Deficiency
- Kidney Yang Deficiency
- Spleen Qi Deficiency
- Blood Deficiency
- Blood Stasis
- Liver Qi Stagnation
- Heart deficiency
- Excess Heat
- Dampness

Most infertility patients have 2-4 diagnoses
- Mental health, social function, emotional roles declined, esp. with qi deficiency or blood stagnation
- No overlap between TCM dx and physical or general health.


Mean (SD) SF36 scores for various TCM diagnoses

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Physical Function</th>
<th>Role Function</th>
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<th>Social Function</th>
<th>Physical Role</th>
<th>General Health</th>
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<td>Kidney Yin Deficiency</td>
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<td>78.2 (34.0)</td>
<td>72.1 (15.1)</td>
<td>73.3 (16.7)</td>
<td>81.1 (33.8)</td>
<td>88.9 (18.5)</td>
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<td>Kidney Yang Deficiency</td>
<td>74.6 (14.4)</td>
<td>73.0 (37.8)</td>
<td>72.4 (13.9)</td>
<td>75.9 (14.9)</td>
<td>86.1 (29.7)</td>
<td>88.6 (21.1)</td>
</tr>
<tr>
<td>Spleen Qi Deficiency</td>
<td>68.4 (18.5)</td>
<td>70.0 (37.2)</td>
<td>67.5 (16.8)</td>
<td>71.2 (18.3)</td>
<td>82.5 (30.3)</td>
<td>89.3 (15.3)</td>
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<td>Blood Deficiency</td>
<td>69.8 (20.1)</td>
<td>57.9 (42.8)</td>
<td>61.7 (18.2)</td>
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<td>87.9 (18.9)</td>
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<td>Liver Qi Stagnation</td>
<td>75.2 (15.7)</td>
<td>86.0 (30.2)</td>
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<td>78.1 (13.4)</td>
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</table>
Numbers (%) of women with various TCM diagnoses by cause for infertility, excluding male factor.

<table>
<thead>
<tr>
<th>TCM Diagnosis</th>
<th>Tubal</th>
<th>Endometriosis</th>
<th>Unexplained</th>
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<tbody>
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<td>Kidney Yang Deficiency</td>
<td>20 (21.3)</td>
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<td>Kidney Yin Deficiency</td>
<td>40 (42.6)</td>
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<td>40 (42.6)</td>
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<td>Kidney Yang Deficiency</td>
<td>59 (62.8)</td>
<td>25 (31.3)</td>
<td>96 (53.3)</td>
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<tr>
<td>Kidney Yin Deficiency</td>
<td>44 (46.8)</td>
<td>40 (42.6)</td>
<td>97 (53.9)</td>
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</tbody>
</table>

Total Number

Damp Blood Stagnation

Kidney Yin Deficiency
- Back pain, knee problems
- Prematurely gray
- Vaginal Dryness
- Fearful
- Little midcycle cervical mucous
- Hot flashes/night sweats
- Points: Ki-3, Ki-6, Lu-7, Sp-6, Bl-23, Bl-52, CV-3, CV-4

Kidney-yin deficiency
Individuals present with frequent or infrequent menstruation. The period between menses is longer than normal. Associated symptoms are being thin in appearance, annoying hot sensations in the chest, palms and soles, soreness in the lumbar and knee regions, insomnia, night sweats, or tingling and a dry mouth.

On examination, the tongue is red and the pulse a little or a little slow. To treat this deficiency and weed out a little toxicity.

Kidney Yang Deficiency
- Cold Feet
- Low back pain, esp premenstrual
- Low libido
- Nocturia
- Dysmenorrhea, responds to heating pad
- Profuse vaginal discharge
- Points: Ki-7, St-36, Bl-23, Bl-62

Kidney-yang deficiency
The main characteristics are deficient warmth and vitality. Symptoms are generally light and  the body is warmer in general. The tongue is red, usually with a thin white coat. The pulse is deep or deep, thready and weak.

