Methodologic Evaluation of the Lumbar Disc Syndrome

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Though the lumbar disc syndrome is a costly and ubiquitous affliction, effective evaluation of the disease process has been confounded by major unaddressed methodological shortfalls. Prominent difficulties include: inattention to the clinical boundaries of the syndrome, neglected co-morbid disease processes, comparison of unequal treatment groups and premature clinical data extrapolation, inadequate diagnostic validation, variability in surgical observation, and reliance upon follow-up techniques faulted by unaddressed distorting factors.

Proposals for improvement include: formulation of suitable stratification subgroups emphasizing age and sign-symptom intensity and duration, techniques for improved diagnostic return from surgical exploration, suggestions toward improved quantitation of clinical testing procedures, and implantation of a quality of life scale.

Though the lumbar disc syndrome—low back pain and radiolpathy caused by a herniated lumbar disc impinging upon an existing nerve—is a quite common affliction, the syndrome is uncertain on many accounts. Despite many retrospective surveys of varying detail [1,2,3,4] no standardized etiology, diagnosis, therapy, or prognosis exists. Major unexplained variances in therapeutic response are not uncommon. Many patients live in continued distress despite, or perhaps partly because of, intensive therapeutic intervention. Although sustained inquiry over the years has profitably illuminated certain narrower details, more general methodological issues may have escaped deserved attention. Unfortunately such neglect has frustrated many of the numerous efforts to treat and understand this widespread complaint.

Since the time of Hippocrates [5] observant physicians have treated sciatic attacks, speculated on their nature, and published many confused, fiercely stated, and often contradictory opinions. Not, however, until the 1934 inquiry of Mixter and Barr [6] did the process seem comfortably clarified. Significantly reported upon in that landmark paper were 11 sciatica sufferers in whom a subsequent surgical exploration revealed a ruptured intervertebral disc impinging upon a compromised nerve root. Aside from one postoperative death, secondary to a wound infection, removal of the offending disc afforded all patients considerable relief. Thus, provided with an understandable cause and an equally applicable cure, sciatica nosologically became the lumbar disc syndrome. (An older definition demarcating the anatomic boundaries of physical discomfort was conceptually replaced by a term implying a measure of etiological certitude.)

In the following years, encouraged by this belief that a widespread clinical manifestation was caused by a simple surgically correctable anatomical defect,
operative techniques were progressively refined while adjunctive diagnostic procedures were greatly improved.

The appeal of this single, cohesive approach was soon altered by the problems of reality. Many patients with the syndrome were not helped by repeated surgery [7] and in some instances, the surgical explorations yielded negative findings [8]. Other etiologic alternatives became accepted explanations for the clinical syndrome. Against this backdrop of etiological and therapeutic uncertainty, the merits of conservative treatments were re-examined [9,10], and alternative surgical [11,12,13] and medical approaches including the efficacy of Chymopapain [14,15] and steroids [16,17,18], were considered.

Thus, the straightforward explanation provided by Mixter and Barr in 1934 is no longer straightforward and the lumbar disc syndrome remains confusing in etiology, diagnosis, and therapy. This essay is concerned with reasons for the persistence of the confusion.

REASONS FOR THE PERSISTENCE OF CONFUSION

The Difficulties of Investigation

Considering the ubiquitous nature of the disease process [19,20,21], research efforts have been surprisingly modest. Not over-estimating this inequity Nachemson has suggested while the next decade will see world-wide two billion low back sufferers, only 50 research scientists and 500 clinicians will scientifically investigate the problem [22]. Yet even these slim resources will not be maximized.

Divided Responsibilities One reason for this minimization is that prevailing professional arrangements and interest patterns are more the product of evolutionary fiat than rational plan. Since the lumbar disc occurs at a structural interface between bone and nerve, in North America major therapeutic responsibility for the syndrome is divided between orthopedic and neurological surgeons. Unfortunately, this schism promotes a rather broad variation in therapeutic protocol as well as in surgical philosophy and technique. Furthermore, despite at least some efforts to the contrary, important papers are still delayed in reaching members of the respective disciplines because of the relative lack of specialty journal cross-circulation.

