

Evaluation of results in lumbar spine surgery

Clinical outcome measures—assessment of severity

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Three principles are generally accepted in evaluating the results of lumbar spine surgery:

1. Follow-up should be for a minimum of 2 years and include at least 80% and preferably 90% of the patients operated on. Ideally, assessment should be based on some cumulative measure of the effect of low back pain over time, rather than at a single end point in time. For example, in one study we measured work loss in the year before surgery and during the second follow-up year (Waddell et al. 1986).

2. Assessment should be carried out by an independent observer, and not by the operating surgeon. The common practice of using a surgical fellow to review a personal series does not fulfil this criteria if the personal fellow is professionally obligated to and dependent on the operating surgeon.

3. Assessment of results should be based on a comprehensive assessment. Subjective judgements such as good/fair/poor by the observer, or worthwhile/doubtful/not worthwhile by the patient may form part of the assessment but are inadequate alone unless supplemented by more comprehensive assessment. Ideally, identical assessment should be carried out pre-operatively and at follow-up, though patients and observers appear to assess the outcome of surgery more on the end result rather than on any change resulting from surgery (Waddell et al. 1988).

Clinical outcome measures are essentially measures of severity. Unfortunately, there has been little agreement on how to assess the clinical severity of low back pain. Severity can be assessed in terms of pain, disability and physical impairment. It is important to make a clear conceptual and clinical distinction between pain and disability and between disability and physical impairment.

Definitions

Pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (Merskey 1979).

Impairment and disability are fundamentally different in kind. Impairment in general is "any loss or abnormality of psychological, physiological or anatomical structure or function" (WHO 1980). In practical clinical terms physical impairment is "pathological, anatomical or physiological abnormality of structure or function leading to loss of normal bodily ability" (Waddell et al. 1992). This includes two fundamentally different aspects of impairment: firstly, pathological or anatomical loss or abnormality of structure and, secondly, physiological loss or limitation of function. Disability is restricted function or, more comprehensively, the resulting "diminished capacity for everyday activities and gainful employment" or the "limitation of a patient's performance compared to a fit person's of the same age and sex" (Waddell and Main 1984). Assessment of impairment is based on objective structural limitation and is solely a medical responsibility while clinical assessment of disability is based largely on the patient's subjective report. Disability rating and compensation awards, however, are ultimately an administrative or legal, not a medical responsibility, and are based both on the patient's report of disability and the doctor's assessment of impairment.

The fundamental distinction is that pain and disability are subjective and based on the patient's self-report while physical impairment is an objective evaluation carried out by the physician.

Pain

- a) Anatomical distribution. The simplest and most reliable distinction is simply into low back pain alone, low back pain with referred pain into the thigh but not below the knee and nerve root pain, with or without neurological deficit (Spitzer et al. 1987).

- b) Time pattern: acute, recurring or chronic (Spitzer et al. 1987).

- c) Pain scale. The simplest and most useful clinical method of measuring the severity of pain is some form of visual analogue pain scale. It is simple to administer

and to score. The major difficulty lies in interpreting exactly what the pain scale measures. It is in no sense an absolute or objective measure of pain and it bears very little relationship to any physiological or pathological change. The patient's report of pain may include physical sensation, distress, pain behavior and communication. With these qualifications, it is obviously important not to over-interpret the pain scale but to accept it simply as a measure of how bad the patient tells the doctor the pain is.

Disability

Clinical assessment of disability must concentrate on loss of function rather than pain. The question is not "is that activity painful" but rather "are you actually restricted in that activity?" "Does your back limit how much you do or do you now require help with that activity?" Restriction must obviously be since the onset of low back pain and because of low back pain. The common or usual effect should be assessed, discounting occasional limitations or special efforts. Our studies (Waddell and Main 1984) have shown that disability in activities of daily living can be assessed reliably during clinical interview:

bending and lifting	walking	sleep
sitting	travelling	sex life
standing	social life	dressing

Alternatively, disability in activities of daily living can be assessed by self-report questionnaires. The best developed and established is the St. Thomas Disability Questionnaire derived from the Sickness Impact Profile (Roland and Morris 1983). A commonly used alternative is the Oswestry Disability Scale (Fairbanks et al. 1980).

Physical impairment

The aim is to provide objective medical evidence of impairment which is reliable, distinguishable from nonorganic and behavioral features, distinguishes patients with low back pain from normal asymptomatic subject and is related to functional disability. We have recently developed such an objective clinical evaluation of current physical impairment applicable to the patient with simple low back pain (Waddell et al. 1992). It should be stressed that this is a measure of current rather than permanent impairment. Moreover, although it is based on objective clinical findings it assesses restriction of function due to pain rather than any anatomical or structural impairment. In terms of the WHO definition it may best be regarded as a measure of physiological impairment.

