Surgery for Breast Cancer

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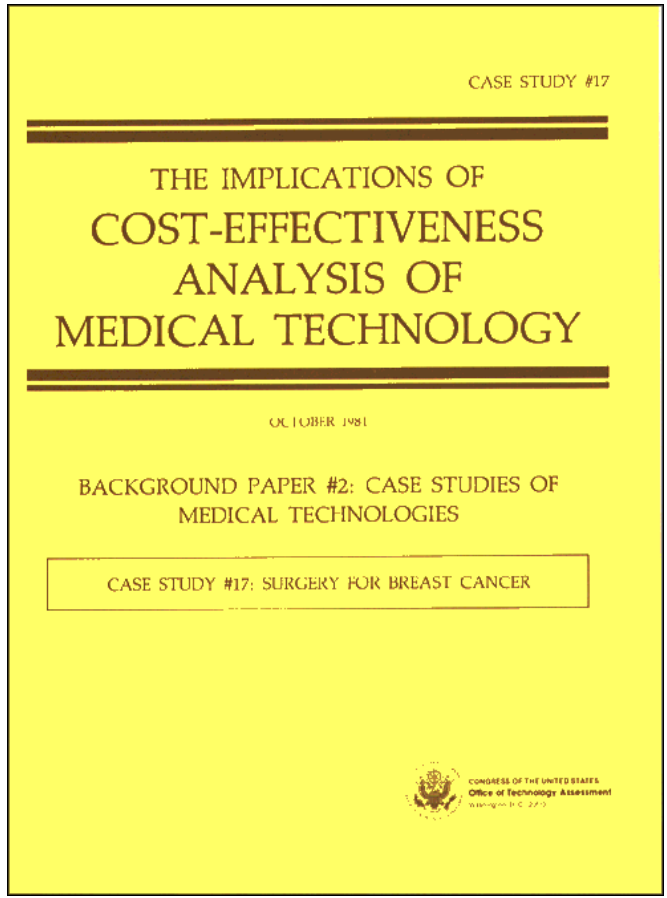

THE IMPLICATIONS OF COST-EFFECTIVENESS ANALYSIS OF MEDICAL TECHNOLOGY

OCTOBER 1981

BACKGROUND PAPER #2: CASE STUDIES OF MEDICAL TECHNOLOGIES

CASE STUDY #17: SURGERY FOR BREAST CANCER

Karen Schachter, M.A.
Formerly, Research Assistant
Harvard School of Public Health, Boston, Mass.

Duncan Neuhauser, Ph. D.
Professor of Epidemiology and Community Health, Professor of Medicine
Case Western Reserve University, School of Medicine, Cleveland, Ohio

OTA Background Papers are documents that contain information believed to be useful to various parties. The information under-girds formal OTA assessments or is an outcome of internal exploratory planning and evaluation. The material is usually not of immediate policy interest such as is contained in an OTA Report or Technical Memorandum, nor does it present options for Congress to consider.

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Foreword

This case study is one of 17 studies comprising Background Paper #2 for OTA's assessment, ***The Implications*** of ***Cost-Effectiveness Analysis*** of ***Medical Technology.*** That assessment analyzes the feasibility, implications, and value of using cost-effectiveness and cost-benefit analysis (CEA/CBA) in health care decisionmaking. The major, policy-oriented report of the assessment was published in August 1980. In addition to Background Paper #2, there are four other background papers being published in conjunction with the assessment: 1) a document which addresses methodological issues and reviews the CEA/CBA literature, published in September 1980; 2) a case study of the efficacy and cost-effectiveness of psychotherapy, published in October 1980; 3) a case study of four common diagnostic X-ray procedures, to be published in summer 1981; and 4) a review of international experience in managing medical technology, published in October 1980. Another related report was published in September of 1979: ***A Review*** of ***Selected Federal Vaccine and Immunization Policies.***

The case studies in ***Background Paper #2: Case Studies*** of ***Medical Technologies*** are being published individually. They were commissioned by OTA both to provide information the specific technologies and to gain lessons that could be applied to the broader policy aspects of the use of CEA/CBA. Several of the studies were specifically requested by the Senate Committee on Finance.

Drafts of each case study were reviewed by OTA staff; by members of the advisory panel to the overall assessment, chaired by Dr. John Hogness; by members of the Health Program Advisory Committee, chaired by Dr. Frederick Robbins; and by numerous other experts in clinical medicine, health policy, Government, and economics. We are grateful for their assistance. However, responsibility for the case studies remains with the authors.

JOHN H. GIBBONS
Director

Advisory Panel on The Implications of Cost= Effectiveness Analysis of Medical Technology

John R. Hogness, ***Panel Chairman***
President, Association of Academic Health Centers

Stuart H. Altman
Dean
Florence ***Heller School***
Brandeis University

James L. Bennington
Chairman
Department of Anatomic Pathology and Clinical Laboratories
Children's Hospital of ***San Francisco***

John D. Chase
Associate Dean for Clinical ***Affairs***
University of Washington School of Medicine

Joseph Fletcher
Visiting Scholar
Medical Ethics
School of ***Medicine***
University of Virginia

Clark C. Havighurst
Professor of ***Law***
School of ***Law***
Duke University

Sheldon Leonard
Manager
Regulatory Affairs
General Electric Co.

Barbara J. McNeil
Department of ***Radiology***
Peter Bent Brigham Hospital

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Executive Vice President
American College of ***Physicians***

Frederick Mosteller
Chairman
Department of ***Biostatistics***
Harvard University

Robert M. Sigmond
Advisor on ***Hospital Affairs***
Blue Cross and Blue Shield Associations

Jane Sisk Willems
VA Scholar
Veterans Administration

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● OTA contract personnel.

Preface

This case study is one of 17 that comprise Background Paper #2 to the OTA project on the *Implications of Cost-Effectiveness Analysis of Medical Technology.* * The overall project was requested by the Senate Committee on Labor and Human Resources. In all, 19 case studies of technological applications were commissioned as part of that project. Three of the *19* were specifically requested by the Senate Committee *on* Finance: psychotherapy, which was issued separately as Background Paper #3; diagnostic X-ray, which will be issued as Background Paper #5; and respiratory therapies, which will be included as part of this series. The other 16 case studies were selected by OTA staff.

In order to select those 16 case studies, OTA, in consultation with the advisory panel to the overall project, developed a set of selection criteria. Those criteria were designed to ensure that as a group the case studies would provide:

- examples of types of technologies by function (preventive, diagnostic, therapeutic, and rehabilitative);
- examples of types of technologies by physical nature (drugs, devices, and procedures);
- examples of technologies in different stages of development and diffusion (new, emerging, and established);
- examples from different areas of medicine (such as general medical practice, pediatrics, radiology, and surgery);
- examples addressing medical problems that are important because of their high frequency or significant impacts (such as cost);
- examples of technologies with associated high costs either because of high volume (for low-cost technologies) or high individual costs;
- examples that could provide informative material relating to the broader policy and methodological issues of cost-effectiveness or cost-benefit analysis (CEA / CBA); and
- examples with sufficient evaluabIe literature.

On the basis of these criteria and recommendations by panel members and other experts, OTA staff selected the other case studies. These 16 plus the respiratory therapy case study requested by the Finance Committee make up the 17 studies in this background paper.

All case studies were commissioned by OTA and performed under contract by experts in academia. They are authored studies. OTA subjected each **case** study to an extensive review process. Initial drafts of cases were reviewed by OTA staff and by members of the advisory panel to the project. Comments were provided to authors, along with OTA's suggestions for revisions. Subsequent drafts were sent by OTA to numerous experts for review and comment. Each case was seen by **at** least *20,* and some by *40* or more, outside reviewers. These reviewers were from relevant Government agencies, professional societies, consumer and public interest groups, medical practice, and academic medicine. Academicians such as economists and decision analysts also reviewed the cases. In all, over *400* separate individuals or organizations reviewed one or more case studies. Although all these reviewers cannot be acknowledged individually, OTA is very grateful for their comments and advice. In addition, the authors of the case studies themselves often sent drafts to reviewers and incorporated their comments.

These **case** studies are authored works commissioned **by OTA. The authors are responsible for the conclusions of their specific case study. These cases are not statements of official OTA position. OTA does not make recommendations or endorse particular technologies. During the various stages of the review and revision process, therefore, OTA encouraged the authors to present balanced information and to recog**nize divergent points of view. In two cases, **OTA decided that in order to more fully present divergent views on particular technologies a commentary should be added to the case study. Thus, following the case**

● Office of Technology Assessment, U.S. Congress, The *lmplications of Cost-Effectiveness Analysis of Medical Technology,* GPO stock No. *052-003 -00765-7 (Washington,* D. C.: U.S. Government Printing Office, August 1980).

studies on gastrointestinal endoscopy and on the Keyes technique for periodontal disease, commentaries from experts in the appropriate health care specialty have been included, followed by responses from the authors.

The case studies were selected and designed to fulfill two functions. The first, and primary, purpose was to provide OTA with specific information that could be used in formulating general conclusions regarding the feasibility and implications of applying CEA/CBA in health care. By examining the 19 cases as a group and looking for common problems or strengths in the techniques of CEA/CBA, OTA was able to better analyze the potential contribution that these techniques might make to the management of medical technologies and health care costs and quality. The second function of the cases was to provide useful information on the specific technologies covered. However, this was not the major intent of the cases, and they should not be regarded as complete and definitive studies of the individual technologies. In many instances, the case studies do represent excellent reviews of the literature pertaining to the specific technologies and as such can stand on their own as a usedful contribution to the field. In general, though, the design and the funding levels of these case studies were such that they should be read primarily in the context of the overall OTA 'project on CEA/CBA in health care*

Some of the case studies are formal CEAS or CBAS; most are not. Some are primarily concerned with analysis of costs; others are more concerned with analysis of efficacy or effectiveness. Some, such as the study on end-stage renal disease, examine the role that formal analysis of costs and benefits can play in policy formulation. Others, such as the one on breast cancer surgery, illustrate how influences other than costs can determine the patterns of use of a technology. In other words, each looks at evaluation of the costs and the benefits of medical technologies from a slightly different perspective. The reader is encouraged to read this study in the context of the overall assessment's objectives in order to gain a feeling for the potential role that CEA/CBA can or cannot play in health care and to better understand the difficulties and complexities involved in applying CEA/CBA to specific medical technologies.