**TCM-Spleen Qi Deficiency**

- Fatigue, poor appetite, crave sweets
- Low energy, bloating after eating
- Cold hands/feet/nose
- Premenstrual spotting, Uterine prolapse
- Easy bruising/poor circulation/varicose veins

**Points:** Sp-6, St-36, CV-6, Sp-4

**Blood and Qi weakness**
The usual manifestations are excessive or scanty menses, which are light-colored and thin. Individuals are usually delayed in menstruation and may have a dull pain in the lower abdomen after each cycle. Often associated with gynecologic disease, oligomenorrhea, hot or cold complexion, fatigue, pale skin, and insomnia.

On examination, the tongue is pale with thin and white fur; the pulse is thready and weak.

**TCM-Blood deficiency**

- Dry, flaky skin, chapped lips
- Hair loss or dry, brittle hair
- Diminished nighttime vision
- Pale lips, tongue, eyelids
- Dizziness/lightheadedness premenstrual

**Points:** Sp-6, St-36, Liv-8

**TCM- Blood Stasis**

- Midcycle ovulatory pain
- Painful breast lumps
- Hemorrhoids
- Endometriosis or fibroids
- Dark Tongue
- Menstrual blood contains clots

**Points:** Sp-6, Sp-8, Sp-10, Bl-17

**Qi and blood stagnation**
The main manifestations are irregular menstruation and dysmenorrhea (painful menses). The menses are purplish dark with plenty of blood clots. Also associated with these symptoms are scaly skin, purplish lips, brownish spots or pigmentation on the face, distending pain in the breasts and lower abdomen, and uterine myoma (muscular tumor), ovarian cysts or masses in the pelvic region.

**Signs of Blood stagnation**
The tongue is dark red. Bleeding spots may be found in the tongue. The pulse is deep and rapid.
TCM-Liver Qi stagnation

- Prone to depression, anger, rage
- Irritable premenstrual
- Bloating/irritable periovulatory
- Premenstrual breast pain and swelling
- Dysmenorrhea
- Insomnia
- Points: LI-4, Yintang, Tai Yang, Bl-2

Liver qi stagnation

The main manifestations are irregular cycles with impeded menstrual flow. In the tongue, there is dark red with small pieces of blood clots. There is distending pain in the breasts and abdomen before the menstruation cycle begins. Associated symptoms are an uneasy mind, irritability, depression, sighing, or feeling sad without reason in severe cases.

On examination, the tongue is dark red with a thin white fur. The pulse is deep and thready.

TCM: Heart deficiency

- Early morning wakening
- Nightmares
- Prone to agitation, fidgeting
- Heart palpitations, esp when anxious
- Lacking in vitality
- Points: Ht-7, CV-14, CV-15, Bl-15, Bl-44
- Auricular point: shen-men

TCM: Excess Heat

- Rapid pulse
- Dry mouth, thirsty for cold drinks
- Feel warm
- Night sweats/hot flushes
- Short menstrual cycles
- Points: Liv-2, Sp-10, LI-11, Bl-40
TCM- Dampness

- Feel tired/sluggish after a meal
- Fibrocystic breasts
- Cystic acne
- Prone to vaginal candidiasis/pruritis
- Overweight
- PCOD

Points: Sp-9, St-40, CV-12, DV-3, Sp-6, Bl-66

Interior struck by phlegm and dampness. The main manifestations are anorexia or a delay in cycles, hypoactive mastalgia and cystic ovaries. Individuals usually have excessive thick vaginal discharge. Other associated symptoms are: chest oppression, poor appetite, bloating, soreness, dizziness, fatigue, palpitations, and headache.

On examination, the tongue is pale, bulky and tender and may have white or greasy fur covering the margin from the teeth. The tongue’s pulse is deep, slow and rolling.

Luteal Phase Deficiency

- Yin condition
- Tonification technique
- Use points Ki-7, St-36, CV-6, GV-4, Bl-23, Bl-52
- Chong Mo

To regulate the HPO axis

- Use curious meridians
  - Chong Mo (Sp-4, MH-6)
  - Conception Vessel (Ki-6', Lu-7)
  - Governing Vessel (SI-3, Bl-62')
- Additional points: Sp-6, St-30, CV-3, CV-4
Summary

- Difficult to study in RCT
- Timing: recommend 3 months
- Protocols focus on Sp, Ki, Liv, Chong Mo
- If known Western diagnosis, treat that also
- If unexplained, look for patterns and treat using acupuncture energetics