Relative Lack of Research Interest The total research effort devoted to the resolution of this major clinical problem has been surprisingly small. Perhaps because of their greater number, orthopedic surgeons have written more voluminously upon the subject than have neurosurgeons [22]. While lumbar disc problems form a large part of the average neurosurgeon's operative case load, especially in the private practice sector [23,24,25], academic interest in the problem seems deflected. Specifically, an inspection of the 702 articles and case reports and technical notes published in The Journal of Neurosurgery between 1976 and 1978, reveals that only about 4.5 percent might liberally be construed to deal with the lumbar disc problem.

Lack of Epidemiological Input Despite several noticeable recent inquiries [9], epidemiological effort has been surprisingly modest [26]. While numerous risk factors at one time or another have been implicated—chronic lung disease [20], sedentary occupations [27], insufficient physical exercise [20], full-term pregnancies [28], tallness [20], driving motor vehicles [29]—genetic, employment, and environmental susceptibility factors have not been adequately defined. Little is known of preventive measures, secular trends, or prevalence rates for most of the world.

Frequent Inapplicability of Prospective Double-Blinded Randomized Clinical Trials Most available information upon the subject is derived from retrospective case
collections which are neither easy to summate or compare. Better data can often be obtained from double-blinded, randomized clinical trials. Indeed, in some quarters, especially in the medical subspecialities, such trials have been regarded as almost the *sine qua non* of correct clinical decision formulation.

Yet, not unreasonably, only a few such trials have been directed toward the lumbar disc syndrome [30]. For despite their undoubted merit, the organization and maintenance of double-blind clinical trials requires great investments in labor and time. Moreover, such studies are of only recent inception [31], and in the face of spectacular improvements and adequate historical controls, may not be necessary; i.e., none were ever conducted to initially validate the efficacy of penicillin or insulin. Furthermore, it is ethically questionable to randomize treatment protocols unless contemporary medical wisdom can discern no real advantage of a particular treatment modality for an individual patient [32,33,34]. With the vast accumulation of diverse data concerning the lumbar disc syndrome, relatively few instances occur when a substantial number of patients fall into this category.

Similarly special problems exist in dealing with surgical issues. It is, for example, almost impossible to institute true “blinded” clinical trials in a surgical setting. Few surgeons or patients would consent to the actual surgeon foregoing his preoperative assessment and postoperative follow-up. Moreover, the ethical inadmissibility of “sham surgery” effectively blocks important comparisons while the use of “cross-over” tactics is generally impossible. Then, too, considering the many variables encountered at surgery and the surgeon’s natural obligation to sacrifice consistency to maximize outcome, it is extremely difficult to establish a standardized extrapolatable level of therapeutic intervention. Thus, while randomized clinical trials can provide excellent data for many issues involving the lumbar disc syndrome, such studies unfortunately can seldom be undertaken.

**Diffuse Spectrum of the Disease**

Unlike many relatively simple diseases, the complicated and varied presentation of the lumbar disc syndrome, coupled with diagnostic difficulties, makes exact delineation of the disease a difficult process.

**Unclear Clinical Boundaries** Within the limits of clinical presentation, the major complaint associated with the lumbar disc syndrome is lower back or buttock pain radiating in a variegated distribution, either constantly or infrequently, to either or both lower extremities. The pain may range from a dull ache to a lightning jab and can be exacerbated and tested by several maneuvers designed to increase the tension placed upon a compromised nerve root. This pain is often associated with muscle spasm and a variety of postural, motor, sensory, and reflex disturbances. In chronic cases muscle wasting may occur often without the presence of pain. When central disc herniation occurs, often without sciatic complaints, cauda equina defects may be present. Unfortunately, no uniformly agreed-upon specification of the clinical limits of the lumbar disc syndrome has been extracted from this broad cluster of signs and symptoms. In defining the syndrome, some authors are inclusive while still others do not clearly specify what diagnostic criteria they have chosen to employ.

