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Measuring Health-Related Quality of Life

GASTROINTESTINAL HEALTH-RELATED QUALITY OF LIFE ASSESSMENT IN CLINICAL TRIALS

You are listening to ReachMD, The Channel for Medical Professionals. Welcome to GI Insights where we cover the latest clinical issues, trends, and technologies in gastroenterological practice. GI Insight is brought to you by AGA Institute.

Your host for GI Insights is Professor of Medicine at University of Illinois, Chicago, Dr. Jay Goldstein.

Welcome. How are health-related quality of life assessment been incorporated into clinical trials and most importantly everyday practice. Joining us to discuss quality of life, what does it matter and how does it help is Dr. Brennan Spiegel, Assistant Professor of Medicine in the Division of Digestive Diseases at the UCLA School of Medicine and a practicing gastroenterologist in the VA Greater Los Angeles Healthcare System.

DR. JAY GOLDSTEIN:

Welcome Brennan, how are you?

DR. BRENNAN SPIEGEL:

Okay. Thanks for having me.

DR. JAY GOLDSTEIN:

Well, let's get right to the point. it's a pleasure to have you and tell us what is health related quality of life?

DR. BRENNAN SPIEGEL:

This is a concept that's been around really since the 1940s. The World Health Organization in its chartered constitution back in 1948 came across a new definition of health. They said that health is a state of complete physical, mental, and social well being, and not merely the absence of disease or infirmity. So that was revolutionary because it emphasized that health has to do with not only (**01:30**) physiologic health, but also social health and psychological health. So when we think about health-related quality of life with our patients or in clinical trials, we are thinking about biopsychosocial health, all three of those concepts together.

DR. JAY GOLDSTEIN:

Is this easily measured, or better yet, how do we measure this?

DR. BRENNAN SPIEGEL:

Well, it can be tricky. There are a lot of different ways of measuring health-related quality of life. We use instruments and an instrument is just another fancy word for a questionnaire and there are two different kinds of instruments. There are disease targeted instruments and there are generic instruments. So generic instrument is a questionnaire that can be applied generically to any number of different conditions. Classic example is the SF36 that's often used across a lot of different areas within gastroenterology and outside and it has 36 different items and an item is just a question and that can get rolled up into different domains and then there are these disease targeted instruments that are specifically designed for particular conditions so like the IBS-QOL is an example of an instrument that was developed specifically for irritable bowel syndrome.

DR. JAY GOLDSTEIN:

How many of these disease specific monitors do we have?

DR. BRENNAN SPIEGEL:

Oh there are a lot, I mean within the field of gastroenterology, we have disease specific instruments for most of the major conditions. So an IBS-QOL is one of about 5 or 6 that are available for IBS. (**03:00**) In GERD, I recently looked at those, there is at least 15 different instruments that have been created. There is IBD-Q for inflammatory bowel disease. We recently created one for hepatitis B. There is some for hepatitis C. So it's hard for me to even estimate, but I would say at least there is 20 or 30 available just within the field of gastroenterology.

DR. JAY GOLDSTEIN:

Are these being used in clinical trials?

DR. BRENNAN SPIEGEL:

More and more trials are starting to look at patient reported outcomes in general. These are so called PROs or patient reported outcomes and a patient reported outcome is just that it's an outcome that relies upon patient report as opposed to some physiologic measure or biochemical measure, the kind of outcomes that were used to in medicine. health-related quality of life is a subset of patient

reported outcomes and more and more companies are interested in obtaining claims to show that their drug or their intervention improves overall quality of life, not just some physiologic measure like, let's say hemoglobin A1c for diabetics or bowel movement frequency for IBS or CDAI for IBD, but actually show that their drug improves the way patients actually feel from a biopsychosocial standpoint.

DR. JAY GOLDSTEIN:

Are those quality of life measures actually parallel qualitatively or quantitatively, physiologic endpoints that have been traditionally used in clinical trials?

DR. BRENNAN SPIEGEL:

Well, the good ones do and there is a concept out there called validity and I talked about (**04:30**) how there are at least 30 or more endpoints that are available, but not all of them are necessarily good and one of the litmus tests that we use to determine if one of these endpoints is good is whether or not it tracts with the physiologic parameters that we care about. A good quality of life measure should correlate somewhat with the important physiologic measures. Now it's not a perfect correlation by any stretch and that's why we measure them separately, but I would be curious if the physiologic measures go up or get better while quality of life gets worse, that's a little bit unusual, though it can sometimes happen. So the short answer is, they don't always correlate perfectly, but they should track with each other in general.

DR. JAY GOLDSTEIN:

Can you give us an example where physiologically things improve, but quality of life worsens?

