IT'S A WIDE WIDE WORLD

Building a Rationale for Evidence-Based Prolotherapy in an Orthopedic Medicine Practice

Part II: How To Meld Scientific Methodology into the Daily Practice of Prolotherapy

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To establish a clinical plan
Ask the right question.
Identify the right premises.
Minimize the variables.
And test the outcome.

Part II of a series of three[1] explains how one may apply scientific reasoning to the daily practice of Prolotherapy in an Orthopedic Medical Clinic. In doing so, this article focuses on a real-time, outcome-centered, database management approach.

An outcome-centered database can provide a platform for intra-practice monitoring and modification of diagnosis and treatment protocols. Such a database might provide a basis for formulating retrospective case series studies. In turn, such case series reporting may offer significant support for controlled pilot studies. Such studies might also point the way toward more controlled investigation. All of these activities, combined, can expand the existing body of evidence to promote universal acceptance of Prolotherapy by Orthopedic Medical doctors and patients, American medical educators, medical peer societal organizations, the FDA, Medicare, and commercial healthcare insurance companies.

GENERAL GUIDELINES FOR IMPLEMENTING THE SCIENTIFIC METHOD

In the practice of Orthopedic Medicine, every patient encounter should be considered a potentially new event, promising potentially brand new revelations! Every practitioner should hope that every patient who walks through the clinic door—whether a new or long-established patient—literally embodies new clinical observations waiting to be experienced, questioned, and analyzed at every office visit. And . . . every patient should expect to be considered by the physician as a potentially unique clinical challenge at each visit.

For those hopes to be met, it would be helpful to have a plan for implementing the Scientific Method in a typical Orthopedic Medical Clinical environment. Although it is important not to rely on a rigid "formula," it is certainly advantageous to have a guide map that illustrates the general process of the Method. The following model demonstrates how an Orthopedic Medical Clinic might be organized on sound scientific principles.

MODEL OF THE SCIENTIFIC METHOD CHARACTERIZING PROLOTHERAPY IN AN ORTHOPEDIC MEDICAL CLINIC

There are five phases with multiple steps in performing the Scientific Method:

- Formulate a Question.
- Formulate a Hypothesis as an Answer to the Question.
- Experimentally Test the Hypothesis.
- Formulate a Conclusion as to Whether the Question is Answered.
- Exercise Peer Review to Reappraise the Outcome Results and Conclusion.[2]

FIRST PHASE: FORMULATE A QUESTION

Step 1. Describe an observation (e.g., empirical or experimental) regarding a specific subject of interest.

This observation could represent patient symptoms, physical signs, or a treatment outcome that is begging for an explanation or verification. The observation might be stated as narrative, as measurements, or both.

Example Observation: A seemingly distinct cohort of patients in an Orthopedic Medical Clinic consistently presents with severe low back pain and multiple symptoms and signs consistent with

a dysfunctional sacroiliac joint—a constellation of seemingly consistent findings referred to herein as "Low Back Pain-Sacroiliac Syndrome (LBPSS)."

Step 2. Formulate a fundamental question as to the cause or resolution of the phenomenon that has been observed, based on Deductive, Inductive, and Abductive Reasoning, as outlined in Part 1 of this series.[1]

Example Question: If LBPSS is due, at least in part, to sacroiliac ligament sprain injury, could Prolotherapy—in this clinic—be a procedurally safe, therapeutically effective, and managerially efficient therapy that can significantly correct that sprain injury and resolve patient pain and dysfunction?

SECOND PHASE: FORMULATE A HYPOTHESIS AS AN ANSWER TO THE QUESTION

Step 1. Gather all existing information relevant to the subject issue of inquiry.

The basic source of information would be LBPSS patient records. Those records should provide all relevant data and information perhaps including:

- Past and current medical history
- Subjective pain locating and scoring
- Objective physical examination findings such as tenderness, decreased joint function, muscle weakness, and joint misalignment
- Additional ultrasound and radiological imaging and laboratory findings
- The course of whatever treatments have been provided, and
- A chronology that trends the patients' clinical response to those treatments.

Step 2. Identify all basic assumptions based on known truths and established principles that are relevant to the inquiry at hand.

Assumptions are supportive premises or maxims and are the foundation of Deductive Reasoning.[1] Identifying these assumptions provides a basis for planning and designing a feasible experiment—or an entire clinical practice.

Managerial and Fiscal Preconditions might include:

- There will be adequate time available to reach the experimental or trial goal.
- There will be adequate monetary support available.
- There will be adequate office staff needed to perform the clerical work required, including database entry.