**Multiple Alternative Causes** The many patients whose difficulties easily remit within this broad clinical spectrum are generally not subjected to more incisive efforts to establish the presence of a ruptured intervertebral disc. However, more intractable cases are generally processed through a series of diagnostic and therapeutic validating procedures. Such procedures have shown that many pathological processes other
than a herniated lumbar disc can produce the sciatic sign-symptom complex. Among these overlapping processes are: (1) spondylitic spurs [35], (2) perineuritis and adhesions about the nerve root [36], (3) the effects of strain and movement [37,38], (4) bony narrowing of the vertebral canal [3,7,39], (5) bony narrowing of the intervertebral foramen [40,41], (6) ligamenta flava hypertrophy [42,43], (7) multiple sclerosis [44,45], (8) spinal tumor [46,47], (9) peripheral damage to the sciatic nerve [48], and (10) ankylosing spondylitis [49].

Unrecognized Co-Morbidity Sir William Osler’s observation that only one cause should be sought to explain a particular sign or symptom, a dictum philosophically descended from the earlier fourteenth century speculations of William of Ockham, may not always be correct. Often one or more alternative pathological processes capable of producing the signs and symptoms of sciatica can co-exist with a herniated lumbar disc. The co-existing disease process may be occult, as with early ankylosing spondylitis among youthful males, or more clinically evident, as in the lumbar stenosis frequently discovered in the older patient. Potentially each co-morbid disease process, with its own natural history, can surreptitiously alter the individual patient’s sign-symptom complex, and thereby tilt therapy toward inappropriate intervention. Similarly, such co-existing disease processes may occur post facto after the diagnosis of a herniated lumbar disc to produce signs and symptoms erroneously attributed to the lumbar disc.

Distortion of the Spectrum of the Disease

1. Patient Presentation It is often tacitly assumed that a patient population reported upon in a particular account of the lumbar disc syndrome reflects the general condition of the general population. This assumption should not, however, be automatic. For while many patients in the general population have some component of the lumbar disc syndrome, not all such sufferers can be expected to seek medical aid with the same consistency.

Various ethnic [50] and social groups [51], for example, have well-known differing responses to pain. On one extreme, one might expect a self-prescreened, long-afflicted, stoic group to present with relatively hard clinical findings. On the other extreme, another patient population, often colored by compensation ambitions and physiological difficulties, can be expected to present quite early in the course of the disease process, and to display softer clinical signs.

2. Referral Patterns Persons who do seek medical assistance generally first come under the care of a primary physician who customarily administers some form of conservative therapy. Those patients whose difficulties remit proceed no further up the referral ladder and thus tend to be under-represented in the case collections of orthopedic and neurological surgeons. Moreover, some non-responders, especially those with obvious co-morbid problems, may be inappropriately referred through a broad range of physicians from psychiatrist to gynecologist and thus from a statistical point of view be hidden. Similarly, some patients dissatisfied with perceived standards of treatment drop completely out of the standard medical system and deliver themselves into the hands of sundry cultists and non-traditional physicians, thereby confounding complete tabulation of the disease process. The majority of patients with persisting complaints, however, ultimately come under the care of an orthopedic or neurological surgeon.

If this process is short circuited, a tertiary physician will treat a somewhat less “sick” population. On the other hand, the tertiary physician, at the end of a lengthy referral chain, will receive a more intractable group of patients, who will have a cor-
respondingly poorer response to therapy. Such referral patterns, if not discounted, will prejudice otherwise acceptable clinical data. Similarly, since contemporary circumstances have altered patient mix and cure expectations, cross-comparison of recent therapeutic standards and results with earlier clinical bench marks, cannot be undertaken in an absolute sense.

3. Extrapolation
Unfortunately, the difficulties just cited often impair the validity of commonly used research tactics. Frequently, for instance, researchers seek to establish a patient study group that is homogeneous as possible—usually young, healthy people without previous surgery, psychiatric complaints, or compensation aspirations. A problem occurs, however, when the results of therapy, directed toward this relatively pure group, are extrapolated to the very diverse general population being treated for the lumbar disc syndrome. Steroid injections may not, for instance, be helpful in a 20-year-old athlete with an acute tear of the annulus fibrosus, but might benefit a 60-year-old chronic sufferer with a slightly protruded hard disc and significant osteoarthritis [16].