The 17 case studies comprising *Background Paper #2* (short titles) and their authors are:

Artificial Heart: Deborah P. Lubeck and John P. Bunker
Automated Multichannel Chemistry Analyzers: Milton C. Weinstein and Laurie A. Pearlman
Bone Marrow Transplants: Stuart O. Schweitzer and C. C. Scalzi
Breast Cancer Surgery: Karen Schachter and Duncan Neuhauser
Cardiac Radionuclide Imaging: William B. Stason and Eric Fortess
Cervical Cancer Screening: Bryan R. Luce
Cimetidine and Peptic Ulcer Disease: Harvey V. Fineberg and Laurie A. Pearlman
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Orthopedic Joint Prosthetic Imp' nts: Judith D. Bentkover and Philip G. Drew
Periodontal Disease Interventions: Richard M. Scheffler and Sheldon Rovin
Selected Respiratory Therapies: Richard M. Scheffler and Morgan Delaney

These studies will be available for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Call OTA's Publishing Office (224-8996) for availability and ordering information.

Case Study #17

Surgery for Breast Cancer

Karen Schachter
Formerly, Research Assistant
Harvard School of Public Health
Boston, Mass.

Duncan Neuhauser
Professor of Community Health
Case Western Reserve University
School of Medicine
Cleveland, Ohio

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Karen Schachter
Formerly, Research Assistant
Harvard School of Public Health
Boston, Mass.

Duncan Neuhauser
Professor of Community Health
Case Western Reserve University
School of Medicine
Cleveland, Ohio

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 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-

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 t'aver 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.

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 Off Ice 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 lookin g 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 vast] y 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 *asso*ciated 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

[a]A 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 ("sectlon") 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 forma ehyde (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.

[2]Radiation 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,

BACKGROUND ON BREAST CANCER

According to American Cancer Society estimates, about 108,000 cases of breast cancer were diagnosed in 1980, nearly all of which will result in surgery. Approximately 35,000 deaths in the past year were due to the disease (1). Nearly 1 out of 12 women will develop breast cancer at some point in their lives. The breast is the foremost site of cancer incidence and cause of death in American women. Despite new technology, the survival rates of women afflicted with the disease are not much improved over the rates of **50** years ago. Although American Cancer Society statistics indicate that when breast cancer is discovered in a localized state, the 5-year survival rate is 85 percent, the general prognosis is not very encouraging. Almost 50 percent of women with breast cancer eventually die of the disease (26,54),

The extent or severity of breast cancer varies from one case to the next. For the purposes of this case study, we will refer to the classifications of the Manchester staging system when discussing the clinically recognizable symptoms of a cancer's spread or extent of severity. That system consists of four "stages" (levels) as follows:

Stage I: Carcinoma (cancer) confined to breast. No evidence of axillary,[3] supraclavicular, [4] or distant[5] metastasis (transfers, or spreading, of disease from one organ or part of the body to another).

Stage II: Carcinoma of breast with apparent axillary node[b] involvement. No evidence of supraclavicular or distant metastasis.

Stage 111: Carcinoma of breast with ulceration, inflammatory changes, or edema (swelling due to fluids in the tissue) of greater than one third of breast. Axillary nodes large and fixed (unnaturally held in place). Satellite skin nodules (attendant lesions on the surface of the skin).

Stage IV: Distant metastasis present (i.e., the disease has spread to distant parts or organs of the body.)

Normally, patients with stages I and II breast cancer are considered "operable," that is, there is merit in applying treatment techniques to try and remove the malignancy or halt its spread. Often for patients at stage 111 and nearly always for patients at stage IV, the medical techniques applied are done for palliation, because there is little likelihood of survival.

Discussion of breast cancer dates back to ancient times. Hippocrates referred to it in his writing, although he believed that it, like all malignancies, was incurable and better left alone. When afflicted women sought medical advice, their tumors were often already ulcerated and so implanted in the chest wall that a slow destruction of internal organs had already begun. In most cases, crude and painful treatment probably hastened the patient's death.

During the Roman era, Celsus, a philosopher of science, advocated the application of caustic agents to symptoms of early breast tumors. He believed that once tumors reached a certain turning point, they became malignant and no treatment could alleviate their damage. In the second century B. C., Galen began to propound theories that cancer was due to a bodily accumulation of black bile. He first noted the crab-like appearance of some tumors, and called the disease "cancer" (16,39).

Until the 19th century, breast cancers were treated by a variety of means, including bleeding, purging, dieting, pressing the breast between lead plates, applying salves and goat dung, and in a brutally crude manner amputating the breast. With discovery of anesthesia in 1848, extended surgical operations became feasible. In 1867, the British surgeon Sir Charles Moore published a paper in the St. Bartholomew's Hospital Report describing the techniques of radical mastectomy.

[3]Involving the axilla (the area between the chest and the arm).
'Involving the area above I he clavicle (shoulder bone).
'Involving distant parts or organs of the body.
[6]The "axillary nodes" refer to the lymph nodes of the axilla, the area between the chest and the arm (including the armpit and surrounding tissue). Lymph nodes are small masses of tissue that serve as sources of lymphocytes (a type of white blood cell) and as bodily defense mechanisms by removing toxins and bacteria.

Moore was the first physician to chronicle the procedure of radical mastectomy, but Dr. William Stewart Halsted of Johns Hopkins University received credit for implementing it. At first, Halsted devised an ultraradical operation in which the lymph nodes of the lower neck were removed as well as the breast, pectoral muscles,[7] and axillary nodes. This procedure had high mortality rates and low cure rates, however, so Halsted returned to Moore's technique, employing the radical mastectomy as the routine treatment for breast cancer. In 1885, he published his first results in a study of 50 patients treated surgically (16,28,30).

[7]The pectoral muscles are the muscles of the chest. The pectoralis major and pectorals minor are the key ones in terms of this discussion.

RADICAL MASTECTOMY AS THE STANDARD TREATMENT

For 80 years, the radical mastectomy remained the "treatment of choice" for surgeons working with breast cancer. In 1970, 80 percent of all women in the United States diagnosed as having breast cancer received a radical mastectomy. This surgery involves removal of the breast along with the muscles of the chest wall (the pectorals major and the pectorals minor). In addition, the axillary chain of lymph nodes is dissected and removed.

Radical mastectomy is a debilitating operation with frequent postoperative complications and side effects. It leaves an extensive scar that extends over the patient's shoulder. Halsted advised removing the fat under the flap of skin left to close the wound, leaving the chest itself covered by a sheet of skin stretched tightly over the ribs. The removal of this fat creates a noticeable depression in the chest that is difficult or impossible to conceal. Skin grafts often are necessary to adequately cover the exposed rib cage (16).

Two principles of surgery for cancer of the breast that were advocated by Halsted have remained deeply ensconced in the minds of many surgeons to this day. The first principle is the removal of the pectoral muscles. Halsted wrote (28):

> About eight years ago (1882), I began not only to typically clean out the axilla in all cases of cancer of the breast but also to excise in almost every case the pectorals major muscle, or at least a generous piece of it, and to give the tumor on all sides an exceedingly wide berth.

One New York surgeon who has strictly adhered to this practice is Dr. Guy Robbins. Robbins, who bases his rationale on the many cases he has seen in which the nodes under the pectoral muscles have been cancerous, is one of those who is convinced that the only way to ensure removal of all local and regional cancer is to perform a radical mastectomy.

Halsted's second principle involves operative technique (28):

> The suspected tissues should be removed in one piece (meaning the muscles and breast) 1) lest they would become infected by the division of tissues invaded by the disease, or of lymphatic vessels containing cancer cells, and 2) because shreds or pieces of cancerous tissue might readily be overlooked in a piecemeal extirpation.

This principle further implies that radical mastectomy is the only way to ensure the excision of all possible cancer cells. In addition, the immediacy that this principle connotes probably fostered the mode of operating that can be characterized as: Perform biopsy with the patient under anesthesia; if malignancy is found, perform an immediate radical mastectomy with the patient under the same anesthesia.

The prospect of going into surgery and awakening without a breast has caused untold anxiety to many women. In recent years, some surgeons have been performing a two-step procedure: 1) incisional or excisional biopsy under local or general anesthesia, and 2) further surgery, if required, several days later. They do

this working within the logical model that cancer cells will not spread appreciably in the short time before further surgery and that a respite of several days before surgery gives the patient with cancer time to cope with the diagnosis.

At the time Halsted was practicing medicine, early detection techniques and routine self-examination were nonexistent. The average case of breast cancer was usually characterized by a tumor so large that it often filled the entire breast or was fixed to the chest. Ulcerating malignant lesions were common and extensive axillary node involvement almost inevitable. For a surgeon confronted with these symptoms, the logical course was to remove as much cancerous and possibly precancerous tissue as possible.

The patient mix today is very different from that of a century ago, and alternative treatments are available. With the present emphasis on bodily self-awareness and routine physical examinations, tumors are frequently much smaller when detected than were the tumors reported by Halsted. A question now common among surgeons is whether a radical procedure is necessary to cure the less extensive cancer. Despite mounting evidence in favor of the lesser procedures, many surgeons still perform radical mastectomies as routine breast cancer surgery.

RADICAL MASTECTOMY RECONSIDERED

Considerable research on the efficacy of the radical mastectomy has been conducted over the last several decades. As stated above, until only a few years ago, it was the nearly automatic treatment of choice for breast cancer. From the point of view of the innovators who advocate less extensive procedures, the radical mastectomy holds a traditional prominence in the minds of American surgeons that has been difficult to break. Only recently have alternatives to the procedure become available, and many of them remain controversial. A large amount of medical literature is amassing on the disadvantages of radical mastectomy, but the radical procedure remains the point of comparison used in clinical trials designed to test the efficacy of other procedures. As yet, no other form of therapy has been proven to give better survival rates than radical mastectomy. However, it should be noted that lesser procedures may be just as effective with respect to survival as the radical operation (55). In addition, lesser surgery produces fewer side effects and may require less extensive restorative or cosmetic surgery.

The basis of radical mastectomy is similar to that of other cancer operations: It is designed to eradicate the primary cancerous growth by removal of that growth along with a wide margin of normal tissue and en bloc resection (removal) of the regional draining lymph nodes. According to Drs. Leslie Wise and Oliver Cope, however, the radical mastectomy does not meet these criteria because the procedure does not involve removal of the supraclavicular and internal mammary nodes (both regional lymph drainage pathways from the breast), R. S. Handley ran a study in which he found that in 25 percent of all operable breast cancers (stage I and II), the internal mammary nodes were already invaded by the disease (33). This observation has been substantiated by a series conducted by Dahl- Iverson, Caceres, and Veronesi (55).

