A New Model for Classification of Diagnostic Errors from Ethical & Statistical Perspectives: Electrodiagnostic Approach

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Abstract: Medical errors are a major problem in all health environment. An important part of medical errors is diagnostic errors. By classifying diagnostic errors we could possible to limit their burden. Between October 2013 and April 2015, a number of experts were asked to analyze the patients’ situation to what was prone to an electrodiagnostic pitfall commitment. They wanted to predict less harmful errors between possible pitfalls list for each client. Experts believe that most of the times, the diagnosis with least adverse effect is predictable. Like other diagnostic tests, electrodiagnostic errors are inevitable. During diagnosis process, we should always try to predict the possible outcomes of our errors & remember that some pitfalls (type 1) are more prone to be harmful for the client than the others (type 2).

Key words: Diagnostic, errors, electrodiagnosis, pitfalls, classification, outcome, type 1, type 2

I. Introduction

Electrodiagnostic studies, including nerve conduction studies (NCSs) and electromyography (EMG), are considered as an extension of clinical anamnecsis and physical examination. The correct interpretation of electrodiagnostic study results and application of those results clinically requires the electromyographers not only to have expert knowledge and experience of neuroanatomy and of peripheral disorders, but also about many pitfalls associated with electrodiagnosis (Edx).

Electrodiagnostic testing is used widely for the full characterization of neuromuscular disorders and for providing unique information on the processes underlying the pathology of peripheral nerves and muscles. However, such testing should be considered as an extension of anamnecsis and physical examination, not as pathognomonic of a specific disease entity. There are many pitfalls that could lead to erroneous interpretation of electrophysiological study results when the studies are not performed properly or if they are performed in the presence of anatomical abnormalities.

According to our knowledge, there is no classification for these pitfalls with regards of the outcomes. There are comprehensive information about factors can lead to pitfalls in electrodiagnostic studies. These factors are included but not limited to limb temperature, gender, age, body mass index, filters, amplifiers, muscle selection, anomalous innervations (Martin-Gruber, Marinacchi communication, Riche-Canieu anastomosis etc), factors related to stimulation & electrodes.

Although there are lots of data about factors that could lead to pitfalls, but according to our knowledge, clinical burden of Edx errors is unknown & there is no model for classification of the errors according to the outcomes. In this study with regards of potential adverse effect, we try to classify electrodiagnostic errors into two main groups in order to limit the territory of harmful pitfalls.

II. Materials & methods

First, we define "basic diagnosis" as the diagnosis between differential diagnoses (DDx) list which predicted to have globally least potential harmful effects on the client. These effects could be waste of golden time to treat, perform unnecessary treatment or surgery, psychiatric adverse effect, missing insurance support & etc. Our study focused on clients to PRM department of Emam Reza hospital who had two different electrodiagnostic reports (before or after admission), at least from the same limb, between October 1, 2013 and April 30, 2015. The maximum acceptable time lag between two reports was 3 months. Then we asked 3 experts, electromyographers to determine if it is possible to consider one of the interpretation as basic diagnosis (regardless as which of the diagnosis was right). The impression of Edx was accepted as the basic diagnosis if there was a consensus between all of the reviewers about that. If there were more than one differences between impressions (or the client had more than 2 different diagnosis), the study was conducted on each possible pair of differences, separately. At the second step of the study we tried to make a model for classifying electrodiagnostic errors according to their possible adverse effects. We considered typing of errors during medical researches as a template to explain our model.
We found 48 clients who had more than one diagnosis for the same situation (67 differences). Regardless as what was the exact diagnosis, for most of clients' situations (63 out of 67), a consensus between EDx specialists was existed about basic diagnosis. So expert electromyographers believe that in a doubtful situation, it is usually possible to predict potentially less harmful diagnosis. (Table 1)