Difficulty of Diagnostic Validation

Because of these difficulties, the establishment of a uniform standard of diagnosis assumes added desirability. However, the nature of the disease process and insufficient diagnostic testing abilities greatly complicate this ambition. Absence of Adequate Diagnostic Testing Procedures

Customarily, non-invasive diagnostic procedures are instituted without undue delay. Plain films and tomograms are helpful in establishing co-existing bony overgrowth or stability problems, while electromyography (EMGs) can indirectly demonstrate nerve malfunction. With the exception, in some instances, of computerized axial tomography [19,52], these non-invasive tests do not establish a primary picture of the lumbar disc impinging upon a nerve root. Nor can such studies specify the exact anatomical point of difficulty, a demonstration that depends on invasive diagnostic procedures, especially myelograms.

Unfortunately, the accuracy of such studies often hinges upon procedural issues and the skill of the investigator undertaking the examination [53,54]. Similarly, even in optimal studies, intrinsic observer variability can confuse results [55,56,57]—a danger exacerbated by the occasional presentation of vague or imperfectly stated clinical information to the responsible neuroradiologist. Likewise, radiological judgements are often conceptually made in a "yes or no" fashion, rather than in a more appropriately scaled system. Considering such difficulties, it is no wonder that the sensitivity and specificity of currently performed diagnostic procedures are imperfect [44,58,59,60].

Moreover, the major morbidities accompanying such invasive diagnostic procedures [61,62,63] naturally limit their use. The resulting concomitant diagnostic delay can inappropriately postpone needful surgery. Likewise, following surgery no picture is usually obtained to demonstrate what anatomical changes therapy has wrought. Finally, diagnostic studies in patients with originally negative procedures are often excessively delayed even though, with the passage of time, dynamic pathological processes alter radiological findings and patient symptoms.

Inadequate Diagnosis by Conservative Therapy

The implicit assumption is often made that a positive response to a trial of conservative therapy indicates that a herniated lumbar disc has successfully been dealt with. However, since diseases such as lumbar stenosis, which present with similar complaints, can respond to conservative therapy, this assumption may not always be true. Thus, the assertion that ninety
percent of lumbar disc problems respond to conservative therapy may not be completely correct because other ailments may have inadvertently been included in the treatment group.

Moreover, since almost every patient with the lumbar disc syndrome receives some degree of conservative therapy quite early in his treatment course, it is difficult to assemble a patient population not affected by earlier varied conservative therapy. In these circumstances, efforts to ferret out the most beneficial type and length of conservative treatment are largely incomplete. The resulting variation in treatment standards decreases the "test" value of conservative therapy. Since the "test" is unstandardized and difficult to apply uniformly, one may expect "test results" to be inconsistent. Unfortunately, such variability can bias the tabulation of both diagnosis and treatment.

Let us, for example, examine two hypothetical groups of sciatica sufferers. A "true herniated lumbar disc" is present in fifty percent of each group. Group A will be initially treated with an intensive prolonged course of conservative therapy, while group B will receive only minimal conservative therapy.

In group A, the intensive initial conservative therapy will "cure" a relatively great number of patients. As per convention, all such cures will be tabulated as successfully treated lumbar disc herniation, even though this "cure" group will contain a large population without true lumbar disc disease. Thus, the number of herniated lumbar disc sufferers will be over counted. The remaining group of non-responders will have a high proportion of true herniated lumbar discs—say 90 percent. The index of validity of myelography and of surgery will thus be high in this latter group.

In group B, however, initial conservative treatment was quite minimal so only a few cures occurred. Since proportionally fewer non-herniated disc patients were weeded out, the remaining group of non-responders will be composed of, say, only 60 percent "true herniated lumbar disc" victims. Thus, the index of validity of myelography and of surgery will be lower in this group than in group A (at the cost, since surgery was delayed, of somewhat prolonging nerve root compression). On the other hand, since more patients in group B received the additional "tests" of myelography and surgery, fewer patients will be misdiagnosed as compared to group A.

