

De Qi or Not De Qi, That is the Question: Is the Chinese Emperor Wearing No Clothes?

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Goals of Discussion

 Expose Crisis in Acupuncture Research & Training in the West
 Detail the Roots of the Crisis
 Outline Path for Crisis Resolution

Scientific Evidence of Crisis

- Review of the Pain literature in Acupuncture leads to the stunning conclusion:
 - Sham Acupuncture Needling is Equivalent to Verum Acupuncture Point Needling using TCM Protocols with *de qi* needling
- Ernst: The better the study design, the more likely acupuncture is shown to be no better than the "placebo group"

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Sham Needling

Attempt in West to introduce Placebo Control into Acupuncture Research

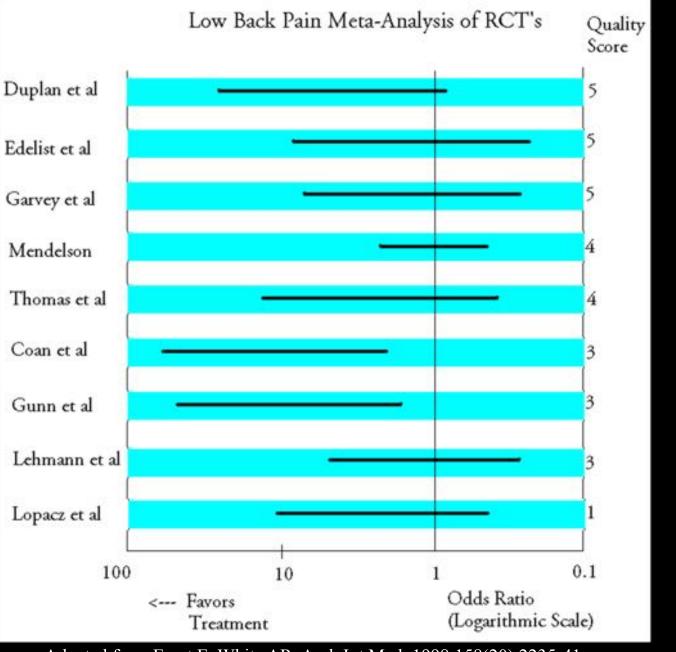
Types of Sham Needling

- Standard TCM Needling Depth (without needling to obtain the *de qi* sensation)
- Minimal Acupuncture (subdermal insertion)
- Point location off Meridian
- Point location on Meridian but off Formula Treatment Point
- \geq ? Sham \neq Placebo ?

The Literature on Sham (or the Sham Literature?)

- Large Reviews
 Cochrane Collaboration
 Meta-Analyses Ernst, Ezzo
 Back Pain
 - Neck Pain
 - Chronic Pain





Adapted from Ernst E, White AR. Arch Int Med. 1998;158(20):2235-41.

氣 Criticism of Studies in Reviews

- Acupuncture Protocols Highly Criticized by "Experts"
- Small n prevents ability to distinguish between verum and sham groups
- Length of treatment and follow-up inadequate

R Optimized Acupuncture Trial

- RCT with Sham Placebo in Chronic LBP (Leibing e, Leonhardt U, et. al Pain 2002, 96(1-2):189-196.)
- Consecutive enrollment of 150 subjects 18-65 years of age
- ► All patients received 26 sessions of PT
- Acupuncture vs. Sham for 20 sessions
 - 5x per week for 2 weeks, then 1/week for 10 weeks



SHAM TREATMENT

- Superficial needle placement 10-20 mm off verum points and off meridian (Minimal Acupuncture)
- ≻No ear points done
- de qi response not obtained with Sham Needling



Acupuncture Protocol

Dr. Chien-Kang Li devised treatment protocol

- Degree from Univ for Chinese Culture Taiwan and Univ. Goettingen, Germany.
 - 9 bilateral body points & 2 single points
 - Positive *de qi* response obtained