Proponents of radical mastectomy find many justifications for the procedure. One is their belief in the disease model which postulates that cancer cells will grow and metastasize until removed by surgery or eradicated by radiotherapy or chemotherapy, A natural progression of this hypothesis is “the more surgery the better. ”

According to the aforementioned disease model, a localized cancer develops and grows, spreads to regional lymph nodes (e. g., the axillary or internal mammary nodes), and then spreads further through the person’s system. The blood stream is not considered important in this spreading. There is, however, a developing alternative hypothesis. This hypothesis considers a tumor to be not merely a locally arising

phenomenon but rather a systemic (of the bodily system) disease. The presence of cancer involvement in the lymph nodes, therefore, is not seen as evidence of a spreading out of the disease from a localized "point of origin" in the breast. This alternative view of breast cancer biology detracts from the Halsted principle that extensive surgery is necessary to stop the spread of the disease (20,21,40,48).

Surgeons who advocate radical mastectomy find intrinsic faults in clinical trials that invalidate or bring into question the results of the trials. According to Dr. George Crile, Jr. (15):

> It is further argued [by such surgeons] that when survival rates from uncontrolled studies are compared, they favor the radical operations, but considering that the criticisms of the randomized series rest on arguments of selection and inadequate randomization, this latter assertion cannot be taken seriously.

Surgeons who advocate radical mastectomy also argue that complete resection of the axillary nodes is an essential diagnostic procedure even if it is not a therapeutic one. According to McPherson and Fox (42), this is a matter of opinion because it depends on the perception of the disease model and possible role of the axillary nodes in immune response.

McPherson and Fox (42) have summarized the results of eight trials reported between 1965 and 1971 (see table 3). Radical and simple mastectomy produced the same results in terms of survival, but simple mastectomy resulted in less mutilation, less morbidity, and less recovery time. These investigators concluded that for stage I patients, tylectomy (lumpectomy) is equivalent to radical mastectomy with respect to survival. For stage II patients, only a 1972 study by Atkins, et al., showed that radical mastectomy prolonged life more than did tylectomy.

Henderson and Canellos, in an extensive literature review (35), have summarized more recent trials (see table 4). They concluded that there is no difference in survival between simple and radical mastectomy.

Dr. George Crile, Jr., argues against radical mastectomy because of the deformity, morbidity, and psychological trauma it causes. He suggests that surgeons in the United States have adhered to the procedure for two reasons. First, Halsted's reputation as a surgeon and the dominant role of Johns Hopkins Medical School helped forge an influential tradition. Second, radical mastectomy was a more difficult and challenging operation than the ones it replaced, and in the fee-for-service medical system of this country, the more complex the surgery, the more financial remuneration for the surgeon. According to Crile, fee-for-service surgery does condition behavior to some extent. In addition, surgeons might be more liable to malpractice suits in the event of a local recurrence after a simple procedure than after extensive surgery.

However, Dr. Guy Robbins recommends radical mastectomy in patients with invasive breast carcinoma who cannot medically tolerate the extended radical mastectomy (47). Patients with the dominant mass in the outer half of the breast are routinely subjected to a radical mastectomy. According to Robbins, breast cancer is multifocal, so nothing short of extended radical, radical, or modified radical mastectomy is adequate treatment. Table 5 is a composite of results cited in one of Robbins' articles (47). His summary of studies shows radical surgery producing greater survival, but there is no demonstration that the patient populations being compared are similar.

After analyzing the survival rates of breast cancer patients, Dr. Maurice Fox suggests that the disease diagnosed as breast cancer includes two entities that are "as yet, not reliably distinguished—one with a fatal outcome and the other with an outcome only modestly different from that of a group of women of similar ages without evidence of the disease" (24). Although nearly all patients with breast cancer are treated, those suffering a rapidly fatal outcome show a mortality not significantly different from untreated patients in the 19th century. Along the same lines, Fox states that "there is suggestive evidence for the existence of an entity that, by histological criteria, is malignant, but is biologically benign" (24).

An ongoing series of controlled clinical trials sponsored by the National Cancer Institute of the National Institutes of Health (NIH) con-

Table 3.—Summary of Some Clinical Trials in the Treatment of Breast Cancer (McPherson and Fox)

Study[a]	Comparison	Stage	Total number of patients	Percentage of patients surviving			Percentage of patients free of recurrence at 5 years		Within stage contrasts
				5 years	10 years	15 years	Local	Any	
Copenhagen: Kaae and Johansen, 1968 (37)	Extended radical	Operable	206	67%	42%	37%	78%	58%	No difference in 10-year survival of operable cases (stage I excluded)
	Simple + XRT		219	66	44	36	81	57	
Cambridge: Brinkley and Haybittle, 1966 (5)	Radical + XRT	Stage II	91	54	49			51	Trial stopped because of excess of patients in radical group experiencing delay in healing of wound
	Simple + XRT		113	66	46			58	
London: Atkins, et al., 1972 *(4)*	Tylectomy + XRT	Stages I & II	182	71	60		63		Large difference in 10-year survival and local recurrence favoring radical treatment among clinical stage II
	Radical + partial XRT[b]		188	74	70		87		
Scotland: Hamilton, et al., 1974 (31)	Radical	Stages 1, II & III	256	73				64	
	Simple + radical + XRT		242	70				60	
U. S. A.: Fisher, et al., 1970	Radical + XRT	Stages I &II	195	56				51	
	Radical + drug		233	62				50	
Hammersmith: Burn, 1974 (9)	Radical + partial XRT	Stages I & II	92	72			91		
	Simple + complete XRT		98	74			95		50% 5-year survival of stage II patients in both treatment groups
Manchester: Cole, 1964 (12)	Radical + postop XRT	Operable	709	57	45		84	66	
	Radical + no initial XRT		752	62	49		86	60	
Edinburgh: Bruce, 1971 (7)	Radical	Operable	200	75					
	Simple + XRT		184	70					

XRT = X-ray therapy
[a]Numbers in parentheses refer 10 references in the list that appears at the end of this case study
[b]Also received chemotherapy

SOURCE: K. McPherson and M. Fox, "Treatment of Breast Cancer," in Costs, *Risks, and Benefits of Surgery,* J. P. Bunker, et al. (eds.) (New York: Oxford University Press, 1977).

Table 4.—Summary of Some Clinical Trials in the Treatment of Breast Cancer (Henderson and Canellos)

Study[a]	Comparison	Stage	Total number of patients	Percentage of patients surviving
Cardiff: Forrest, et al., 1977 (23)	Radical + XRT Simple + XRT			55% 61
USA: Fisher, et al., National Surgical Adjuvant Breast Project, 1977 (20)	Radical Simple + XRT Simple	Axillary nodes clinically uninvolved	354 282 344	79 81 76
	Radical **Simple +** XRT	Axillary **nodes** clinically involved	**277** 224	**62** 62
Manchester: Lythgoe, et al., 1978 (41)	Simple + XRT + oöphorectomy Radical + oöphorectomy	Stage II	139 129	38 53

XRT = X.ray therapy
[a]Numbers in parentheses refer to references numbers in the list that appears at the end Of this case study
[b]All three of these trials report followup 3 to 5 years; none of the survival result differences are statistically significant

SOURCE 1. C Henderson and G P Canellos, "Cancer of the Breast," *N Eng J* **Med 302(1) 17, Jan 3.1980. and 302(2) 78, Jan 10, 1980**

Table 5.—Ten-Year Survival in Breast Cancer

Source	Years	Stage	Surgical method	Number of patients	Percentage of patients surviving
Crile	**1955-57**	**I-II**	**Simple mastectomy**	**69**	48%
Crile	1955-57	I-II	Radical mastectomy	62	34
Crile	1957-66	I-II	Partial mastectomy	32	34
Crile	1957-66	I-II	"Total mastectomy"	32	?
Memorial	1960	I-II	Radical mastectomy	304	61
Payne	1955-64	all op.	Radical mastectomy	2,171	59.4
Atkins[a]	10 years	I-II	Radical mastectomy	188	70[b]

[a]Randomized clinical trial
[b]Approximately.
SOURCE G F Robbins, **"The Rationale for Treatment of Women With Potentially Curable Breast Carcinoma,"** *Surg C/In N Am* 54(4)793,1974.

tinues to provide information indicating that there is little significant difference in outcomes between extensive surgery and less extensive surgery. Some of the earlier results of these trials—conducted under the auspices of the National Surgical Adjuvant Project for Breast and Bowel Cancers (NSABP), with Dr. Bernard Fisher as project chairman—have already been summarized (see tables 3 and 4). More recent results (21,22) add to the evidence concerning the lack of advantage in survival rates with extensive surgery. These results also lend additional weight to the hypothesis that breast cancer is a systemic disease—a hypothesis from which the lack of advantage of more extensive surgery is both logical and expected. For example, findings from a trial involving 1,665 women with primary breast cancer indicate no significant difference in outcomes for women treated by radical mastectomy v. women treated by simple (total) mastectomy plus radiation therapy (22) . Further, results from that trial of women treated with simple mastectomy alone v. women treated with simple mastectomy plus radiation therapy indicate that the radiation therapy did not change the probability of death due to "distant" disease (disease at a site away from the breast–a metastasized cancer (22). This finding emerged despite the fact that in the nonradiated cases, axiliary and internal mammary nodes with positive involvement of cancer were left untreated. This finding adds weight to the systemic disease hypothesis and further detracts from the Halstedian hypothesis.

As evidenced by the above material, the radical mastectomy is no longer the unqualified standard treatment, although versions of it continue to be the most widely used form of treatment. An extensive literature is developing on the various forms of radical mastectomy, on the alternatives to radical mastectomy, and on the appropriate role of each in the treatment of breast cancer. The history of these arguments and the rationales behind the various treatments for breast cancer are presented in the references cited in appendix B. Otherwise, it is sufficient for the purposes of this case study to note that the arguments over rationales and outcomes gradually led to a reconsideration of what the standard treatment for breast cancer should be and thus were part of a process of change in medical practice. The debate led NIH to hold a consensus development conference on the subject in 1979.

NIH CONSENSUS PANEL

Several conclusions regarding the treatment of primary breast cancer were reached by the NIH consensus panel. It was the consensus of the panel that **(46):**

> . . . a procedure which preserves the pectoral muscles, i.e., a total mastectomy with axillary dissection, provides equivalent benefit to women who) have stage I and selected stage II breast cancer. Therefore, total mastectomy with axillary dissection should be recognized as the current treatment standard.

The panel also agreed that a two-step procedure should be performed in most cases. This procedure would involve the study of a diagnostic biopsy before discussion of therapeutic alternatives with the patient.