<table>
<thead>
<tr>
<th>Number of impressions there was consensus on</th>
<th>Basic diagnosis was</th>
<th>B diagnosis</th>
<th>A diagnosis</th>
<th>Number of impressions</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>NL</td>
<td>NL</td>
<td>Mild CTS</td>
<td>11</td>
</tr>
<tr>
<td>2</td>
<td>NL</td>
<td>Mild CTS</td>
<td>Moderate CTS</td>
<td>2</td>
</tr>
<tr>
<td>7</td>
<td>Mild CTS</td>
<td>Mild CTS</td>
<td>Moderate CTS</td>
<td>7</td>
</tr>
<tr>
<td>1</td>
<td>Mild CTS</td>
<td>Mild CTS</td>
<td>Severe CTS</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>Multilevel radiculopathy</td>
<td>Multilevel radiculopathy</td>
<td>MND</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>NC</td>
<td>Less severe (or less number) of roots involvement</td>
<td>Less severe (or less number) of roots involvement</td>
<td>Several (or more severe) roots involvement</td>
</tr>
<tr>
<td>3</td>
<td>NC</td>
<td>Several (or more severe) roots involvement</td>
<td>Several (or more severe) roots involvement</td>
<td>Several (or more severe) roots involvement</td>
</tr>
<tr>
<td>11</td>
<td>NL</td>
<td>NL Or not significant</td>
<td>Polyneuropathy</td>
<td>Polyneuropathy</td>
</tr>
<tr>
<td>1</td>
<td>NC</td>
<td>Mild or severe</td>
<td>NL</td>
<td>Polio</td>
</tr>
<tr>
<td>1</td>
<td>NL</td>
<td>Polio</td>
<td>NC</td>
<td>Polyneuropathy</td>
</tr>
<tr>
<td>1</td>
<td>NC</td>
<td>Polyneuropathy</td>
<td>Myopathy</td>
<td>Myopathy</td>
</tr>
<tr>
<td>1</td>
<td>NC</td>
<td>Ulnar neuropathy at wrist</td>
<td>Ulnar neuropathy at wrist</td>
<td>Ulnar neuropathy at wrist</td>
</tr>
<tr>
<td>1</td>
<td>Severe ulnar nerve lesion</td>
<td>Partial ulnar nerve lesion</td>
<td>Severe ulnar nerve lesion</td>
<td>Severe ulnar nerve lesion</td>
</tr>
</tbody>
</table>

Table 1: Presence of consensus about basic diagnosis in some situations which were prone to errors

NL: Normal, NC: No consensus between experts

### III. Conclusion

This study shows that it is possible most of the time to determine the most conservative diagnosis (with least predictable upcoming clinical adverse effect) among differential diagnosis list. We called it “basic diagnosis”. In simple word, basic diagnosis mostly is the diagnosis that if the electromyographer would be in client situation, likes to be reported by the physician (not necessarily normal report).

In the main part of this article, we use statistics rules (basic diagnosis is considered similar to null hypothesis) as a template for our model so that two types of error are distinguished:

**Type 1 Edx errors and Type II Edx errors**

*Type 1 Edx error* occurs when the basic diagnosis is true, but is rejected or occurrence of misdiagnosis when it is impossible (relatively rare situations) to consider a basic diagnosis for the client.

*Type II Edx error* occurs when the basic diagnosis is false, but erroneously fails to be rejected.

**Example 1:**

A soldier complains of LBP radiate to left lower limb. An Electrodiagnostic consultation was asked. We know that he will be retired if his L5 radiculopathy documented in Edx. He asked for help. (He wants to be retired) Basic diagnosis in this situation is L5 radiculopathy. (Table 2)

Which of these 2 types of errors is less acceptable?

**Example 2:**

A person with chronic low back pain without neurologic deficit is a candidate for laminectomy at the same level. An Edx was asked for decision making.

In contrast to example 1, as the patient does not have any red flags, basic diagnosis is normal lower limbs Edx (when uncertainty is between normal or mild L5 radiculopathy or mild L5 radiculopathy (when uncertainty is between mild or more severe L5 radiculopathy (Table 2)

Which one is worse? Perform an unnecessary surgery or postpone a surgery with some possibility to decrease pain?

**Example 3:**

Suppose a young lady with hands paresthesia have come for Edx. Usually basic diagnosis will be normal diagnosis (when the uncertainty is between normal & mild CTS) & mild CTS (when uncertainty is between mild & moderate CTS) . . . (Table 2)
Example 4:

A 10 years old girl with acute onset of lower limb weakness has been referred to rule out AIDP. We know that the treatment of AIDP is IVIG, an expensive drug with little known side effects.

