

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 distant⁵ 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 III:** Carcinoma of breast with ulceration, inflammatory changes, or edema (swelling due to fluids in the tissue) of greater than one third of breast. Ax-

illary 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 III 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.

³Involving the axilla (the area between the chest and the arm).

⁴Involving the area above the clavicle (shoulder bone).

⁵Involving distant parts or organs of the body.

^bThe "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

⁷The pectoral muscles are the muscles of the chest. The pec-

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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 pectoralis major and the pectoralis 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 pectoralis 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 can-

cerous 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. Ac-

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

XRT = X-ray therapy

^aNumbers in parentheses refer to references in the list that appears at the end of this case study

^bAlso 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			55%
	Simple + XRT			61
USA: Fisher, et al., National Surgical Adjuvant Breast Project, 1977 (20)	Radical	Axillary nodes	354	79
	Simple + XRT	clinically	282	81
	Simple	uninvolved	344	76
	Radical	Axillary nodes	277	62
	Simple + XRT	clinically involved	224	62
Manchester: Lythgoe, et al., 1978 (41)	Simple + XRT + oöphorectomy		139	38
	Radical + oöphorectomy	Stage II	129	53

XRT = X-ray therapy

^aNumbers in parentheses refer to references numbers in the list that appears at the end of this case study^bAll three of these trials report followup 3 to 5 years; none of the survival result differences are statistically significantSOURCE 1. C Henderson and G P Canellos, "Cancer of the Breast," *NEng 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

^aRandomized clinical trial^bApproximately.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, axillary 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 II) 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 oophorectomy (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 observed³ 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 pa-

tients, 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 10-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.	132/173 = 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%

^a14/32 (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 iridium small dose of implanted radioactive material treatments. He has had some of the Cleveland Clinic's radiotherapists trained in France, so that iridium 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, in-

ternist, 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 fully 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 con-

servatism 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 counter-argument. 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