Clinical Preconditions: The most basic clinical premise might be that performing Prolotherapy is a scientifically rational medical decision. The legitimacy of Prolotherapy is supported by all measures and levels of scientific confidence:

- Prolotherapy is authenticated by compelling clinical research literature as shown in past literature reviews in this Journal.
- It is authenticated by compelling tutorial literature and well established training programs, which award legitimate continuing education credits from reputable medical education organizations, e.g., the American Academy of Osteopathy, the American Association of Orthopedic Medicine, and the Hackett-Hemwall Foundation.
- Prolotherapy is taught and performed at accredited osteopathic and medical schools and clinics, including the University of New England's College of Osteopathic Medicine and the University of Wisconsin.

Other clinical preconditions might include:

- Generally, all Orthopedic Medical therapies will be consistently, correctly performed technically and safely, according to current state-of-the-science-and-art instruction and professional standards.
- Specifically, all treatment of musculoskeletal sprain injuries by Prolotherapy will be based on the most current scientific evidence regarding ligament and tendon enesthiopathy (i.e., sprain injury) and the role of inflammation in sprain injury healing.
- All patients will be adequately educated by informed consent as to the nature of their specific injury, how Prolotherapy heals that injury, how Prolotherapy is performed, what therapeutic alternatives are available, what the potential risks and complications are, and what the cautionary do's and don'ts are regarding medications not to take and activities not to pursue during the course of treatments.

- All patients will be followed for compliance with all instructions.
- All patients will perform a "Use of Medical Data Agreement," allowing the clinician's use of the data derived from the patients' treatment for case study reports, anonymity being assured.

Experimental preconditions might include:

- Data integrity: All medical records of medical history, examination, treatment, and outcome will be legible, complete, consistent (standardized), accurate, transparent, and objective (unbiased)—including those reflecting adverse events.
- The number of patients (i.e., the statistical lower case "n") will be large enough to confer statistical significance to the resultant data.
- The Scientific Method will be used at every date of service as reflected by use of SOAP notes, pain level scoring, and clinical database entry.

Step 3. Formulate a theoretical hypothesis as to the cause or resolution of the observed phenomenon.

Example Hypothesis: Prolotherapy is a procedurally safe, therapeutically effective, and managerially efficient therapy for the sacroiliac joint sprain injury of LBPSS.

THIRD PHASE: EXPERIMENTALLY TEST THE HYPOTHESIS

Step 1. Using all current information on the subject, identify all variables.

There are independent, dependent, controlled, and extraneous variables:

- Alteration of an *independent variable* (ie, what we change—e.g., introduction of inflammation via Prolotherapy) causes alteration of the *dependent variable* (ie, what we observe—e.g., change in patient's symptoms and signs). In an experiment, one purposefully alters the independent variable (e.g., introduction of inflammation via Prolotherapy) to some measurable degree while observing for measurable changes in the dependent variable (e.g., change in the patient's symptoms and signs).
- One maintains constancy of a *controlled variable* (what we maintain unchanged—e.g., patient's avoidance of anti-inflammatory medications, needle gauge) to prevent its influencing the effect of an independent variable on a dependent variable.
- An *extraneous variable* (e.g., patient gender) is an inherent characteristic of the population being studied. It is not directly part of the independent-dependent variable relationship, but the extraneous variable might be useful in further characterizing or clarifying that independent-dependent relationship.[3]

Independent variables: In this case, the independent variables might be all those treatment modes that are manipulated by the experimental method—or clinical practice. Some medical treatments used for treating LBPSS might include Osteopathic Manual Therapy (OMT), Neural Therapy, and Prolotherapy. Also, Rolfing, Pilates Instruction, and Physical Therapy are often recommended for supportive rehabilitation.

One needs to take into account ahead of time the various components of the Prolotherapy procedure, itself, that might produce some ancillary healing effects. First, OMT joint realignment and restriction relief is often performed in concert with Prolotherapy. The OMT may very well reduce symptomatic evidence of ligament/tendon stress—as well as reduce nerve impingement symptoms and signs. Why not? That is why we perform it!! Ancillary rehabilitative bodywork therapy, such as Rolfing, Pilates, and Physical Therapy, also may reduce musculoskeletal stress or nerve impingement symptoms.

Injecting local anesthetic before the Prolotherapy also might produce some Neural Therapy effect. Since the Prolotherapy proliferant solution is diluted in local anesthetic, that additional anesthetic may also produce Neural Therapy effect.