Variability in Surgical Observation The results of earlier clinical history and various diagnostic tests are validated by the findings discovered at surgery. Said another way, surgical observations are the gold standard or bench mark against which all diagnostic variables are measured. A classic clinical history and strongly positive myelogram are confounded by a surgical exploration incompatible with the diagnosis of a herniated lumbar disc. On the other hand, those patients in whom surgery discloses positive findings are often categorized as having lumbar disc disease rather than syndrome—implying a higher level of certitude.

Unfortunately, this form of diagnostic validation is not without its difficulties. For instance, the position of the disc as viewed at surgery may not reflect its constant location [64,65]. Considering the general flexed prone operative position most surgeons employ and the well-known alteration in interdiscal pressure in response to body posture [66], such an hypothesis is not without its logic (Similar alterations may also confound diagnostic procedures.) In such circumstances, many would argue that a natural, often unaware, human tendency exists among surgeons to upgrade pathological processes discovered at surgery; turning, for instance, a "slightly bulging" disc into a "protruding" one. These tendencies are increased by the delay between the time of observation and the time of dictation of that observation.

Similarly, the well-known observer variability frequently described among pathol-
ogists [55,56] and radiologists [57] reasonably exists in a surgical setting where observations are made under a firing-line duress rare in the less interventionist subspecialities. Then too, in some instances questionable lighting, poor hemostasis, and cosmetically small incisions, coupled with minimal bone removal, can decrease observational standards.

The lack of commonly accepted descriptive terminology in regard to nerve root compression and disc herniation further obscures accuracy. What do terms such as “swollen,” “protruding,” “compressed,” and “atrophic” really mean? The absence of definite linguistic standards is especially evident when operative reports are retrospectively reviewed—the major source of information in this area. Different surgeons have different degrees of verbosity and descriptive precision. Often brief vague reports coupled with absence of any general form of intraoperative measurement may sabotage later data extraction.

**Therapeutic Factors**

This is an area of major controversy. Although many different ideas have been advanced, much present difficulty centers on the role of conservative therapy vs. surgical intervention.

**Inappropriate Comparisons** Occasionally, patients whose treatment has been confined to conservative therapy will be compared with a group which has failed conservative therapy and received a more invasive treatment. Superior results would obviously be expected in the former group since their disease process was more easily contained. Therefore, such comparisons, while having some validity from a prognostic point of view, can not really speak to the respective merits of differing therapies applied to unequal patient populations.

**Conservative Therapy** Almost every patient with the lumbar disc syndrome receives some trial of conservative therapy. Conservative therapy, however, is not a single factor as it is sometimes portrayed, but may or may not include bed rest, traction, narcotics, and differing modalities of physical and psychological therapy for varying lengths of time. Such variability obviously makes its efficacy as a treatment difficult to quantitate.

In assessing conservative therapy, its merits in sparing numerous patients more invasive procedures are often emphasized. However, less attention is focused on its financial and social cost, morbidities associated with prolonged bed rest, and the occasional irreversible nerve root damage resulting from too long delayed surgery. In the absence of meaningful statistics and testing procedures, most physicians have adopted an attitude of empiricism in balancing these costs against expected gains. Not surprisingly, however, the standards of empiricism vary rather widely.

**Surgery** Although surgery is often regarded as a constant therapeutic variable, the skill and expertise of the surgeon performing the procedure vary considerably. The surgeon’s choices of magnification, style of operative illumination, technique of bone removal, method of hemostasis, efforts to protect the nerve root, and the extent of operative exploration are all factors in surgical judgment. Moreover, the surgeon frequently adjusts his attack style, as operative information is obtained. Such factors make differing surgical approaches difficult to cross compare.

This difficulty is compounded by the absence of any intraoperative cybernetic information loop. The surgeon frequently has no knowledge of the final quantitative results of a particular intraoperative maneuver or decision until much later. How much of the disc was removed? Were disc fragments left behind? Was the nerve root properly decompressed? Was excessive traction placed upon a nerve root? Since
actual intraoperative tests are missing, since there is a general reluctance to employ routine postoperative procedures, and since suitable noninvasive diagnostic procedure has not yet been perfected, the patient's postoperative course is almost sole marker of major and minor successful surgical innovation. Unfortunately, the many intraoperative and patient variables coupled with the difficulty in adequate follow-up call for more individualized and quantitative standards of measurement.

