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No convincing evidence to support use of new hip and knee implants

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Several new and widely used hip and knee implants appear to have no clinically relevant improved benefits compared with older, more established implants, according to a review of the evidence published in *BMJ* today.

Furthermore, the safety of several new technologies "could be compromised," warn the researchers, who call for improved stakeholder oversight to prevent patients from being further exposed to new devices "without proper evidence of improved clinical benefits and safety."

Since the failures of some metal on metal hip implants were brought to light, the introduction of new joint implants has been the focus of major scientific and policy discussions.

An International research team, led by Art Sedrakyan, Associate Professor at Weill Cornell Medical College in New York, argues that the momentum for change generated by these recent high profile failures is important and there is an urgent need to evaluate the evidence for introducing new implants.

Working with the US Food and Drug Administration (FDA), they reviewed the evidence for five recently introduced and widely used implantable devices for total joint replacement surgery.

Data from clinical trials and observational studies involving 15,384 implants in 13,164 patients and data from national joint registries were

used to compare safety and effectiveness over existing, well-proven and comparable devices for the same condition.

After study design and quality were taken into account, none of the five device innovations was found to improve functional or patient-reported outcomes. Comparative data with well-established alternative devices (over 1.2 million implants in registries) did not show improved device survival.

The researchers also found higher rates of repeat surgery (revisions) associated with three of the new devices, used in both hip and knee replacement surgery.

"We did not find convincing high-quality evidence supporting the use of five substantial, well-known and already implemented device innovations in orthopaedics," they say. "Furthermore, none of these five technologies were found to be safer or to have better survival compared to the established implants."

This indicates that new technologies "are being introduced to the commercial market without sufficient high-quality evidence for improved benefit over existing, well-proven and safe but equally suitable alternative implant solutions," they argue.

They call for improved stakeholder oversight "to prevent patients from being further exposed to these or future innovations introduced without proper evidence of improved clinical efficacy and safety."

These data "shine a light on the limited regulatory oversight that exists in Europe, the US, and other countries regarding incremental device innovations," write researchers at Brigham and Women's Hospital and Harvard Medical School, Boston, in an accompanying editorial.

They support the study authors' recommendation for controlled introduction of new versions of medical devices "so that they are not used widely until there is more clarity about their comparative effectiveness and safety." They also call for better communication of the benefits and risks of new technology to patents "to inform their health care decision-making."

They conclude: "Reforms that provide for more robust post-market oversight of incremental innovations in medical device technologies will be key in helping to promote more rational use of these products."

More information: www.bmj.com/cgi/doi/10.1136/bmj.g5133
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