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Open Label Studies in PD are Still Useful

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Editorial

We all appreciate conducting studies which can answer a question directly and unambiguously. Such studies may well be possible under the conditions prevailing in a laboratory but only rarely under the everyday contingencies in the clinical treatment of Parkinson's disease which necessarily involve a large number of variables. The course of development of the syndrome can vary in fact quite broadly making the effects or side effects of one treatment strategy in an individual case impossible to predict. Thus, we are directly concerned with probabilities and frequencies. This makes the results of any one study a statistical variable which may not be particularly relevant on a case-by-case basis. To give an example: A publication might well demonstrate that one medication is superior to a placebo with one specifically defined patient population, but this does not exclude the possibility that a particular sub-group, with a unique gene polymorphism, will fail to respond to it at all or will even develop negative effects. In addition, any such defined group is not necessarily representative of the overall collective. Thus, the more a research question can be formulated in a focussed or specific way, the better will its validity turn out. And that is precisely where the problem lies: We should present the results of a study only for the defining group and not for individual persons or even for a sub-group, because these results do not in any way represent the full spectrum of reality. In effect, we are only exchanging a physician bias for the patient bias.

Unfortunately this problem cannot be adequately solved. There just will never be a study that can answer all questions on both the global and the specific levels. We see this situation in meta-analyses which show studies with very similar questions and design still comming up with disparate results. And even these meta-analyses cannot resolve the question precisely and for all time: They merely represent the best evidence we have at the moment. The ultimate goal realizable at the present is still only to collect the most reliable and extensive data. And that is, once again, precisely where a major default can be identified. Real life can only be seen in real life. Controlled studies are artificial and only allow for conclusions on their own artificial subject groupings (under consideration for criteria of inclusion and exclusion). If we insist that we are doing scientific work correctly, then we surely require controlled studies: Double blind parallel-group, placebo-controlled trials are the gold standard for clinical trials. But when we look for long-term experience with a large number of cases, then we need open label studies. And this automatically applies in relation to safety concerns. A good many side effects and interactions can only be documented after a longer time of treatment, which is obviated in controlled studies which have but a brief time window, especially considering the fact that criteria of inclusion and exclusion in controlled studies seriously limit the range of possible observations. For just this reason any number of controlled studies are later extended but under open label conditions.

At the present and probably well into the future, the number of potential controlled studies is by necessity limited. As a case in point, they will rarely include all ethnic groups of interest, but rather involve almost exclusively Caucasian subjects. Because the effort involved and the expenses are constantly increasing, well controlled studies will probably decrease in number over time. And in that case, it is standard conviction that good open studies are better than missing data. But today, according to an internationally accepted codex, monetary reward and academic advancement are very rarely associated with open label studies.

Of course we have to insist on open studies being planned and conducted optimally, as well as being published. We cannot be satisfied with work done merely for marketing reasons intending to boost productivity and sales. The basic truth in this matter lies, as so often, in the middle: We need of course both controlled and open label studies for advancing our research, but the essential criterion for both is that a sense of professionality should guide how we formulate the initial questions, decide on the design, conduct the empirical work, and perform the evaluation. In the final analysis these criteria also hold for operative therapies. The times when fewer requirements were seen as satisfactory for doing invasive work clearly belong to the past. It may well be true that lessening the standards in this way reduced the potential risks for "placebo" groups, but these studies also have a reduced degree in generalization and at the same time immensely increase the possible risks for the patients then.