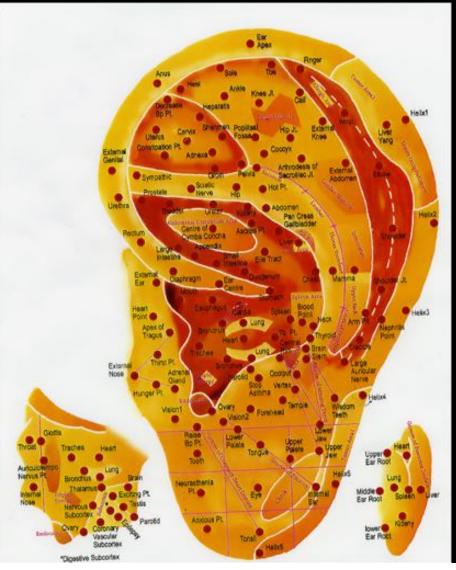
Body Points

➤ UB 23, 25, 31,32,40,60 GB 34, SP 6 ➤ GV 3, 4 ➤ Hand points Yautungdien for LBP ➤ De Qi obtained on verum points



EAR POINTS

Os sacrum
Parasympathicus
Lumbosacrum
Shenmen
Kidney
Nervus ischiadicus



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RESULTS

Both Groups showed significant improvement in Pain and Functional Impairment compared to PT alone

No significant difference in function and pain between Verum and Sham groups following treatment and at 9 month followup

Other Pain Syndromes

- Neck pain (White AR, Ernst E. Rheumatology 1999;38:143-47.)
 Majority of high quality studies show no difference between Sham and Verum
- Chronic Pain (Ezzo J, Berman B, et al. Pain 2000;86:217-225.)
 - The proportion that improved with Sham acupuncture was significantly higher than inert placebo controls (sham tens, placebo needle)
 - 22 RCT's in review used sham needling for control and 15 of the 22 (68%) showed no difference when compared to Verum needling methods.

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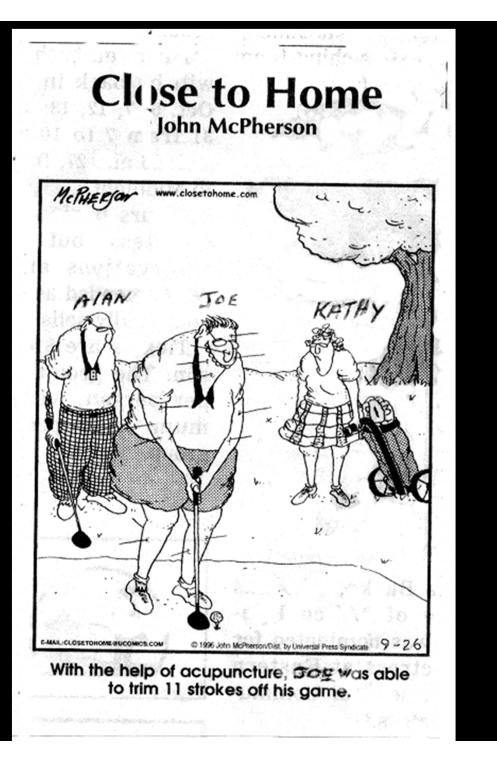
Possible Conclusions

- Acupuncture is no better than the nonspecific effects of sham needling
- TCM formulas are no better than random point selection for Pain conditions
- ► Needle method is flawed
 - Is the production of a *de qi* sensation sufficient to verify adequacy of needle placement for a particular condition?









Origins of Acupuncture in China

- Yellow Emperor's Canon of Medicine (Nan-Ching)
 Acupuncture is most cited therapy in ancient text
- By 18th Century Acupuncture had become more of an Artisan class activity
 - Much as "surgery" was in West until improvements occurred in anesthesia and sterile technique
 - ZHENJIU (ACUPUNCTURE)
 - WAIKE (SURGERY)



Classic 9 Needles





Imperial Court

► Variable degree of endorsement

- Herbal Treatments preferred
- Diagnostic Methods forced to minimize touch

In 1822 Imperial edict banned the teaching and practice of acupuncture and moxibustion in the Imperial Medical Academy

Andrews BJ. Acupuncture and the Reinvention of Chinese Medicine APS Bulletin 1999;9(3).

