AMERICAN COLLEGE OF SURGEONS ONCOLOGY GROUP

DEPARTMENT OF SURGERY
DUKE UNIVERSITY MEDICAL CENTER

CENTER FOR CLINICAL TRIALS
AND EVIDENCE BASED MEDICINE

Summary of the Educational Program Conducted by the American College of Surgeons Oncology Group with Support from the Foundation for Advanced Medical Education

Rectal Cancer Skills Optimization Program and Mentored Breast Sentinel Lymph Node Program

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Surgical Oncologists are continually working to develop targeted, accurate and minimally invasive surgical therapies for the treatment of patients with solid tumor malignancies. The ideal process for disseminating new technological procedures or operations into clinical practice has yet to be defined. Although surgical educators have devised an excellent process for "training' surgical house officers in a broad range of diagnostic and therapeutic procedures, the area of continuing medical education, for graduate surgeons in active practice has been woefully inadequate. Currently, there is no standard process whereby a practicing surgeon can acquire the skills necessary to be proficient in the performance of a new operative procedure, the use of a new technology or the use of a new device. The surgeon wishing to learn how to use a new device usually attends one or two courses offered by experts in the field or by the companies who developed the device. The courses may consist of didactic course work or a practical experience. Upon completing the course, the surgeon usually receives a document stating that he or she has successfully completed the course. The credentialing board of the institution where the surgeon practices may ask him or her to perform a certain number of cases with a mentor. This mentoring

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process, and subsequent peer-review evaluation, is not standardized nationally and there is no oversight by any educational, professional or credentialing body.

Recently the technique of laparoscopic surgery has served as the model of an on-site preceptor and mini-fellowship program, designed to educate the practicing surgeon in how to perform a new surgical technique. What has not been fully described, is the effect of a standardized didactic program, developed by a group of experts in the field with subsequent surgical mentoring by the experts, on the performance of a learned technique by the surgeon performing a novel therapy or method.

The American College of Surgeons Oncology Group (ACOSOG) and the Foundation for Advanced Medical Education (FAME) developed a skills education program to evaluate the optimal methodology for dissemination of new surgical technology or standardization of an established operative procedure. As clinical trials developed by ACOSOG and the National Cancer Institute (NCI) are introduced an efficient and reliable method for educating surgeons to perform a new technique or a standard operation (with which they are inexpert) is necessary to assure uniformity of performance of a procedure by trial participants. We developed two educational programs and recently completed them. We sought to evaluate the effect of combining a didactic program and surgeon mentoring for optimal skills acquisition and dissemination.

The first program, under the direction of Dr Alfred Cohen, Director of the Markey Cancer Center at the University of Kentucky Medical Center, evaluated the optimal methodology for teaching surgeons to perform a Total Mesorectal Excision (TME) for Rectal Carcinoma. The TME procedure requires precise dissection in a plane outside the visceral fascia that envelops the rectum

and its mesentery. In contrast to conventional blunt dissection techniques, the envelope encompassing the pelvic tissue is removed intact, without the risk of mesorectal or rectal perforation. Several institutions outside the United States have reported local recurrence rates less than 7% with the use of TME. As only retrospective and prospective studies have been performed to date, the TME Skills Optimization program developed by ACOSOG was designed to identify the ideal method for disseminating the TME procedure to non-colorectal trained surgeons, with potential eventual development of a randomized clinical trial evaluating optimal treatment for the rectal cancer patient. The program's hypothesis states that completion of a didactic program with cognitive testing and subsequent mentor evaluation of a TME on-site will improve the student's anatomical understanding of rectal carcinoma and improve performance of the technique. Through development of the didactic course, the program's leaders evaluated and described a standard technique for the operation which was disseminated via varied media. Results for the program are described below:

1. Fifteen leaders in the field of colo-rectal surgery developed, over a 6-month period, a standard TME operation, based on review of the literature and their personal experience. A standard pathological assessment of the operative specimen was described as well. A Global Rating Scale for operative performance of a TME, Overall Operative Performance and Skills Checklist were developed for surgeon assessment.
2. Sixteen surgeons who did not complete a colo-rectal fellowship attended the didactic course which included a laboratory utilizing pro-section dissection to describe the pertinent rectal anatomy

3. A cognitive assessment test was developed and administered prior to the course and at the course's completion. The average score for the 16 students improved from 79% on the pre-test to 83% on the post-course test.
4. A thorough assessment of the student's experience with the didactic course was obtained. Using a 1-5 assessment scale, with a rating of 5 being the optimal education experience, the students rated the courses technical demonstration at 4.2 and the level of mentor instruction at 4.4. The overall rating for the course was excellent from 87% of the student participants. Student survey 2 years following the course identified an increase in value for the course with a final rating score of 4.83.
5. The second component of the course involved on-site observation of an expert performing a TME operation. Fifteen (94%) students traveled to a mentor surgeon's institution to observe a TME operation. On a 1-5 rating scale, the student's reported an average score of 4.1 for this component of the educational program.
6. The third component of the program involved mentor assessment of the student with the 3 rating scales. Originally, this component was to be accomplished through mentor review of 3 videos provided by the student of TME operations. This assessment tool was abandoned due to the difficulty with the video acquisition and review. The mentor survey at the program completion reflected the difficulty in utilizing this technology for surgeon assessment. The mentor average impression for this aspect of the program on a 1-5 scale was 1.86 with a score of 1 representing a score of "not valuable". As a result, the program was altered to include on-site mentor assessment of the student during a TME operation. Nine or 56% of the students completed this portion of the program. Student failure for this component of the program was due to surgeon disabilities, difficulty with mentor credentialing at student institutions and student volume of

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rectal cancer cases. Each of the participants in this component of the educational program received a score greater than 80% on the skills checklist and a score greater than 3 on the Global Rating Scales. The score of 3 reflecting competency with the procedure. The one surgeon who had a second evaluation of a TME surgery improved his score from 81% to 100% on the TME operative skills checklist. The student's evaluation of this component of the program was a 4.0 on a 1-5 scale, while the mentor's average score for this component was 4.6.

