



RISKS OF ACUPUNCTURE

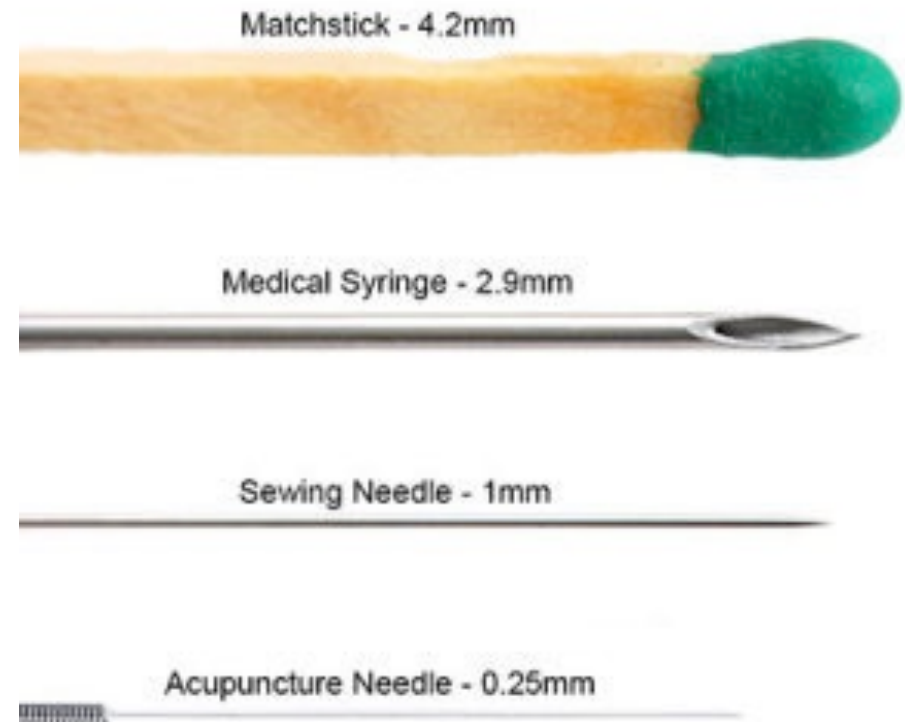
Joseph Audette, MD

Historic Considerations

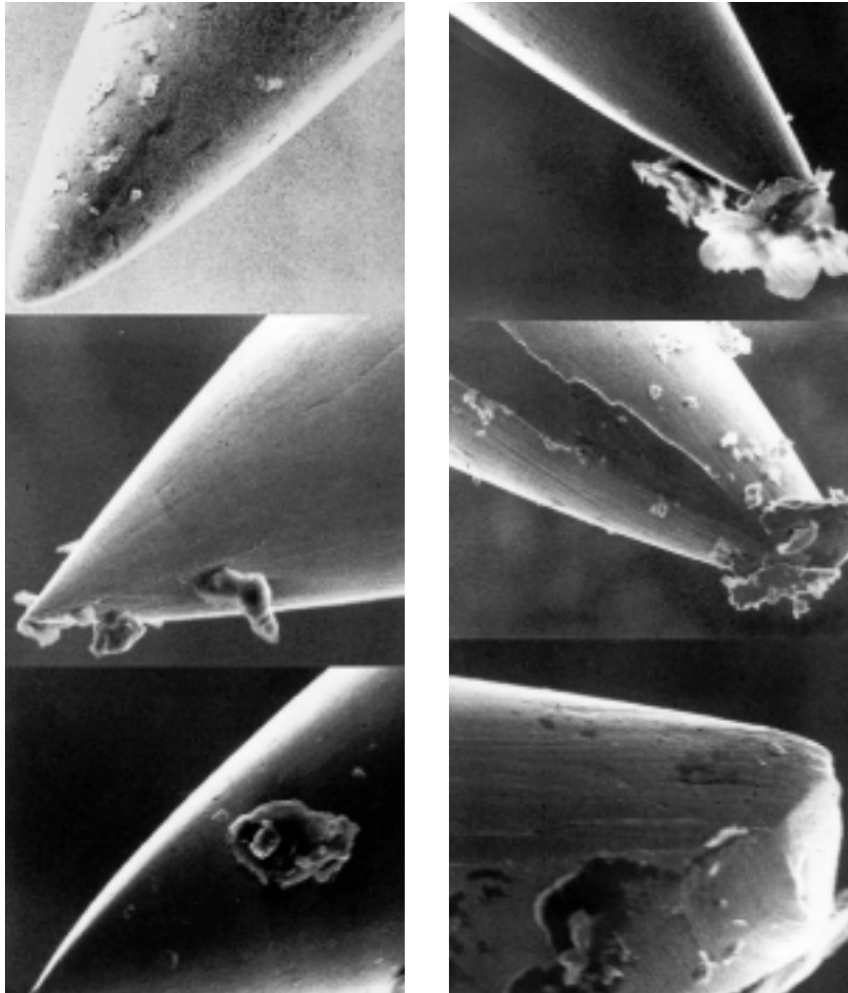
- Han Dynasty Texts
 - Acupuncture considered safer than herbal therapies
 - Toxicity of herbs not well understood early in development of early pharmacopeia
 - Despite this, the lack of sterile needles and potential use in more than one individual made infection a major risk
 - Size of needles also an issue – Stainless steel acupuncture needle not developed until 1980s.
 - Advent of sterile, stainless steel, single use, filiform needle
 - AcuMedic designed the first stainless steel disposable acupuncture needle in 1978
 - Gamma-ray sterilization streamlined manufacturing process
 - By 1990's modern acupuncture needle widely disseminated
 - In 1995 the acupuncture needle was approved as a medical device by the FDA in the US

Acupuncture Needle and Infection Risk

- Filiform needle likely reduces risk of infection
 - Lack of hollow bore found in medical syringe may reduce risk of introducing bacteria into sub-dermal space



Bullet shaped needle tip: Not all manufacturers the same



Ideal Needle by electron microscopy



Acupuncture Needle and Infection Risk

- To swab with ETOH or not to swab
 - Unclear if use of standard alcohol swabs reduces infection
- Recommendations
 - Before introducing needle into skin