Application of Acupuncture to Male Fertility

Bruce R. Gilbert, MD, PhD, FAAMA
Associate Clinical Professor of Urology
Associate Clinical Professor of Male Reproductive Medicine
Weill Cornell Medical College

Two recent papers suggest an improvement in motility with acupuncture

- Effect of acupuncture on sperm parameters of males suffering from subfertility related to a low sperm quality, S Siterman, Archives of Andrology, 39:155-161, 1997
- Quantitative evaluation of spermatozoa ultrastructure after acupuncture treatment for idiopathic male infertility, J Pai et al, Fertility Sterility 84:141-147, 2005

- Prospective, Controlled (historical) study of 32 men with impaired semen quality
- Semen specimens were analyzed before and one month after treatment for 16 men, treated 2 times a week for 5 weeks
- 16 matched controls (semen specimens given 6 months apart)
  - Age 26.1 ± 6.2 years
  - Similar decrease in sperm count, motility and morphology
  - 60% chronic prostatitis
  - 48% varicocele


METHODS:
- TCM diagnosis
- Maximum 12 points used: LU-7, LI-4, LI-11, ST-30, ST-36, SP-6, SP-9, SP-10, HT-7, BL-20, BL-23, BL-33, KI-6, KI-7, MH-6, LR-5, LR-8, CV-1, CV-2, CV-4, CV-6, GV-4
- De Qi noted
- 25 minute treatment
- 2 treatments a week for 5 weeks


RESULTS: (treated group)
- No Change
  - Sperm Concentration
- Improvement
  - % Viable sperm
  - Total Motile Sperm
  - Total Functional Sperm Fraction (TFSF)

<table>
<thead>
<tr>
<th>Sperm Parameters</th>
<th>Control (pre)</th>
<th>Control (post)</th>
<th>Treated (pre)</th>
<th>Treated (post)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Density (10^6/ml)</td>
<td>25.7 ± 6.5</td>
<td>25.5 ± 6.7</td>
<td>25.5 ± 6.5</td>
<td>25.7 ± 6.5</td>
</tr>
<tr>
<td>Viability (%)</td>
<td>50.5 ± 10.7</td>
<td>50.6 ± 10.7</td>
<td>50.6 ± 10.7</td>
<td>50.5 ± 10.7</td>
</tr>
<tr>
<td>Total motile sperm (10^6/ml)</td>
<td>14.0 ± 2.0</td>
<td>14.0 ± 2.0</td>
<td>14.0 ± 2.0</td>
<td>14.0 ± 2.0</td>
</tr>
<tr>
<td>Total progressively motile sperm (10^6/ml)</td>
<td>14.0 ± 2.0</td>
<td>14.0 ± 2.0</td>
<td>14.0 ± 2.0</td>
<td>14.0 ± 2.0</td>
</tr>
<tr>
<td>Normal morphology (%)</td>
<td>34.2 ± 14.1</td>
<td>34.7 ± 14.4</td>
<td>34.7 ± 14.4</td>
<td>34.2 ± 14.1</td>
</tr>
<tr>
<td>TFSF</td>
<td>34.5 ± 10.4</td>
<td>34.2 ± 10.0</td>
<td>34.2 ± 10.0</td>
<td>34.5 ± 10.4</td>
</tr>
</tbody>
</table>

* = Total cells x % motility x % normal morphology
Quantitative evaluation of spermatozoa ultrastructure after acupuncture treatment for idiopathic male infertility, J Pei et al, Fertility Sterility 84:141-147, 2005

Prospective controlled study of 40 men with impaired semen quality (IRB approved)

- 28 treated patients
- 12 untreated matched controls
  - Age 33 (range 25 to 46) w/ 2 y infertility
  - Normal hormonal profile (T,FSH,LH,PRL,E2)
  - 2 semen analyses confirming impairment
  - Female partners evaluated. Tubal patency confirmed
  - Exclusions: identifiable infertility, azoospermia, infectious disease, abnormal psychological stresses

METHODS:

- Points used: CV-4, BI-23, BI-32, LR-3, KI-3, ST-36, SP-6, SP-10, ST-29, GV-20
- De Qi noted, 25 minute treatment, 2 treatments a week for 5 weeks
- 2 Semen analyses were obtained prior to treatment and afterwards
- Transmission electron microscopy was used for ultramorphologic analysis of sperm

RESULTS:

- No change:
  - Condensed Chromatin
  - Apoptosis
  - Immature sperm
  - Necrosis

- Improved with treatment:

<table>
<thead>
<tr>
<th>Improved with Treatment</th>
<th>Control (pre)</th>
<th>Control (post)</th>
<th>Treated (pre)</th>
<th>Treated (post)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% motile (median)</td>
<td>32 %</td>
<td>37 %</td>
<td>46 %</td>
<td>64 %</td>
</tr>
<tr>
<td>Assorted (tubal)</td>
<td>0.16 %</td>
<td>0.10 % (approx)</td>
<td>0.06 %</td>
<td>0.06 % (approx)</td>
</tr>
<tr>
<td>Acrosome (tubal)</td>
<td>62 %</td>
<td>71.5 %</td>
<td>66.5 %</td>
<td>77.5 %</td>
</tr>
<tr>
<td>Acrosome (normal)</td>
<td>29 %</td>
<td>22 % (approx)</td>
<td>30 %</td>
<td>25.5 %</td>
</tr>
<tr>
<td>Axoneme (tubal)</td>
<td>52 %</td>
<td>30.3 %</td>
<td>40 %</td>
<td>40 %</td>
</tr>
<tr>
<td>Axoneme (normal)</td>
<td>67.4 %</td>
<td>55.9 %</td>
<td>63.0 %</td>
<td>67.7 %</td>
</tr>
<tr>
<td>Nuclear shape (tubal)</td>
<td>29 %</td>
<td>20 %</td>
<td>28 %</td>
<td>32 %</td>
</tr>
<tr>
<td>Fibrous sheath (tubal)</td>
<td>44.4 %</td>
<td>40.0 %</td>
<td>33.3 %</td>
<td>43.3 %</td>
</tr>
</tbody>
</table>
Need for objectivity to make acupuncture mainstream

- Measurement of Tongue and pulse diagnosis (TCM) is common modality used by the classically trained acupuncture practitioner to treat complex multisystem disorders such as infertility.
- However, it is difficult to become expert in, subjective and foreign to our conventionally trained colleagues. Even to the acupuncture trained Physician treatment is usually based on learned treatment paradigms instead of a TCM Diagnosis.
- Without objectivity the Eastern practitioners approach is often viewed as suspect by Western practitioners.
- Goal: An objective measurement of the Eastern Paradigm which can be readily understood and provide initial and post treatment documentation that can be critically evaluated.

Meridian Measurements: The Science Behind it

- Acupuncture points correspond to high electrical conductance points on the body surface
- The high electrical skin conductance is associated with a high density of gap junctions at these acupuncture points
- The electrical charge produced at these acupuncture points creates an electrical field both of which varies with physiologic change and pathogenesis
  - TD Oleson, Pain, 8:217, 1980
- Therefore, measurement of the electrical conductance at these surface acupuncture points might identify pathogenesis and offer insight into the treatment
  - C Shang, Clin Acupuncture: Scientific Basis, Stux & Hammerschlag (Eds)Spinger, 2001
- Diagnostic software is available that allows for rapid measurement of the conductance of meridian points and provides recommended treatment protocols based on the 5-element (phase) paradigm or, if preferred by the practitioner, specific Luo, sedation and tonification points to treat.

Meridian Evaluation: Application to Male Fertility

- Question: Can meridian measurement assist with the diagnosis and acupuncture treatment of the azoospermic male?
- Methods:
  - 5 Patients with Azoospermia
  - Source points were evaluated
- Results:
  - Distinct patterns emerged
    - All patients were found to have a predominant lower energy balance (Figure 1).
    - All five patients had deficiencies in Qi energy and energy stability (Figure 1).
    - All five patients had an excess in the kidney meridian with 2 of the 5 also having a split kidney meridian (Figure 2).
Meridian Evaluation: Application to Male Fertility