The question of the benefits of postoperative radiotherapy was left open until further results of clinical trials could be obtained. Lesser surgical procedures such as segmental (partial) mastectomy, the combination of minimal surgery plus primary radiotherapy, and radiotherapy alone were considered as possibilities, but the panel felt that trials exploring these modes of treatment were at too early a stage to allow definitive conclusions.

The consensus panel expressed enthusiasm for the possibilities posed by segmental mastectomy and primary radiotherapy. It supported further clinical investigation of these treatments and suggested that patients and physicians do the same, so that the optimal treatment for greater patient survival and minimal patient morbidity might be found.

THREE SURGEONS

It is evident from the discussion presented so far that changes in surgical opinion and practice with respect to the treatment of breast cancer have occurred and that these changes have been institutionalized in the actions of the NIH consensus panel. We turn now to the experiences of three surgeons during the formation of these changes. Our intention here is to shed light on the importance of personal and social context factors in the changing of surgical opinion.

Dr. Leslie Wise

Dr. Leslie Wise has been chairman of the Department of Surgery at Long Island Jewish/ Hillside Medical Center in New Hyde Park, N. Y., since September of 1975 (49). The Hillside Medical Center comprises a 59&bed acute care hospital, a 527-bed geriatric unit, and a 203-bed psychiatric facility. Wise is responsible for the surgical service of the hospital, its six residency programs, research projects, and the teaching of

medical students. He is also a professor of surgery at the State University of New York at Stony Brook and oversees the surgical service at the affiliated Queens Hospital Center, a municipal hospital in the City of New York.

Wise has long been an advocate of less radical surgery (lumpectomy, local excision) for breast cancer. In three articles on the treatment of breast cancer he has published over the last 10 years, Wise has taken a nontraditional point of view, arguing that lesser surgery and followup radiation therapy is as effective a mode of treatment as the Halsted radical mastectomy. In the first article, entitled "Local Excision and Irradiation: An Alternative Method for the Treatment of Breast Cancer" (1971) (54), Wise and his colleagues proceed from the premise that despite technical progress and variation in mastectomy technique, the overall survival rate of patients has not changed over the last several decades. This suggests "that no single approach is clearly superior to others and that survival rate is influenced more by the biological behavior of the tumor than by the particular method of treatment employed. "

Wise argues that since all mastectomies result in deformity, often accompanied by emotional trauma and physical complications, and since the type of surgical intervention does not have a marked effect on mortality rates, then logically the treatment which has the least mutilating results and fewest complications would be most satisfactory. According to his research, local excision of the tumor (lumpectomy or tylectomy), combined with followup radiation therapy, seems a viable solution to the problem.

The main text of the 1971 article by Wise and his colleagues (54) describes a British study that they performed on a group of women with clinically curable (stages I and 11) breast cancer. The project critically compared the progress of 96 patients treated by local excision and radiation with that of 207 women treated by radical mastectomy with or without adjuvant radiotherapy, depending on the histology of the axillary nodes. In summary, the results of the study showed no significant difference between the survival rates of the two groups over a 15-year period (1950 to 1964). Apparently, the mode of treatment did not alter the overall prognosis in these ***cases.*** Wise and the other investigators concluded (54):

> The present study together with previous publications on this subject would suggest that local excision with modern irradiation may be a suitable alternative to radical mastectomy for early breast cancer.

Subsequent publications on breast cancer by Wise reiterate his hypothesis that lumpectomy and radiotherapy are as effective a cure for breast cancer in some circumstances as any other method. In "Controversies in the Management of Potentially Curable Breast Cancer" (1974) (55), he summarizes a number Of studies performed on patients receiving different modes of treatment, including radiotherapy, prophylactic oöphorectomy (removal of an ovary or ovaries), and chemotherapy. For clinical stage I cancers, the results of his research strongly suggest the use of local excision followed by radiation, and for clinical stage II tumors, "simple mastectomy with removal of accessible palpable **axillary glands followed by prophylactic radiotherapy gives just as good results as with** the more mutilating procedures. "

In his third article, "Routine Axillary Node Removal in the Treatment of Breast Cancer: An Illogical Approach" (1976) (38), Wise further investigates these contentions supporting lesser surgery through an analysis of the relation of lymphatic drainage pathways to malignant metastasis. En bloc routine axillary dissection is criticized as extensive and unnecessary surgery. Wise and the other authors of the 1976 article contend that:

> . on the basis of data accumulated at the present time, formal axillary dissection probably has no role in the management of women with primary breast cancer. The morbidity and cosmetic deformity accompanying the procedure are further grounds for rejecting its use.

Local excision of the tumor, limited excision of affected axillary nodes when feasible, and postoperative irradiation are again advocated as treatments preferable to, and as adequate **as,** any of the more debilitating procedures.

Since his arrival at Long Island Jewish, Wise has sought to acquaint his colleagues with his point of view. In 1978, a study was conducted there in order to determine trends in the treatment of breast cancer and to ascertain whether Wise **was** successful in encouraging his staff to perform less radical breast surgery (lumpectomy) as a more frequent mode of treatment for the disease. Data were obtained from the operating room log, tumor registry, and Wise's surgical files. Samplings were taken as to the types of surgery performed during two 2-year intervals. The first interval covered the period from September 1973 through August 1975 (the 2 years before Wise's arrival). The second covered the period from September 1975 through December 1977 (the 2 years after he became chief of surgery). In March of 1979, another review of data was obtained to cover the entire year of 1978. The results, listed by procedures, are shown in table 6.

The most obvious change since Wise's arrival at Long Island Jewish has been the increase in the use of the modified radical procedure. In the years since September of 1975, the modified radical operation has been performed nearly twice as often as the Halsted radical mastectomy, Wise himself is still performing the majority of lumpectomies. In his first 2 years, he performed 5 out of 9 procedures; and in 1978, he performed 12 out of 19.

As of January 1977, there had been a noticeable increase in the number of lesser operations that Wise has performed. This may indicate that as a result of popular books and articles on the subject, more women in the community are seeking alternatives in breast cancer treatment.

Dr. George Crile, Jr.

Dr. George Crile, Jr., holds the position of Emeritus Consultant in Surgery at the Cleveland Clinic, an institution founded by his father in 1921. The Cleveland Clinic is equipped with 1,010 beds. All physicians practicing at the facility are salaried, and there is no fee-for-service surgery. No radical mastectomy has been performed at the Cleveland Clinic since 1968. Crile has spent the last 20 years involved in clinical research on the relative efficacy of lesser procedures such as simple and partial mastectomy compared to the radical Halsted operation.

Although trained to use the Mayo Clinic radical mastectomy, Crile began to investigate other procedures after seeing the results of the 1955 McWhirter studies in Great Britain (16). McWhirter treated women with breast cancer by a combination of simple mastectomy and radiation, and in Crile's words, the results of the treatment "appeared to be as good as or better than those I was obtaining with radical mastectomy" (16). Impressed by those results, Crile himself began to try the same method, removing the cancer-bearing breast and irradiating the axillary nodes.

Although results of the treatment seemed as good as those of the radical operation, the high-dose radiation needed to destroy malignant cells caused frequent complications. In response to this, Crile reasoned that equally good results might be obtained if the breast were removed and the muscles left intact during surgery, and if no positive nodes were detected during the surgery, no nodes were removed or irradiated

Table 6.—Types of Breast Cancer Surgery Performed at the Hillside Medical Center, 1973-78

Period	Standard radical mastectomy	Modified radical mastectomy	Simple mastectomy	Lumpectomy	Lumpectomy for patient over 80 years, or 2d operation
September 1973-August 1975. . .	71	67	12	1	5
September 1975-December 1977	47	89	12	7	2
January 1978-December 1978 . . .	19	32	6	18	3

SOURCE: Data obtained from the Long Island Jewish/Hillside Medical Center operating room log, tumor registry, and Dr. Wise's surgical files

after the surgery. If moderate nodal involvement were apparent, the nodes would be excised, but radiation would be used only if nodal metastasis was extensive.

In 1955, Crile and his colleagues began a clinical study in which he treated his patients as simply as possible, using no prophylactic radiation and removing the nodes only if they showed malignant involvement. His colleagues treated patients by the conventional radical mastectomy, often using prophylactic X-ray therapy. After 5 and 10 years, more patients were living after the simple operations than after the more radical operations in which nodes were removed. Although the study was small, necessitating a larger trial in which the diseases were of the same stage before definite conclusions could be drawn, Crile observed" three apparent points (16):

> 1) If there were microscopic deposits of cancer in nodes, the patients whose nodes were not removed until the involvement could be felt had just as high a rate of survival as did those whose similarly involved nodes had been removed prophylactically at the first operation (in short, we had lost nothing by deferring operation until the presence of cancer in the nodes could be felt); 2) the patients whose nodes did not contain any cancer and were not removed did better than a similar group whose uninvolved nodes were removed; **3)** the necessity for performing a secondary operation for cancer that appeared in nodes later on was much less than we had expected.

By 1958, Crile was beginning to perform partial mastectomies. This procedure involves removal of the tumor, of at least an inch of apparently healthy breast tissue on each side of it, and of the overlying skin and underlying fascia (connective tissue). The breast is left at about two-thirds of its original size. A study of patients receiving partial mastectomies was begun in 1955. In the early years of the study, only 10 to 12 percent of patients with operable cancers were treated with this procedure. Because the efficacy of the partial compared to the simple mastectomy was not known, the lesser procedure was reserved for old or debilitated patients, for those who refused mastectomy, or for patients whose degree of axillary metastasis necessitated radiation. Patients with small (2 cm), favorable, peripherally located, and nonmulticentric tumors were also eligible for the procedure.

