

Case Study #17: Surgery for Breast Cancer

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INTRODUCTION

Review of the best evidence leads to the conclusion that radical mastectomy is rarely if ever justified for the treatment of breast cancer. Less extensive surgery is as beneficial and less costly.

These assertions are likely to provoke irritation, and what follows in this case study has not pleased several of the reviewers of an earlier draft. Consider the individual parts of that initial sentence again. What is “the best evidence?” Randomized clinical trials are considered the best technique for evaluation in clinical medicine, but they are not the only source of evidence. How, for example, should longstanding professional-expert opinion be weighed? Although statisticians will be comfortable in voting for evidence from randomized clinical trials, some surgeons feel that such evidence is inadequate to overthrow existing logical models of cancer treatment.

“Leads to the conclusion” implies a system by which decisions are made. The scientific method, formal logic, consensus methods, the courts of law, and Congress are all mechanisms

IOTA Note: As with all OTA case studies, this case was reviewed by a large number of medical and health policy experts. It is interesting to note that some reviewers felt the case was biased in favor of less extensive surgery, others felt that the authors were too conservative despite “overwhelming evidence” in favor of lesser surgery, and others felt that the case was balanced. Thus, despite some movement toward less extensive surgery, the medical profession still holds a range of strong feelings about the proper methods of treating breast cancer.

for coming to conclusions. In the treatment of breast cancer, there are several less extensive surgical alternatives to the Halsted “radical mastectomy” (see table 1). The existence of these several alternatives, particularly when used with chemotherapy and radiation therapy in varied combinations, provides a broad array of possible courses of action. In this case study, we would like to simplify the problem by focusing on more surgery —radical mastectomy —or less —the several simpler alternatives.

The assertion that radical mastectomy “is rarely if ever justified” implies that because of variation in each human being no simple rules are possible in medicine. To rule out all radical mastectomies under every conceivable circumstance—a course that is almost implied—would be folly indeed. Decision rules in medicine must be subject to modification based on the individual patient and the wise clinical judgment of the physician. One can also go to the other extreme of saying that an intelligent woman, fully informed of the options, may choose any type of treatment including none at all.

What is “beneficial?” The debate in the clinical literature focuses on prolongation of life. There has been little debate over the issue of quality of life—the quality of life with less extensive surgery is greater. There is little or no debate on that point. The statement that less ex-

**Table 1.— Definitions of Treatments
for Breast Cancer**

Surgery

(A mastectomy is the excision (removal by cutting) of the breast.)

- A. *Radical mastectomy (or Halsted radical mastectomy):* The excision of the breast, pectoral (chest) muscles, axillary lymph nodes, and associated skin and subcutaneous tissue.

If the above form of mastectomy is coupled with en bloc resection (removal as a whole) of the internal mammary nodes, it is often termed an *extended radical mastectomy*.

If a radical mastectomy is performed, except that the pectorals major muscle is left in place, the procedure may be termed a *modified radical mastectomy*.

- B. *Simple mastectomy, complete mastectomy, or total mastectomy:* Excision of the entire breast and the immediately adjacent lymph nodes. This is a less extensive procedure than any of those listed in "A" above, although sometimes the term "simple mastectomy" is used when "partial mastectomy" is meant. This form of mastectomy preserves the pectorals muscles, but the fascia (fibrous tissue enclosing the muscles) is removed.

- C. *Partial mastectomy (or segmental mastectomy):* Excision of that portion of the breast including the tumor, an area of surrounding normal tissue, and associated skin (but not normally the areola or nipple). Exploration of the normal breast tissue surrounding the tumor extends down to the fascia of the pectorals major.

The terms *lumpectomy* and *tylectomy* have come to be commonly used interchangeably with partial mastectomy. However, some experts feel that techniques such as lumpectomy often involve only the removal of the "lump" or actual tumor and a minor portion of surrounding tissue and should therefore more accurately be termed *local excision*.

Radiation therapy

The use of high-voltage ionizing radiation as an adjuvant (assisting; in combination with) therapy for treatment of localized or disseminated (spread) cancer. Radiation therapy may also be used as a primary (sole) treatment.

Chemotherapy

The use of antitumor drugs or hormones as an adjuvant therapy for breast cancer. Subsequent forms of chemotherapy may be used to treat remaining symptoms after the initial treatment of the cancerous tissue is completed. Chemotherapy may also be used as the primary treatment for breast cancer.

SOURCE: Office of Technology Assessment, U.S. Congress, 1981 (Synthesis of definitions provided in H.S. Gallagher, et al (eds.), *The Breast*, 1978, and D. Eddy, *Screening for Cancer* 1980)

tensive surgery is "less costly" than radical mastectomy implies a cost-benefit or cost-effectiveness analysis (CBA or CEA). A brief cost analysis is presented in appendix A to this case study. However, if one accepts the conclusion that radical mastectomy does not lead to greater life expectancy, but lowers quality of life and is more costly than "lesser" surgery, a formal CBA

or CEA is unnecessary. The answer in that case is: Do not perform radical mastectomies. Readers of this case study, therefore, should not expect a formal economic analysis.

