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RADIOACTIVE IODINE TREATMENT FOR REFRACTORY CASES
OF ANGINA PECTORIS AND CONGESTIVE HEART FAILURE

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INTRODUCTION

Reduction of function of the normal thyroid gland as a treatment for severe heart disease including congestive heart failure, angina pectoris or both was introduced less than thirty years ago. Prior to this it had long been known that cardiac symptoms when associated with hyperthyroidism were markedly improved when the hyperthyroidism was surgically relieved.

RATIONAL OF TREATMENT

Treatment of cardiac disease by reduction in function of the normal thyroid is aimed toward a lessening of the work which the heart must do. All types of chronic cardiac disease reveal a disproportion between what the heart is able to do and the demands placed upon the heart. Treatment of such disease entails curtailment of physical activity and medical treatment of the cardiac function. In some cases these measures are carried out to the utmost and the heart is still unable to meet the bodily demands. However, if the total body metabolism is reduced, the required cardiac work is reduced. The heart may then

be able to keep up with the demands placed upon it.

It has been shown that relative hypothyroidism and not myxedema is the desirable state for accomplishing this purpose. Myxedema itself may produce cardiac decompensation as well as many other undesirable physiological reactions.

HISTORY

TOTAL THYROIDECTOMY

It was in 1927 when Samuel A. Levine (1) made an interesting observation. A patient with cardiac disease was suspected of having hyperthyroidism causing the cardiac symptoms. Following a subtotal thyroidectomy the patient showed remarkable clinical improvement but when the extirpated thyroid was examined it was found to be perfectly normal. This observation suggested that removal of a normal thyroid gland might be of aid in heart failure not due to thyrotoxicosis. In 1933 the first report of such work was published. Blumgart, Levine and Berlin (1) summarized the results of four patients, three with congestive failure and one with angina pectoris on whom thyroidectomys were done. On two patients with failure a subtotal thyroidectomy was performed. Immediately after there was disappearance of edema,

and increased vital capacity of the lungs, and the patient was able to be up and about the ward without discomfort. The BMR had its maximum decrease in three weeks and then began to rise again with the return of clinical symptoms of cardiac disease. On the third patient a total thyroidectomy was performed and the BMR stayed down, with the patient showing marked clinical improvement. In the fourth patient who had angina pectoris it was found that after a subtotal thyroidectomy there was no recurrence of symptoms although he had had attacks at rest before. This experiment in general showed that subtotal thyroidectomy was not sufficient to produce lasting results.

Blumgart and his associates in 1935 (2) reported upon the results of 75 patients over a period of 18 months following surgical extirpation of the normal thyroid gland. Of these patients 50 had recurrent congestive heart failure and 25 had severe angina pectoris. Of the 50 patients with congestive failure 24 had maintained compensation and had shown decided improvement and were able to work for from 2 to 18 months. The average duration of postoperative improvement was $7\frac{1}{2}$ months. Of the 25 patients with severe angina, 8 had no recurrence of angina attacks

in spite of activity for from 3 to 18 months and required no glyceryl trinitrate. The average duration of complete relief was 10 months. Of the remaining 17 patients, 5 had only occasional attacks after operation and were capable of being considerably more active.

Only patients who had a relatively stable clinical course were chosen for operation. The operative mortality for the entire group was 8%. Following operation they had to find the optimum metabolic level for each individual patient and the amount of thyroid necessary to maintain it. In most cases this was $\frac{1}{4}$ grain per day to maintain a BMR of -25% to -30%.

Parsons and Purks (3) in 1937 collected data on total thyroidectomy for heart disease on 362 patients from 59 individuals or clinics. For congestive heart failure 229 operations were performed and there were 24 operative deaths. Of the remaining patients, 71 had no recurrence of symptoms, 59 had less frequent and less severe attacks although they were more active, 6 had less frequent attacks while activity range was not changed and 69 showed no improvement.

There were 133 operations for angina pectoris with 5 operative deaths. Of these, 71 had no recurrence,

36 had less frequent and less severe attacks with increased activity range, 5 had less frequent and severe attacks with no change in activity and 16 showed no improvement. Overall results for congestive failure were 60% good and for angina pectoris 80% to 90% good.