Examination

The first step is to identify the anatomical landmarks. They can be palpated most easily with the patient lying prone with relaxed muscles. Horizontal marks are made on the skin in the midline at S2 and T12-L1. For S2 palpate the inferior border of the posterior superior iliac spines which lie at the bottom of the posterior part of the iliac crest just below and lateral to the dimples of Venus. Then count up to the spinous processes of T12-L1 checking that the iliac crests approximate to the L4-5 level. Make vertical marks in the midline over the spinous processes of T12 and T9.

The next step is to have the patient perform warm-up exercises: flexion/extension twice, left/right rotation twice, left/right lateral flexion twice and one more full flexion/extension.

It is then necessary to standardize the examination positions. We found particular difficulty achieving a consistent erect position but this is essential as reliable measurement of movement depends on a standard starting point. We finally found the most satisfactory position to be with bare feet, heels together, knees straight with the weight borne evenly on the 2 legs, looking straight ahead, arms hanging at the sides, relaxed. If there is severe muscle spasm then ask the patient to get as close to that position as they can hold comfortably for several minutes. The supine position is lying relaxed flat on the back, head lying on the couch without a pillow, arms at the sides with hips and knees extended as fully as possible without tension. The prone position is lying with no pillow, head and shoulders relaxed on the table, arms by the side.

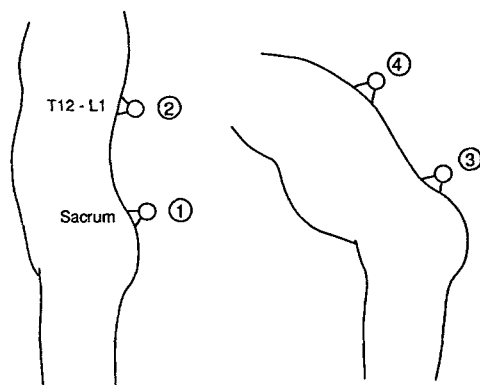
The only equipment required is a ballpoint pen, a small spring-loaded centimeter tape from any haberdashery store and an inclinometer. Although not essential we find an electronic inclinometer more convenient.

The following tests can be carried out in whatever order you prefer but we generally arrange them in sequence in the erect, prone and supine positions.

Lumbar flexion is measured with the inclinometer (Figure 1). With the patient in the erect position recordings are made at S2 and then at T12-L1. Next instruct the patient to bend forward and reach down with the finger tips of both hands as far as possible towards their toes. Make sure they keep their knees straight. Keep the patient fully flexed and obtain the third recording at T12-L1 and the fourth recording at S2. These 4 readings permit simple calculation of true lumbar flexion, pelvic flexion and total combined flexion.

Lumbar extension is measured at T12-L1. Obtain the first reading with the patient in the erect position. Then instruct the patient to arch backwards as far as possible looking up to the ceiling. Support the patient

Figure 1. Inclinator measurements of flexion.



Pelvic flexion = 3 - 1.

Total flexion = 4 - 2.

Lumbar flexion = total flexion - pelvic flexion.

with your free hand on one shoulder to maintain balance and give some feeling of security. Hold this position and obtain the second reading. Simple subtraction gives the measure of total extension.

Lateral lumbar flexion is also measured at T12. A longer bar is needed on the inclinometer. Obtain the first inclinometer reading with the inclinometer bar lined up tangentially with the spinous processes at T9 and T12. Then instruct the patient to lean straight over to one side as far as possible with their fingertips reaching straight down the side of the thigh. Avoid flexing forwards or twisting round. Support their shoulder with a hand and make sure that both feet stay flat on the ground. Repeat to the other side.

Tenderness can only be evaluated by particularly careful standardization. This is carried out with the patient prone and it is important to make sure the muscles are relaxed. Palpation should be done slowly without sudden pressure and without hurting the patient unduly. Start by making sure that there is no superficial tenderness to light skin pinch: this is behavioral in nature and invalidates palpation for deep tenderness (Waddell et al. 1980). Local tenderness is then sought to firm pressure with the ball of the thumb over the spinous process or inter-spinous ligaments within 1 cm of the midline from T12 to S2. It is important to use specific wording: "is that painful?" ANY response apart from a specific NO is taken as positive. Any qualified response such as "only a little bit" is counted positive. If the patient is doubtful or does not answer then repeat the question "Is that painful when I do that?" Widespread non-anatomical tenderness is again discounted as behavioral (Waddell et al. 1980).