The primary issue this case study does cover is: Why does change in medical treatment occur? Change in medical practice requires convincing other individuals that such change is desirable. The local social context of medicine in general, and surgery in particular, falls in the orbit of the hospital medical staff. To examine the subject of change, this case study undertakes to describe the experiences of three surgeons who became convinced that less extensive surgery for the treatment of breast cancer was preferred: Dr. Leslie Wise, at Long Island Jewish Hillside Medical Center; Dr. Oliver Cope, at Harvard Medical School; and Dr. George Crile, Jr., at the Cleveland Clinic. These three surgeons are singled out because they have been advocates of a view running counter to conventional surgical wisdom, not because they are representative of all surgeons, and not necessarily because they were the first to change nor because their research was definitive. The present study examines the subject of change in medical practice by considering the personal and social factors that led some individuals to depart from the mainstream. It is our belief that this approach is a departure from the clinical, statistical, economic, and decision-analytical literature.

Readers looking to this case study for an exhaustive literature review are directed elsewhere. Statisticians looking for a close critique of research designs or a formal comparison of medical conservatism to Bayesian priors will not find them here. Decision analysts and economists looking for formal decision models or CBAs will not find those either. Our concern in this study is with the interplay of evidence, logic, and the social context of surgery. This is because we feel central issues and problems are to be found in that interplay.

Any description of the current debate on how to detect and treat breast cancer can at best be a distant photograph of a vastly complex and rapidly moving target. That debate involves a large and complicated set of topics and issues. Before

the questions concerning surgical alternatives can be put into context, the topics and issues need to be defined. The sequence of steps associated with breast cancer detection and treatment is shown in table 2. Three sets of related questions and issues are as follows.

Population.—There is major debate over whether routine examination (screening) of asymptomatic patients is worth doing.

- Is the benefit from new cases found sufficient to offset the risks of exposure to radiation and the costs involved?

Table 2.—Sequence of Steps Associated With Breast Cancer Detection and Treatment

Identify population for detection:

Symptomatic
Asymptomatic (screening?)

If to be evaluated, select test for diagnostic evaluation:

Patient self-examination
Physician physical exam
Mammography
Thermography
Needle biopsy^a

If results of evaluation are positive, select type of section biopsy:

Inpatient and frozen section biopsy^a
Outpatient and permanent section biopsy^a

If section biopsy is *positive*, *select* primary treatment (based on assessment of quantity and quality of life):

Chemotherapy
Radiation therapy
Surgery
 Partial mastectomy (lumpectomy, tylectomy)
 Simple mastectomy (total mastectomy)
 Modified radical mastectomy
 Radical mastectomy
 Extended radical mastectomy

If further treatment is necessary, select adjuvant treatment:

Radiation therapy
Cosmetic surgery

^aA biopsy is a procedure, usually employed for diagnostic purposes, whereby cells or tissues are removed from the living body and examined under a microscope or with various chemical procedures. A needle biopsy revolves the removal of cells by extraction with a needle. A section biopsy, by contrast, entails the removal of a piece ("section") of the questionable tissue, the specimen thus obtained may be fixed for microscopic examination by freezing (frozen section) or by use of a permanent fixing agent such as formaldehyde (permanent section)

Diagnostic Evaluation.—Several tests are available.

- How accurate are they?
- How should they be sequenced?
- What cutoff points define positive and negative findings?
- What added information is obtained with each added test?
- What decision rules define positive?
- What decision rules should be used for repeated testing?
- Once a patient is found to be positive by preliminary tests, should a section biopsy be performed on an inpatient basis or on an outpatient basis?

Treatment.—Breast cancer patients may be treated with chemotherapy, radiation therapy,² surgery, or a combination of these alternatives.

- How sure are we that treatment provides benefit?
- How should benefits—which can be expressed as increases in either the quantity or the quality of life—be combined, weighted, and assessed?
- If treatment includes surgery, as it usually does, what followup radiation therapy, if any, should be used? Should cosmetic surgery be performed?

The answers at each step affect the other steps. Each answer has major cost and benefit implications. Because there is little agreement on the answers to these questions, many combined strategies are possible and worth consideration. Although prior to 1970 there was little question that radical mastectomy was the standard treatment within the United States, that standard is now changing. This analysis draws a number of observations about the change process involved.

²Radiation therapy alone (without surgery) is sometimes used as primary treatment, often on patients refusing surgery. Although the studies are few and have used small numbers of patients, the results seem to be comparable to surgery,