Emerging Treatments: Face of the Future or Flop?

Chairperson:

Phyllis Phillips, Esq.

Owner/Member, Mediation Works

Williston, Vermont

Tuesday, March 26th, 2024

11:40-12:00pm

Ethical Considerations

Andrew B. Stein, MD
Boston Medical Center

When Should New Technology be Adopted?

- There have been incredible technologic advancements in orthopedic care (arthroscopy, prosthetic joint replacement, etc.), but field is also littered with examples of failed "new devices"
  - Metal on metal THA, Artelon implant, silicon radial heads, artificial ligaments, etc.
  - 510K exemption allows ortho devices to be brought to market if one can demonstrate equivalence to a product in clinical use prior to 1976 (large loophole)
  - Direct to consumer marketing adds pressure to use new products
- In this age of information, the ethics of business rather than the ethics of medicine may create more confusion and deception than help for the patient
  - More than 50% of claims in orthopedic print advertisements not supported by published data (Bhattacharyya et al., *JBJS.* 2003)
- **Should novel technology be introduced for patients with conditions for which we already have effective treatments or reserved for conditions with no good options?**

New Tech

- Left to the influences of the free market, the use of new technology will most often occur where the greatest business opportunity exists
- **There is a responsibility to provide data from well-designed studies to validate a new approach before we encourage or even allow widespread use**
- We should not impede progress, but *"First do no harm."*
  - Cost effective medicine should also be considered – who should pay for new treatments even if the risk is low, but there's no proof of superiority to existing options?
    - PRP, Stem Cell Therapy (SCT)

Of 896 practice websites included in analysis, **95.9%** contained at least 1 statement of misinformation, from errors in the basic science of stem cells to outright false and misleading claims of their clinical effectiveness.

Online Direct-to-Consumer Advertising of Stem Cell Therapy for Musculoskeletal Injury and Disease

Misinformation and Violation of Ethical and Legal Advertising Parameters

Kingery, Matthew T. BA; Schoof, Lauren BS; Strauss, Eric J. MD; Bosco, Joseph A. MD; Halbrecht, Joanne MD

Author Information

The Journal of Bone and Joint Surgery 102(1):p 2-9, January 2, 2020. | *DOI:* 10.2106/JBJS.19.00714

Open vs Endoscopic CTR – No current "best practice" consensus

ECTR first introduced in 1992 - equally effective at relieving CT symptoms as open release, no difference in long term outcomes (same incidence of pillar pain)

- ECTR
  - Quicker RTW: mean differences range from 7-9 days (no distinctions made for patient occupation)
  - Decreased incidence of scar pain, but 2x higher incidence of transient neuropraxia and 2.4x higher risk of median nerve laceration (Trehan 2019) <1%
  - More expensive: direct costs 44% higher; surgeon wRVCU 29% higher (adds bias), societal costs lower?
- **Triumph of technology over reason?**
  - Limited potential benefits with higher risks (limited visualization of surgical field)
  - OCTR is simple, safe, effective, well-established procedure

Emerging Treatments: Face of the Future or Flop? Basivertebral Nerve Ablation

Chadi Tannoury, MD-FAOA-FAAOS

Medical Director, Orthopedics
Associate Professor, Orthopedics
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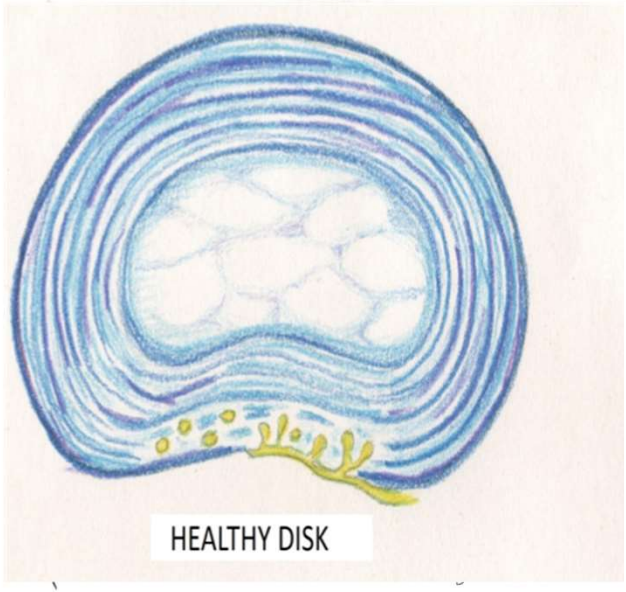
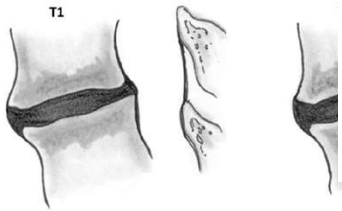
Back Pain Generators: Disc vs Vertebra?





