Researchers Offer New Framework To Improve Safety, Effectiveness Of Surgical Procedures

An international team of investigators co-led by Weill Cornell Medical College is offering a new framework for evidence-based surgery and device research, similar to the kind of risk and benefit analysis used in evidence-based medicine.

"Currently, there is no dynamic research framework to systematically detect devices and surgeries that don't offer any benefits to patients or may even be harmful," says co-lead investigator Dr. Art Sedrakyan of Weill Cornell Medical College.

In the June 18 issue of the *British Medical Journal* (*BMJ*), Dr. Sedrakyan and his colleagues suggest ways that clinical trials, observational databases and registries can be used to provide quality assessment and surveillance of both surgery and the use of implanted medical devices.

"The failure to conduct methodologically rigorous studies has led to some devices/surgical interventions, such as metal-on-metal hip implants or robotic surgery, becoming popular without high quality supporting evidence," says Dr. Sedrakyan, associate professor of public health and cardiothoracic surgery at Weill Cornell. Dr. Sedrakyan worked with a team of researchers from the United Kingdom, and U.S. Food and Drug Administration (FDA) who are part of the IDEAL (Idea, Development, Exploration, Assessment, Long-term follow-up) Collaboration. This group is working on ways to improve research in surgery and on medical devices as a way to spur surgical excellence, as well as innovation.

At Weill Cornell Medical College, Dr. Sedrakyan leads the Medical Device Epidemiology Network's Science and Infrastructure Center, one of two FDA-funded centers in the country that evaluates medical devices, especially implantable devices. He is the vice-chair of the IDEAL Collaboration advancing device evaluation and, prior to joining Weill Cornell, has worked on post-market surveillance and modernization surveillance at the FDA.

Regulatory agencies in a number of countries, and surgeons themselves, are now seeking ways to address the current lack of evidence-based research in surgery and device fields, Dr. Sedrakyan says.

"We have to recognize that not every surgical procedure that is offered is as safe and effective as we thought and so these techniques need to be evaluated," Dr. Sedrakyan says. "In addition, new innovative research methods need to be developed that are quite different than those used for the evaluation of pharmaceuticals."

Research in Surgery

Unlike the way drugs are tested, it isn't easy to conduct randomized clinical trials in surgery.

For example, if medical investigators want to know if an experimental cancer drug is more effective than an agent being used in the clinic, they test the new drug against the old one in a randomized clinical trial. Randomly assigned patients use the new drug or old drug.

However, when surgeons are trained to perform a specific kind of operation or have a preference for a particular technique they can't be easily asked to conduct an alternative surgery or apply a different technique so that new and old methods can be compared in a randomized clinical trial. On top of that, there is a variation in the choice of medical devices.

"Historically, the focus of government-funded research has been on pharmaceuticals and often not surgical/device interventions, which has been limited as a consequence. Drugs have certainly dominated the agenda," says Dr. Sedrakyan.

But in their new study, researchers point out that there are methodological ways to use available data that will allow a researcher to compare the safety and effectiveness of different surgical techniques and devices. One method, highlighted in the study, involves the right way to scrutinize observational data that has already been collected within registries or other observational data sources. The study also suggests ways that clinical trials can be conducted in surgery and in the field of implantable devices.

"Our framework can potentially be used by agencies to guide regulatory science related to implantable devices. We can look at the performance of surgery and devices by recognizing the unique aspects of specific types of surgery and by developing robust new methods," says Dr. Sedrakyan.

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