 - Make sure skin clean
 - Do not insert through open wound or area of skin breakdown
- Special situations
 - Lymphedema – Avoid needles in compromised limb or use sterile technique
 - Immuno-compromised patient – Generally if vascular supply to limbs good, no additional risk
 - Serious vascular compromise – Use sterile technique (Chlorhexidine)

Categories of Non-Traumatic Adverse Events

- Delayed or Missed Diagnosis leading to patient harm
 - Cannot abrogate the standards you are held to as a physician when providing acupuncture
 - Standard of Care in conventional medicine must be upheld
- Vegetative Reactions (Vertigo, sweating, fainting)
- Bacterial or Viral Infections

Prospective Study of Adverse Events Acupuncture and Moxibustion in Japan

- Multicenter trial over a 7 month period involving 32 practitioners with 2180 patient treatments
- Acupuncturists all worked in acupuncture educational facilities in Japan
 - 6% AE of the treatments led to an adverse event
 - Most common was subcutaneous bleeding and/or hematoma (2.64%)
 - No infections or serious AE's reported
- Acupuncture technique
 - Majority used needles < 0.2 mm with insertion tubes
 - Approximately half of the respondents did not use gloves
 - Interesting the non-glove wearers had less AE's although this group was also more experienced (approx. 16 years experience vs. 7 years)