In all, 173 patients treated by partial mastectomy were observed for 5 and 10 years. The high proportion of deaths noted in the l0-year followup period was due primarily to causes other than cancer, because the patient mix included a number of elderly, debilitated women or women whose treatment could only be considered palliative. By 1970, the results of the 15-year followup of partial mastectomy patients by Crile and his colleagues were encouraging enough so that the option of this treatment was offered to all. The breakdown of indications for the 173 partial mastectomies performed from 1955 on was as follows:

Refused mastectomy *8*
Palliation for advanced (stage 11 +) cancer. 6
Inoperable—advanced or other disease
(until **1971 many** older patients and those with concurrent diseases were selected) 6
Suitable size and location. 153

The results of the study by Crile and his colleagues are summarized in table 7. These figures include the 5-year survival rate of the 173 patients treated by partial mastectomy and the 10-year survival of the 63 patients operated on before 1968. The incidence of recurrence is also shown (this does not include the first ap-

Table 7.-Results of Partial Mastectomy, 1955-72

Results	
Lived 5 years.	**132/1 73 = 76%**
Lost, counted dead	**2 =** 1%
1955-67—lived 10 years.	**28/63 = 44%**
Lost, counted dead	**2 =** 3%
Local recurrence	21 = 12%
Axillary nodes later	14 = 8%
New cancers same breast.	6 = 3%
New cancers other breast	6 = 3%

[a] 14/32 (44%) of those who died before 10 years died of causes other than cancer

SOURCE: G. Crile, et al., "Results of Partial Mastectomy in 173 Patients Followed From Five to Ten Years," *J. Surg. Gynecol. & Obstet.* 150:563, 1980

pearance of an involved node in a previously untreated axilla).

None of the patients seen from 1970 on has been followed for 10 years. Because of this, Crile finds it impossible to draw final conclusions, but he does state that it appears that in properly selected patients with small peripheral cancers of the breast treated by partial mastectomy, with or without axillary dissection, the survival rates are comparable to those obtained by total mastectomy and radiation. In Crile's view, when a local recurrence or axillary metastasis after limited treatment is treated adequately, there is little lost in terms of life expectancy. Patients should be warned of the potential for recurrence and followup treatment. Secondary mastectomy is not usually indicated in these instances (7.5 percent in the study).

In terms of the breast cancer controversy as a whole, Crile believes that there has been a definite nationwide change from the performance of routine radical mastectomies to the performance of the less debilitating modified radical mastectomy. Crile has also noted an increase in the use and potential for reconstructive surgery. He believes that in the long run, surgery will take second place to radiation and irridium small dose of implanted radioactive material treatments. He has had some of the Cleveland Clinic's radiotherapists trained in France, so that irridium implants would be available for use at that facility. In Crile's view, chemotherapy has only a limited role to play in the treatment of breast cancer. Crile further believes that widespread change in the treatment of breast cancer is imminent, noting that women **as** consumers and as those most affected by treatment will be a great part of the force behind the changing trends.

Dr. Oliver Cope

Dr. Oliver Cope is an Emeritus Clinical Professor of Surgery at the Harvard Medical School and a consulting surgeon at the Massachusetts General Hospital. For the last 20 years, he has been pursuing alternatives to mastectomy for the treatment of breast cancer. In 1977, Cope published a book entitled The Breast: Its *Problems,* ***Benign and Malignant, and How to Deal With Them (13).*** This work is a comprehensive guide intended for the layperson that covers all aspects of breast disease, the intricacies of cancer treatment, and alternatives in surgery. Cope believes (13):

> An informed public can help expedite the new opportunities for care. If women know what questions to ask, physicians will have to pay attention, to be alert to these advances.

Since the publication of this book, Cope has become a well-known figure both to the medical and nonmedical world in the breast cancer controversy.

Until 1956, Cope routinely performed radical mastectomies on patients with breast cancer. Although he was aware of the emotional trauma experienced by women over the loss of breast and equally conscious of how little was known about the disease itself, he adhered to the traditional surgery. In 1956, Cope came upon his first patient who refused a mastectomy in any form. She consented to local excision of the tumor and was given radiation treatment after the initial surgery. In 1958, a similar experience with another patient led Cope to critically evaluate the radical mastectomy and its accomplishments. He found evidence against the radical to be so convincing that he stopped performing it altogether in 1960. He states (13):

> The years since 1956 have shown me only the more clearly that mastectomy has not lived up to expectations, that it cures but the minority, that the results have not improved over the last **40** years, that it is long outdated and is to be superseded.

Cope is against radical or modified radical mastectomy in any form. He has spoken out against them because "such operations are disfiguring, thoughtless of a woman's feelings about herself, and damaging to her well-being" (13). Cope concedes that 50 or 75 years ago there was no alternative to extensive surgery, but says that now, with an understanding of sophisticated radiation techniques and drug therapy, there are alternatives. Instead of mastectomy, Cope recommends lumpectomy, followed by radiation given in a specialized radiation center using a high power linear accelerator. If the cancer is advanced, special types

of radiation would be used without surgery (unless otherwise indicated). Cope stresses that tumor drugs, not adjuvant radiotherapy, would be used in conjunction with lumpectomy. He also believes that prompt and prolonged chemotherapy for women with metastasized disease is a hopeful and frequently successful treatment.

Cope is a proponent of a combined approach to the treatment of breast cancer. Treatment should consist of a carefully monitored combination of surgery, medication, and radiation therapy carefully oriented to the patient's illness and psychological makeup. Cope believes that teamwork among colleagues is essential for proper treatment of the disease. For several years, he has sought to create a "Women's Care Center" at the Massachusetts General Hospital. A group of specialists, including a surgeon, internist, radiotherapist, health educator, and psychiatrist, would work with the patient to map out an appropriate treatment regimen. Because 9 out of 10 breast lumps are benign and only 7 percent of women ever develop cancer, the center would try to educate women about the appearance and disappearance of benign tumors. This could reduce the cost of unnecessary biopsies and doctor visits.

So far, Cope notes, the vast majority of physicians, especially surgeons, still adhere to the traditional treatment of mastectomy in some form. Many of these physicians are concerned about the dangers of radiation therapy or chemotherapy. Nevertheless, increasing numbers of physicians, especially radiotherapists, are encouraging and performing the "lesser" surgery.

CHANGES IN MEDICAL PRACTICE: PERSONAL FACTORS

Drs. Wise, Crile, and Cope are unusual in several respects. They are outspoken proponents of changing a traditional medical practice. They are successful and well-known members of their professions who have become to a substantial extent public figures because of their outspokenness. At the same time, however, these three surgeons have a great many traits in common with their colleagues, with the medical profession as a whole. They all received a traditional, conservative medical education. They are or were all career-oriented individuals who sought to serve their patients as well as make a reputation for themselves. They believe in the scientific method and the importance of evidence. The championing of less extensive forms of surgery for breast cancer by these three surgeons did not just happen. It was the result of subtle, complex, personal, and (ultimately) not full y understandable experiences and attitudes.

Wise, Crile, and Cope, we believe, illustrate the role that personal factors can play in the evaluation of medical practices. The last three decades were a time of growing awareness and sensitivity on the part of women and men alike concerning their responsibility toward their own health. The automatic authority and conservatism of professions such as medicine became increasingly questioned. Technologies of all types often came under harsh scrutiny. Within this social backdrop, many members of the medical and other professions also came to challenge the unquestioning acceptance of prevailing methods of doing things.

The qualities that led any one such individual to join in this questioning could be (and have been) the subjects of many sociological studies. For the purposes of this analysis, only two need to be suggested: personal experience and personal sensitivity. Those factors seem to have been present in each of the three surgeons singled out for this case study.

It is particularly important to note that each of these surgeons became aware very early of the physical disfigurement, psychological trauma, and other secondary elements of morbidity that accompanied the more extensive forms of breast cancer surgery, especially the Halsted radical mastectomy. Wise realized that "less mutilation is better;" Crile hypothesized that his training in the radical surgery may have been appropriate in *earlier* years; and Cope, even while performing radical surgery, was aware of the emotional trauma involved for the women.

Crile's skepticism may have been further conditioned by his association with the Cleveland Clinic—a progressive private medical institution.

These personally felt sensitivities either led directly to attempts by these surgeons to test the necessity of the more extensive (and thus mutilating and traumatizing) forms of surgery or allowed them to be more open to new evidence on nontraditional terms of surgery. For example, Cope first began questioning the radical mastectomy procedure he had been using because of his experiences with a few individual women. The results of those individual cases were enough to encourage a more complete and more regimented investigation of the efficacy of lesser procedures as compared to the radical standard. Wise's experiences with groups of U.S. and British patients similarly led him to continue and expand his activities in regard to evaluation of alternatives.

Thus, it may be a reasonable hypothesis that personal sensitivities, perhaps conditioned by the accelerating social activism in this country, prompted or at least reinforced a tendency by these and many other physicians to subject the traditional treatment mode to a more rigorous test of scientific value and outcome.

Again, these three surgeons were not the only ones to bring about the debate on the relative merits of radical mastectomies versus less extensive methods. The forms of personal influences that they experienced and were subject to, however, may represent a less definable though critical element in the process by which traditional forms of therapy are modified or discarded in favor of new ones.

Whether the aforementioned hypothesis will turn out to reflect reality is impossible to say. Clearly, however, the standard method of treating breast cancer is changing. Simply examining the medical literature, with its reports of clinical experience and trials, may not be enough to explain this. It is our hope that the possible influence of personal factors will be examined further in an effort to expand understanding of how changes in medical practice occur.

CHANGES IN MEDICAL PRACTICE: PROFESSIONAL FACTORS

The preceding part of this case study set out some possible motivating factors, from the perspective of individual physicians, that led to the change in the standard method of treating breast cancer. It is important to note, however, that individual physicians have to operate within the professional and institutional structure of American medicine. One of the paramount characteristics of that structure is conservatism. To a substantial extent such conservatism serves patients well, but in certain circumstances, it can also be a disadvantage.

This dual possibility—of beneficial and harmful effect—is well illustrated in the case of treatment for breast cancer. The conservatism of medicine, and in this case surgeons, was in part responsible for the lack of an earlier challenge to the more extensive forms of breast cancer surgery. On the other hand, that same conservatism does force today's proponents of change to provide adequate evidence relating to the appropriate use of alternative forms of surgery.

Medicine cannot change with the appearance of each new issue of a medical journal. Skepticism prevents a good deal of medical nonsense. Science, including medical science, does and should proceed by argument and counterargument. Hasty change is as bad or worse than no change. Obviously, a balance must be sought.

In the case of radical mastectomy, surgeons' experience with, and thus their expectations for, that treatment had accumulated over a period of 90 years. Halsted's and Johns Hopkins University's reputations, combined with the probable fact that early surgery was performed on advanced cancer cases (stage III), ensured that the method became firmly ensconced in medical practice. Abrupt change was unlikely, and the evidence for change had to be very strong. The

personal, individual physician-related factors discussed above, plus the shift in the patient population from the **1930's** onward (especially beginning in the 1960's) to those with less advanced disease, helped precipitate trials of less extensive surgery.

