The term "evidence-based medicine" was first coined by Sackett and colleagues[1] as "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients." The key to practicing evidence-based medicine is applying the best current knowledge to decisions in individual patients. Medical knowledge is continually and rapidly expanding and it is impossible for an individual clinician to read all the medical literature. For clinicians to practice evidence-based medicine, they must have the skills to read and interpret the medical literature so that they can determine the validity, reliability, credibility and utility of individual articles. These skills are known as critical appraisal skills. Generally, critical appraisal requires that the clinician have some knowledge of biostatistics, clinical epidemiology, decision analysis and economics as well as clinical knowledge.

The Canadian Association of General Surgeons and the American College of Surgeons jointly sponsors a program entitled "Evidence-Based Reviews in Surgery (EBRS)," supported by an educational grant from Ethicon Inc and Ethicon Endo Surgery Inc. The primary objective of this initiative is to help practicing surgeons improve their critical appraisal skills. During the academic year, eight clinical articles are chosen for review and discussion. They are selected not only for their clinical relevance to general surgeons but also because they cover a spectrum of issues important to surgeons; examples of issues are causation or risk factors for disease, natural history or prognosis of disease, how to quantify disease (measurement issues), diagnostic tests and the diagnosis of disease, and the effectiveness of treatments. Both methodologic and clinical reviews of the article are performed by experts in the relevant areas and posted on the EBRS website. A listserve discussion is held where participants can discuss the monthly article. Fellows and candidates of the College can access Evidence-Based Reviews in Surgery through the American College of Surgeons website (www.facs.org).

All journal articles and reviews are available electronically through the website. Currently we have a library of 40 articles and reviews which can be accessed at any time. Beginning in October, a new set of articles will be available each month until May ONLINE. Surgeons who participate in the current (modules) packages can receive CME credits by completing a series of MCQ. For further information about EBRS the reader is directed to the ACS website or should email the administrator, Marg McKenzie at mmckenzie@mtsinai.on.ca.

In addition to making the reviews available through the ACS and CAGS websites, four of the reviews are published in condensed versions in the *Canadian Journal of Surgery* and another five will be published in the *Journal of the American College of Surgeons* each year.

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SELECTED ARTICLE

Prerandomization Surgical Training for the National Surgical Adjuvant Breast and Bowel Project (NSABP) B-32 Trial. A Randomized Phase III Clinical Trial to Compare Sentinel Node Resection to Conventional Axillary Dissection in Clinically Node-Negative Breast Cancer

Harlow SP, Krag DN, Julian TB, et al. Ann Surg 2005;241(1):48–54.

Reviewed by

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ABSTRACT

Objective: To train surgeons in a standardized technique of sentinel lymph node biopsy and educate them in complete and accurate data collection and source documentation.

Participants: Surgeons from centers throughout the US participating in the NSABP B-32 trial.

Educational Intervention: A training and quality-control program was established for surgeon entry into the NSABP trial. The program focused both on performance of the SNB procedure as well as the methods of recording data and generating source documentation accurately and completely. It consisted of (1) a training manual, (2) site visit by a core group of surgeons where a

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Published by Elsevier Inc.

ISSN 1072-7515/07/$32.00
doi:10.1016/j.jamcollsurg.2007.01.042

intra-operative instruction to the practicing surgeons was given and (3) follow-up of 5 pre-randomization sentinel lymph node procedures.

Outcome Assessment: (1) Success at identifying sentinel nodes; (2) compliance with the protocol and documentation.

Results: Of the 226 registered surgeons, 187 surgeons completed training and were approved to randomize patients in the trial. In 815 cases, the success rate of identifying the sentinel node was 96.2%, with a false negative rate of 6.7%. Compliance with the protocol was 98.6% for procedures, 95.0% for source documentation and 95.5% for data entry.

Conclusions: This training and quality control programs resulted in a large number of surgeons capable of performing sentinel lymph node biopsy in a standardized fashion with a high percentage of protocol compliance and pathologic accuracy.

