Evidence-Based Medicine with Drug-Eluting Stents

This monthly column in Cath Lab Digest reviews important points of distinction in drug-eluting stents, from characteristics to techniques, to provide valuable and relevant information about this technology.

By Dr. Sigmund Silber

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What is evidence-based medicine?

In my opinion, evidence-based medicine is the treatment of patients according to current knowledge, that is, evidence from major studies. Due to the large number of exclusion criteria in most of these studies, you will probably not be able to treat the majority of your patients according to evidence-based medicine. Evidence-based medicine can only be applied if your patient is similar to those who have been studied in these trials.

How do you assess evidence?

The first question you have to answer when applying evidence-based medicine is, what is the primary goal? Do I want to make the patient feel better, or do I want to treat a surrogate parameter? A surrogate parameter substitutes for a clinical endpoint. In other words, it provides an indication of how well a treatment may affect clinical endpoints such as mortality. Most studies use surrogate parameters, not primary clinical endpoints, because surrogate endpoint studies are smaller and more cost-effective. But with a small, underpowered study, you have a higher likelihood of arriving at the wrong conclusion. For example, in Europe, many drug-eluting stent (DES) trials are small, with only 20 to 25 patients. A stent may be approved based on these studies.

A study that has a primary clinical endpoint is powered to evaluate whether a patient feels better or not. For these larger trials, important points to note are whether the study is double-blinded and the timeframe of the primary endpoint. Effects of DES also occur after nine months, so longer observation periods are needed. Studies like TAXUS, SIRIUS and ENDEAVOR are examples of good trials.

What happens if you have too little data?

You have a higher chance of being wrong. Meta-analyses attempt to compensate for this, but if you have many small, underpowered studies that lead to wrong conclusions, putting them together does not make them better. I think meta-analyses are good for generating a hypothesis, but then the hypothesis must be proven in a large, randomized clinical trial.

What is the Silber score and why did you develop it?

The Silber score (Figure 1) is my suggestion for a better evidence-based medicine scoring system. It’s not perfect, but it’s a very nice tool to stimulate the discussion. I developed the Silber score because I feel that the traditional systems for proving a hypothesis generating rather than hypothesis proving.

Figure 1. The Silber score.

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For more information on the Silber score, visit the Evidence Based Medicine Center (EBM) on www.tctmd.com, which is made possible by support from Boston Scientific Corporation. EBM was developed to help physicians evaluate the strength of evidence from the currently available clinical studies and initiate discussion about how to interpret such evidence.