There are several other possible reasons for the reluctance of the medical profession to accept less extensive surgery for breast cancer. One is that the "burden of proof" has been viewed as resting with the innovators as opposed to those surgeons performing the traditional forms of mastectomy. That the radical mastectomy clearly was regarded as the treatment of choice for about **90** years is evidence enough that the burden was on the proponents of lesser surgery. The impact of burden of proof is as powerful in medicine as it is in law. It was clearly up to the proponents of change to make a strong case for that change. Radical mastectomy is "innocent until proven guilty. "

The structure of medical specialization has also contributed to the situation. Chemotherapy, radiotherapy, and surgery are the domains of three separate medical specialties—internal medicine, radiology, and surgery (or obstetrics-gynecology in certain parts of the United States). It is human nature to believe in what one does. Thus, to design and carry out a clinical trial of surgery v. radiation therapy is not as easy or feasible as it would be if these treatment modalities were under the domain of the same specialty. And because several of the less extensive forms of surgery are used in conjunction with radiotherapy or chemotherapy (to a greater extent than is radical mastectomy in most cases), comparative trials among the forms of surgery are also difficult to set up. Similarly, surgeons who become identified with specific forms of surgery for breast cancer form what are very much like special ties-within-a-specialty. Here, too, trials are difficult to conduct, and their persuasive value is diminished.

One other point regarding medical specialization and its influence on the acceptance or rejection of innovation is applicable to the present case. Surgeons (to make a broad but generally accurate observation) tend to be more concerned with prolongation of life than do other specialists, such as psychiatrists. The innovators in surgery for breast cancer observed here (e.g., Cope and Wise) have had significant associations with or interest in psychiatry and have been more concerned with quality of life issues such as the psychological impact of radical procedures.

There is also an international aspect to the change process we have been examining. Much of the early testing of less extensive *surgery* **was** conducted abroad, especially in England, and the acceptance of such surgery occurred earlier in other countries than it did in the United States. Several possible factors explain this situation. Surgical intervention is less frequent and less aggressive in England than it is in the United States (8). Also, Halsted's reputation was much greater in the United States than abroad; in the United States, he has often been called the country's greatest surgeon. A possible economic motive may also play a role in the international difference: In England, most physicians are salaried members of the National Health Service, while in the United States, fee-for-service medicine predominates.

CONCLUSIONS: REFLECTIONS ON THE CHANGE PROCESS

This is a case study on change in medical practice. It has examined the personal and social or professional elements that may have contributed to or worked against the reduction in use of radical mastectomy in favor of the use of less extensive forms of surgery. All of the material presented so far has been descriptive. In this concluding discussion, we offer some observations concerning the change process and possible areas where it might be made *more rational.*

First, physicians should write and speak directly to the public on controversial issues and not be criticized by their peers for doing so (34).

Breast cancer is a topic to which the public media are willing to devote substantial space, and most women are willing and able to follow and enhance this sort of technical and social debate.

Second, medical conservatism has strengths and weaknesses. Rushing to the latest fad is by no means desirable. Conservatism, however, often implies that a specialty group has developed a consensus, and that an outsider, fresh to the debate, may not be in agreement with it. Specialty groups should be willing to test their consensus by having outsiders inquire into the state of knowledge.

Third, an intelligent, informed patient could reasonably choose between clearly explained alternatives and ought to be allowed to do so. The surgeon who is willing to provide only one procedure and gives the patient no option does harm. This practice is common and has led State legislatures to propose bills requiring that options be explained and presented to all breast cancer patients. Such laws should be unnecessary.

Fourth, although economic incentives can explain the present situation in part, this does not justify overhauling fee-for-service surgery. There is no neutral economic system. Perhaps this case study makes the point that fee-for-service surgery and institutions with surgeons on salary should compete in an environment where patients can choose the economic system they prefer. Choice and competition certainly may be beneficial, but, in order to be so, will require active cultivation.

Fifth, the research community and the governments that support research have failed in several respects. Randomized clinical trials are expensive and often difficult to perform. Why did it take seven separate trials, performed over 15 years, to change expert consensus? A trial ignored is almost as bad as a trial not performed and is also a waste of scarce research resources. Much more attention should be given to considering what types of research methods and administrative procedures are needed to appropriately change expert consensus. Such consideration requires thought about strength of prior opinion, participation by opinion leaders, and careful marketing of the results to the practicing surgical community. This suggests study of the personal and social context of change, which we have attempted to begin in this case study.

Sixth, the ground rules for consensus formation need clarification. Where does the burden of proof lie? If the burden of proof had been shifted, the history of the breast cancer surgery debate would have been very different. Imagine that in 1966 the Kaae and Johansen (37) and the Brinkley and Haybittle (s) studies had been declared the best available evidence at that time. The burden of proof for demonstrating the desirability of radical mastectomy would then have fallen on those who believed in it. Since quality of life is lower with radical surgery, any surgeon wishing to perform radical mastectomies would have had to have conducted a trial whose results showed enough gain in prolongation of life to offset the loss in quality. If this situation had existed in 1966, it is likely that almost no radical mastectomies would have been performed in the last 15 years.

APPENDIX A: COST ESTIMATES

Two different treatment strategies that were analyzed in terms of costs in one hospital are considered below: inpatient v. outpatient tissue biopsy (11). After considering these alternative strategies, we will attempt an analysis of national data on breast cancer surgery.

Figure A-1 shows the alternative strategies, inpatient v. outpatient biopsy, as observed for 1976 at Massachusetts General Hospital. For inpatient biopsy, the patient is admitted to the hospital and the operating room is scheduled for a possible radical mastectomy. Under total anesthesia, she has a biopsy and immediate frozen section (tissues fixed for microscopic examination by freezing). The pathologist concludes negative, doubtful, or positive cancer. If negative or doubtful, the patient is returned to her room to await the results of a permanent section, which is considered slightly more accurate. If positive, radical mastectomy usually is performed, followed by discharge, radiation therapy, and perhaps later reconstructive surgery. If the frozen section is positive, radical mastectomy usually is performed immediately. Note that this approach means the patient does not know at the start of the operation what condition she will be in when the operation ends.

For outpatient biopsy, the patient undergoes total anesthesia in the ambulatory surgical service and goes home the same day to await the results of a permanent section, which are usually known within 24 hours. If positive, admission and radical mastectomy follow. Note that the outcomes are certain here, but two total anesthesias are required for patients needing surgery.

Table A-1 shows the cost differences and number of cases for 1976 a t Massachusetts General Hospital. If one excludes the patients with treatment other than surgery, then the total cost for the 284 patients, using the inpatient alternative is $657,664. If the outpatient alternative costs were applied to these patients the costs would be $501 ,056—a savings of 24 percent. This calculation does not consider the effect on costs of more limited surgery or the effect of not using radiation therapy afterwards. It also does not consider the effect of doing limited surgery such as tylectomy or the reduced need for later reconstructive surgery.

Figure A-1.—Alternative Strategies of Inpatient v. Outpatient Biopsy at Massachusetts General Hospital, 1976

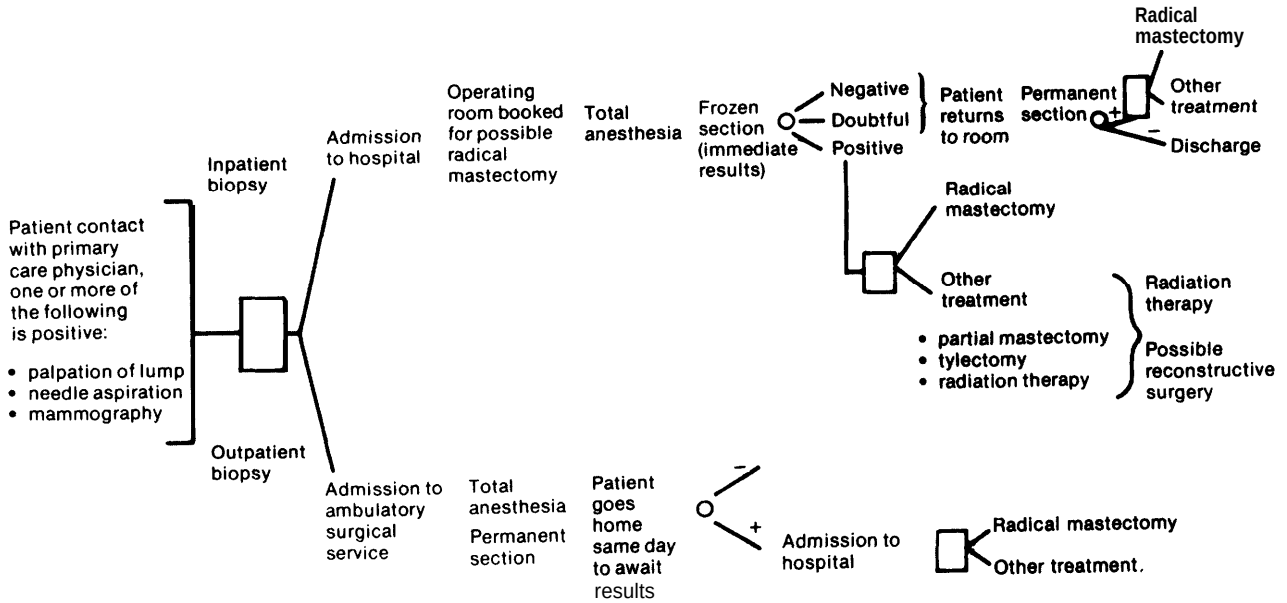

Table A-1 .—Breast Surgery at Massachusetts General Hospital, 1976

	Average cost	Number of cases
Inpatient alternatives		
Negative biopsy	$1,223	152
Positive biopsy, immediate mastectomy	3,270	84
Biopsy, permanent section positive, mastectomy	4,106	48
Biopsy, permanent sect ion positive, other treatment (patient refused surgery, radiation only or incomplete chart)	1,850	16
Outpatient alternatives		
Negative biopsy	316	244
Positive, radical mastectomy	3,432	52
Positive, other treatment	940	12
Total		608

NOTE. The cost of postsurgical radiation therapy for 6 to 9 weeks is not included above This would be an added $2,000 Surgeons' fees not Included.

SOURCE: Massachusetts General Hospital operations log and other medical records.

Table A-2 shows the total number of procedures for the United States in 1975. Unfortunately, the national data do not separate out biopsy only and partial mastectomy and tylectomy. One can only guess at the amount of less extensive surgery. A simple calculation of total patient days and costs yields an aggregate cost of $413.6 million, excluding radiation therapy.

A very rough estimate is made in table A-2 to show the possible cost savings that would result if outpatient biopsies were used uniformly and radical surgery were replaced with more limited surgery. The savings would be $185 million per year or a 45-percent reduction in costs. This does not consider reducing the use of radiation therapy or changing from complete mastectomy to tylectomy. So the 45-percent potential reduction in total costs is probably a substantial underestimate.

