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A Philosophical Foundation for Diagnostic Blocks, with Criteria for Their Validation

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Abstract

Background. In the absence of a suitable reference standard, diagnostic local anesthetic blocks cannot be validated in the manner conventionally used for diagnostic tests. Consequently, diagnostic blocks are vulnerable to criticism for lacking validity, or being "not proven."

Study Design. Philosophical essay.

Methods. Inspired by the "viewpoints" proposed by Bradford Hill for testing cause and effect in epidemiology, a set of axiomatic criteria was developed with which the validity of diagnostic blocks could be assessed.

Results. Eight criteria were established: plausibility, experiment, target-specificity, effect, duration, consistency, control, and replication. Applying weighted scores to these criteria produces a metric by which the validity of a particular diagnostic block can be quantified.

Conclusion. The eight criteria provide an axiomatic, philosophical basis for diagnostic blocks in general, and serve to show what empirical evidence needs to be gathered in order to validate a particular block. The associated metric allows the scientific evidence for different blocks to be quantified and compared.

Key Words. Diagnostic; Block; Local Anesthetic; Validity

Introduction

Diagnostic blocks constitute a critical component of the practice of pain medicine. When a diagnosis is not available through other means—such as history, examination, or medical imaging—diagnostic blocks can be used to determine the source of pain, or to identify the nerves that are mediating the pain or associated symptoms [1].

In this regard, a diagnostic block is a procedure in which a local anesthetic agent is injected into or onto a structure, in order to anesthetize it, or onto the nerve or nerves that innervate the structure. The following remarks do not pertain to procedures in which local anesthetic is administered for therapeutic purposes, or in which a putative therapeutic agent is mixed with or added to the local anesthetic.

In the past, the validity of diagnostic blocks has largely been taken for granted, or at least not challenged. Older textbooks of pain medicine described various diagnostic blocks, but with little regard, if any, to formal evidence of their validity [2–5]. This has left the validity of diagnostic blocks open to challenge. Insurers have been able to deny reimbursement for diagnostic blocks, or to deny diagnoses based on them, on the grounds that diagnostic blocks have not been "proven." Some pundits have published overtly hostile comments about diagnostic blocks [6].

Many other diagnostic tests in medicine can be validated using conventional means. These involve comparing the results of the test with the results of a criterion-standard [7,8], typically a physical one, such as a blood test, a biopsy, a surgical observation, or a feature on imaging. For diagnostic blocks and pain, such a physical criterion-standard is not available. Pain cannot be seen, biopsied, or photographed. Consequently, diagnostic blocks cannot be validated by conventional means. However, in this

regard, diagnostic blocks are neither unique nor alone. Other concepts in medicine have faced similar problems but have overcome them.

When first introduced, germ theory faced philosophical objection—as an incredible and, therefore, unacceptable belief. In response, Koch introduced his three postulates, later expanded to four [9] which, if satisfied, would secure philosophical credibility of the concept. Essentially, they were: 1) the organism must regularly be isolated from cases of the illness; 2) the organism must be grown in pure culture *in vitro*; 3) when such a culture is inoculated into a susceptible animal the typical disease must result; and 4) from such experimentally induced disease the organism must again be isolated. Once these postulates were satisfied, germ theory became accepted.

A similar problem arose in occupational medicine in the determination of cause and effect. Untested conjectures, on questions such as the causes of scrotal cancer or lung cancer, were regularly rejected *ex cathedra* on the basis that they were not proven. For this problem, Bradford Hill proposed nine "viewpoints" of association that should be considered before causation might be claimed [10] (Table 1). These became widely accepted, in epidemiology and occupational medicine, as the "Bradford Hill criteria" against which the credibility of cause and effect should be assessed.

More recently, Howick et al. [11] proposed an adaptation of the Bradford Hill criteria to fill another vacuum in medicine: How to assess credibility of cause and effect when randomized controlled trials were lacking, not feasible, or outrightly superfluous. Although their guidelines were not directly equivalent to the criteria of Bradford Hill, Howick et al [11] showed how the precepts of Bradford Hill could be adapted to form a sensible checklist against which the credibility of a clinical proposition could be assessed, and even quantified.