- Treatment paradigms had commonality:
  - HT-9 and MH-9 were indicated as part of the treatment protocol for azoospermic patients with spermatogenesis present on biopsy.
  - LV-2 was indicated for patients with Germ Cell Aplasia.
  - The most common meridians used for treatment were:
    - 4/5 LV
    - 3/5 BL, MH, HT, LU, GB, KI, TH, SP, LU
    - 2/5 SI

Take home message:

- Points useful for treatment of male infertility:
  - Siterman: LU-7, LI-4, LI-11, ST-30, ST-36, SP-3, SP-9, SP-10, HT-7, BL-20, BL-23, BL-33, KI-6, KI-7, P-6, LV-5, LV-8, CV-1, CV-2, REN-4, CV-6, GV-4
  - Pei et al: CV-4, BL-23, BL-32, LV-3, KI-3, ST-36, SP-6, SP-10, ST-29, GV-20
  - Meridian measurements: HT-9, MH-9, LV-2
    - 4/5 (LV)
    - 3/5 (BL, MH, HT, LU, GB, K, TH, SP)
    - 2/5 (SI)

Part 3
Infertility Treatments
Acupuncture & IVF Research

Paul C. Magarelli, M.D., Ph.D.
Diane K. Cridennda, L.Ac.
18 Ways to Make a Baby

1. Natural sex
2. Artificial insemination — of mother with father’s sperm
3. Artificial insemination — of mother with donor sperm
4. Artificial insemination — with egg and sperm donors, using surrogate mother
5. In vitro fertilization (IVF) — using egg and sperm of parents
6. IVF — with Intra-Cytoplasmic Sperm Injection (ICSI)
7. IVF — with frozen embryos
8. IVF — with Preimplantation Genetic Diagnosis (PGD)
9. IVF — with egg donor
10. IVF — with sperm donor
11. IVF — with egg and sperm donor
12. IVF — with surrogate using parents’ egg and sperm
13. IVF — with surrogate and egg donor
14. IVF — with surrogate and sperm donor
15. IVF — with surrogate using her egg, sperm from baby’s father
16. IVF — with surrogate using egg and sperm donors
17. Nuclear transfer and cloning

Western Treatment of Infertility

- **Timed Intercourse**
- Clomid therapy, aka **Ovulation Induction** (can be used with injectable medications also, e.g., Pergonal™)
- **Intrauterine Insemination** (IUI), aka Artificial Insemination
- **In Vitro Fertilization** (IVF)—“Test Tube Baby”

Timed Intercourse: “natural”

Women: Egg, natural state

Men: Sperm, natural state
Male Factor Treatments

versus

ICSI

Test Tube Babies = IVF

In Vitro means "In Glass" which is another name for "In the Lab"

In Vitro Fertilization

Egg collection

Embryo

Ovary

Uterus
Incubate Fertilized Eggs for 3 to 5 days

IVF last step: Embryo Transfer

What outcomes should we expect from infertility treatments?

Fertility Treatment Outcomes

- Maximum Human "Natural" Fertility
- Sex
- Clomid + IUI
- IVF - Own Eggs
Acupuncture & IVF Research
Diane K. Cridennda, L.Ac.

- Outline Research
- “biology of acupuncture”
- Studies
  - Overview
  - Results
- Impact of Acupuncture on IVF

Traditional Chinese Medicine (TCM)
Diane K. Cridennda, L.Ac.
East Winds Acupuncture, Inc.

Acupuncture & IVF
Study Design

- Acupuncture Consortium
  - Agreement (written) to follow protocols
  - Agreement to provide 7 day/week coverage
  - Agreement that SV and Paulus treatments would have suggested fee
  - Agreement that access to consortium would be through one lead acupuncturist
- All patients would have choice to have acupuncture or not
  - Information provided to IVF patients by physician, nurses, posters and flyers in each exam room
- Investigators would (did not) look at overall data outcomes for 3 years

Key Components of Research

- Two groups
  - Controls – no acupuncture
  - Treatment – acupuncture (one or both protocols)
- IVF procedures
  - One REI did all procedures
- Acupuncture procedures
  - Acupuncture Consortium
    - Lead by one Acupuncturist
    - Treatments are reported to Consortium leader for analysis
- Statistical Analysis
  - Performed by independent researcher

