

CONSERVATION SURGERY AND RADIATION THERAPY FOR THE TREATMENT OF BREAST CANCER

Hypothetical objections and historical perspective

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The U.S. National Cancer Institute reports that approximately 76% of the 130 000 women with new breast cancers diagnosed in 1987 will receive more extensive surgery than conservation surgery, i.e. a simple mastectomy, modified radical or radical mastectomy. That is, almost 100 000 women will have their entire breast removed for breast cancer. Only 14%, approximately 10 000 to 15 000 women will have conservation surgery and radiation therapy (CS + RT). It is interesting to note that approximately 40 000 women or more could be candidates for this procedure, and the percentage of eligible patients increases yearly (8, 52). Presently, over 60% of the patients eligible for this approach will not receive it and in the future the eligible percentage may be even higher, thus it is important to establish the validity of the CS + RT approach for the breast cancer patient.

The rationale for not treating more women who could appropriately be treated with CS + RT for the most part is based on a number of hypothetical objections. We will evaluate the major objections in this report.

The method is unproven and experimental

Hutchinson, in 1936, surveyed in literature on the treatment of breast cancer with radiation at that time (19). He noted that there had been a number of patients treated by radiation therapy alone. He reported that Pfhaler and Parry, (40, 41) and Lee (25) from the United States and Schreiner and Kronig in Germany had used this approach. Pfhaler and Parry reported treating patients as early as 1902 and noted a 5-year cure of 87% in early breast cancer (41). Among the first publications to appear in the literature were those by Hirsch from Germany in which he reported a 95% 3-year and a 78% 5-year survival in early

breast cancer (18). Keynes in Great Britain reported a 71% 5-year survival in lesions confined to the breast and a 29% survival in lesions involving the breast and axilla. He compared these results to those in a similar group of patients treated with surgery alone in which there was a 69% and 31% 5-year survival respectively (20, 21). Keynes was probably one of the foremost early advocates of this method of treatment of breast cancer. In the U.S., Lee published encouraging results with the use of irradiation alone or combined with 'palliative' surgery. Thus there were a number of studies ongoing in the early years of this century of radiation treatment of breast cancer with conservation surgery reporting promising results.

Keynes pronounced the philosophy which underlies this approach to breast cancer. He said, 'I can lay claim to speak without any antisurgical bias since pure surgery is the chief preoccupation of my life, yet I feel that it must be the ambition of every conscientious surgeon to assist in the gradual elimination of an operation so extensive and severe as the radical operation for cancer of the breast.' The cosmetic results of his treatment were excellent.

Unfortunately, attempts by others, especially McKittrick (30) in the U.S., to reduplicate Keynes results, were disastrous with very severe complications found in patients after some of the treatments. The reason for this difference lay in the fact that while Keynes advocated and prescribed a very orderly and scientific arrangement of the radium needles, other authors, especially McKittrick, were unable to duplicate Keynes techniques; they subsequently performed implants which had crossed ends of needles, irregularly placed needles, obvious hot spots and obvious problems which would lead to the subsequent

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Table 1

Percentage 10 year NED survival by clinical stage (No. patients) (29)

	Memorial Rad mast (\pm RT)	Curie CS + RT*	Marseille CS + RT	M.D. Anderson CS + RT	Marsden CS + RT
Stage I	89.4 (66)	84 (87)	81 (111)	78 (54)	54 (54)
Stage II	52.6 (175)	67 (234)	69 (163)	73 (46)	29 (44)

Note: In stage I all adequate radiation therapy results (Curie, Marseille, M.D. Anderson and Memorial) are significantly better than Marsden. (Inadequate radiation therapy). In stage II all adequate radiation therapy results (Curie, M.D. Anderson, Marseille) are significantly better than Memorial or Marsden.

* Some stage II patients had biopsy and radiation alone.

RT = Radiation therapy; CS = Conservation surgery; Rad mast = radical mastectomy.

†Montague, personal communication, April, 1985.

complications. The results of these disasters were published and created a negative attitude towards CS + RT in the minds of most surgeons.

Work with CS + RT continued in other parts of the world and reports appeared in the literature in the 1950's, 1960's and 1970's from Canada, France, and England. These reports demonstrated excellent results with this breast conservation approach. One of the authors was Vera Peters, who in 1967 and later in 1975 reported on a 30-year follow-up of patients treated with excision and irradiation, matched to patients treated with mastectomy and irradiation according to the extent of the disease and she found that the survival in both groups of patients were similar (37-39). From the Nordic countries, Mustakallio, in 1953, reported on his results and techniques and noted an 84% 5-year survival in his 127 patients. He further reported a 10-year relative survival rate of 74% in patients who had regional disease (34-35).

Thus, the treatment is not in any way experimental (49); it has been going on for at least 60 years and the results reported on the majority of these studies have been quite comparable to surgery for patients with similar stage. In 1982, Bluming reported on a number of clinical trials of conservation surgery plus radiotherapy as primary treatment for cancer of the breast (5). He noted that some 4290 patients had been treated successfully with this approach. Since that time, of course, the number of reports and literature have increased tremendously and it is almost impossible to list all of the studies in reporting on this approach, but in any event, there must be at least 20000 to 30000 patients who have been successfully treated in this manner.

