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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.BetweenOctober 2013 andApril 2015, a number of experts wereasked to analyze the clients' situation whowas prone to an electrodiagnostic pitfall commitment. They wanted to predict less harmful error between possible pitfalls list for each client.Expertsbelieve that most of the times, the diagnosis with least adverse effect is predictable.Like other diagnostic tests, electrodiagnosticerrors are inevitable. During diagnosis process, we should always try to predictthe possible outcomes of ourerrors & remember that some pitfalls (type 1) are more prone to be harmful for the client than the others (type 2).*

***Key words:** Diagnostic, errors, electrodianosis, 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 anamnesis and physical examination. The correct interpretation of electrodiagnostic study results and application of those results clinically requires the electromyographersnot only to have expert knowledgeandexperience of neuroanatomy and of peripheral disorders, but also aboutmany 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 anamnesis 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 aberrations .

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 tolimb temperature,[1] gender,[2] age,[3]body mass index,[4] filters,[5]amplifiers,[6]muscle selection,[7]anomalous innervations (Martin-Gruber, Marinaccicommunication,Riche-Cannieu anastomosis&etc),[8-13] factors related to stimulation [14-18]& electrodes.[19-23]

Although there are lots of data about factors that could lead to pitfalls, but according to our knowledge, clinical burden of Edx errors are 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 groupsin 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 haveglobally least potential harmful effects on the client.Theseeffects could bewaist of golden time to treat,perform unnecessary treatment or surgery, psychiatricadverse effect, missinginsurance 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,betweenOctober 1, 2013 and April 30, 2015.The maximum acceptable time lag between two reports was 3 months. Then we asked 3expertelectromyographers 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 ofEdx 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 electrodiagnosis errors according to their possible adverse effects. We considered typing of errors during medical researches as a template to explain our model.

We found48 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 isusually possible to predict potentially less harmful diagnosis.(Table 1)

Number of impressions there was consensus on	Basic diagnosis was	B diagnosis	A diagnosis	Number of impressions
11	NL	NL	Mild CTS	11
2	NL	NL	Moderate CTS	2
7	Mild CTS	Mild CTS	Moderate CTS	7
1	Mild CTS	Mild CTS	Severe CTS	1
1	Multilevel radiculopathy	Multilevel radiculopathy	MND	3
2	NC			
23	Less severe (or less number) of roots involvement	Less severe (or less number) of roots involvement	Several (or more severe) roots involvement	27
3	Several (or more severe) roots involvement			
1	NC			
11	NL	NL Or not significant	Polyneuropathy	
1	NC	Mild or severe		12
1	NL	NL	Polio	1
1	NC	Polyneuropathy	Myopathy	1
1	NC	Ulnar neuropathy at wrist	Ulnar neuropathy at elbow	1
1	Severe ulnar nerve lesion	Partial ulnar nerve lesion	Severe ulnar nerve lesion	1

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 mostconservative 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[24] (basic diagnosis is considered similar to null hypothesis) as a template for our model so that two types of error are distinguished:

Type I Edxerrors and**type II Edxerrors**
A**type IEdx error**occurs when the basic diagnosisis true, but is rejected or occurrence of misdiagnosis when it is impossible (relatively rare situations) to consider a basic diagnosis for the client.
A**type II Edxerror**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 wantsto be retired) Basic diagnosis in this situation is L5 radiculopathy.(Table 2)
Which of these 2 typesof errors is less acceptable?

Example 2:

A person with chroniclow back pain without neurologicdeficitis a candidatefor laminectomy at the same level. An Edxwas 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 asurgery with some possibility to decrease pain?

Example 3:

Suppose a young lady with hands paresthesis 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 limbsweaknesshas 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 AIDPchild as normal or another diagnosis(lose the opportunity of IVIG) or prescribe IVIG for a non AIDP person?

This reviewindicates 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

Example number	Basic diagnosis	Type 1 error	Type 2 error
Example 1	L5 radiculopathy	Report: Nl Fact: L5 radiculopathy	Report: L5 radiculopathy Fact: Nl client
Example2	Nl	Report: L5 radiculopathy Fact: Nl	Report: Nl Fact: L5 radiculopathy
	Mild L5 radiculopathy	Report: more than mild L5 radiculopathy Fact: mild L5 radiculopathy	Report: mild L5 radiculopathy Fact: more than mild L5 radiculopathy
Example 3	Nl	Report: mild CTS Fact: Nl	Report: Nl Fact: mild CTS
	Mild CTS	Report: moderate or CTS Fact: mild CTS	Report: mild CTS Fact: moderate CTS
	Moderate CTS	Report: Severe CTS Fact: moderate CTS	Report: moderate CTS Fact: severe CTS
Example 4	AIDP	Report: other diagnosis without effective treatment Fact: AIDP	Report: AIDP Fact: other diagnosis with no significant treatment

enough documents during your NCS& EMG, donot change this basic diagnosis in your last interpretation.It was very interesting that all of well-known electromyographer we asked(3 person), toldthat this model is what is exactly they do spontaneously, when there is uncertainty about true diagnosis at the time of decision making.

Table 2: Types of errors in examples 1-4

AIDP: Acute inflammatory demyelinating polyradiculoneuropathy, CTS: Carpal tunnel syndromeNl: normal

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. Itshouldencourage policymakers, healthcareorganizations and researchers to start measuringand reducingelectrodiagnostic errors**.**

The model has some disadvantages. First it could shift the errors to type 2& increase theterritory ofthis type of errors. Anotheris what we actually call type I or type II error depends directly on the basicdiagnosis 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 this situations any misdiagnosis should be considered as type 1.

The main limitation of our study was the number of experts involve 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 wasacandidate for lumbosacral canal stenosis surgery. He hadtwo completely different EDxreports. (ALS & bilateral L4-S1 roots lesion) Two of our electroctromyographers believed that (due to catastrophic psychiatriceffect 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 surgeryon ALS patient)the basicdiagnosis 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 oftype 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 electromyographerin different situationsis agood 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) istolerable& how many percentages of mild CTS patients reported as normal(type 2) is acceptable?

Abbreviations:

AIDP: Acute inflammatory demyelinatig polyradiculoneuropathy, ALS: Amyotrophic lateral sclerosis, CTS: Carpal tunnel syndrome,DDx: Differential diagnoses, EDx:Electrodiagnosis, EMG: Electromyography, IVIG: Intravenous immunoglobulin, NC: No consensus, NCS: Nerve conduction study, NL: Normal

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