Early 20th C Practice

- Influence of the West led many in the government to believe that traditional medical practices in China were old fashioned, not hygienic, and superstitious
 Critical of traditional practitioners lack of knowledge of precise internal anatomy
- Concern about common complications such as festering wounds and disfiguring burns



Circa 1900 Surgical and Acupuncture Instruments





Medical Education

- 1905 Civil service examination replaced by technical schools based on the German-Japanese model
- By 1910 Supporters of traditional Chinese medicine had developed colleges as well but did not teach acupuncture
- 1936 Government regulations regarding medical licensure were developed
 acupuncture skills not included

Acupuncture Modernization

 Cheng Dan'an as scholar and physician in 1930's revitalized the teaching of Acupuncture to physicians by relating the meridians and points to nerve pathways
 Illustrated text with meridians precisely drawn on naked bodies written 1932 (*Chinese Acupuncture and Moxibustion*)



Cheng Dan'an, 1930

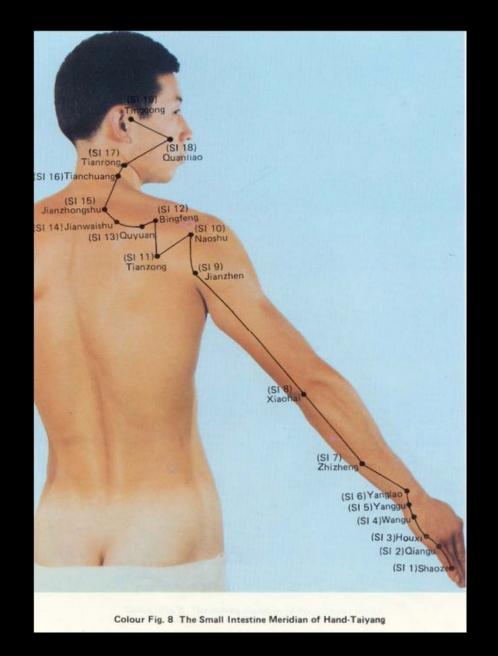
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Acupuncture Formulas

 Parallels model for teaching herbal formulas
 Lends itself to Dissemination in Text form and teaching in University setting

- Moves away from Master Apprentice Relationships
- Point location reduced to specific anatomic locations that are relatively fixed
- Time constraints lead to increased use of Electro-acupuncture

Post-revolution Acupuncture

- Cheng appointed to Communist national committees in charge of medical policies
- Cultural Revolution of 1960's and 1970's heightened the regard concerning the indigenous genius of these traditional medical practices
 - Handbooks disseminated to the untrained on acupuncture and herbal therapeutics





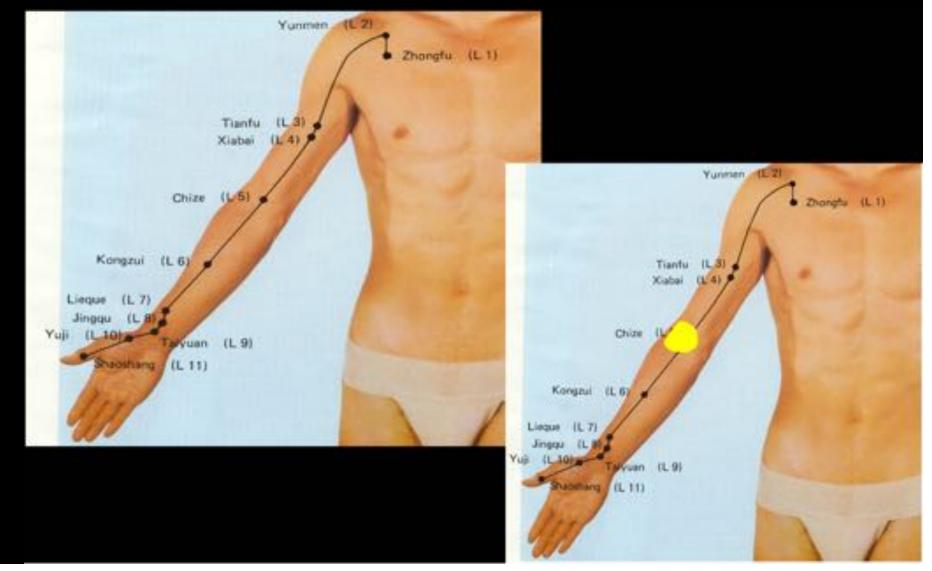
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Education in West: Non-physicians