In their original form, neither the Bradford Hill criteria [10] nor the guidelines of Howick et al [11] directly lend themselves to the validation of diagnostic blocks. However, it is possible to propose a set of axiomatic criteria, in the manner of Bradford Hill, that provide a philosophical basis for the validation of diagnostic blocks. In turn, these criteria indicate the type of clinical evidence that would be required to establish that validity beyond doubt and immunize it against *ad hoc* sophism.

Table 1 The original criteria for cause and effect as proposed by Bradford Hill [10]

Strength
Consistency
Specificity
Temporality
Biological gradient
Biological plausibility
Coherence
Experiment
Analogy

Criteria

Plausibility

This criterion asks if the proposed link between cause and effect has a plausible biological basis. In the context of diagnostic blocks, at issue is not if local anesthetics have a plausible effect on nerves. That is not in question, for the ability of local anesthetic agents to block nociception is well established, in terms of physiology and pharmacology [5]. Rather, this criterion applies to the plausibility of the target structure being a source of pain.

When a structure is generally accepted as a source of pain, plausibility becomes a superfluous criterion for the evaluation of a diagnostic block. However, plausibility becomes more pertinent if the proposed source is contentious and is met with incredulity. Implausibility, *per se*, does not invalidate a block, but it does provide a basis for rhetorical objection to the block. This objection, however, can be refuted by studies that show that the structure in question can be a source of experimentally induced pain in normal volunteers. Doing so establishes in principle that the structure is a feasible source of pain in patients and, therefore, that the diagnostic block is potentially justified.

Experiment

If a diagnostic block is supposed to block pain naturally arising from a particular structure, the same phenomenon should occur in normal volunteers. Performing the block in normal volunteers should protect them from experimentally induced pain from the target structure. Demonstrating this effect in normal volunteers establishes a principle: that the block actually can stop pain from the target structure. In formal terms, studies in normal volunteers establish the face validity of the diagnostic block, by showing that the block succeeds in achieving what it is purported to achieve.

Target-Specificity

A diagnostic block should be target-specific, in both positive and negative connotations. Positive target-specificity means that the block succeeds in anesthetizing the target structure. Negative target-specificity means that the block does not anesthetize other structures that might feasibly be a rival source of pain. Negative target-specificity is as important as positive target-specificity because, if a positive response is due to rival sources of pain being anesthetized but not recognized, the diagnostic inferences drawn will be wrong.

Ideally, target-specificity would be achieved if physicians could see that their injection reached the target and did not spread elsewhere, but this is not feasible, currently, in

vivo. Perhaps in the future, micro-endoscopic techniques might be developed that permit direct visualization of a diagnostic block.

Akin to direct visualization is testing the block in cadavers, with injections of dye, whose spread can then be visualized upon dissecting the cadaver. Such studies can serve to set the parameters of a block, such as optimal placement of the needle, and optimal volume of injectate, but they do not guarantee that the same specificity will be achieved in a given patient. That requires methods that can be recurrently applied *in vivo* in each and every patient.

To different extents, various techniques have been used to secure target-specificity, or check for it, in given patients. For certain nerve blocks, physical examination can be used to check for signs—other than the relief of pain—that show that the target nerve has, indeed, been blocked. Examples include the onset of numbness when a nerve with a cutaneous distribution is blocked, or a change in temperature when a sympathetic nerve is blocked. However, although such features might be reassuring that the target has been adequately infiltrated, they do not ensure that the block has not anesthetized rival structures.

The foremost means, currently available, of securing target-specificity is the use of fluoroscopic guidance and a test injection of contrast medium. Initially, fluoroscopy serves to guide the needle accurately onto, or into, the target structure. Subsequently, the injection of contrast medium indicates how much injectate needs to be delivered in order to infiltrate the target structure adequately, and how little must be injected to avoid spread to adjacent structures, and thereby achieve a specific and discrete block. For small nerves, the volume required may be as little as 0.5 mL or less [12].