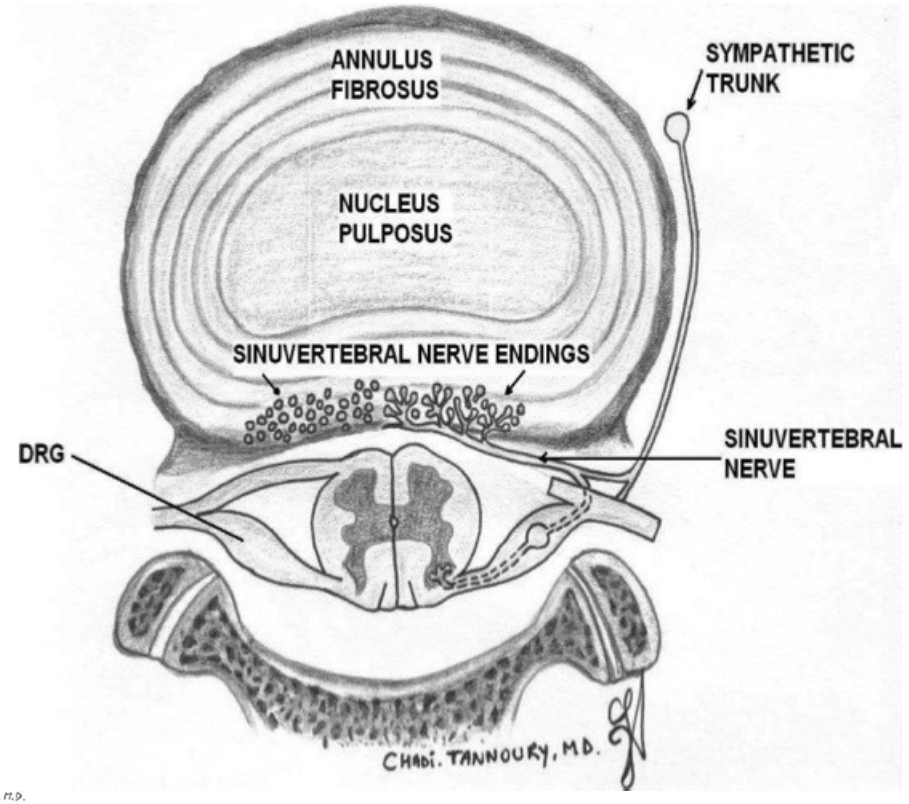
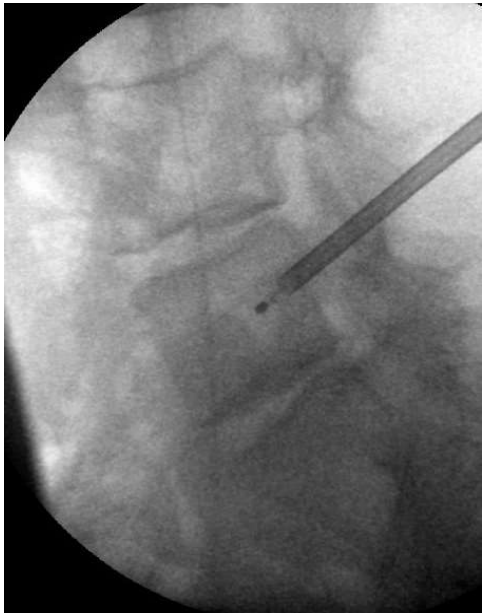
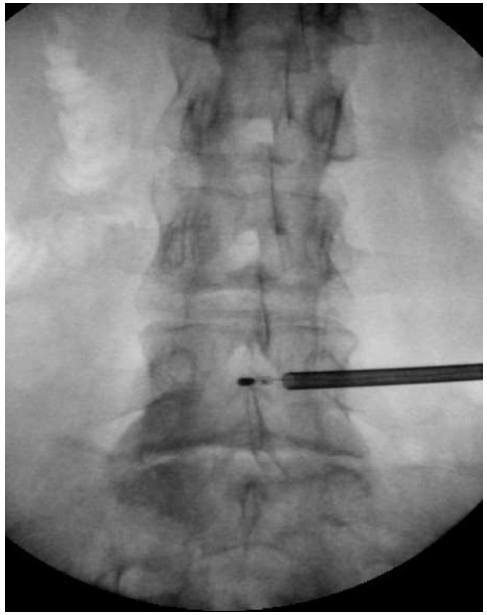