Straight leg raising (SLR) is carried out with the patient supine, making sure that the head remains relaxed and that the patient does not look up to watch what is happening. Hold the foot with one hand and make sure that the hip is in neutral rotation. Position the inclinometer on the tibial crest just below the tibial tubercle with the other hand and set zero. Passively raise the leg and at the same time hold the inclinometer in position with the other hand which also holds the knee fully extended. Raise the leg slowly to the maximum tolerated SLR (not the onset of pain) and record the maximum reading obtained. If SLR is less than 75 degrees then note if it is limited by back pain, hamstring tightness or radiating leg pain. Limited SLR on formal examination should always be checked with distraction at a later stage of the examination (Waddell et al. 1980).

Bilateral active SLR is tested in the supine position. Ask the patient to lift both legs together six inches off the couch and hold that position for five seconds. Only count as positive if both calves and heels are clear of the couch. Do not count aloud or use verbal encouragement. Do not allow them to use their hands to lift the legs. Record if they fail to lift their legs clear of the couch at all, can lift clear but for less than 5 seconds or manage to hold the position for a full 5 seconds.

Active sit-up is again tested in the supine position. Flex the knees to 90 degrees and place the soles of the feet flat on the couch. The examiner should hold down both feet with one hand. Instruct the patient to reach up with the finger tips of both hands to touch (not hold) both knees and hold that position for 5 secs. Only count as successful if the finger tips of both hands reach the patellae. Again record if they fail to reach their knees, are able to reach their knees but for less than 5 seconds or are able to hold the position for the full 5 seconds.

These 7 items are simply scored on a scale from 0-7:

Total flexion	< 87 degrees
Total extension	< 18 degrees
Average lateral flexion	< 24 degrees
Average SLR	
female	< 71 degrees
male	< 66 degrees
Lumbar spinal tenderness	positive
Bilateral active SLR	< 5 seconds
Sit up	< 5 seconds

When pain, disability and physical impairment are all proportionate, clinical severity can be assessed with confidence. When the patient's report of pain and disability is out of proportion to the clinician's evaluation of physical impairment, more comprehensive assessment is required of the patient's attitudes and beliefs, psychological distress and illness behavior.

Work

From the community perspective workloss is the most relevant and compelling measure of the social and economic impact of low back pain on the community as a whole, employers, productivity, the economy and social cost. This is reflected in political awareness. Workloss and return to work are also the "hardest" and most objective measures whereas most clinical endpoints are subjective.

Workloss does, however, have a number of limitations. Workloss may be less important to the individual patient than subjective, clinical measures of pain, psychological distress and satisfaction with care. Nevertheless, other studies suggest that increasing functional status and return to work are associated with reduced pain, while chronic disability and unemployment in themselves lead to psychosocial disturbance. While work capacity may be a more indirect and secondary measure of the effectiveness of medical care on pain and disability, it is nevertheless a final summary measure of that effectiveness. Workloss is however correlated poorly with biomedical measures of low back pain. Workloss is only applicable to the working population and omits low back disability in the young, the elderly, housewives and the unemployed. Workloss only registers the more severe disability and only one specific aspect of the functional disability due to low back pain. It omits lesser degrees of pain and disability and more refined aspects of work performance such as restricted duties, reduced productivity, loss of overtime and loss of promotion. Statistically workloss and return to work for the individual is basically a dichotomous variable with limited statistical properties. This can however be overcome by aggregating individuals in the population and also by considering more continuous measures of workloss such as duration of workloss and survival curves for post-operative recovery, recurrence rates and timing and summary statistics of cumulative workloss over time. Finally, workloss and return to work are very dependant upon and vulnerable to non-health related socio-economic variables such as specific employment conditions and general economic and labour market conditions.

After consideration of all these issues, the International Association for the Study of Pain Task Force on Pain in the Workplace has recommended that workloss is the most important consequence of low back pain and that return to work is the most important outcome measure of medical care.

Conclusion

It may be suggested that the ideal evaluation of results of lumbar spine surgery should give information about both clinical outcome measures of pain, disability and physical impairment and also about social outcome measures of return to work and loss of time from work over the second follow up year. This should be put in context by baseline measures of pre-operative pain, disability and physical impairment together with pre-operative work status (working/off sick, job open/lost job) and loss of time from work over the pre-operative year. Unfortunately, very few reports of the outcome of lumbar spine surgery approach this ideal.

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