Literature

Two major studies were done on the efficacy of acupuncture being used in conjunction with IVF or ART:

1. Reduction of blood flow impedance in the uterine arteries of infertile women with electro-acupuncture. Stener-Victorin et al.
   - Eight treatments before retrieval using electro-stim
2. Influence of acupuncture on the pregnancy rate in patients who undergo assisted reproduction therapy. Paulus et al.
   - This was the protocol set up for the pre and post embryo transfer we modified the protocol slightly
Stener-Victorin et al. Protocol

- **Protocol**
  - Eight treatments before retrieval
    - Treat the patient twice a week for four weeks up to retrieval
  - Point Locations (all points are needled bilaterally)
    - UB 23 to UB 28 (one lead)
    - SP 6 to UB 57 (one lead)
  - Electro-stimulation set from 0 – 100 Hz for 30 minutes
    - (ALFA-100D digital Electro Acupuncture Stimulator)
  - TDP lamp on the low back is optional for the patient (our variation)
  - Needles
    - 36 g 1-1 ½ inch needles
    - Patient has panic button in case e-stimulation stops or gets too strong.

Paulus et al. Protocol

- **Protocol**
  - Treat 12-24 hours before embryo transfer (this was a variation of Paulus protocol)
    - Treat within 1 hour after embryo transfer
  - Pre transfer points
    - Du 20, PC 6, ST 29, SP 8, LIV 3
    - Ear points
      - Rt. Shen, brain
      - Lt. Uterus, endocrine
      - place press tacks in each ear using the same pattern and ask pt to stimulate them during transfer.
  - Post transfer points
    - LI 4, SP 10, ST 36, SP 6
    - Ear Points
      - Rt. Uterus, endocrine
      - Lt. Shen/brain
      - place press tacks in each ear using the same pattern instruct patient to remove in 3 days
    - Needles
      - 32 g 1 ½ inch needles
      - Patient should remain q10 minutes until first Q & take off Briggs drapes
Theoretical Basis “biology of acupuncture”

Acupuncture points in Stener-Victorin Protocol

- **UB 23** (kidney shu point)
  - Powerful point which tonifies and regulates the kidneys, affects the low back, regulates whole body
- **UB 28** (bladder shu)
  - Local points over the uterine arteries, regulates the uterus
- **UB 57** (supporting mountain)
  - Relaxes sinews, invigorates the blood
- **SP 6** (three yin crossing or meeting of the yin)
  - All female issues, affects kidneys, liver and spleen

Theoretical Basis “biology of acupuncture”

Acupuncture points in Paulus Protocol: Pre Embryo transfer

- **DU 20 Hundred meetings**
  - Any pre and post partum issues, prolapse of any kind
- **PC 6 Inner gate**
  - Calms heart regulates Qi
  - Regulates middle jiao
- **SP 8 Earth mechanism**
  - Regulates uterus

All points are needled bilaterally

Theoretical Basis “biology of acupuncture”

Acupuncture points in Paulus Protocol: Post Embryo transfer

- **LI 4 Union of the Valleys**
  - Pain in uterus, tonifies and regulates Qi
- **ST 36**
  - Regulates Qi and blood, strengthens whole body, treats any weak and deficient conditions
- **SP 10**
  - Moves and cools the blood, tonifies blood, moves blood (a heparin like affect)
- **SP 6**
  - Regulates the uterus, calms the mind by relationship to the heart, benefits kidney, liver and spleen. Nourishes yin and blood.

All points are needled bilaterally
Auricular Acupuncture

- Points
  - Uterus
  - Endocrine
  - Shen Men
  - Brain

Impact of Acupuncture on IVF Good Prognosis Patients

<table>
<thead>
<tr>
<th>Patients</th>
<th>Normal FSH &lt; 10.3</th>
<th>Age &lt; 39</th>
<th>Pulsatility IndexI &lt; 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acupuncture</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

# Normal FSH < 10.3
# Age < 39
# Pulsatility IndexI < 3

p < 0.05

Impact of Acupuncture on IVF Poor Responder (PPr) Patients - Pregnanacies

<table>
<thead>
<tr>
<th>Patients</th>
<th>Std IVF Control</th>
<th>PPr Control</th>
<th>PPr Acupuncture</th>
</tr>
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<tbody>
<tr>
<td>p &lt; 0.001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>p &lt; 0.05</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>p &lt; 0.001</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Impact of Acupuncture on IVF Patients:

- Integrating Acupuncture into an IVF program improves reproductive outcomes
  - Fewer Miscarriages
  - Fewer Ectopics
  - More Pregnancies
  - Fewer Multiples
  - More Take Home Babies!

