Safety, standardization, and surgical innovation: lessons from the development of sentinel node biopsy in gynecologic oncology

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It is 25 years since sentinel lymph node biopsy was introduced into the care of women with vulvar cancer.[1] Congratulations to Moloney and co-authors for taking an analytic approach to standardizing sentinel lymph node biopsy in the management of endometrial cancer.[2] They enrolled credible gynecologic oncologists from around the world into a structured process to explore their management strategies and surgical preferences. The process results in a detailed description of exactly what is lymphatic mapping and sentinel lymph node biopsy in women with endometrial cancer. This work is another important step towards realizing a long-held goal of mine to eliminate regional lymphadenectomy from the staging of gynecologic cancers.

The importance of standardizing new surgical procedures cannot be overstated. It is best if new procedures are not introduced into the operating room—especially when they involve new medical devices—until surgeons and other operating room professionals can reach agreement that it is safe to do so.[3]

The development of sentinel lymph node biopsy in vulvar cancer is illustrative. In 1979 Di Saia et al[4] suggested that superficial inguinal lymph nodes were the 'sentinel nodes' of the vulva based on their location, not on a mapping procedure. Gynecologic oncologists were quick to adopt superficial inguinal lymphadenectomy, even though it was based on a faulty understanding of earlier work by Ramon Cabanas in patients with penile cancer. It soon became clear that the results of Di Saia et al could not be replicated and there was no consensus on exactly what 'superficial inguinal lymphadenectomy' meant.[5] In 1992 the modern sentinel node procedure was described by Morton et al.[6] Lymphatic mapping and sentinel node biopsy were studied in GOG 173[7] and GROINS V.[8] The procedure was validated; however, in both studies there were failures that could be linked to poor technique or inexperience.

Just giving a procedure a name for publication, professional communication, and billing purposes does not mean all surgeons are actually following the same steps and are getting similar outcomes. Moloney and colleagues are making an enormous contribution to the quality and safety of sentinel lymph node biopsy with this painstaking work.

As surgical care hurtles forward into the future with new devices and procedures, our goal should be to prospectively do what Moloney and colleagues have done retrospectively. Repeatedly high reliability organizations demonstrate that deviations from standardized safety procedures based on individual preferences increase the risk of harm. Would you fly with a pilot who does not use a pre-flight checklist repeatedly validated in simulators? Would you choose a surgeon for endometrial cancer who has not read and followed the recommendations of Moloney and co-authors?

The future of surgery is to similarly use simulators and non-surgical safety experts to test new procedures and devices before bringing them to the operating room. We should be far past the days of learning new procedures on patients. We should not accept a spike in complications with a new procedure or device. Seniority, reputation, and organizational titles are not replacements for mandatory training and retraining requirements. To bring us closer to our sworn duty to "first do no harm", let us find ways to make our procedures as reliable as possible before they become standard care for the patients who trust us with their lives.

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