Basic diagnosis: AIDP (Table 2)

Which error is more tolerable? Considering an AIDP child as normal or another diagnosis (lose the opportunity of IVIG) or prescribe IVIG for a non AIDP person?

This review indicates a novel approach to electrodiagnostic field. EDx is a true study: like any medical study that researchers make a null hypothesis at the time of making proposal, we recommend to build the basic diagnosis (instead of null hypothesis) in our mind during EDx process for each clients. Unless you gather enough documents during your NCS & EMG, don’t change this basic diagnosis in your last interpretation. It was very interesting that all of well-known electromyographer we asked (3 person), told that this model is what they actually do spontaneously, when there is uncertainty about true diagnosis at the time of decision making.

Table 2: Types of errors in examples 1-4

<table>
<thead>
<tr>
<th>Example number</th>
<th>Basic diagnosis</th>
<th>Type 1 error</th>
<th>Type 2 error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example 1</td>
<td>L5 radiculopathy</td>
<td>Report: L5 radiculopathy</td>
<td>Report: L5 radiculopathy</td>
</tr>
<tr>
<td>Example 2</td>
<td>NI</td>
<td>Report: L5 radiculopathy</td>
<td>Report: L5 radiculopathy</td>
</tr>
<tr>
<td></td>
<td>Mild L5 radiculopathy</td>
<td>Report: more than mild L5 radiculopathy</td>
<td>Report: more than mild L5 radiculopathy</td>
</tr>
<tr>
<td></td>
<td>Mild CTS</td>
<td>Report: moderate or CTS Fact: mild CTS</td>
<td>Report: mild CTS Fact: moderate CTS</td>
</tr>
<tr>
<td>Example 4</td>
<td>AIDP</td>
<td>Report: other diagnosis without effective treatment Fact: AIDP</td>
<td>Report: AIDP Fact: other diagnosis with no significant treatment</td>
</tr>
</tbody>
</table>

This classification has several advantages. In many practical applications type I errors are more delicate than type II errors. Likewise this model, which was derived from elite expert’s suggest that some errors (type 1) are more embarrassing than others (type 2) so by remembering that, it will be possible to limit the burden of less tolerable misdiagnoses. This model could be considered as a template for Edx education in academic centers. It should encourage policymakers, healthcare organizations and researchers to start measuring and reducing electrodiagnostic errors.

The model has some disadvantages. First it could shift the errors to type 2 & increase the territory of this type of errors. An other is what we actually call type I or type II error depends directly on the basic diagnosis considered for the clients. Negation of the basic diagnosis causes type I and type II errors to switch roles. There are some situations that there is no agreement on basic diagnosis, in those situations any misdiagnosis should be considered as type I.

The main limitation of our study was the number of experts involved in it & also the limited number of situations evaluated by us. Although because of long time of the study most of common clinical situations was considered.

By asking more experts to involve in future studies, we believe this classification will be completed. For example we had a 62 years old client who was a candidate for lumbosacral canal stenosis surgery. He had two completely different EDX reports. (ALS & bilateral L4-S1 roots lesion) Two of our electromyographers believed that (due to catastrophic psychiatric effect that ALS diagnosis has on patient & his family) the basic diagnosis was L4-S1 roots lesion, while the other believed that (because of severe adverse effect of surgery on ALS patient) the basic diagnosis was ALS. If the number of specialist will increase, consensus about basic diagnosis may be achieve in such cases. It is obvious when type 1 errors are decrease, type 2 errors are increased & vice versa. In most of medical researches the tolerable amount of type 1 (α usually = 5%) & type 2 (β usually = 20%) errors is determined at the start of study. The acceptable type of each one of these errors for a certified electromyographer is different situation is good subject for future studies. For example in a common situation for controversies (Mild CTS or normal), how many percentages of normal clients reported as mild CTS (type 1) is intolerable & how many percentages of mild CTS patients reported as normal (type 2) is acceptable?
Abbreviations:

References