The second program developed by ACOSOG and FAME to evaluate a standardized didactic program and surgical mentoring evaluated the optimal educational program for breast sentinel node (SLN) technology. Unlike the introduction of any prior new technique in recent surgical history, the dissemination of breast sentinel node mapping has undergone intense review via single and multi-institutional registries to define the "optimal surgeon experience". The novice is no longer advised to "see one, do one, teach one", rather they are encouraged to see one, do twenty five and then teach one. Breast carcinoma is a prevalent disease where women are treated at both low and high volume hospitals and at urban and rural locations. A low-volume general surgeon may not evaluate 25 breast cancer cases in 1 year, thereby decreasing their ability to acquire the technology and skills to perform a sentinel node procedure. As sentinel node technology becomes standard in the oncologic community and is applied to additional solid malignancies other than breast and melanoma, the "refined" technique and instructional methods required to teach this technique become more important.

Similarly to the TME education program, the SLN skills education program was developed with the hypothesis that a standardized didactic program and on-site expert mentoring will improve surgeon

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knowledge of the breast and axillary anatomy and decrease the learning curve required to achieve mastery of the technique. Previously, the literature and oncologic community has defined the "mastery" of SLN technology as a SLN identification rate of >85% and a false negative rate of <15%. In this educational program, where a large number of surgeons are required to prove statistical significance if identification and false negative rates are utilized, an alternative approach for mastery was chosen through use of a SLN skills checklist and on-site mentoring with follow-up intraoperative student testing. As described for the TME program, a didactic course was chosen with instruction on standard operative procedure. Students were exposed via multiple media venues to live surgical procedures and interactive dialogue with the operating surgeon. An animal laboratory facilitated hands-on evaluation of the SLN technique. Preliminary results for this program are described below:

1. Twenty general surgeons with minimal or no experience with SLN technology attended a didactic program developed by a panel of 14 breast cancer surgeons with experience of greater than 100 SLN operations each. Multi-disciplinary training was included for each surgeon's pathologist or nuclear medicine physician if they had no experience with SLN technology
2. Cognitive assessment regarding the key components of the technique and its appropriate application to the breast cancer patient was performed. The mean pre-course test score was 76% with improvement to 89% on post-course written testing.
3. The second component to this educational program was on-site mentoring for the individual students. Each student was paired with one of the expert mentors and arrangements made for individual instruction at the student's institution. Continuing Medical Education (CME) credits were given to the students for mentored instruction. CME was obtained and

approved by the American College of Surgeons and American Medical Association. Each student had to perform 3-5 SLN cases with completion axillary node dissection prior to on-site mentoring. Information regarding the false negative rate and identification rate for these cases was obtained from the students. The mentors received credentials to assist the student surgeon during the SLN operation. Twelve (60%) of the 20 students completed the on-site mentoring. Problems sited for failure to complete this component of the program were surgeon disability, credentialing difficulties with remote, rural hospitals, surgeon failure to see more than 3 breast cancer cases in 6 months and inability to purchase the required device for radioactive node identification. Average skills task list score for these surgeons was 96%. The false negative rate for the 4 -6 cases performed by these surgeons ranged from 0-33%. The identification rate was 98%.

4. The third component of this educational program involved on-site testing by the mentor of the student surgeons. Prior to testing, each student had to perform 3-5 additional SLN cases with completion axillary node dissection. Testing involved mentor observation of the student during a complete SLN operation. Eleven of the 12 surgeons who had been mentored completed this evaluation by one of the expert panel members. Only 1 of the 11, or 9% of the student surgeons did not achieve a score of 100% on the skills assessment. None of the 11 surgeons had a false negative SLN case in the post-mentored cases. The SLN identification rate was 100% for this cohort of mentored and tested surgeons.
5. Final student and mentor evaluation of the program is pending.

In summary, two educational programs providing instruction on two different techniques were developed and implemented by a panel of surgical experts convened by ACOSOG . Each program,

upon final analysis, has shown benefit for the development of a standardized operative technique and didactic course with follow-up on-site mentoring. Through the use of skills assessment evaluation and checklists, the student surgeons can be accurately compared and their competency evaluated. Though these on-site evaluation and checklists cannot replace long-term surgical outcome assessment, they facilitate the development of a standardized educational program for new surgical technology, utilized either in a clinical trial or routine operative practice.

The difficulties encountered were primarily related to the practical problems of scheduling the onsite educational and mentoring programs. It was the feeling of the preceptors of both educational programs that such impracticalities could be overcome with improved organization and centralization of the practical aspect of the educational program.

Respectively submittetd,

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