Impact of Acupuncture on IVF Pregnancies:

- Kaplan Meier’s Survival Curve for Acupuncture Treatments - Pregnant vs Non Pregnant
**Embryology Outcomes: Impact of Acupuncture on Egg & Embryo Characteristics**

<table>
<thead>
<tr>
<th>Pregnancy</th>
<th>Ac</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number Eggs Retrieved</td>
<td>14.6</td>
<td>15.7</td>
</tr>
<tr>
<td>Number FertilizedNormally</td>
<td>8.9</td>
<td>8.4</td>
</tr>
<tr>
<td>Number Implanted</td>
<td>1.6</td>
<td>1.5</td>
</tr>
<tr>
<td>Number Frozen</td>
<td>1.6</td>
<td>2.2</td>
</tr>
<tr>
<td>Number Embryo Transferred</td>
<td>3.7</td>
<td>3.4</td>
</tr>
<tr>
<td>Day of Transfer</td>
<td>3.1</td>
<td>3.2</td>
</tr>
<tr>
<td>Number previous IVF cycles</td>
<td>0.6</td>
<td>0.4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Not Pregnant</th>
<th>Ac</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number Eggs Retrieved</td>
<td>12.8</td>
<td>13.1</td>
</tr>
<tr>
<td>Number Fertilized Normally</td>
<td>6.9</td>
<td>7.2</td>
</tr>
<tr>
<td>Number Implanted</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Number Frozen</td>
<td>1.3</td>
<td>1.2</td>
</tr>
<tr>
<td>Number Embryo Transferred</td>
<td>3.3</td>
<td>3.2</td>
</tr>
<tr>
<td>Day of Transfer</td>
<td>3.2</td>
<td>3.2</td>
</tr>
<tr>
<td>Number previous IVF cycles</td>
<td>0.5</td>
<td>0.4</td>
</tr>
</tbody>
</table>

**Results: Pregnancy & Embryology**

- **Pregnancy Outcomes** were superior in the Acupuncture Group vs. Non-Acupuncture group (p < 0.05)
  - Significantly more pregnancies at p ≤ 0.05
  - Significantly fewer ectopic pregnancies at p ≤ 0.05

- **Embryology Outcomes** were the same between the Acupuncture Group and the Non-Acupuncture group
  - Number Eggs Retrieved
  - Number Fertilized Normally
  - Number Implanted
  - Number Frozen
  - Number Embryo Transferred
  - Day of Transfer
  - Number previous IVF cycles

**IVF: Western + Eastern**

*Source CDC 2001*
Other Research

• Impact of Acupuncture on Stress Hormones in IVF patients
  – Results
  • To be discussed

Conclusions

• Biology of Reproduction
  – Female
  – Male
• Treatment of Infertility – Western Perspective
  • There have been significant improvements in infertility treatments utilizing Western Medicine
  • Acupuncture has been shown to enhance and improve fertility for thousands of years
  – Literature supports both primary and adjunctive role of Acupuncture in evaluation and treatments of infertility
  • Research done utilizing Acupuncture in conjunction with IVF has demonstrated improved pregnancy rates, lower miscarriage rates, very low ectopic pregnancy rates, possible reduced multiple pregnancies!
  • Our research demonstrates significant improvements in IVF outcomes and for the first time significant improvements in THB (take home babies)... the REAL desired outcome!

Recommendations

1. Discuss Acupuncture for IVF patients
2. Develop Acupuncture Consortium
3. Work with Reproductive Endocrinologist and Infertility Specialist
4. Give patients references related to impact of Acupuncture on IVF outcomes
5. Educate patients to seek an acupuncturist who specializes in infertility
Questions?