Regenerative Medicine is now a first line treatment to avoid or delay Pharmacological or Surgical treatments

SEPTEMBER 08, 2017

Using the Body’s Natural Healing Process
PRESENTATION

BENEFITS SUB COMMITTEE OF THE STATE AND PUBLIC SCHOOL LIFE AND HEALTH INSURANCE BOARD
Dr. David Harshfield, Jr. M.D., M.S.

Born in Little Rock, Arkansas

University of Arkansas for Medical Sciences

- Medical Doctorate in 1981, graduating with honors.
- Work in the Honor’s Program during medical school pertained to stem cell therapy for the treatment of Diabetes resulted in a Masters Degree in Physiology and Biophysics.
- Board certified in Radiology in 1981
Interventional Cellular Medicine Clinics of Arkansas

ICMC Physicians are Certified in IROM
(Interventional Regenerative Orthopedic Medicine)
through the AAOM
(American Association of Orthopedic Medicine)

Clinics are certified by the ICMS
(International Cellular Medicine Society).
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The Problem: Aging & Age-Related Diseases

If you survive one disease, you may get the next...

- Heart disease
- Cancer
- Stroke
- Diabetes
- Alzheimer's

Lifespan vs Healthspan

Now: Age 50
Target: Age 85
Dr. David Harshfield, Jr. M.D., M.S.

• Fellowships in:
  1. Angiographic and Interventional Radiology
  2. Musculoskeletal Radiology

• Director of Special Procedures at UAMS upon completing fellowship in 1982.
• Chairman of the Institutional Review Board (IRB) for the International Cellular Medicine Society (ICMS), as well as serving on the advisory board for the ICMS.
• Board of Directors for the American Association of Orthopedic Medicine (AAOM)
Patient and Family Centered Functional Medicine

Guidelines - **Regenerative Injection Therapy (RIT)**

Buffered 5% Dextrose (D5W) plus

1. Platelet Rich Plasma (PRP),
2. Hematopoietic,
3. Mesenchymal and/or
4. Amniotic Cellular Solutions
The patient-centered medical home (PCMH) is the offspring of the Affordable Care Act that, among other things, mandates that going forward Primary Care physicians must acquire and store all patient electronic health records (EHR).

There is a growing confirmation that we are moving into another cultural shift.

An emerging 21st century intersection of industry, social healing and diverse contemplative practices is bringing about more compassionate, meditative and mindful medicine.
Health care is not just about what is being injected or even who is administering therapy to our patients.

The skill set of the administering physicians is extremely important.

But overall success of regenerative medicine is highly dependent on the overall health and psychological well being of our patients including; comorbidities, pharmaceuticals and nutritional status.
6 Co’s of MAXIMIZING EFFECTIVENESS OF RIT- Avoid Co-petition!

1. **Collaborate** with patient’s Primary Care Provider (PCP)
2. **Coordinate** with patient’s Chiropractor and/or Manual Therapist to ensure the patient the dignity of a **proper diagnosis**.
3. **Collate** existing health care records with all prior medical and surgical history with an updated pharmaceutical history, **Microbiome (gut) assessment/therapy**, blood laboratory and hormone status and QANS testing to determine **appropriate oral and I.V. nutrition**.
4. **Correlate** prior imaging studies with appropriate **up-to-date imaging** to arrive at the correct diagnosis.
5. **Communicate** overview of Regenerative Injection Therapy (RIT) in sync with patient’s understanding of their existing health care regimen (making clear that RIT is ‘in addition to’, not ‘instead of’ the patient’s existing and evolving ‘patient specific’ integrative health care regimen).
6. **Complete patient registry** following RIT.
Functional medicine has long been guided by six core principles:

1. An understanding of the biochemical individuality of each human being, based on the concepts of genetic and environmental uniqueness;
2. Awareness of the evidence that supports a patient-centered rather than a disease centered approach to treatment;
3. Search for a dynamic balance among the internal and external body, mind, and spirit.
4. Familiarity with the web-like interconnections of internal physiological factors
5. Identification of health as a positive vitality not merely the absence of disease emphasizing those factors that encourage the enhancement of a vigorous physiology;
6. Promotion of organ reserve as the means to enhance the health span, not just the life span, of each patient.

**Functional medicine**

*noun*

medical practice or treatments that focus on optimal functioning of the body and its organs, usually involving systems of holistic or alternative medicine. “you don’t have to have a disease to benefit from functional medicine”
Does Age Affect Cellular Treatment Success?

- Not surprisingly, older patients do not do as well as younger patients with injection of their own cells.
- For example, hip arthritis patients younger than 55 years old are more likely to report improvement than older patients.
- Poorer hip-arthritis outcomes can be improved by bolstering the patient’s immune system/gut health with I.V. and oral nutrition.
Regenerative therapies for Osteoarthritis and Diabetic neurovascular therapy

• **Degenerative arthritis** is a challenging disease with limited treatment options, and has become the leading cause of disability in elderly people.