An obverse application of fluoroscopy is to guard against false-negative effects. Injectates may pass into blood vessels, instead of onto the target structure. Having been washed away from the target, the local anesthetic will fail to anesthetize it, even though the target may, indeed, be painful. Checking for vascular uptake of contrast medium guards against this possibility. Fluoroscopy is the only means currently available for checking for vascular uptake. If vascular uptake is encountered, the needle can be readjusted to regain target-specificity.

Fluoroscopy may not be a perfect test of target-specificity. It might be argued that where the contrast medium flows is not necessarily where the subsequently injected local anesthetic flows, because of differences in viscosity, or because the contrast medium opens previously occluded planes of least resistance into which the local anesthetic deviates. However, there is no evidence of such effects; they are only theoretical concerns, and even if qualitatively correct they may nevertheless be quantitatively insignificant. Consequently, fluoroscopy remains the best available means by which a physician can visualize where their injection does and does not go.

An emerging alternative is ultrasound. Ultrasound can be used for peripheral nerve blocks [13–15]. Some studies have sought to replace fluoroscopy with ultrasound guidance for spinal diagnostic blocks [16–18], but ultrasound has not yet been generally validated for these blocks.

Effect

The paradigm of diagnostic blocks is that they should stop the pain if the target is the source of the pain. This implies that the pain is relieved completely. Although other criteria would still need to be satisfied, complete relief of pain should constitute *prima facie* evidence that the target is the source of pain, and only source of pain.

Certain adaptations to this criterion can be elaborated. In a patient with multiple sources of pain, a diagnostic block of one of those sources should not be expected to relieve pain from all sources. For example, in a patient with bilateral pain, a diagnostic block of a structure on the left might completely relieve their left-sided pain but not their pain on the right. In patients with two consecutive painful joints in the spine, blocking the lower of the two might relieve the lower half of the patient's pain but not the upper half, while reciprocally, blocking the upper joint would relieve the upper half of their pain but not the lower half. In all cases, however, the requirement for complete relief nevertheless applies. The pain targeted in a particular anatomical region should be completely relieved.

In such cases, the diagnosis should ideally be perfected. If a left-sided block completely relieves left-sided pain, and if a right-sided block completely relieves right-sided pain, then subsequently, simultaneous left and right blocks should completely relieve all pain. Similarly, if a block of a lower structure relieves the lower half of a patient's pain, and a block of a higher structure relieves the upper half, then subsequently, simultaneous high and low blocks should completely relieve all pain. Such responses fully satisfy the paradigm of diagnostic blocks.

Problems arise when relief is not complete. One example is when a diagnostic block reduces the intensity of pain by, say, 50% but does not provide complete relief. In such cases the response is ambiguous. Although some physicians might claim that there is another undisclosed source of pain responsible for the remnant pain, an equal, competing conjecture is that the 50% response indicates that the patient has been uncertain of the effect, or is trying to comply with the physician's expectations of a response, or is reporting some form of placebo effect. Without additional evidence, this latter conjecture is no less valid than the proposition that the patient has another source of pain. For the diagnostic process to be perfected, that other source of pain should be identified, be that by a different, additional diagnostic block or by other means. If this is not done, the undisclosed source of pain remains hypothetical, and the 50% relief remains ambiguous.

In some cases, it may not be practical to identify all sources and block them all simultaneously, in order to

satisfy the criterion for complete relief. In that event, the validity of the block will rely on satisfying other criteria. For example, 50% relief from a diagnostic block becomes more credible if, under double-blind conditions, the patient consistently reports 50% relief when an active agent is used but reports no relief from a placebo control. If this is not done, the 50% relief remains ambiguous and contentious.

Duration

The essence of a diagnostic block is that its effect must be temporary. The local anesthetic wears off. Therefore, for a block to be diagnostic, it must be biphasic. Not only must the block completely relieve the patient's pain, but that pain must also return when the local anesthetic ceases to act. Failure to do so invalidates the block.