Then, there is a lot of needle puncturing involved in the local anesthetizing and performing the actual Prolotherapy. That needling, alone, might produce some acupuncture effect experienced as pain relief.

As always, one might expect some patients to react with the, so-called, Placebo Effect. The patient might demonstrate some healing effect just because he or she is in a doctor's hands, going through a procedure—perhaps

changing something in the patient's physical or mental constitution, daily routine, or lifestyle unbeknownst to the patient or the physician. There is nothing wrong with this. The more placebo the better.

We must recognize that all of these potential independent therapeutic variables undoubtedly have some impact on the effect of the Prolotherapy treatment—and there might be others. Suffice it to say that the entire palette of Orthopedic Medical techniques, including Prolotherapy, can produce a positive—or negative—healing effect. We can sort out at least some of the relative importance of those individual elements as we proceed through our Scientific Method.

Dependent variables: The dependent variables are all those variables that are being measured throughout the course of the experiment or clinical practice that characterize the patient's diagnosis—exemplified in this case by LBPSS. The precise characterization of the patients' low back problem may vary as determined by individual causal complexity.

Such dependent variables might include:

- The patient's symptoms of pain and dysfunction, including documented pain locating and scoring based on a 10-point Visual Analog Scale or Verbal Analog Score, all varying in type, location, severity, and complexity.
- The physician's physical findings, including physician illustrations, all varying as to exact musculoskeletal function, severity, and complexity.
- Imaging findings, e.g., radiological or ultrasound.
- Laboratory findings.

Step 2. Design an unbiased experimental test or clinical practice protocol, taking into account all known, important assumptions and variables.

An Orthopedic Medical Clinic can adopt a formally written clinical practice protocol that takes into account the above-mentioned question, hypothesis, assumptions, and variables. That protocol can be written out at length for each diagnosis that is being treated, reflecting the scientifically-based guidelines presented in this article. On the other hand, the protocol might be simply incorporated into the clinic's medical records forms and database system. Such standardized forms and database can ensure and protect all the major aspects of a written practice protocol, as well as simplify all of the paper work of a scientifically-based practice. In a sense, such a system—no matter how documented—acts as an "SOP"—a standing operating procedure, which implies that it can be easily modified based on ongoing outcome assessment—it is not written in stone.

In designing a clinical protocol based on the scientific method, it is most ideal to incorporate a control group—controlling for the independent variable for Prolotherapy. As in this example of LBPSS, it is very difficult to exercise control in the normal clinical setting. Thus, controlled studies are usually carried on in the more academic clinical environment.

Clinical Practice Protocol Database Model for LBPSS: Design a database matrix to test the previously determined scientific hypothesis by recording the most basically relevant independent (e.g., treatments) and dependent (e.g., sacral alignment) variables for patients with low back pain presumably due to sacroiliac joint dysfunction on a visit-by-visit basis. This database matrix should provide adequate reporting of current patient symptoms, salient physical examination parameters, treatment description, and any adverse incident as a visit-by-visit record. That's a rather large order for a relatively small area on the computer screen! But it is very possible. (*See Figure 1.*)

Therefore, it is important to select the least number of symptoms and physical examination parameters that are most important diagnostically. This simplifies and focuses the examination process. Select only important enough parameters that are also sufficiently redundant to cross-confirm each other. Be consistent and thorough.

Step 3. Perform unbiased experimental testing to prove or disprove the hypothesis.

Such testing may be at the laboratory bench, the clinical bedside, the treatment table—or the computer. For example, the illustrated database matrix for low back pain-sacroiliac joint dysfunction can be incorporated into your clinic's medical records system using a personal computer. One can use the simple, "stubby pencil" Windows Excel® Table function or the more elegant, automated Access—or hire a programmer to develop a customized system, even melding it into a larger electronic medical record system.

Figure 1. Sample Database Parameters for LBPSS Patients.

Low Back Pain-Sacroiliac Syndrome Patient Database									
Date of visit	Patient's Name Gait	Patient's Report of Pain	Functionally Short Leg	Weak Gluteus medius	Restricted Sacroiliac Joint tested at the Anterior Superior Iliac Spine Pub Sym Alignment	Sacral Base Alignment Inferior Sacral Angle Alignment	Lumbar Spine Alignment	Diagnosis Treatment	Adverse Event
08/11/04	Patient A R Limp	Central Low Back Pain 8/10	L 8 mm	L 4 fingers	L Restricted Anterior L Posterior Inferior	L Inferior Anterior L Inferior Anterior	L45 Rot L	Dx: L SIJ Dysfunction Prolotherapy	None

Each patient's identification is encrypted. Each individual patient's database information is reviewed at the beginning of every office visit, providing a real-time window into each patient's past and present disease process and recovery. All new data are entered at the end of every office visit.