Absence of Adequate Follow-Up Techniques

Incomplete Patient Sample  Since most studies on the subject are not longitudinal over time but take place at some definite point after the institution of therapy, it is important to follow up as many patients as possible receiving the particular therapeutic modality studied. Those lost to follow-up, or who refuse to cooperate with follow-up efforts, often have not done well and their exclusion may bias results. Moreover, especially in situations where explicit effects are minimal, some attention should be paid to obtaining large enough numbers of patients to demonstate statistical significance.

Defects in Short-Term Follow-Up  Important errors are also committed if the point of assessment is too close to the actual point of intervention. For instance, in the immediate postoperative period, the placebo effect [36,37], continued bed rest, increased narcotics, and the masking factor of incisional pain all occur. Also, the natural course of the disease waxes and wanes and many potential sources of damage such as perineuronal fibrosis, increased instability, or disc herniation at other levels may take time to occur. Moreover, a short-term follow-up will not quantitate recurring sciatica episodes in patients initially benefiting from conservative therapy. Difficulties of Long-Term Follow-Up  Long-term follow-up is, however, not without its problems. Co-morbid disease risk increases. The symptoms caused by the appearance of gynecological problems or osteoarthritis may erroneously be blamed on the earlier lumbar disc problem. Moreover, some patients adopt an aggressive or inappropriate physical activity regimen which worsens their ultimate prognosis. Other patients, however, exercise great restraint and have, over the years, access to superior conservative therapy which may greatly improve their ultimate course.

Lack of Adequate Follow-Up Markers

1. Clinical Examination  With indisputable good cause, physicians have traditionally regarded physical examination as the linch-pin of their art. In following patients with the lumbar disc syndrome, general clinical signs have the advantage of rendering, with relatively little difficulty or expense, an immediate assessment of a particular patient's status. Obviously, a well-performed physical examination is and should be a mandatory part of every patient's follow-up.

However, implicit in the raison d'être of the clinical examination is the assumption that the individual physician has internalized an exact range of normal and abnormal which approximates the notions of his colleagues. Yet since in large measure such notions are fashioned by contact with one's peers and mentors rather than by reference to some absolute standard, the peculiarities of different training backgrounds might be expected to cause a disparity in the internalized view of normal. (Actually the range of normal, especially as influenced by age, may vary more than many physicians routinely suppose. For instance, some evidence indicates that ankle jerks may become markedly less brisk with age [68], while in the general population rather large variations of strength can normally occur between the lower extremities [69].)

Moreover, such difficulties are compounded by confusion over scaling of abnor-
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mal results. Often, for instance, the boundaries between a +2 or a +3 ankle jerk are only generally defined and indeed may reflect the unnamed personal system of the examining physician. Similarly, individual physicians may display differing degrees of energy and skill in conducting examinations while common distorting factors such as variance in drug dosage, physiological status, patient cooperation, and pain may skew examined populations.

Furthermore, several particular patient subgroups are but poorly followed with neurological and clinical exams. Obviously, for instance, other adjunctive follow-up techniques must be relied upon for the many patients whose positive symptoms rather than signs provoked therapeutic intervention. Likewise, the neurological deficits caused by various co-morbid disease processes—thyroid dysfunction, alcoholism, diabetes, vascular disease, nutritional deficiencies—deflates the value of follow-up exam in a substantial patient population.

In view of these problems, the traditional clinical examination is clouded by unaddressed observer variability [70] and often by overt observer bias. Regrettably those physicians in charge of administering a particular therapy to a victim of lumbar disc syndrome are generally and inappropriately (from a scientific point of view) in charge of assessing procedural benefits.

2. EMG Because of the difficulties of neurological examination, other efforts to ensure proper follow-up have been undertaken—especially use of multiple EMGs. However, EMGs have major procedural and interpretation difficulties and are often either not performed or were negative prior to invasive therapy. Furthermore, EMGs seldom reflect subtle changes in function [22,69,71].