It may be satisfying, both to the patient and to the physician, if and when a block completely relieves pain permanently. In that event both can be grateful for the mercy, and the block can be regarded as having fortuitously become therapeutic. However, in doing so, the block lapses for diagnostic purposes, because the response is not compatible with a physiological response to an agent with a temporary effect. The response may be genuine and worthwhile, but for diagnostic purposes, it is ambiguous, because it cannot be distinguished from a therapeutic placebo response.

An extension of this argument is that if the response to a diagnostic block is to be biphasic, the pain should return after a period compatible with the known duration of action of the agent used for the block. For a block to be physiologically and pharmacologically sensible, the relief of pain should be short-lasting whenever a short-acting agent is used, and long-lasting whenever a long-acting agent is used. This is the conceptual basis of so-called comparative local anesthetic blocks [19].

Comparative local anesthetic blocks were introduced, and subsequently developed, as a form of control, that did not require the administration of a placebo [19]. On separate occasions the same diagnostic block is repeated using agents with different durations of action. The credibility of the blocks, and the patient's response to them, is enhanced if the responses are temporally consistent with the known pharmacology of the agents used on each occasion. Responses are "concordant" when the duration of relief matches the duration of action of the agent used, and "discordant" when relief outlasts the expected duration [19].

Since their introduction into pain medicine, comparative local anesthetic blocks have attracted some degree of favor and popularity, particularly as they seem to be a convenient and practical alternative to placebo-controlled blocks. However, this faith in comparative local anesthetic blocks may be misplaced, for it has been shown that the validity of comparative local anesthetic blocks is critically dependent on the prevalence of the condition being diagnosed [20].

Comparative local anesthetic blocks have been validated, statistically [19] and against placebo controls [21], but only in the context of diagnostic blocks of the cervical medial branches. In that context, concordant responses to comparative local anesthetic blocks have a sensitivity of 54%, a specificity of 88%, with a positive likelihood ratio of 4.5. With these parameters, they are sufficiently valid for practical purposes because the prevalence of the condition being diagnosed is high (60%) [20]. For other conditions, with a much lower prevalence, comparative blocks may not be valid, because the false-positive rate substantially compromises the post-test odds and, therefore, the diagnostic confidence [20].

A caveat applies to comparative local anesthetic blocks. The expected duration of action of local anesthetics has been determined in normal volunteers, or patients undergoing surgical procedures, not in patients with persisting pain. The "normal" duration of action in patients with pain has not been measured. Although the majority of patients report durations of relief consonant with the expected durations determined in normal volunteers, some have temporary but inordinately prolonged responses to local anesthetics [19]. Those "discordant" responses are not necessarily placebo responses [21] and are compatible with local anesthetics having different sites of action depending on whether sodium channels are open or closed [1].

When they have been studied, discordant responses have lesser specificity but greater sensitivity than concordant responses, resulting in a positive likelihood ratio that is somewhat smaller than that of concordant responses [20,21]. However, for practical purposes, discordant responses are no less valid than concordant responses when the prevalence of the condition being diagnosed is high (greater than 60%), but as the prevalence decreases, discordant responses become increasingly less valid because the diagnostic confidence they provide (post-test likelihood) becomes substantially less than that of concordant responses [20].

Consistency

The logical basis for consistency as a criterion is that if a structure really is the source of pain, then that pain should be relieved whenever the structure is anesthetized. This criterion would be satisfied if a repeat block reproduced the same effect as the previous block. However, reproduction of relief provides only circumstantial evidence of the validity of the block. It is compatible with a stable source of pain being consistently anesthetized, but it is also compatible with consistent placebo responses. Therefore, consistent responses become valid only when they occur in the context of controlled blocks.

As a criterion, consistency becomes more discriminating when it is not satisfied. Lack of consistency arises when a repeat block fails to reproduce the previously encountered relief. The literature attests to large proportions of patients failing to report relief when the same block is repeated, despite having had complete relief after the first block [19,20,22–26]. This warns physicians against relying on a single, diagnostic block. Not repeating a block avoids encountering failure to reproduce relief, and the diagnostic implications of that failure. The cardinal purpose of repeating a block, therefore, becomes to rule out lack of consistency.