Thus, performance of the clinical testing of the safety and efficacy of Prolotherapy can be concurrent with each patient encounter, examination, and treatment. Informal (nonstatistical) trend finding is easily achieved by concurrent review. It is relatively simple to bring up the individual record of any patient encounter at the click of a mouse and "eyeball" the patient's treatment and response trends.

FOURTH PHASE: FORMULATE A CONCLUSION AS TO WHETHER THE QUESTION IS ANSWERED

Step 1. Collect, collate, and analyze the resultant data.

Investigational data is the food for Inductive Thought. With the database matrix immediately available at a simple mouse click, clinical test data are immediately available. Just cut, paste, organize, and print.

Aside from the main cohort grouping of the total patient population that was treated, one can scrutinize various subgroupings or subcohorts of LBPSS patients as to their response to the Orthopedic Medical treatments.

Descriptive statistical analysis may characterize the various cohort groupings in terms of ranges and averages of occurrence of various population dimensions, such as gender, age, and right versus left-sided physical parameters. Then, inferential statistical analysis may characterize the various cohort groupings, including control groups, as predictors of the general patient population response—or nonresponse—to Prolotherapy.

Step 2. Interpret the resultant data and present all applicable information.

Interpretation requires review, analysis, illustration, and explanation of all of the collected information. This is the opportunity to describe the given cohorts and their variables in statistical terms and in terms of inferential relationships between the independent and dependent variables—projecting how these sample groupings might predict the larger, general patient population's response to the treatments provided. These descriptive and inferential population characteristics of comparison, correlation, and trending are the springboard for conclusive Deductive, Inductive, and Abductive Thought.[1]

Step 3. Draw a conclusion in reference to the original hypothesis.

The conclusion as to the efficacy of Prolotherapy in treating LBPSS would be based on interpretation of the information, which has been derived from the test data that have been collected by exercising the database matrix. The conclusion might offer a starting point for a new hypothesis.

FIFTH PHASE: EXERCISE PEER REVIEW TO REAPPRAISE THE OUTCOME RESULTS AND CONCLUSION

Step 1. Distribute the results to other clinicians and researchers.

Distribution of the results and conclusion(s) derived from analyzing the clinical database is accomplished by publishing written reports and offering oral presentations of case reports and case series studies.

Step 2. Reobserve, replicate, retest and form a new, more refined hypothesis.

This step speaks for itself. The scientific process in a medical practice should be a continuously reiterative, recycling intellectual process shared with the Orthopedic Medical Community—and continuously recapitulated within the subject Clinic.

SUMMARY

We have been taught the Scientific Method since grade school and it has been emphasized throughout our professional education and training. But do we really apply it to our Orthopedic Medical Clinic practices? Can we?

The above guidelines might help you organize your Orthopedic Medical Clinic by exercising the Scientific Method in a practical manner—*helping you plan ahead by continually looking behind*—and preventing your embarking and (even worse) continuing down the wrong diagnostic or therapeutic path. Adopting an outcome database system can aid in simplifying and standardizing examination, diagnostic, and treatment parameters … yet, at the same time, reaping an astounding amount of information out of a relatively small amount of data.

I have stressed the importance of the Orthopedic Medical Clinic and Community. Prolotherapy cannot be practiced as a solo technique in a clinical vacuum, completely apart from other Orthopedic Medical diagnostic and therapeutic approaches. It is important to note, likewise, that the Scientific Method is not practiced as a static event—but as a continuously dynamic reiterative cycle of observational and investigative events that might reinforce your whole Orthopedic Medical approach on a daily basis.

Part III of this series will present a retrospective case study series based on the methodology and database matrix modeled above. The process and conclusions may be of interest.

REFERENCES:

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2. "Scientific method." Wikipedia. 19 April 2010: http://en.wikipedia.org/wiki/Scientific_method.
3. "Dependent and independent variables." Wikepedia. 18 September 2010: http://en.wikipedia.org/wiki/Dependent_and_independent_variables.

AUTHOR'S NOTE:

As in Part I of this series, I have resorted to using Wikepedia extensively for reference material. Although Wikepedia is often faulted for weak reference support, the sites that I have used have been replete in background referencing and illustrations—much better referenced and illustrated and much easier to access than the Encyclopedia Britannica sites.

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