The reader must realize the very approximate nature of this cost analysis. However, the magnitude of the difference in costs is sufficient to warrant further investigation.

Table A-2.—Breast Surgery in the United States, 1975

	Number of procedures	Average length of stay (in days)	Total number of days
Surgical mix in 1975			
Biopsy and partial mastectomy	223,000	3.5	780,500
Complete, modified radical, radical mastectomy	103,000	12.5	1,287,500
			2,068,000
		Total cost @ $200/day=	$413,600,000
Possible alternative surgical mix			
Outpatient biopsy	200,000	1.0	200,000
Partial mastectomy	23,000	3.5	80,500
Complete mastectomy	103,000	8.3	854,900
Radical mastectomy	0	—	0
			1,135,400
		Total cost @ $200/day=	$227,080,000

Difference in costs between actual surgical mix and possible alternative for 1 year= $413,600,000– $227,080,000 = $185,720,000, or 45% savings **with alternative.**

SOURCES: Number of cases in 1975: National Center for Health Statistics. Surgical Operations in Short-Stay Hospitals. United States, 1975, Vital and health statistics data: National Health Survey, Series 13, No. 34. DHEW Publication No. (PHS)78-1785. (Hyattsville, Md.' DHEW, April 1978), Average length of stay. National Health Survey Series 13, No. 34. DHEW Publication No. (PHS)78-1785, Average length of stay for complete mastectomy only: Commission on Professional and Hospital Activities (CPHA). *Length of Stay in PAS Hospitals by Operation, United S'ates 1975* (Ann Arbor, Mich., CPHA, 1976).

APPENDIX B: EVIDENCE ON SELECTED TREATMENTS FOR BREAST CANCER

Extended Radical Mastectomy

Extended radical mastectomy is the most extensive surgery used in the primary treatment of cancer of the breast. The rationale behind this technique is to eliminate the cancer and stop its spreading by removing all of the lymphatic drainage pathways in the breast region. Halsted noted the existence of malignant metastasis to the chest wall and breast bone via the chain of internal mammary nodes under the sternum, but soon abandoned the resection of the supraclavicular nodes because the "procedure did not improve upon long-term survival rates" (29).

Sampson Handley of the Middlesex Hospital in London further researched Halsted's comments on the role of the internal mammary nodes and began to report the resection of this chain of nodes (32). Finding that the internal mammary nodes were not uncommonly involved in the spread of cancer, Handley devised an operation to remove them as well as the axillary nodes. The procedure did not improve mortality rates and was soon discontinued.

After World War II, the extended radical mastectomy was again pursued. Dr. Jerome Urban of Memorial Hospital in New York (51) and Drs. Andreassen, Dahl-Iverson, and Sorenson of Copenhagen (3) began to perform and report upon results obtained by the extended radical. Andreassen and his associates ran four series of trials. In the first series, involving 98 patients, the supraclavicular as well as axillary nodes were removed. None of the **98** patients manifested clinically palpable supraclavicular nodes, but microscopic metastasis was present in these glands in 17 patients (33 percent). All 17 patients were clinical stage II cases. In the second series of the study, involving 53 patients, the internal mammary nodes were removed along with the axillary glands. Of 53 patients, 24 percent of those with metastasis in the axillary nodes were found to have microscopic metastasis in the internal mammary glands. In the third and fourth series (1951 and 1952), the axillary glands, supraclavicular and internal mammary nodes were removed. The third series of **76 patients** showed the internal mammary nodes to be involved twice as often as in the second series, but this difference was due in part to an alteration in operative techniques, In all the series, there were no cases of supraclavicular node involvement without axillary node involvement. After retrospective analysis, Dahl-Iverson abandoned the extended radical mastectomy in 1957. Its results, in his view, were not superior to those of the standard radical mastectomy **(3).**

Caceres and Urban (10,50,52) also noted the high incidence of cancer metastasis to the internal mammary nodes. In a large retrospective nonrandomized study, Caceres compared results from the radical mastectomy v. the supraradical mastectomy. The latter consists of a radical mastectomy combined with en bloc extrapleural resection of the internal mammary chain together with the overlying chest wall; the supraclavicular nodes, however, are not excised. The results of this study are shown in table B-1. The difference in survival rates between the two groups was not considered statistically significant.

In 1952, Urban and Baker (53) published the results of including the en bloc resection of the internal mammary lymph nodes, while performing the standard radical mastectomy on women manifesting invasive breast carcinomas located in the central and medial quadrants of the breast. They followed the long-term progress of these women, reporting that "as compared with results following radical mastectomy the patients had fewer local recurrences, longer survivals and approximately the same morbidity and mortality. "

Urban's data are used as a guideline at Memorial Hospital in New York for the treatment of patients with circumaureolar and inner quadrant lesions. The extended radical is recommended for these patients, providing their ages are not too advanced and there are no other medical contraindications. Adjuvant prophylactic radiation therapy is prescribed when there is extensive nodal involvement. Patients manifesting noninvasive lesions, histologically low-grade invasive carcinoma, lesions less than 1 cm in diameter with a negative internal mammary node biopsy are subject to radical or modified radical mastectomies and subsequent radiotherapy when indicated.

The extended radical mastectomy is considered by some surgeons to be a massive and disabling operation. According to Dr. Oliver Cope, it has now been largely abandoned by most surgeons because of the morbidity associated with it and because its results seem no better than those obtained by the standard Halsted procedure.

Modified Radical Mastectomy

Until very recently, radical mastectomy was considered the treatment of choice for patients with breast cancer. Over the last several years, however, the trend has shifted and the modified radical is now the favored procedure. In 1971, a poll of New Jersey

Table B-1.—Survival Rates by Type of Operation: Radical v. Extended Radical Mastectomy: 5. and 10-Year Survival

Type of operation	5-year survival			1 O-year survival		
	Patients	Survivors	Percentage of patients surviving	Patients	Survivors	Percentage of patients surviving
Without axillary metastasis						
Radical mastectomy.	43	32	74.4%	43	28	65.17.
Extended radical mastectomy.	184	153	83.1	52	35	67.3
With axillary metastasis						
Radical mastectomy.	70	33	47.1	70	22	31.4
Extended radical mastectomy.	241	106	44	77	19	24.7
Total						
Radical mastectomy. ., ...	113	65	57.6	113	50	44.2
Extended radical mastectomy.	425	259	60.9	129	54	41.8

SOURCE, E Caceres, "Incidence in the Internal Mammary Chain in Operable Cancer of the Breast, " *Surg Gynecol Obstet* 108(6) 715, 1959

surgeons showed that **83** percent preferred the radical mastectomy and only 15 percent performed modified radicals. In 1977, a similar survey showed only 37 percent of surgeons performing the radical procedure and **60** percent favoring the modified operation. It is estimated that today the figure for the radical procedure has dropped to 15 percent (14).

A 1974 survey of breast surgeons in Pennsylvania showed less than half the procedures were radical. A similar 1978 survey would probably show less than 25 percent were radical (17). Tables B-2 and B-3 report types of surgery from the American College of Surgeons' review of breast cancer treatment (2).

The modified radical mastectomy removes all of the breast tissue, its overlying skin, and the contents of the axilla nodes. In a procedure designed by Patey in the 1930's to reduce cosmetic deformity, the pectoralis minor muscle is removed, but the pectorals major is left intact. Auchinchloss devised a variation of the surgery that preserves both muscles (17). The modified radical is less debilitating than the radical because there is less chance of impaired arm movement and postoperative edema of the arm.

At the Long Island Jewish/Hillside Medical Center in New York City, most of the staff and attending surgeons have begun to perform the modified radical nearly twice as frequently as the traditional Halsted procedure. One surgeon affiliated with the Community Health Program at the Medical Center states (49):

> I believe breast career to be multi-focal and feel it absolutely essential to view the axillary nodes before I begin the operation [think best for the patient, In general, I prefer the modified radical mastectomy to the radical procedure, but will do a radical if called for by medical or anatomical considerations.

Table B-2.— Distribution of 15,132 Cases of Breast Cancer Diagnosed in 1972, by Type of Surgery

Type of surgery	Percentage of cases
None	5.4%
Wedge excision (lumpectomy, tylectomy).	3.4
Total (simple) mastectomy	11.5
Total mastectomy with axillary dissection	6.4
Modified radical mastectomy	26.2
Radical (Halsted) mastectomy	45.3
Radical mastectomy with internal mammary node biopsy	1.5
Super (extended) radical mastectomy	0.3
Total.	100%

SOURCE: American College of Surgeons, Commission on Cancer, "Final Report. Long-Term Patient Care Evaluation Study for Carcinoma of the Female Breast" (mimeo) (Chicago ACS, Feb. 21, 1979)

According to Dr. Leslie Wise (55):

> The two arguments usually given against modified radical mastectomy are that it does not provide adequate access to resection of the axillary lymph nodes and that the pectoral lymphatics are not removed. If the arm is 1 if ted so that the forearm lies in front of and parallel to the chest, then the pectoralis major is relaxed and can be retracted to expose the pectoralis minor, which may be divided; under these conditions the upper reaches of the axilla come in full view. There is supportive evidence that removal of the pectoralis major and the interpectoral nodes is unlikely to be of value unless the internal mammary nodes are also removed.

Although there have been few clinical trials testing the efficacy of the modified radical mastectomy, a series run by Handley gave results which seem to be comparable to those published for radical mastectomy.

Table B-3.— Distribution of 24,136 Cases of Breast Cancer, by Stage of Cancer" and Type of Surgery, 1950-72

Type of surgery	In situ (N= 462)	Localized (N= 11,845)	Regional (N= 10,040)	Distant (N= 1,626)
None	2.2%	1.60/0	3;5%	'-42.90/.
Wedge excision	12.6	3.3	1.3	8.5
Total (simple) mastectomy	32.5	14.1	5.8	19.9
Total mastectomy with low axillary dissection	9.1	5.8	5.5	4.4
Modified radical mastectomy,	20.1	24.3	26,1	9.9
Radical (Halsted) mastectomy	23.2	49.3	54.5	12,4
Radical mastectomy with Internal mammary node biopsy	0.4	1.4	2.0	1.6
Super (extended) radical mastectomy.	0.0	0.2	0.2	0.4
Total	1 000/0	100%	1000/0	1 00%

[a] 163 cases stage not known

SOURCE American College of Surgeons Commission on Cancer Final Report Long-Term Patient Care Evaluation Study for Carcinoma of the Female Breast" (mimeo) (Chicago HI ACS Feb 21 1979)

Simple or Total Mastectomy

The simple or total mastectomy is considered one of the "lesser" surgical procedures used to treat breast cancer. The simple mastectomy was the first operation used in clinical trials to test the efficacy of the radical mastectomy against a less extensive surgical technique. It was also the procedure used in trials featuring comparisons between radical surgery and combination forms of treatment —usually total mastectomy plus radiation.