Control

Unlike physical diseases, pain is not tangible and is subject to psychological influences, such as placebo effects. In order for a diagnostic block to be valid, measures need to be taken to control for these influences. The criterion of control requires that the pain stops when the block is applied but does not stop when a placebo block is applied. This is, perhaps, the most convincing criterion for the validity of a diagnostic block. Failure to respond to placebo refutes the competing conjecture that the response is psychological, and thereby establishes that the positive response to the local anesthetic must have been genuine.

However, certain logistic caveats apply. In most jurisdictions, covert placebo blocks—to "test" the patient—would be considered unethical. Therefore, placebo controls would require informed consent. Thereafter, placebo blocks would have to be randomized and be double-blind. The placebo block could not routinely follow an active block with a positive response, for then the patient would know that the second block is the one that is not supposed to work. Placebo blocks could not routinely be the first block. An active block is required to provide *prima facie* evidence that the structure in question is actually a source of pain. Otherwise a physician could find themselves performing placebo blocks of a structure that is not even the source of pain. Consequently, placebo controls need to be conducted in the context of three diagnostic blocks: the first being an open-label, active block to determine, *prima facie*, that the target structure is possibly the source of pain; and the second and third blocks being conducted under double-blind conditions, with an active agent and placebo randomized.

In some situations, comparative local anesthetic blocks could serve as a practical alternative to placebo-controlled blocks, but as discussed above, in the context of duration, the requirement is that the condition being diagnosed has a high pretest probability. For conditions with lesser prevalence, the false-positive rate of comparative blocks fatally compromises their validity [20].

Another alternative is to use anatomic controls. Blocking a structure that is not the target structure should not relieve the patient's pain. However, in order for anatomic controls to be credible, the patient should not be able to distinguish if and when a different structure is blocked. This means that the two procedures should look alike and feel alike. The control structure should not be perceptibly remote from the target structure.

Replication

The criterion of replication means that others have encountered the same experience with a particular diagnostic block used in the same manner. It is akin to repeating the experiment and confirming the results in fields of science such as physics or chemistry. Replication guards against early descriptions of a new block being based on unrepresentative or rogue samples. Satisfying replication provides external validity, i.e. generalizability, of the block.

This criterion disadvantages physicians who announce a new diagnostic block. Initially, they need to rely on other criteria to demonstrate validity of their procedure, but subsequently the block will inherit further credit if and when others replicate the results.

Discussion

The eight criteria for diagnostic blocks can be assembled into a metric that can be applied to assess the validity of a given block, either in general or in a particular case. The metric is hierarchical in that certain criteria are essential, others are critical, and others less critical. The metric can be described in the form of an algorithm (Figure 1) and a checklist (Table 2).

Target-specificity is an essential criterion. If a block is not target-specific, it cannot be valid, because any diagnostic inferences cannot be legitimately attributed to the purported target.

Likewise, duration is an essential criterion. Because local anesthetic agents have a temporary effect, pain should return when that effect wears off, which should be in a matter of hours. If prolonged relief occurs after a block, the block converts into a therapeutic event, and is disqualified as a diagnostic procedure.

Less critical criteria are effect and consistency. As evidence that the source of pain has been identified, complete relief of pain is more attractive than partial relief, but partial relief does not necessarily invalidate a block. Partial relief could be validated by satisfying subsequent and more critical criteria. Reproducing relief by repeating the block is attractive to some degree in verifying the response, but alone is not enough to establish validity. More critical is failure to reproduce relief, in which event the diagnosis should be regarded as indeterminate.