Dr. Frank H. Lahey (3) in a discussion following the above article said that patients operated on for cardiac decompensation by total thyroidectomy had a limited cardiac reserve. Myxedema, which was an undesirable state for a decompensated heart, was produced. Then thyroid extract had to be given to maintain a BMR of -25%. This level was too difficult to maintain with accuracy. In the majority of cases there was a return of decompensation. There had been some cases of angina pectoris distinctly benefited but the patient then had to exchange an active state for the sluggish state associated with myxedema. In addition, total thyroidectomy proved to be a difficult procedure. There was a definite mortality and a high percentage of complications in many cases. In summary, Lahey believed that in future years it would occasionally be used on well-selected cases but that as the years went on, the number of cases operated on

by total thyroidectomy would diminish.

Parsons agreed with Lahey but believed that before abandoning this procedure, which was reported valuable in a high percentage of cases, some therapy must be sought which was at least equally beneficial if not more so.

Stuppy (4) in 1951 reported that 25 to 30 patients were operated on in the Cedars of Lebanon Hospital in Los Angeles, but results were completely unsatisfactory and were not published. From Boston where Blumgart had been reporting promising results, no more reports appeared after 1935.

ANTITHYROID DRUGS

Thiouracil suppresses the formation of thyroxin by the thyroid gland. When it became available, it was employed to produce the physiological changes that had been attempted by total thyroidectomy, and in a seemingly safer and simpler way.

Raab (5) in 1945 reported on a series of 10 patients with angina pectoris whom he had treated with thiouracil. Treatment was very effective in 7 patients of whom 4 were made entirely symptom free. Slight improvement was obtained in the eighth patient. Doses initially ranged from 0.4 grams to 1.2 grams per day

with a 0.1 gram maintenance dose. When medication was discontinued, symptoms reappeared in from 10 days to 7 months.

In 1946 Reveno (6) reported a group of 8 patients with angina pectoris treated with thiouracil. Of these, 5 were made symptom free, 2 were not improved and the last patient had not been treated long enough to evaluate. The 2 patients who did not improve showed little change in BMR with treatment. The 5 who were made better began improving at about 2 months and were treated for an average of 7 months. Lowest BMR levels reached ranged from -20% to -24%.

DiPalma and MaGovern (7) in 1946 administered thiouracil to 8 patients. Therapy was terminated in 4 cases; in 2 because of toxic skin rashes, in 1 because of severe dyspnea, and in 1 because of failure to lower the BMR with the dosage used. The other 4 patients were benefited for a time. These men did not recommend thiouracil for angina pectoris as a routine procedure, but only when the BMR was elevated. They also suggested that it might be used as a therapeutic test to select patients for thyroidectomy.

In a report of 37 patients treated with thiouracil, Ben-Asher (8) in 1947 found it to be

beneficial in 25 patients. Duration of treatment varied from $3\frac{1}{2}$ months to 7 months. Duration of improvement after the drug was stopped ranged from 2 months to 16 months. The patient at 16 months was still maintaining improvement at the time the article was written. Toxic effects appeared in 8 patients, 5 developing fever and 3 developing neutropenia. These effects cleared when the drug was discontinued.

Schoenewald (9) in 1948 reported the successful use of methylthiouracil in either abolishing or markedly reducing the frequency of angina attacks in 3 cases of angina pectoris.

In 1948 Frisk and Lindgren treated a series of patients with methylthiouracil. Of 7 patients with congestive failure, 4 were considerably improved for a long period of time, 2 were moderately improved but had to discontinue therapy because they developed toxic reactions to the drug, and 1 patient relapsed in spite of continued treatment. Of 9 patients with angina pectoris, 8 showed marked lasting improvement. It was found that 3 to 6 months of treatment were required before any improvement was noted, and 6 to 8 months were required before there was a clinically proved decrease in thyroid function. When this point

was reached, it required a daily dose of 15 to 50 mg. of the drug to maintain the BMR at -15%. When the drug was discontinued, it was found that the patients soon went back to their original condition.

RADIOACTIVE IODINE

Just as total thyroidectomy was found to be helpful but still not the answer to the problem, so were the antithyroid drugs helpful but not the best solution because of their toxicity. Accordingly when radioactive iodine (I_{131}) became available, it seemed natural that it should be given a trial.