Fig. 10. Reactive vertebral body marrow changes. These bone marrow signal changes adjacent to a degenerated disc on magnetic resonance imaging. T1- and T2-weighted sequences are frequently classified as (Top Left) Modic I, (Top Right) Modic II, or (Bottom) Modic III.

What is BVNA?


- Pooled data RCT / prospective arm CLBP: 94 Patients – 4 years follow up (Bias!!)
- 61.7% of patients reported ≥ 50% reduction in pain on VAS at 4-years post-BVNA (p= 0.023)
- Evidence: Moderate - Quality
- Safe (no serious adverse events) – 83% patients satisfied; 70% resumed pre-LBP activity

Conclusion

Success = Good Patient Selection!

First Rule Out!

- Neural compression: LEG pain!
  - Disc herniation
  - Lumbar stenosis
- Mechanical issues:
  - Spondylolisthesis – Olisthesis
  - Scoliosis
  - Severe Degenerative Disc Disease: Vacuum disc
- Multilevel disease

Reasonable Candidates

- Axial back pain > 6 months
- Modic Endplate Changes
- Mild-moderate disc degeneration
- No Stenosis – No instability
- Failure alternative methods (ESI, PT, etc)
- Avoid Fusion (Personal or Medical)

Emerging Treatments: Face of the Future or Flop? Orthobiologics

Peter S. Vezeridis, MD

Orthopaedic Shoulder and Sports Surgeon

Excel Orthopaedic Specialists

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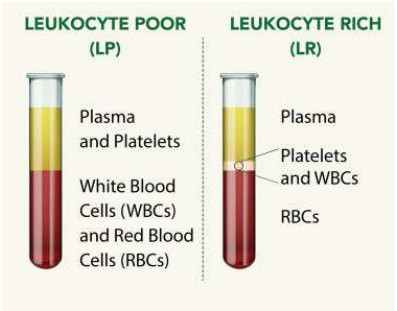
Orthobiologics

Types

- Platelet-rich plasma (PRP)
- “Stem cells” → connective tissue progenitor (CTP) cells
- Bone marrow aspirate concentrate (BMAC)
- Viscosupplementation (ex: Euflexxa)