The most critical criterion is the use of controls under randomized, double-blind conditions. Randomization is essential in order to control for expectation bias, and blinding is essential to control for observer bias and response bias. Placebo controls are the premier form of control. Comparative blocks might serve as a surrogate

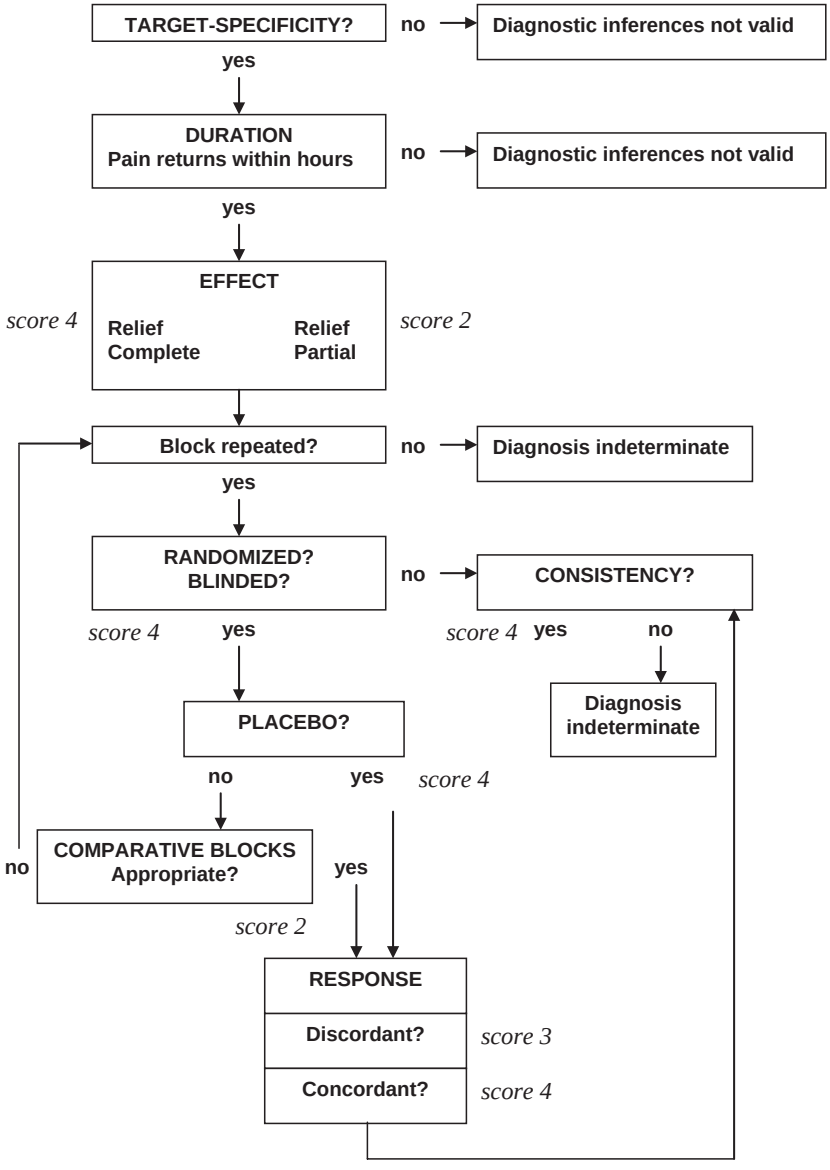

Figure 1 An algorithm for assessing the validity of a diagnostic block. A block that reaches a particular point in the algorithm receives the score accorded to that point.

but only if epidemiologically appropriate, i.e. when the pretest odds of the condition being present are relatively high. They would not be appropriate for conditions with a low prevalence because the post-test odds will be confounded by a high false-positive rate.

Placebo controls and comparative blocks each involve repeating the block. Therefore, each can be evaluated for consistency of both effect and duration during the repetition. The same degree of relief should be achieved with each repetition, and the duration of relief can be assessed as being discordant or concordant with the expected duration of action of the agents used.

Some authors have proclaimed that performing placebo controls raises "issues" with respect to ethics [27–29] but without elaborating these issues. Placebo controls are not unethical if performed under fully informed consent. The real impediment to the use of placebos in most clinical practices is the logistic burden of having to perform a series of three blocks, and the financial risk of not being reimbursed for some or all of these blocks when insurers or others decline to pay for controlled blocks. The price for avoiding these logistic and financial impediments is foregoing the consummate evidence of validity that placebo controls provide. Ironically, the converse case could be made. Uncontrolled blocks should not be reimbursed, because the ambiguities inherent in uncontrolled diagnostic blocks preclude making a valid diagnosis.