Prospective Study of Adverse Events Acupuncture and Moxibustion in Japan

- Burn injuries
 - Moxibustion commonly used in Japan
 - 0.96% of patients reported minor burn injuries (19/24 cases 1st degree burn)
- Bleeding AE's
 - 71 of the 130 patients reporting bleeding AE's were on anticoagulants
- Many practitioners use a needle insertion technique described in Han Dynasty texts called Oshi-De in Japan
 - Practitioners hold the body of the needle with bare thumb and index finger
 - No increased risk of AE or infections noted

Prospective Observational Trial of AEs German Acupuncture Studies

- Prospective observational trial of patients enrolled in studies sponsored by the German Health Insurance Companies
 - 229,230 patients included
 - Average number of treatments 10
 - 8.6% reported at least 1 AE
 - 2.2% reported an AE that required treatment
- Most common AEs
 - Bleeding or hematoma – 6.1 %
 - Increased pain – 1.7%
 - Vegetative symptoms – 0.7%

Prospective Observational Trial of AEs German Acupuncture Studies

- Serious AE's
 - 2 patients developed pneumothorax
 - Nerve injuries were reported 0.26%
 - Most minor with temporary paresthesias or nerve irritations
 - 1 nerve injury in lower limb took 180 days to resolve
 - Local infection at needle site
 - 0.014%

Prospective Observational Trial of AEs German Acupuncture Studies

- Recommendations for Consent Form “Risks of Acupuncture Treatment”
 - Common Side Effects (1/100 people treated)
 - Bleeding and/or hematomas (some bleeding may be a desired effect of needle insertion)
 - Uncommon Side Effects (1/1000 people treated)
 - Vegetative signs (headache, fatigue, vertigo, nausea)
 - Inflammation at needle site
 - Strong pain during needling that may linger for a short time after treatment
 - Nerve irritation is possible that can cause temporary numbness and possible temporary weakness

Prospective Observational Trial of AEs German Acupuncture Studies

- Recommendations for Consent Form “Risks of Acupuncture Treatment”
 - Rare Side Effects (1/10,000 people treated)
 - Local infection
 - Low Blood pressure with light headedness, difficulty breathing
 - Brief Loss of consciousness
 - Generalized muscle pain
 - Mood issues including restlessness, anxiety depression, sleep disturbance
 - Disturbed vision, tinnitus
 - Very Rare Side Effects (>1/10,000 people treated)
 - Systemic infection
 - Broken needles that may require surgical excision
 - Pneumothorax
 - Rarely central nervous system injuries have been reported in literature and injury to the pericardium

Risk of Traumatic Adverse Events

- Acupuncture needle penetrates from a few millimeters to several centimeters depending on location and technique
 - Potential for the needle to cause traumatic injury to various vital structures in the body
 - Risk somewhat abrogated by needle structure
 - Tip with bullet shape, not beveled and sharpened as in a hypodermic needle that is designed to go through a vein or artery

Risk of Traumatic Adverse Events

- Penetration into Thoracic Viscera
- Penetration into retroperitoneal or abdominal viscera
- Peripheral Nerve Damage
- Central Nervous System Damage
- Vascular Damage

Traumatic Adverse Events – Thoracic Viscera

- Penetration into ***Thoracic Viscera***
 - 6 cases of cardiac tamponade described in literature
- Anatomy of Sternum –
 - Congenital abnormality of incomplete fusion of the sternal plates occurs in 5-8% of population
 - Not identifiable by standard plain films, requires CT scan
 - Distance between skin and posterior surface of sternum is 15-25 mm based on cadaver study
- Acupuncture Point at Risk CV 17
 - If needling, use tangential angle not perpendicular
 - Do not penetrate more than 1/3 or a standard 30 mm needle

Traumatic Adverse Events – Thoracic Viscera

- Penetration into **Lungs**
 - >90 cases of pneumothorax described in literature
 - Most common serious complication
 - Most likely reason for a patient to bring a malpractice suit against you
 - Importance of Informed Consent
- Anatomy of Pleura and Lungs –
 - Lungs extend far above the clavicle and points along trapezius, scalenes and anterior border of levator scapuli put patient at risk for pneumothorax
 - Distance between skin and lung is 10-20 mm based on cadaver study in region of anterior, midclavicular line.
 - 15-20 mm distance posteriorly between ribs
 - Patients with COPD, even less room for error