The results of radical surgery are superior in survival and recurrence rate

There have been many recent reports and literature comparing conservation surgery and radiation to radical and modified and radical mastectomy in non randomized trials from a number of institutions (9, 10, 12, 13, 36, 42-44, 47). MD Anderson Hospital recently reported on minimal breast cancer, stage I breast cancer and stage II

breast cancer comparing CS + RT to radical (RS) or modified radical (MRS) mastectomy. The results in local regional recurrences and survival were essentially similar (31, 32). In an evaluation of a number of studies we compared the results of the best radical surgical (RS) results from Memorial Hospital to those from 3 institutions whose patients were treated with CS + adequate RT (CS + ART) to one institution (The Royal Marsden) (Table 1) whose patients were treated with CS + inadequate RT (CS + IRT). When we compared the stage I Memorial results to the stage I results of the Curie Institute, Marseille, and MD Anderson Hospitals, adequate (CS + ART) at 10 years the NED survival was not significantly different. (IART) Royal Marsden stage I results were significantly worse from the other studies. In stage II, the NED survival in the institutions which treat patients with CS + ART were significantly superior to the Memorial results of surgery alone and to the CS + IRT data (29) from Royal Marsden.

However, it is in the randomized studies of conservation surgery and radiation therapy that the best answer to this hypothesis can be found. One of the oldest studies is the Milan trial which compared the Halsted mastectomy to a quadrantectomy plus radiation CS + RT therapy in essentially stage I and II patients. At 10 years, in node negative patients, there was no significant difference in NED survival or survival. In the node positive group, those patients who had the quadrantectomy and radiation therapy had a significantly better NED survival than patients who had the Halsted procedure alone. In these same patients, (CS + RT) in the 10-year survival results approached significance ($p=0.08$) and certainly were not inferior to radical surgery (RS). The causes of death were equivalent in both groups and the local recurrence rate, contralateral cancer rate, other new cancer rate and distant metastases rate were essentially the same in both groups (50).

The Gustave-Roussy Institut also performed a randomized study comparing the conservation surgery plus irradiation to mastectomy in stage I and II patients. Relapse-free survival and survival were not significantly different in the 2 groups at 5 years (45).

Table 2
Relapse in breast related to treatment (29)

Reference	CS + RT* (%)	CS† (%)	(A)	Stage	Follow-up years	Disease disseminated (%)
Clark R. M. (11)	13	28	p<0.001	I, II & III	10	-
Cedermarck B. et al. (10)	2.9	15.5	p<0.01	I	3	-
Fisher B. et al. (14)	8	28	p<0.001	I & II	5	-
Lagios M. et al. (23)	7.5	28	p<0.05	I & II	2	-
Tagart R. (48)		37		I & II	3	31
Montgomery A. et al (33)		33		I & II	5	18

*CS + RT = Conservation surgery plus radiotherapy.

† = Conservation surgery.

(A) statistical analysis by test of equality of proportions.

More recently, Fisher et al. have reported on their NSABP B-06 trial which compared total mastectomy to segmental mastectomy plus radiation therapy and segmental mastectomy alone. This trial was limited to stage I and II patients without fixed nodes. The overall results in stage I and II comparing total mastectomy to segmental mastectomy plus radiation therapy were recently updated. This report noted a significant improvement in NED survival for patients treated with CS + RT. Distant disease-free survival and survival were not significantly different (15).

Insofar as long-term follow-up is concerned, studies up to 30 years following CS + RT show continuously good results. Kurtz et al. (22) recently reported follow-up studies of stage I and II patients treated with CS + RT who had survived at least 10 years following treatment. Some patients were followed for as long as 26 years. Kurtz reported NED survival of 90%, metastasis-free survival of 91%, second tumor-free survival of 93%, and 78% of patients surviving.

It is important to note that of the patients with no evidence of disease between 80 and 95% have conserved their breast at 10 years in a number of series (31, 36). Marseille patients who did not recur had an 85% 5-year survival, if they recurred in the breast only their 5-year survival was 62%. For MD Anderson patients, the results were 81 and 67% respectively. The Curie Institute results were 90 and 75% respectively (32).

Radiation is unnecessary because conservation surgery alone or combined with chemotherapy is adequate to treat and control the disease

Evaluation of a number of studies in which patients were treated without radiation shows that the recurrence rate varied between 15 and 37% and these recurrences developed within a 2- to 5-year period (17). If the margin of the resection was involved the incidence of recurrence was extremely high in patients treated without radiation as compared to patients who had radiation. In those pa-

tients there is a high incidence of disseminated disease developing at the same time the recurrence develops in the breast or shortly thereafter (29) (Table 2).

Probably the best evaluation of the importance of radiation following CS is the Fisher B-06 study which noted that the disease-free survival was significantly better in patients who had segmental mastectomy or lumpectomy plus radiation compared to those who had segmental mastectomy alone. This difference was significant both in the node negative patients and even more evident in the node positive ones. It should be noted that the node positive patients in this study all had chemotherapy (15). Thus, chemotherapy and segmental mastectomy are not adequate treatment alone for patients with breast cancer. These patients who have this conservation procedure must have radiation postoperatively in order to prevent local and possibly distant recurrence.