- Western Interpretation and simplification of TCM Formulaics and Non-palpatory diagnostic methods become institutionalized in the NCCA exam (National Commission for the Certification of Acupuncturist).
- Needling techniques not emphasized given lack of mentors and fear of causing pain
- Many Chinese Physicians teaching in this country have MD from China in Ortho, Int. Med and so on and have had very brief educational background in Acupuncture (1-1.5 years)



Point Location Fiasco



Education in West: Physicians

 Physician courses simplify diagnostic and point verification methods even more
 Emphasize expediency rather than efficacy
 Emphasis on endorphin theory of Acupuncture Analgesia and other reductionist physiological models which makes point verification irrelevant

Recent Meta-analysis LBP

- ➤ 33 Studies on Chronic LBP included comparing acupuncture to sham, other active treatments, and no additional treatment
 - 7 trials with Sham control
 - Acupuncture is significantly more effective than sham treatment (standardized mean difference, 0.54 [95% CI, 0.35 to 0.73]

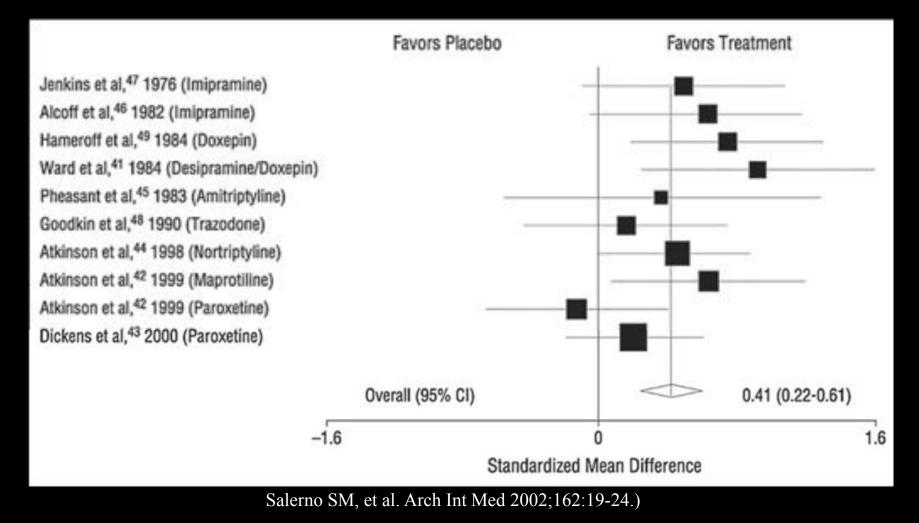
Manheimer E, et al. Ann Intern Med. 2005 Apr 19;142(8):651-63