3. Pain The inadequacy of suitable objective markers has placed much of the follow-up burden upon a subjective appraisal of pain alteration. Unfortunately, because of compensation ambitions, secondary gain, psychological factors, differing physical activity levels, and varying drug usage, pain is a difficult variable to quantitate. Similarly, retrospective studies require patients implicitly to judge their pain state prior to the institution of a particular therapy—an often difficult task because of the “immediate” nature of pain.

4. Employment Patterns Many observers, aware of the subjective nature of pain appraisal, have used employment patterns as a therapeutic marker. However, the same general factors which confound pain appraisal trouble the utility of this tactic. Moreover, accumulating epidemiologic evidence [72,73] hints at not fully delineated risk factors associated with different occupations. The tactics of identifying and discounting high-risk or low-risk occupations are not perfected.

PROPOSALS FOR IMPROVEMENT

The general difficulties just discussed are far from insurmountable considering the prevalence of the affliction and the number of diagnostic and therapeutic innovations at hand; careful attention to clinical research design and quantitation techniques should yield important future dividends.

Better Surveys and Analysis

Major advantages can be reaped from relatively simple attention directed toward research design, even in the more easily instituted retrospective studies. Ideally, randomized studies offer important advantages but the numerous frustrating difficulties in this direction should not stand in the way of maximizing validity with currently available resources. Explicit attention should be paid to the definition of
which patients are being treated under the rubric lumbar disc syndrome. Some care should be undertaken not to confuse patients whose diagnosis has been made on a clinical basis with a population whose disease has been defined by more definitive tests or at surgery. From a statistical point of view, efforts should be made to assemble adequate numbers of patients, a difficulty often overcome by multi-center studies. Appropriate statistical techniques should then be used to evaluate gathered data—a task requiring some sophistication. When possible, prospective randomized clinical trials should be performed (as exemplified by the recent studies comparing "placebo" disc injection with chymopapain [14]).

For instance, as data accumulates in carefully selected circumstances (following myelographic identification of a herniated lumbar disc) it might be possible to conduct a randomized clinical trial of continued conservative therapy vs. surgical intervention.

**Prognostic Stratification of Important Variables**

Even from a retrospective point of view, one may study a relatively heterogeneous population and prognostically stratify the population according to important variables. Such variables could then be subjected to multivariate analysis and the most important associations identified. If every variable in the lumbar disc syndrome complex could be identified and followed, results would be of unimpeachable veracity. However, seldom is there "world and time enough" for such perfection. Differing authorities might choose to include any number of important variables such as psychological status or myelographic findings. However, a good argument can be made that age and degree of nerve root damage deserve special attention.

**Age** Unlike many other variables, age is easily determined. Moreover, considering the well-known physiological alterations associated with disc age [42,74], it may broadly define an important variation in the presentation of the lumbar disc syndrome. In younger patients acute primary annulus fibrosus rupture and nerve root compromise are relatively more common. The process is often rapid and commonly reversible if treatment is instituted soon enough. On the other hand, the presentation of older patients is more likely to be blurred by co-existing morbidity factors, such as osteoarthritis and osteophytic overgrowth. Indeed, many such patients with a component of lumbar disc syndrome may actually be treated for lumbar stenosis and so statistically computed [3]. In this group, because of the higher incidence of osteophytic difficulties, one would expect less benefit from chymopapain injection and, perhaps, more from steroids. Similarly, one would expect older patients to come forward less readily than younger sufferers because of more pressing medical problems and decreased activity requirements, and to require treatment appropriate to their relatively reduced life expectancy.