During a simple mastectomy, only the breast tissue and overlying skin are removed. The chest remains intact as does the axilla. The surgery is often accompanied by adjuvant radiotherapy. Unlike a radical mastectomy, a simple mastectomy leaves no cosmetic deformity of the chest wall.

In 1948, Dr. Robert McWhirter of Scotland began performing simple mastectomies followed by radiation therapy at Edinburgh's Royal Infirmary (45). McWhirter's results after 5- and 10-year studies were no worse and no better than results following radical mastectomy (44). A similar study was carried out in Finland by Professor Mustakallio (45). About 30 years age, Mustakallio began removing only the breast and irradiating supicious lymph nodes in order to destroy any remaining cancer. In some cases when the lesiion was tiny, he removed only the tumor itself. His reports also showed results comparable to those obtained by radical mastectomy (45).

Two fairly recent prospective clinical trials utilizing simple mastectomy are also available for study. Brinkley and Haybittle (5) compared the results of simple mastectomy plus radiation and radical mastectomy with radiotherapy for clinical stage 11 (axillary node involvement) cases of breast cancer. The patients were randomly allocated to a particular treatment group; 113 received simple masectomies and 91 had radicals. In many cases, the simple mastectomy involved removal of accessible axillary nodes, but there was no formal en bloc dissection of the axilla. Results suggest that patients with simple mastectomies did slightly better than patients with radicals in a 6-year recurrence-free followup. In 1971, the two groups were again reviewed. At this point, all patients had been followed for at least 5 years and some for 12 years. There was no significant different in survival rates between the groups (radical, **49.2** percent; simple, **46.4** percent). An increased incidence of edema of the arm was noted in the radical mastectomy patients **(5,6,55).**

From 1951 to 1957, a prospective clinical trial was carried out in Copenhagen by Kaae and Johansen (37). The results of extended radical mastectomy (removal of the breast, chest muscles, axillary, supraclavicular, and internal mammary nodes) without postoperative radiation were compared with simple mastectomy with postoperative radiation. A group of 335 patients were randomly selected for extended radical mastectomy and 331 patients for simple mastectomy plus radiation therapy. For a variety of reasons, not all of the patients were included in the results. The 5-year study includes only **206 patients** from the extended radical group and **209** from the simple mastectomy. The overall survival and recurrence rates at 5- and lo-year intervals were similar with both treatments.

Dr. George Crile, Jr., of the Cleveland Clinic, an early advocate of simple mastectomy (1957), has studied comparative, but not randomized, groups of simple mastectomies and radicals (15). His results showed that in clinical stage I cases, simple mastectomy, and, if necessary, later therapeutic axillary dissection, was as good as initial treatment with the radical mastectomy. The 5-year survival rates for radical mastectomy with or without radiotherapy

were 71 percent; for simple mastectomy without radiotherapy, 82 percent; and for simple mastectomy with radiotherapy, 73 percent.

Although a number of clinical trials have suggested that the combination of simple mastectomy and postoperative radiation therapy is as effective as radical mastectomy in most cases, critics of the simple procedure cite the Haagensen and Miller study **(27) as** evidence against it. All patients included in that trial had cancers defined as Columbia clinical classification stage A lesions, The 10-year survival rate for the radical mastectomy group was **70.2** percent, while that for simple mastectomy patients was 39 percent. Dr. Leslie Wise points out that one element often disregarded in the presentation of this study is the fact that the radical mastectomy group came from Haagensen's series at New York's Columbia-Presbyterian Hospital, whereas the simple mastectomy patients were treated in Detroit by Kennedy at a much earlier period when cancers were much larger (55). The two groups were completely unmatched.

Local Excision, Lumpectomy, Tylectomy

A local excision or lumpectomy involves the removal of the cancerous tumor and a margin of healthy tissue surrounding it (36). As early as 1943, F. E. Adair experimented with local excision, reporting **on 63** cases of operable breast cancer treated in this way. In seven patients, only the lumpectomy was performed; of this group, six patients survived 5 years. Preoperative radiotherapy followed by excision of the tumor was used in **27 cases.** These patients had a 70-percent 5-year survival rate. There was no mention of clinical staging of the disease in this study (55).

A further inquiry into the efficacy of local excision was made in Helsinki by Professor Mustakallio. In 1954, he published the results of a study involving 127 patients with clinical stage I cancer who were treated by lumpectomy and postoperative radiation to the remaining breast (45). The results compared favorably with those treated by radical mastectomy: 84 percent survived 5 years, and 72 percent survived 10 years. These results were backed up by F. Baclesse in Paris, who, like Mustakallio, began to treat women refusing mastectomy by local excision and irradiation. Baclesse began his study of 100 patients in 1940 and reported on the work in 1960 showing comparable results to the Helsinki study (13). By 1958, J. G. DeWinter, of Brighton, England, had also reported on a smaller series of patients treated by lumpectomy. In a 1961 publication, DeWinter stated that local excision and radiotherapy in an unselected group offered, "a reasonable alternative to the standard operation, " that is, radical mastectomy (55).

In 1963, Sir Arthur Porritt presented the results of a series of 265 patients with operable breast cancer who were randomly selected to undergo radical mastectomy with radiation therapy (156 cases) or local excision plus irradiation (107 cases). The **5- and 10-**year survival rates were respectively: radical mastectomy, 50 and 34 percent; local excision, 65 and 45 percent. According to Dr. Leslie Wise, these data suggest that the lesser operation is at least as effective as the radical procedure (55).

Dr. George Crile, Jr., reported several series of trials with local excision. In one series reported in 1965, 20 patients who received local excisions achieved a 65-percent survival rate that was comparable to that obtained by more extensive procedures. In that series, 12 patients had stage I tumors and 8 had stage II cancers. Crile reported on an additional 24 patients treated by local excision in 1967. In that group, the 5-year survival rate was 67 percent. Crile and Hoerr published the results of local excision on 55 patients in 1977. The patients, 40 of whom had clinical stage I cancers and 15 of whom had stage II lesions, were treated from 1955 to 1964. Thirty-one of the patients with stage I cancers were treated by local excision alone; 6 patients had axillary dissections as well as lumpectorny (local excision); and 3 had postoperative C. teletherapy. Of the stage 11 cases, 4 patients had axillary dissections and 11 had postsurgical C. teletherapy. The 5-year survival rate for the entire group was 67 percent. There was an Ii-percent incidence of local recurrence.

In 1971, Vera Peters of Toronto reported another similar trial. Treated by local excision and irradiation, her patients showed 5- and 10-year survival rates of 76 and 45 percent (55). These results were similar to those of her radical mastectomy series. Taylor and his associates from Great Britain also reported on a group of 77 patients manifesting stage I and 11 cancers. Seventy-seven patients were treated by local excision and radiotherapy. The 5- and 10-year survival rates were 71 and 50 percent. The incidence of local recurrence or the appearance of a new cancer which was treated by simple mastectomy was 18 percent (55).

Drs. Leslie Wise, Aubrey York Mason, and Lauren V. Ackerman conducted a comparative retrospective survey of 96 patients treated by local excision followed by radiotherapy on a 1,500 Curie telecesium unit and 207 patients treated by radical mastectomy with or without radiation therapy, depending on the histologic status of the axillary nodes (54). That study was carried out between 1950 and 1964 at St. Helier's Hospital in London. Only patients with stage

I and stage II breast cancer, designated according to the Manchester Plan, a clinical method of rating the progression of the disease, were included in the study. All of the patients were women. The age range of patients was 25 to 90 years, and the age distribution between the two groups was statistically similar. There was no statistically significant difference in the distribution of the local excision and radical mastectomy cases as to the size of the tumor. The 5- and 10-year survival rates by stage were, respectively: stage 1, local excision-96 percent and 68 percent; stage I, radical mastectomy-81 percent and 69 percent; stage II, local excision —74 and 53 percent; stage II, radical mastectomy —70 and 59 percent.

The Wise, Mason, and Ackerman study was the first published attempt to critically compare the results from a group of local excisions of mammary carcinoma with radical mastectomies. According to Dr. Wise, the mode of treatment apparently did not significantly alter the overall prognosis. There was no significant difference between the survival rates of the two groups, a finding **which suggests that local excision with moderate irradiation** may be a suitable alternative to radical surgery for early, operable breast cancers. Dr. Wise plans to run a 15-year followup on the patients involved in the trial.

The results of a prospective, randomized trial for stage I and 11 breast cancers were reported in 1972 by Atkins, Hayward, Klugman, and Wayte. A total of 370 patients, all aged 50 years and over, participated in the trial, which was carried out between 1961 and 1971. One group of 188 patients was treated by radical mastectomy, and another group of 182 patients received lumpectomy and postoperative radiation. There was no significant difference in overall survival rates between the two groups at any time up to 10 years after surgical intervention.

The arguments against local excision are varied. Some say that lumpectomy is an inadequate cancer operation, partly because the tumor and its draining lymph nodes are not removed en bloc. Proponents of the procedure argue that if this criterion is applied, then radical mastectomy is not adequate either, because only the axillary nodes are resected. Two other drainage pathways are left intact: the supraclavicular and internal mammary nodes.

Another argument used against local excision is that some breast cancers are multicentric and therefore local recurrence rates will be much higher with lumpectomies than mastectomies. Dr. Guy Robbins, of the Memorial Sloan-Kettering Hospital in New York, stresses this point as one that completely invalidates the use of such limited surgery (47). Advocates of local excision counter by pointing out that there are no facts that support the assertion.

A third argument against lumpectomy is that any breast in which a cancer has developed is likely to be the location of a second tumor; thus, local excision would leave the patient with the possibility of a second breast malignancy. Supporters of lumpectomy argue in response to this that a breast cancer patient has a 7-percent chance of developing a contralateral cancer in her lifetime. Supposedly, this applies to the remaining breast, but if that breast is irradiated, the chance of a second cancer may be less. If concern over the 7-percent possibility of recurrence was so great, **then according to the argument every breast cancer patient should have a prophylactic total mastectomy** on the opposite side (54).

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