Commentary: This article reports on the pre-randomization training prior to surgeons enrolling patients in a surgical trial (NASBP B-32).[1] This pre-randomization training was to serve not only as training for the surgeons, but also in part to ensure standardization of the technique for the patients entered on the study. Two-hundred-twenty-six surgeons initially registered to be trained. Of those, 187 (83%) completed the training and these are the surgeons for whom the data are presented. The training process consisted of many detailed steps. Prior to randomizing any patients in the trial, the surgeon had to review the training manual, undergo a site visit and have follow-up of five prerandomization sentinel node biopsy procedures. Specifically, after registration surgeons were provided with a detailed training manual and a core trainer was assigned. The training manual included the protocol, material detailing the "critical steps" of sentinel lymph node biopsy, a pathology section on the processing of the nodes and sample forms and instructions as to their completion. During the site visit, the core trainer provided perioperative instruction to the surgeon and non-surgeon members of the team including detailed guidance as to the procedure itself and the completion of the study forms. The five training cases were performed, forms completed and data reviewed at the study center as well as by the core trainer. The cases were evaluated for protocol compliance, source documentation and accuracy. In the first six months of the study, the five cases were batched and reviewed together. After the first six months, the case forms were completed, submitted and reviewed as the cases were done and feedback was immediately given to the surgeon. After completion of all five training cases, the cases were reviewed in detail over the phone by the core trainer and the surgeon. The surgeon could then start entering patients into the study. Surgeon proficiency was assessed by success rate for identifying sentinel nodes, and false negative rate. Success of the type of review process (batched or immediate) was measured by determining the percentage of surgeons that were successfully approved to randomize after completing the minimum number of training cases. Protocol compliance was measured by evaluation of 94 potential fields divided into three groups: procedural, source documentation, and data entry. They found that surgeons who received batched feedback were much less likely to successfully complete the training process within the first five cases than those who had feedback after each of the first five cases (48% vs. 80%).

The authors are to be commended for including a pre-randomization training requirement with measurable goals. This step, as discussed by the authors, is often missing in surgical trials, despite knowledge of quality variability in surgery.

The weaknesses of the study are that the characteristics of the surgeons entering the trial are unclear. The literature on SLNB learning curves suggest 20–60 cases are required for proficiency.[2-4] Thus, were the majority of surgeons already familiar with the techniques? One would assume so, because the learning curve was a relatively short 5 cases, with, only one case being preceptored. As SLNB also likely has an institutional learning curve, characteristics of the participating institutions would also be helpful information. Finally, no information on the trainers themselves was available, such as their performance data, and how they were trained.

This missing information may make it difficult to generalize these results but also, for those of us interested in teaching surgical techniques, the study provides an incomplete framework. Based on the relatively short learning curve in this study, it may be that rather than "surgical training," the surgeons participating in this trial were being trained on standardization of a technique they already knew, and on data collection for the

purposes of the trial. This is obviously still an important step for quality control in performing a surgical trial, but generalizing the training to a large cohort of practicing surgeons unfamiliar with a technique, and assuming similar results may be problematic.

The issue of how to best teach practicing surgeons new techniques is a difficult one, which has, as outlined in Rogers et al,[5] not been well addressed by surgical educators or professional bodies. But drawing on the Continuing Medical Education literature and guidelines developed by groups such as (Society of American Gastrointestinal Endoscopic Surgeons), components of an education program that are likely to be effective for training surgical techniques would include:

1. knowledge of the technique, its indications and contraindications
2. skills education which is simulation based
3. preceptorship/mentorship in one's own practice setting
4. audit of practice
5. continuing education in the area

The NSABP trial training process incorporated all five steps. Although not reported as part of the training manuscript, the trial included audits of every operative report and feedback to the surgeon on missing data and deviations from the 94 step standardized process.

It is important to look at how these training results translate into actual trial performance. For example, in the NSABP initial report of the B32 trial at the San Antonio Breast Cancer Symposium, the false negative rate in the trial after surgeons were certified was 9.7% compared with 6.7% for the training cases, while the identification rate was 97%, similar to the training case rate of 96.3%.[6]

It is possible that incorporation of all the steps was at least in part why this study was very successful in truncating the learning curve of participating surgeons. It is also possible that the surgeons were only learning a new technique that built on years of experience. Although the demographics and prior experience level of the surgeons in sentinel node biopsy or in axillary dissection was not reported, it would not be unreasonable to assume that the interested surgeons were more experienced than the "average" general surgeon in the area of breast and/or axillary surgery. Just as patients who agree to participate in clinical trials are inherently different, surgeons who agree to participate are inherently different. To participate in this trial, the surgeon had to be willing to follow a very detailed, step-by-step standardized process with real-time review of all records, even beyond the training period. The willingness of the surgeon to undergo such scrutiny of his or her procedures in itself sets this group apart.

The area of education for effective and safe implementation of new techniques in surgery is in the early stages of its evolution, and many of the challenges are only starting to be addressed. But by taking each component of implementation of innovation, and addressing the issues one step at a time, surgical educators will meet the challenges, enhancing safe and effective patient care.

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