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Study, Year (Reference)	Patients, n	Effect (95% CI)			
Sham acupuncture					
Leibing et al., 2002 (41)	75	0.60 (0.13 to 1.08)			
Mendelson et al., 1983 (43)	77	0.45 (-0.01 to 0.91)			_
Molsberger et al., 2002 (45)	126	0.50 (0.14 to 0.85)			
von Mencke et al., 1988 (56)	65	0.90 (0.38 to 1.42)			—
	343	0.58 (0.36 to 0.80)			-
Sham TENS					
Carlsson and Sjolund, 2001 (24)	50	0.47 (-0.15 to 1.08)		-	_
Kerr et al., 2003 (36)	46	0.39 (-0.22 to 0.99)		_	
Lehmann et al., 1986 (40)	28	0.41 (-0.38 to 1.20)		-	_
	124	0.42 (0.05 to 0.79)			<u> </u>
No additional treatment					
Cherkin et al., 2000 (25)	175	0.15 (-0.15 to 0.45)		-	- - -
Coan et al., 1980 (26)	39	0.78 (0.10 to 1.47)			
Leibing et al., 2002 (41)	74	1.23 (0.72 to 1.74)			_ I _ ∔
Mazieres et al., 1985 (15)	34	0.86 (0.12 to 1.59)			
Meng et al., 2003 (44)	47	1.06 (0.42 to 1.69)			- + -+
Molsberger et al., 2002 (45)	125	0.62 (0.25 to 0.98)			
Thomas and Lundeberg, 1994 (48)	40	0.43 (-0.32 to 1.17)		-	
Yeung et al., 2003 (52)	52	0.67 (0.09 to 1.24)			
	586	0.69 (0.40 to 0.98)			+0-
Massage					
Cherkin et al., 2001 (25)	167	-0.11 (-0.41 to 0.20)			-
Medication					
Giles and Muller, 1999 (30)	38	-0.51 (-1.18 to 0.16)			-
Giles and Muller, 2003 (31)	74	0.79 (0.31 to 1.28)			
Ite, 2000 (35)	26	0.06 (-0.75 to 0.88)			•
Point and the second second	138	0.14 (-0.69 to 0.97)			
Spinal manipulation					
Giles and Muller, 1999 (30)	50	-1.02 (-1.65 to -0.39)		-	
Giles and Muller, 2003 (31)	69	-1.58 (-2.14 to -1.03)			
TENE	119	-1.32 (-1.87 to -0.77)			
TENS	67			_	
Grant et al., 1999 (32) Lehmann et al., 1986 (40)	57 27	-0.47 (-1.01 to 0.07) 0.37 (-0.43 to 1.17)			
Nobili et al., 1985 (46)	48	0.61 (0.01 to 1.21)			
Nobili et al., 1965 (46) Sakai et al., 2001 (47)	64	0.18 (-0.32 to 0.69)			-
2000 11 m. 2001 (47)	196	0.15 (-0.33 to 0.63)			-
	170	4.13 (-4.33 III 4.63)			<u> </u>
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			Con		Acupuncture

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Mean Pain Improvement with Antidepressants



RCT Acupuncture & Standard Orthopedic Treatment

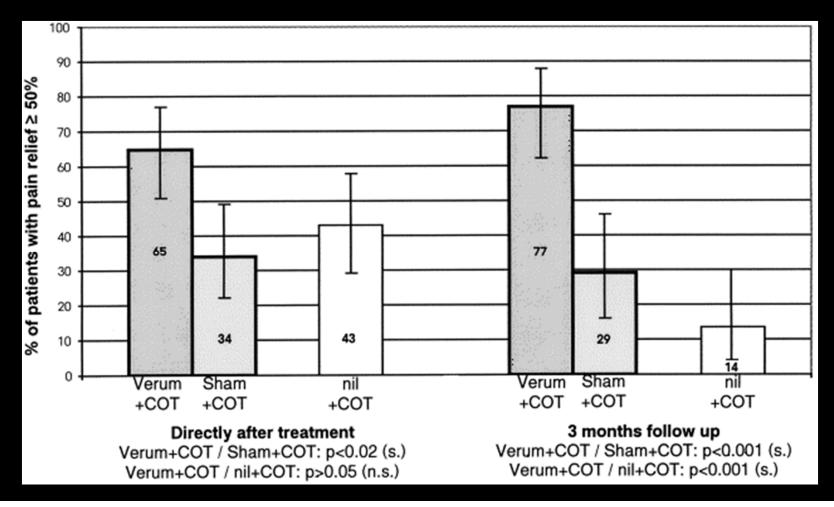
- RCT Acupuncture + COT vs. Sham + COT in vs. COT alone in chronic low back pain
 - 186 subjects 18-65 years with pain for 6 weeks or longer, no sciatica
- COT: Conventional Orthopedic Treatment
 PT, Back School, Diclofenac PRN, infrared, Mud packs
- Acupuncture and Sham for 12 sessions