Blumgart and his associates (11, 12, 13, 14) at Beth Israel Hospital in Boston were the pioneers in this field, beginning their studies in 1947. Their criteria for selection of patients for radioactive iodine therapy included angina pectoris patients in whom the disease, regardless of its severity, had been fairly stationary or only slightly progressive, over a period of a year or more. It included patients with congestive failure who showed evidence of some cardiac reserve; such evidence as improvement of failure and other symptoms on bed rest or upon the use of digitalis and diuretics. The BMR should be no less than -10%. The patient should be cooperative, alert and stable

emotionally. Hyperactive, tense patients made excellent candidates. Recent onset of or rapidly progressive cardiovascular disease was considered poor risk material. As about 2 to 6 months pass before the hypothyroid state is attained, patients in terminal phases of their disease should not be treated. This treatment was not advised for the majority of patients with angina pectoris or congestive failure, but rather for those in whom medical measures had not alleviated discomfort. Other contraindications were such associated conditions as rheumatic fever, bronchiectasis, emotional instability, cirrhosis of the liver, recent acute myocardial infarction, intermittent claudication and severe hypertrophic arthritis.

Tracer doses of 100 to 150 microcuries were administered and on the basis of these, the first doses were determined. In their first series of 18 cases (11) each patient received an oral dose of 25.5 to 150 millicuries in single or divided doses, of which 7.3 to 39 millicuries were retained in the body after 72 hours. The largest single dose was 53 millicuries. The average total dose was 54.4 millicuries, and the average retention after 72 hours was 17.9 millicuries.

It was found that about 40 millicuries was usually sufficient to produce myxedema. Because thyroiditis resulted in some of the first cases, the total dose although it was increased slightly, was given in three doses at 10 to 14 day intervals. In a later report (14) they stated that when the radioactive iodine uptake was in the euthyroid range such as 30%, the initial dose was no larger than 20 millicuries. If the uptake was higher or if the angina pectoris was very severe, smaller doses of 10 millicuries were given initially. These doses were given weekly for 3 weeks. Additional doses were given at 1 to 2 month intervals until the hypothyroidism became apparent. Following this dosage schedule, thyroiditis became less of a problem.

It was found that the onset of improvement coincided with the occurrence of hypothyroidism and this was usually 2 to 6 months after the therapy was started.

In their first reports (11, 12) of 29 patients, mild or moderate transitory thyroiditis was observed in 18 cases, severe thyroiditis in 1 case and no thyroiditis in 10 patients. Temporary mild hyperthyroidism was seen in 2 patients. When the initial doses were cut to 10 or 20 millicuries, the incidence

of thyroiditis decreased markedly. There was no radiation sickness and no toxic effects observed on the blood, kidneys, or parathyroids. These investigators permitted marked hypothyroidism or complete myxedema to develop so that all thyroid tissue was affected. They then were maintained at the lowest metabolic level at which the individual patients received the maximum relief of their cardiac disease and the minimum discomfort from the myxedema. Most patients were maintained at a BMR of -20% to -25% on a daily dosage of 1/10 to 1/2 grain of thyroid. In some cases symptoms recurred because of regeneration of residual thyroid tissue. In these instances, thyroid medication was withdrawn and if tracer doses of radioactive iodine showed uptake, another therapeutic dose was given.

The results of Blungart and his associates (14) were evaluated in 1955 as excellent, good, or not worthwhile. Excellent implied that the patient was markedly improved with either no recurrence or a great decrease in frequency and severity of symptoms despite greatly increased activity. A good result implied a decrease in frequency or severity of symptoms on the same amount of activity as before therapy. There were

62 cases of angina pectoris, 42 of which had been followed for more than a year. The results were excellent in 24, good in 20, and not worthwhile in 18. There were 25 cases of congestive failure, 18 of whom had been followed more than a year. The results were excellent in 4, good in 9, and not worthwhile in 12.

Wolferth (15) and his associates of Philadelphia first used radioactive iodine on a euthyroid patient with cardiac failure in 1948. Their criteria for selection of patients with angina pectoris for radioactive iodine therapy included: 1. Those with angina attacks at rest; 2. Those with an unsatisfactory response to medical treatment along with a careful regimen of life; 3. Those with an unlikely chance for spontaneous improvement after the condition had persisted; 4. Those with a normal iodine uptake; 5. Those with a blood cholesterol level fairly close to normal; 6. Those with a willingness to cooperate by adhering to a low fat diet and by refraining from excess use of tobacco.

Dosage was determined after a preliminary tracer dose. Depending on this 10 to 20 millicuries of radioactive iodine were given. In many patients this

much was satisfactory while in others additional doses were required.