Traumatic Adverse Events – Thoracic Viscera

- Common Acupuncture Points at Risk
- GB 21,
- LU 1, 2;
- ST 11, 12, 13; KD 27,
- BL 11-18 and BL 41-49
 - If needling, use tangential angle not perpendicular
 - Do not penetrate more than 1/3 or a standard 30 mm needle

Traumatic Adverse Events – Abdominal and Retroperitoneal Viscera

- Penetration into ***Abdominal and Retroperitoneal Viscera***
 - Rare, 1 case report of finding a needle lodged in the Kidney
 - Rare case reports of Bladder and Intestinal injuries
- Anatomy –
 - In normal weight adults, safety margin of 2-4 cm between skin and abdominal peritoneum

Traumatic Adverse Events – Peripheral Nerves

- Penetration into ***Peripheral Nerve***
 - Rare, 1 case report of finding a needle lodged in the median nerve
 - Another case report of needle insertion in region of fibular head causing foot drop
- Anatomy –
 - PC 6 and 7 are anatomically situated over the median nerve
 - GB 34 is close to region of peroneal nerve
 - BL 39 and 40 are anatomically over peroneal and tibial nerves which are 2-3 cm in depth below skin
- Rarity of reports of injury likely due to fact that as needled approaches the perineurium, there is typically a nerve like reaction causing a shooting sensation, leading one to withdraw the needle

Traumatic Adverse Events – Central Nervous System

- Penetration into **CNS**
 - 10 case reports of injuries to spinal cord or spinal nerve roots
 - 4 cases were due to broken needles and needle migration
 - C1-2: 4 cases
 - C6: 1 case
 - L4-L5: 2 cases
 - S1: 1 case
 - A number of case reports as well for subarachnoid or epidural hemorrhage
- Anatomy –
 - Distance between skin and spinal nerves range from 25-45 mm
- Points at risk
 - BL 11-20
 - Huato Jiaji points

Traumatic Adverse Events – Peripheral Vascular System

- Penetration into ***Arteries and Veins***
 - 4 case reports of vascular injuries
 - Costocervical artery
 - Popliteal artery at knee
 - Deep vein thrombophlebitis occurring 48 hours after acupuncture treatment
 - Case report of anterior compartment syndrome in patient on anticoagulation when needling in region of ST 36
- Anatomy
 - Needle design again provides some degree of safety given lack of beveled

Skin preparation prior to Acupuncture

- Historically, use of isopropyl alcohol 70% solution is recommended for skin preparation prior to superficial injections (skin and muscle)
 - No evidence to support
- Recent studies argue against use of alcohol preparation
 - In a retrospective review of therapeutic BOTOX injections between 1999-2004 (Perry JD. Ophthalmic Plastic & Reconst Surg. 2009; 25(3): 178-179.)
 - 142 patients underwent BOTOX injections without use of alcohol prep
 - No infections occurred
- Survey of 225 patients with IDDM who had an estimated 9,472,040 injections over time period of survey
 - Those who did not use alcohol prep had incidence of 1.72 infections per 1,000,000 injections
 - Those who did report use of alcohol prep had incidence of 7.48 infections per 1,000,000 injections

Key Points

- No clear evidence to support use of medical gloves or alcohol prep prior to acupuncture
 - Historically not used
 - Recent reviews have not shown increase in risk of infections
 - Skin and your hands should be clean
 - Do not reuse needles
- Patients on anticoagulation can receive acupuncture
 - Avoid deep needling (compartment syndrome)
- Immuno-compromised patients
 - Safe to receive acupuncture
- Special situations
 - Severe vascular compromise (ischemic foot) – do not insert needles
 - Lymphedematous limb – either use sterile technique or do not insert needles