3x per week for 4 weeks

The acupuncture therapy was carried out by an experienced medical doctor, who had studied acupuncture in China (Beijing).

Molsberger AF, et al. Pain 2002;99(3):579-87.

Acupuncture with Conventional Orthopedic Treatment (COT) vs. COT Alone



Recent German Trials in Pain

- German Insurance Companies Sponsored Trials (GERAC)
 - Headache (Diener HC, et al Lancet Neurology 2006)
 - © LBP (Haake M, et al. Arch Int Med 2007)
 - © Knee OA (Scharf HP, et al. Ann Int Med 2006)
- ➤ All had similar findings
 - Sham Needling = Verum Formulaic Approach
 - Significant Improvement over Standard of Care both groups

German Acupuncture Research Trials

≻ Knee OA

1007 patients who had had chronic pain for at least 6 months due to osteoarthritis of the knee (American College of Rheumatology [ACR] criteria and Kellgren-Lawrence score of 2 or 3). (Scharf HP Ann Int Med 2006)

► LBP

- 298 Patients were randomized to treatment with acupuncture, minimal acupuncture (superficial needling at nonacupuncture points), or a waiting list control.(Brinkhaus B, et al Arch Int Med 2006)
 - 1162 patients aged 18 to 86 years (mean +/- SD age, 50 +/-15 years) with a history of chronic low back pain for a mean of 8 years. (Haake M, et al. Arch Int MED 2007)

➢ Migraine

960 Patients who had two to six migraine attacks per month (Diener HC, et al Lancet Neurology 2006)





Donger

<u>Opportunity</u>



Crisis Resolution

Return to Basic Principles

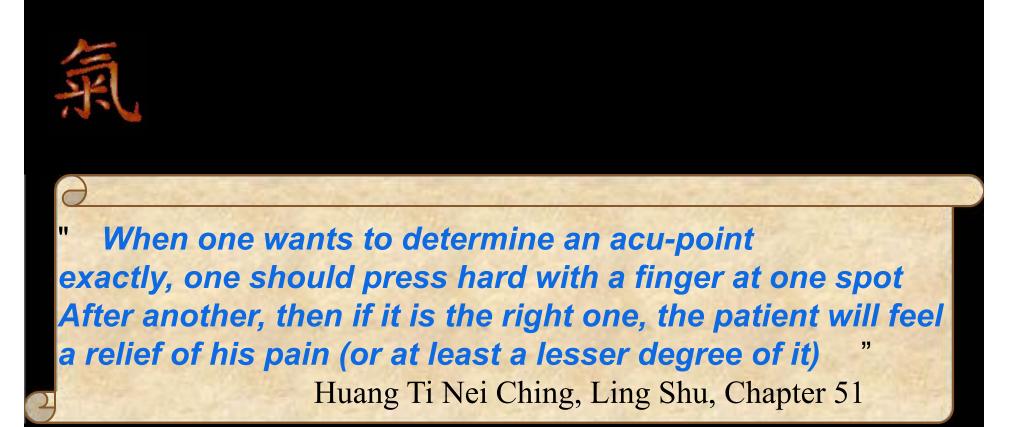
- Must move towards Point Verification not Point Location based on formulas or abstract theories
- Must keep preeminent the concept that treatment must be individualized
- Education and Research must move towards incorporating styles of Acupuncture not influenced by Historic factors in China in 19th and 20th Century but instead are founded on the Chinese Classics (CCM rather than TCM)



