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Where Is Consumer Reports When We Need It? A Clinician's View of Surgical Innovation

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Commentary

Some surgical innovations are no-brainers. No randomized clinical trial was needed when Ann Miller awoke from her puerperal sepsis after an ''off-label'' injection of penicillin. The Institutional Review Board did not complain when Harvey Cushing, after a bloody initial foray, successfully resected a hypervascular parietal tumor using William T. Bovie's new electrodesiccator.[1] When Reuben Setliff showed a short lunchtime video of nasal polyp removal with an orthopedic microdebrider, a crowd of excited otolaryngologists poured from the lobby into the lecture hall to see something really new and better.

These remarkable innovations contrast with the bulk of new product offerings.[2] In their rush to fame and fortune, surgeons and instrument manufacturers often cooperate to bring products to market and clinical use with less attention to efficacy and safety than what patients have a right to expect. While some widely touted devices and techniques have found a place in clinical practice (electric temporal bone drills, operating microscopes), others have proved expensive alternatives with little demonstrable benefit (coblation tonsillectomy,[3] laser myringotomy[4]). Still others were downright lethal (silicone injection, argon beam coagulator tonsillectomy[5]).

If only the world of medical devices resembled that of consumer goods. The federal government runs the Consumer Product Safety Commission as a watchdog for defective toys, cribs, and electrical devices. UL (formerly, Underwriters Laboratory) is an independent insurance industry–sponsored safety science company that tests and monitors new consumer devices. And then there's Consumers Reports, ''the largest, most trusted independent product testing organization in the world.'' It is a nonprofit organization that accepts no advertising and provides unbiased reports on thousands of products annually.

Instead, we in medicine get the Food and Drug Administration, which clears 99% of new devices as 510(k) exceptions without proof of safety or efficacy. We get the Centers for Medicare and Medicaid Services, which is prohibited by law from using its market clout to negotiate for competitive pricing.[6] We get industry-sponsored trials that are often statistically underpowered by design to demonstrate the ''noninferiority'' of a new product, rather than assessing its true worth.[7] Independent, evidence-based efforts such as the Cochrane Collaboration scrutinize the existing literature but too often leave us with ''At present there is no convincing evidence supporting the use of endoscopic balloon sinus ostial dilation. . . . There is an urgent need for more randomised controlled trials.''[8]

What's a clinician to do? First, resist the urge to be the ''first on the block'' to use a new product. If a new device proves defective or worthless, case reports generally take a year or two to percolate through the system. Second, ''if it ain't broke, don't fix it.'' If you have a satisfactory, time-tested approach to a problem, resist the seductive sirens of journal advertisements and equipment representatives and do what is sensible. Third, know if it is broken. The AAO-HNS guidelines for pediatric tonsillectomy wisely advise ''that clinicians who perform tonsillectomy determine their rate of primary and secondary posttonsillectomy hemorrhage at least annually.''[9] Finally, if you know it's broken, don't be afraid to fix it. Be alert for new techniques and devices that address inadequacies in surgical practice. Do not be afraid to change when confronted by new or evolving challenges. But do so in a careful, thoughtful, ethical, and collaborative fashion.[10] Share your doubts and a procedure's potential risks with your patients. Be true to yourself in evaluating the results of innovative treatment.

Author Contributions

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