The three remaining criteria are not critical and can be regarded as supplementary because of their essentially academic nature. Plausibility, experiment, and replication are not essential because a block can be sufficiently

Table 2 A checklist and scorecard of criteria for the assessment of positive responses of diagnostic blocks. A block that satisfies a particular criterion is accorded the score available for that criterion

Criteria		Description	Score
Essential	1. Target-specificity	The block must be shown to block the target selectively.	
	2. Duration	The response to local anesthetic must wear off within hours.	
Relative	3. Effect		
	Partial relief	Pain relieved by 50% or more.	2
	Complete relief	Pain completely relieved.	4
	4. Consistency	Repeating the block reproduces the same response in terms of effect and duration.	4
Critical	5. Controls	Randomized double-blind controls are used.	4
	Placebo control	Pain is not relieved by placebo.	4
	Comparative blocks	Comparative blocks are used and applicable, i.e. not subject to inordinate false-positive rates.	2
	Discordant response	Relief consistent but duration exceeds expected duration of one or both agents.	3
	Concordant response	Relief consistent, and duration concordant with each agent used.	4
Academic	6. Plausibility	Target shown to be a source of pain in normal volunteers.	1
	7. Experiment	Blocking target protects normal volunteers from experimental pain.	1
	8. Replication	Others have reproduced the results.	2

validated by satisfying other criteria, but the academic criteria serve to complete the picture. Other factors being equal, a diagnostic block would be considered more thoroughly studied, and more fully validated, if and when plausibility and experiment are satisfied, and replication has been achieved.

The metric can be rendered quantitative by according scores to various criteria with different weights. The weighting suggested is not entirely arbitrary. It is based on the extent to which would-be users rate one criterion as more important than another. Different users might care to apply somewhat different relative values to certain criteria, downgrading some and upgrading others; however, in the light of the arguments raised in this essay, we trust that they would agree on the direction of their relative weighting.

No scores are applied to target-specificity or duration because these are absolute criteria. Either they are satisfied or not, and no amount of credit for other criteria can compensate for lacking target-specificity or for a block failing to wear off.

Relatively low scores are accorded to effect and consistency if a block is repeated, because alone these criteria do not validate a block, but when satisfied they reinforce the credibility of the response. Greater credit is accorded if a block provides complete relief than if it provides only partial relief.

Greater scores are accorded if the block is subjected to controls. A block inherits credit if patients are randomized to double-blind blocks. Here, the credit is accorded, not for simply repeating the blocks on an open-label basis, but for formally randomizing the blocks, and adopting double-blind conditions. Subsequently greater additional credit is accorded for using placebo controls than for comparative blocks. Further credit is accorded for consistency of effect during the controlled blocks, with concordant responses receiving slightly greater credit than discordant responses, in proportion to the magnitudes of the likelihood ratios of concordant and discordant responses.

Nominal scores are accorded to the academic criteria so that some credit can be gained from satisfying these criteria, but not of such magnitude that this credit might significantly offset failing to satisfy more critical criteria. Replication is accorded slightly greater credit than are plausibility and experiment, on the grounds that replication serves to satisfy external validity or generalizability.

When scored in this way, the relative standing of blocks performed with different rigor can be expressed quantitatively. For example, a block that consistently (4 points) provides complete relief (4 points), no relief from placebo (4 points), and concordant responses to different local anesthetic agents (4 points) under randomized, double-blind conditions (4 points), would score 20 points, with a further 4 points being available if the academic criteria have been satisfied. A block that consistently provides partial relief when repeated would score 6 points; however, if that same response was reproduced in the context of randomized, placebo-controlled repetitions, it would score 18 points, if the responses were concordant.

A metric such as this can serve two purposes. In general, it can be used to gauge the extent to which a given block has been validated in the literature and to identify what further evidence might be required to improve that validity. In a particular case, the metric can be used by insurers or

others to assess the validity of a block in a given case, and either approve or reject the block on transparent, objective, grounds.

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