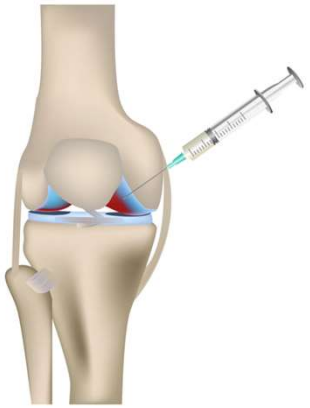
PRP

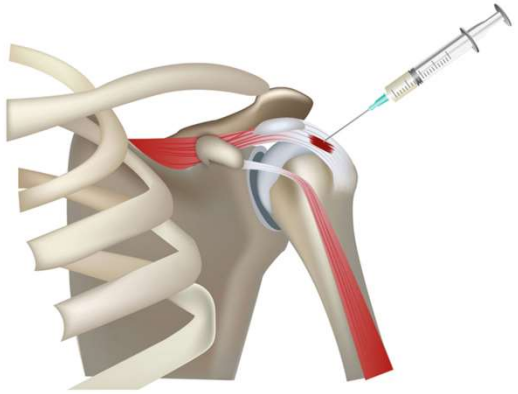
- Leukocyte rich vs. poor
- Variability



Mechanism of Action

- Anti-inflammatory effects
- Augmentation of tissue repair





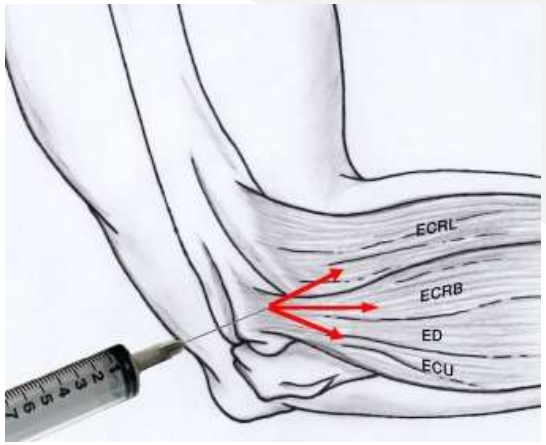
Applications

- Tendinopathies
  - Lateral epicondylitis
  - Patellar tendonitis
  - Achilles tendinopathy
- Partial-thickness tendon tears (rotator cuff)
- Osteoarthritis
  - Knee
  - Hip

PRP

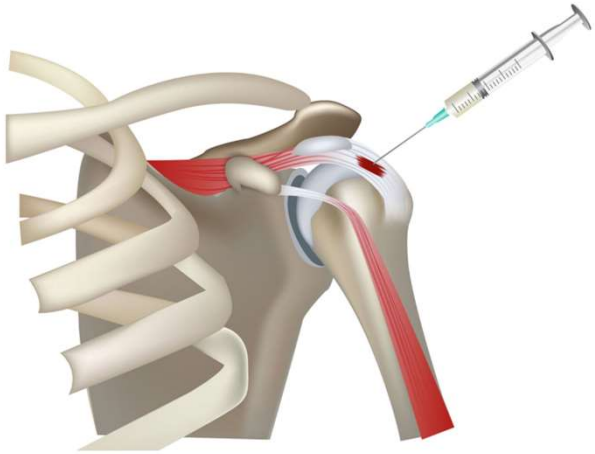
Results

- Data still emerging
- Variable preparations, applications
- Lack of extensive high-quality (Level 1) evidence



Application

- Patient factors
  - Pathology
  - Functional limitations
  - Age
  - Comorbidities
  - Job demands
  - Treatment expectations and goals
- Shared decision making



PRP - Rotator Cuff

Meta-analyses

Platelet-Rich Plasma Injection Can Be a Viable Alternative to Corticosteroid Injection for Conservative Treatment of Rotator Cuff Disease: A Meta-analysis of Randomized Controlled Trials

Long Pang, M.D., Yang Xu, M.D., Tao Li, M.D., Yinghao Li, M.D., Jing Zhu, M.S., and Xin Tang, M.D., Ph.D.

Arthroscopy: The Journal of Arthroscopic and Related Surgery, Vol 39, No 2 (February), 2023: pp 402-421

- 13 RCTs, 725 patients
- PRP vs. cortisone injections
- No statistically significant differences
  - Functional recovery
  - Pain relief
  - ROM improvement

Brand JC, Hardy R. Arthroscopy. 2023 Feb;39(2):422-424.

Corticosteroid Injection	Platelet-Rich Plasma Injection
Subsequent surgery—greater risk of poorer outcomes and revision surgery[10-15]	Subsequent surgery—unaffected
Causes further rotator cuff degeneration[16,17]	Possibly leads to healing[18]
Possibly earlier pain relief[4]	Possibly longer lasting pain relief[4]
Frequently covered by insurance in the United States	Often requires out of pocket payment in the United States[19]
Risk of infection—infrequently reported[14]	Risk of infection—infrequently reported[20]