• **Diabetes** is growing at an epidemic rate in the United States. According to the Centers for Disease Control and Prevention (CDC), nearly 30 million Americans have diabetes and face its devastating consequences.
Regenerative therapies for Degenerative Arthritis and Diabetic neurovascular therapy

What is true nationwide is also true in Arkansas

• The bottom five states in Health care in the U.S. are in order Nevada, Arkansas, Texas, Mississippi and Oklahoma.
Regenerative therapies for Degenerative Arthritis and Diabetic neurovascular therapy

Emerging Therapies Act

3 Proposed study groups

1. Osteoarthritis (OA) of the Knee
2. Low back pain
3. Diabetic extremity disease
Regenerative therapies for Degenerative arthritis and Diabetic Neurovascular therapy

Emerging Therapies Act

1. Degenerative Arthritis (DA) of the Knee
   • Knee pain can be caused by a wide range of diseases or injury.
   • **Knee pain**
     • Second most common cause of the chronic pain that affects over 100 million Americans.
     • Second most common musculoskeletal complaint that brings people to their physician.
   • **Degenerative arthritis is caused by incompetency of ligaments**, the dense fibrous bands that connect bones to each other.
The lateral view of the knee shows the optimum axis of rotation, that depends on integrity of the cruciate and other key ligaments (static stabilizers of the knee).
1. **Articular “under load”** is consequently reducing the cellular activity, causing shrinking of the matrix, reduced joint stability and secondary absorption of the tissue.

2. During static compression ("over load") we see an even more severe reduction in the cellular synthesis.

3. As cells die the reduction in matrix and joint dysfunction cause permanent degeneration.

• Cartilage health is a “Goldilox” effect, in which load on the knee must be “just right” (not too much, but not too little either).

• The needed load depends on the integrity of the cruciate and other key ligaments (static stabilizers of the knee).
Emerging Therapies Act

2. Low back pain

- **80% of us** will get back pain at some time in our lives.
- In 2007 alone, about **27 million US adults** aged 18 or older (11% of the total adult population) reported having back pain.
- Health economists have reported the **annual cost of chronic pain in the United States** is as high as **$635 billion a year**, which is more than the yearly costs for cancer, heart disease and diabetes combined.
- Individuals 18 and older to represent **210.7 million U.S. adults**, with a mean health care **expenditures per adult of $4,475**.

3. Diabetes:
   - Total direct medical expenses for diagnosed and undiagnosed diabetes, prediabetes and gestational diabetes in Arkansas was over $2.3 billion.
   - In addition, another 1 billion spent on indirect costs from lost productivity due to diabetes.
FDA Critical Limb Ischemia (CLI) Trial

**TREATMENT OF NO-OPTION CLI WITH A CONCENTRATE OF AUTOLOGOUS BONE MARROW CELLS**

David L. Harshfield, Jr., M.D., M.S.
Co-Principle Investigator
Director of Interventional Radiology
MCSA Medical Center of South Arkansas

Director of Integrative Imaging
College of Integrative Medicine - coimed.org
Little Rock, Arkansas

Chairman of the Institutional Review Board (IRB)
International Cellular Medicine Society (ICMS)
Ceradini, D, and Gurtner, G; *Trends in Cardiovasc Med: 2005*

**NATURAL RESPONSE:**
**BONE MARROW STEM CELLS ARE RECRUITED TO ISCHEMIC TISSUE**

SDF-1 released from ischemic tissue recruits bone marrow cells
Bone Marrow Aspirate Concentrate (BMAC) System: Facilitates Autologous Bone Marrow Therapy
STUDY DESIGN: Randomized (2:1), Double Blind

- **SALINE**
- **BLOOD**
- **PLACEBO**

**CONTROL GROUP** + **INVESTIGATOR BLINDED TO INJECTATE**

- **ASPIRATE**

**BMAC GROUP**

**PROCESS**

- **9/4/2017**
- **CONFIDENTIAL**

- 40 injections
- 1 mL per injection
Targeting the Delivery of BMAC
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<th>Fiscal Year 2016</th>
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<th>Workers Compensation</th>
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<td>Regenerative Intervention Success</td>
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<td>Regenerative medicine Procedural Savings</td>
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<td>Employer Potential Savings</td>
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<tr>
<td>Total Savings</td>
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Key Points

Clinical Outcomes: IROM, with credentialed providers and certified protocols, provides safe, affordable and effective therapy resulting in improved healing and overall patient outcomes.

Financial outcomes: Lower costs to The State and Public School Life and Health Insurance Board, with avoidance of not only of unnecessary pharmaceuticals, surgery but of complications, as well.

Quality of Life: IROM is not just financially beneficial, but allows patients a faster return to work and activities of daily living.

Treatment Access: Increasing payer adoption of the use of regenerative and cellular medicine, with Arkansas playing a leadership role.
D.L. Harshfield M.D., M.S.

- Board certified Radiologist with specialty training in NMSK, Ultrasound, Interventional Radiology and Cellular Medicine
- Director of the College of Integrative Medicine - coimed.org
- Member Board of Directors International Society for Cellular Medicine (ICMS)
- Chairman of the Institutional Review Board (IRB) of the ICMS
- Member Board of Directors American Association of Orthopedic Medicine (AAOM)
- Editor AAOM e-Journal