The complication rate is high

This is another hypothetical objection to CS + RT. Actually, the complication rates of CS + RT are very low, particularly in the institutions in which radiation therapy is applied adequately and appropriately (12, 13, 31, 32). Complications vary from symptomatic pneumonitis, to rib fracture, arm edema, breast edema, skin ulceration, plural effusion, pericardial fibrosis, perineuropathy or arm weakness, severe fibrosis and painful myositis. The incidence varies from 1 to 9% for arm edema and 5% for the myositis in most studies. The complication of breast edema usually subsides after 6 months to a year and is probably the most common complication that develops. It has occurred in 22% of patients in the MD Anderson series but disappeared, for the most part, within a year. The development of complications is essentially not related to the radiation regimen as pointed out by Yeoh et al. but is complicated by the amount of surgical involvement in the axilla and his patients who had a complete axillary dissection had a higher rate of complications than those who had lesser procedures (51). The incidence of compli-

cations seems to be higher in those patients who received chemotherapy than in those who have not (7, 26).

There is a strong probability of radiation carcinogenesis is another hypothesis

It is important to note first that although there has been some concern about carcinogenesis due to mammography, the possible lifetime risk of breast cancer attributable to diagnostic radiography is almost negligible. Based on extrapolation from epidemiologic data Boice assessed that incidence of breast cancer due to mammography is probably 52 cases per 100000 women compared to the reality of one out of every 11 women will develop breast cancer (6). However, extrapolation of this kind is not relevant in connection with radiotherapy of cancer, partly due to its cell-killing effect. The real risk concerning the treated breast can only be estimated by long-term follow-up of treated patients. As far as present experience goes the risk is small.

Insofar as risk of carcinogenesis following CS + RT to the opposite breast is concerned, a recent study found no significant evidence of change in relative risk of new cancer in the opposite breast. Among 14000 women with breast cancer treated between 1946 and 1982, 194 developed a second primary tumor in the contralateral breast more than one year after the diagnosis of the first primary. Comparison of this group with a group of matched patients who did not develop a second primary in the opposite breast was performed. No evidence for radiation induced carcinogenesis on the contralateral breast in these patients was found in this case-control study (3).

We have also tried to theoretically assess the risk of carcinogenesis in the opposite breast (28). If 10000 women with breast cancer treated with CS + RT received 3 to 4 Gy in the normal opposite breast the 10 years cumulative incidence of cancer in this breast would increase by 0.24%. Given that the incidence of second breast cancers in women having an initial breast cancer is 7%, the additional incidence from irradiation is quite small and only 3-4% of the expected incidence (28).

Finally, the hypothesis that cosmetic effect is poor

Beadle and Recht reported from Harvard that the results of CS + RT and no chemotherapy are excellent to good in 90% of the patients. Pierquin reported excellent to fair results in approximately 90% of all patients treated with T1, T2 or T3 lesions with the best results in the T1 group (42). In our own experience we have had similar results in the over 100 patients treated in this manner over the last 15 years.

Conclusions

The CS + RT method is not experimental, the results of radical surgery are not superior to conservation surgery

and radiation therapy. Irradiation is necessary to prevent local recurrence, the complication rate is not high, there is probably an insignificant incidence of carcinogenesis related to the irradiation and the cosmetic effect is, by and large, excellent.

It is most appropriate at this point to quote a number of our predecessors who pioneered in this effort. Keynes who noted, 'In speaking of breast cancer, I believe very importantly there is a psychological aspect. Most women know what is meant by the surgical treatment of cancer of the breast and I am sure that very often they are intimidated by the prospect. As surgeons, we constantly regret the fact that patients do not come to us soon enough, very often hiding their disease until 2 years or more have elapsed since it was first noticed. I am afraid it is the fact that we are surgeons that is partly responsible for the attitude on the part of the patients. They are afraid of us and frankly I am not surprised that they should be. It is this feeling that deters them from seeking advice and so prevents any considerable improvement in the end results such as might follow earlier diagnosis and earlier treatment in the aggregate.'

Conservation surgery and radiation therapy approach to the treatment of breast cancer is not a simple one. It requires appropriate selection of patients, adequate surgery by knowledgeable surgeons, evaluation of the specimen by knowledgeable pathologists, and careful, precise radiation therapy treatment and follow-up of these patients. As any other treatment of cancer, the quality of the results is dependant on the quality of the treatment.

As Pfahler noted over 50 years ago 'we, as radiologists, are convinced that radiation therapy is of definite value in carcinoma of the breast, but a mere opinion is not sufficient for others. Some careful and conscientious surgeons, who realized fully the importance of skill and clinical judgement in the use of surgical instruments, fail to appreciate that similar skill and clinical judgement must be used with both radium and the roentgen rays in order to obtain good results. Dependence upon the magic of the radiation agents themselves rather than upon their skillful application is the cause of the skepticism that follows.'

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