Nan-Ching 78:

七十八难曰: 针有补泻, 何谓也? 然: 补泻之法, 非必呼吸出肉针也。知为针者,信其左;不知为针者, 信其右。当刺之时,必先以左手压按所针荥俞之处, 弹而努之,爪而下之,其气之来,如动脉之状,顺针而 刺之。得气,

The answer is the tonification and dispersion not only using inhalation and exhalation Expert The person who knows (how to use) the needle, trust the left. Beginner who does not know, Trusts the right When one insert the needle, you must primary use the left hand and press the Point then tap the point with fingernail and *Qi comes* under the fingernail, you feel like some Pulsing, then you can insert the needle,



Needling Technique

- Must re-evaluate the importance of the *de qi* response as the sole marker for authentication of Acupuncture Point or Treatment Protocol
- Science must work to differentiate the effect of differing needling styles
- Science must work to differentiate active from latent acupuncture points

Non-TCM styles

- Broaden Research and Education to include styles that have an overt methodology to verify accuracy of treatment
 - © Kiiko Matsumoto's and other Japanese Styles
 - Palpatory Methods
 - Yamamoto New Scalp Acupuncture
 - Korean Pulse Diagnosis
 - Nogier/Bar Pulse Diagnosis
 - Gleditsch Very Point Technique



Education

- Education should focus on Needling Methods and Verification of effect as much as on Diagnostic Skills and Point Memorization
- Emphasis should be on educating Researchers in the clinical and historic aspects of acupuncture

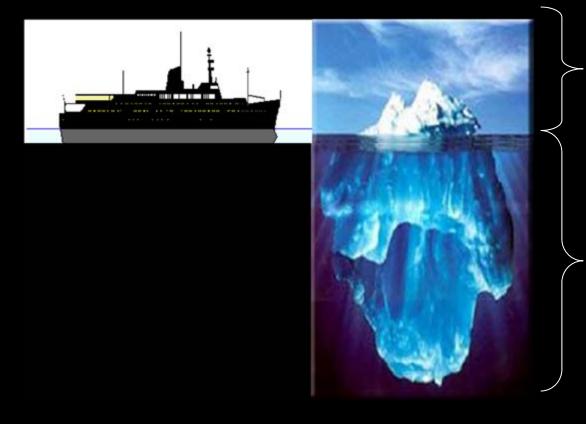
Scientific Grounding

Must focus research not just on "Does it Work" but on "How it works"

► What is an Acupuncture Point?

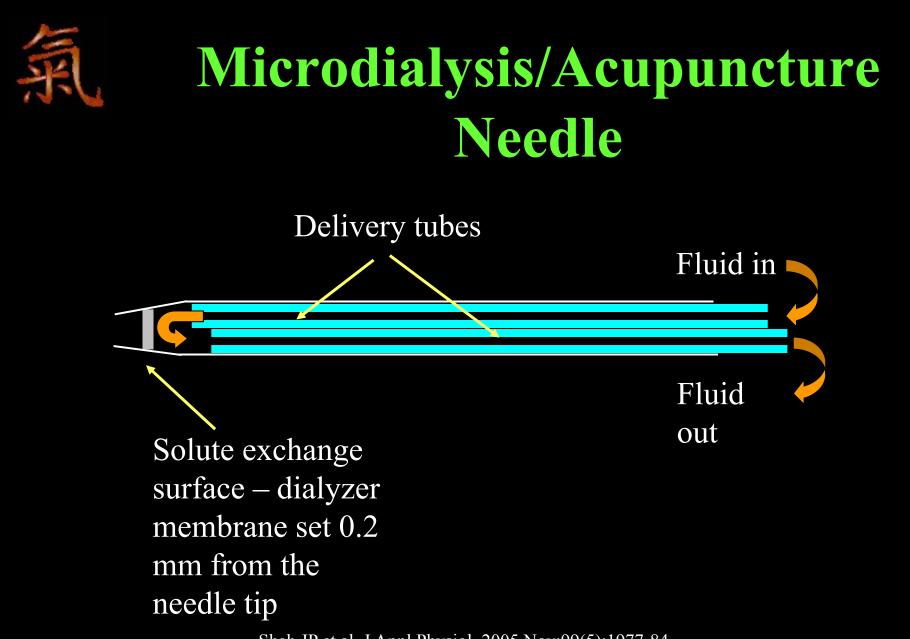
- [©] Why should one point work more than another?
- Does the method of needling matter?
- Does the angle of needling matter?
- Are there objective physiological changes that can be measured or monitored to authenticate accurate needle placement