DR. BRENNAN SPIEGEL:

There are a lot of examples like that and a good example might be an irritable bowel syndrome. We are trained to ask patients a lot about their bowel movements and what their Bristol Stool Scale is and you know how frequently they have them and you know all sorts of stuff about bowel movements, and we can make someone's bowel movements get better with something like loperamide or Imodium, but the patient may not feel better whatsoever. In fact, may feel worse. So we have many instances where patient's quality of life continues to get worse and worse, although were improving what we think is the important outcome, but patients may value things differently than we value them. We think bowel movement frequency is important (**06:00**). Patients may not care at all because their abdominal pain is still there even though their bowel movement frequency is getting better. So there is an example and IBS is a classic one where there is a disconnect between what we care about and what patients care about.

DR. JAY GOLDSTEIN:

Is the FDA buying this, are they incorporating this, do they want it, will they put it in the label?

DR. BRENNAN SPIEGEL:

Slowly they are coming around to it. It used to be very difficult to get any kind of a claim on the basis of a patient reported outcome, but

more recently there is a group within the FDA that is called the Sealed Group and they are specifically created to look at patient reported outcomes like quality of life and to consider their use in clinical trials. They have come a long way in the FDA and now they are actually, I'd say at the forefront amongst different regulatory agencies across the world in accepting quality of life as a valid and important endpoint for clinical trials. So the important thing for drug companies is to make sure that they follow their guidance and they have developed a document called the PRO Guidance Document. This is a very detailed handbook on how to develop a clinical trial using their rules, using health related quality of life as an endpoint and if a company can follow their rules to the T, the FDA will indeed give them a claim on the basis of quality of life, but that's a lot easier said than done.

DR. JAY GOLDSTEIN:

Do you think there will be a time where quality of life endpoint will trump a physiologic endpoint? (**07:30**)

DR. BRENNAN SPIEGEL:

Yeah, I suppose. It depends on your perspective. For a patient's perspective and they may not care at all what their physiologic parameters are looking like if they are not feeling well. So if the major stakeholders are patients which really it is, we have an additional responsibility to our patients to make them feel better. For using that perspective, health-related quality of life may often trump the physiologic parameters that we are accustomed to follow.

If you are just tuning in, you are listening to GI Insights on ReachMD XM160, The Channel for Medical Professionals. I am your host Dr. Jay Goldstein, and joining me to discuss quality of life – what does it measure and how does it help is Dr. Brennan Spiegel, Assistant Professor of Medicine in the Division of Digestive Diseases at UCLA School of Medicine and a practicing gastroenterologist at the VA Greater Los Angeles Healthcare System.

DR. JAY GOLDSTEIN:

Well, let's go back to quality of life here for a second and ask a very simple question. Can this actually be incorporated in day-to-day practice and used as a measure of success or failure by a practicing physician?

DR. BRENNAN SPIEGEL:

It can and it has been used in everyday clinical practice, but it's a little easier said than done. So earlier I was talking about the SF36 and this is a questionnaire that has 36 items so you can imagine how difficult it would be for a patient to sit around in a waiting room, filling out a questionnaire with 36 items and then having a nurse (**09:00**) or someone else score this and then give it to the physician. This is something that's going to take too much time to be tenable in regular clinical practice. So there have been other instruments that have been created specifically for use in everyday clinical practice that are short and easy to fill out and create an index, a number that could be put on an intake sheet, almost like a vital sign. So the idea is to use quality of life like a vital signs so you can see where your patient is today and compare it to where your patient was on the last clinic visit and see if their quality of life has improved over time. If their quality of life is getting worse, it might mean that you are not serving the patient well and you need to think about changing which you are doing. That's the theory of how to do this, but the reality is that it's frequently not done, so we need to come up with better ways to penetrate this into everyday clinical practice.

DR. JAY GOLDSTEIN:

Well, how does one know that if there is a change in the score that it's a significant change and it's meaningful?

DR. BRENNAN SPIEGEL:

That's a great question because there is a big difference between statistically significant and clinically relevant. This is a big issue that the FDA looks at also when designing clinical trials. So there is something called the MCID which just stands for minimally clinically important difference and this is a number that could be used like a yardstick to lay over changed scores over time and see if someone has exceeded this or not exceeded it. So as an example, the IBS-QOL (**10:30**) is an instrument that's been developed for irritable bowel syndrome and on that scale if someone gets better by 10 points overtime, that's considered to be at least minimally important. If the patient exceeds that, it's important, if they don't exceed that amount, it's probably not really clinically relevant. So you can look at your patient and if they come in with a 70 and the last time they were in clinic, it was a 50, they got better by 20 points, higher is better, and you can say to the patient looks like you are feeling better according to this instrument or as if they had only gotten better by 5 points, it probably isn't clinically important and is within the margin of error.

DR. JAY GOLDSTEIN:

Well I want to thank you for convincing our audience here today that there is a level of objectivity to measurement of quality of life and its incorporation into clinical care and in clinical research. I think you have been at the forefront of this issue over the last several years and we look forward to having you back here in the future. I would like to thank you for being my guest from the UCLA School of Medicine, Dr. Brennan Spiegel. Dr. Spiegel, thank you very much for being here on GI Insights.

DR. BRENNAN SPIEGEL:

Thanks so much for having me.

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