**Degree of Nerve Root Damage as Measured by Persistence and Intensity of Signs and Symptoms** Similarly, it is well known that disc or bone impingement may irreversibly damage an involved nerve root [75]. Many laboratory experiments [76,77] point to a definite pattern of loss and return of neural function in the fact of compression. Unfortunately from a prognostic point of view, this sequence of events in the clinical setting is somewhat blurred, perhaps because of the multitude of forces—ischemia, mechanical pressure, stretch insult—acting upon a compromised nerve root. However, it does seem that a correlation exists between the severity and persistence of signs and symptoms and the degree of neural damage, and thus outcome.
Better Diagnostic and Therapeutic Markers

Improved Surgical Diagnostic Return  Given the importance of surgical observation in the diagnosis of the syndrome, more attention should be directed in this area. While good surgical technique is meant to maximize observations, standard, routine, and facile use of operating microscope besides aiding hemostasis and minimizing iatrogenic neural damage might also greatly enhance the diagnostic and prognostic function of surgery, especially in regard to the appearance of a compound nerve root.

Moreover, a common practice of intraoperative photography might be extremely useful as a validating tool. Additionally, measurement of the distance which the disc is judged to be, visually, clinically free of impingement and the intraoperative weighing of disc fragments might help to quantitate for the surgeon exactly what has been accomplished. Such information might be compared against the autopsy-established range of normal expected for a particular patient age groups. Finally, on the spot, suitably extensive intraoperative dictation, much in the manner of pathologists and radiologists, may promote later, more accurate data extraction and minimize subjective influences upon the operative record.

Better Clinical Testing Techniques

1. Improved Observations  Every effort should be employed to minimize observer bias. Ideally, both in the baseline and follow-up states, neutral, independent observers should assess the individual patient's clinical status. Such examiners can often be "blinded" as to the type of therapy a particular patient has or will receive. The greater the number of such observers and the more frequent their observations, the more reliable is the data produced toward this end. The criteria for judging clinical status should be carefully enumerated and rigorously adhered to.

2. More Quantitative Clinical Testing Procedures  Over the years, because of the worrisome subjective nature of the clinical examination, several more quantitative mechanical adjuncts have been developed. Such devices offer the possibility of establishing a reliable range of normal against which patients may be tested, and of summatting multiple tests for enhanced validity. Unfortunately, possibly because of the inconvenience and loss of time such devices entail, these innovations have been underemployed. Moreover, such tests offer great advantage in quantitating change in a particular patient's clinical state over the years.

   a. Photomotograph Reflex Measurement  For over twenty years, Achilles tendon reflex latency has been measurable and used the diagnosis of thyroid disease. Available technology can be easily adapted to monitor quantitative reflex response by standardizing the amount of force used to elicit a particular reflex.

   b. Quantitation of Straight Leg Raises  Since this test is employed with such consistency in the diagnosis and follow-up of the lumbar disc syndrome, clinicians should strive for quantitation. A modified goniometer can be used to determine the exact angle at which a sciatic victim first experiences pain. Additional accuracy may be obtained by noting at what point the contra-lateral anterior iliac spine moves and the changes in hamstring muscle tension as measured by a spring gauge [78].

   c. Quantitation of Muscle Strength  As outlined by Weber [69] it is possible to outline rather precisely quantitative muscle strength by the use of built-in strain gauge transducers. With such an apparatus, the maximal amount of isometric force generated by a particular muscle group over a precise amount of time can be measured.

Quality of Life Index  Given the difficulty of both objective and subjective patient
follow-up, another strategy is to extend post-therapeutic patient assessment to include a fuller inquiry into general life situations. Follow-up validity is enhanced by considering more numerous subjective variables. For increased validity, close relatives or other knowledgeable observers can render additional judgments on these variables. Such techniques have already been employed for patients with debilitating disease [79,80,81]. For victims of the lumbar disc syndrome, inquiries into general leisure activities, personal care, family situation, and social activity could be summated into a quality of life scale. Careful scaling would greatly enhance the utility of such a scale. Traditional ordinal and nominal scales are troubled by occasional descriptive bias, absence of enough markable points, uneven distances between markable points, and tendency of respondents to arbitrarily pick central choices. In obviating such difficulties, as suggested by Spitzer [82], a uniscale has important advantages.

Summary

Numerous intellectual and methodological difficulties confuse the treatment of the poorly defined lumbar disc syndrome. Since diagnostic markers are inadequate, conservative therapy and surgery perform major diagnostic functions. To help adjudicate such problems, emphasis is placed upon improved formulation of clinical trials, prognostic stratification, and strategies of more quantitative measurement.

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