What is the Biochemical Milieu of an *Active* Acupuncture Point?

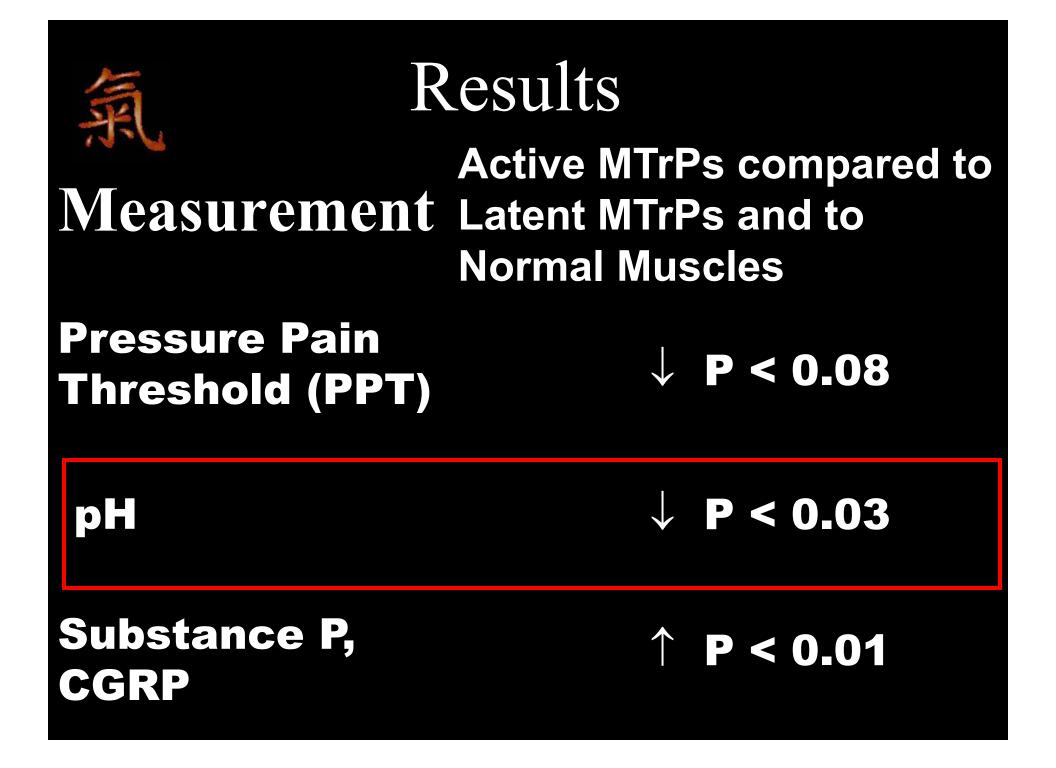


Clinical findings

Underlying milieu?



Shah JP et al. J Appl Physiol. 2005 Nov;99(5):1977-84.



Scientific Evolution

Basic Scientists must explore other theoretical models of "How Acupuncture Works"
 Must get beyond Endogenous Opioid Mechanism
 Scientific Model must be able to explain

- Point specificity, angle, methods of stimulating
- Local Distal relationships between points
- Somato-Visceral/ Viscero-Somatic Relationships
- Disease Modification