These investigators pointed out that patients who had ingested 20 millicuries of radioactive iodine were a radiologic hazard and should be under the care of personnel who were aware of the dangers of radiation from the excreta and of the dangers of external radiation. In almost all of the patients who benefited by improvement in cardiac symptoms, there was an increase in the blood cholesterol even though hypothyroidism did not occur. From this, it was thought that possibly the progress of atherosclerosis was enhanced. A few patients became myxedematous and desiccated thyroid had to be given. They also pointed out the possibility of late radiation effects with respect to carcinogenesis and to injury of germ plasm.

There were 28 patients with severe angina pectoris in Wolfarth's series in whom therapy had been started 6 months to 2 years before the report was written. Of the 28 patients, 9 had congestive failure, 9 had severe hypertension, 6 had aortic valve disease with an enlarged left ventricle and many had had one or more myocardial infarcts. There were 10 patients who died but this was anticipated because patients with far

advanced disease were treated. Radioactive iodine was not considered a cause of death in any case. In the remaining 18 cases the results were arbitrarily classified as good, fair and unsatisfactory. The results were good in 12, fair in 4 and unsatisfactory in 2 patients.

Jaffe and a group (4, 16, 17, 18, 19, 20) at the Cedars of Lebanon Hospital in Los Angeles began their studies in 1950.

Patients in their series had severe angina pectoris, severe congestive heart failure or both. Some patients had paroxysmal acute pulmonary edema. Many patients had, along with serious heart disease, troublesome cardiac arrhythmias which were not well controlled by drug therapy. All patients had advanced heart disease which was refractory to the usual forms of treatment. Patients with active rheumatic fever or recent coronary occlusion were not treated. The average age of those treated was between 50 and 60 years.

Jaffe (16, 19) and his associates utilized a plan of therapy whereby the radioiodine was given in multiple small doses. A tracer dose of radioiodine was first given to the patient and the uptake

measured. The first course of treatment was then given. This consisted of 6 millicuries of radioiodine orally at weekly intervals until a total of 30 millicuries had been given. After an interval of 2 months the iodine pickup was again measured. If the patient at that time showed no improvement, or only slight improvement and had not yet reached myxedema level a second course of treatment identical to the first was given. After a 2 month interval another tracer study was done and the patient re-evaluated. A third course was given in those cases which indicated it. In a later report (20) because of an improved technique for measuring the function of the gland they were able to shorten the period between courses of treatment from 2 months to 1 month. They found that almost half of the patients required only 1 course of treatment and the other half required 2 courses of treatment. Only a few patients required 3 courses. Some of the patients regenerated thyroid tissue and eventually at a later date required more treatment.

They tried to reach a level of maximum clinical improvement without making the patient myxedematous. When the patient showed symptoms of hypothyroidism, 1/5 to 1/2 grain of thyroid was administered daily.

It was found that multiple small doses of radiiodine were just as effective as single or multiple large doses. By the multiple small dosage technique thyroiditis, temporary thyrotoxicosis, and bone marrow depression were almost always avoided. There was no damage to parathyroid glands or to the recurrent laryngeal nerve, and no radiation sickness. Because of the smaller doses, the hazard of beta and gamma radiation from the patient and the problem of excreta disposal were not so great, as radioactive iodine has a half-life of only 8 days. Therefore with small doses, the patient could be treated as an outpatient rather than as a hospital patient.

In 1955 Jaffe and his associates (20) reported on 231 patients who had been treated with radioactive iodine. They rated their results as excellent, good, and no improvement. Complete symptomatic relief was not the prerequisite for an excellent result. If a patient had angina pectoris and he did not have to take nitroglycerin repeatedly day and night, he received real help even though walking without pain was still an impossibility. A patient with angina pectoris who was comfortable while at rest but could not work received great benefit if he improved enough

to return to work. A patient with congestive failure and ascites was helped if the therapy relieved the necessity of repeated paracenteses, and he could be maintained on sodium restriction or mercurial diuretics. Therefore the improvement of each patient was evaluated individually.

Of the 231 patients, 100 had been followed for 4 years or more. Of these 100, 45 died. There were 55 patients with excellent results of which 23 died, 28 patients with good results of which 7 died, and 17 patients with poor results of which 15 died.

Of the other 131 patients who had been followed for 6 to 36 months there were 67 who had excellent results of which 5 had died, 48 with good results of which 10 had died, and 16 showing no improvement of which 6 had died. In no case was radioactive iodine implicated as a cause of death.

Of the 231 patients, 94 had been treated for angina pectoris, 78 had been treated for congestive failure, and 59 had been treated because of both angina pectoris and congestive failure. In the group of 94 patients treated for angina pectoris, there were 53 excellent results, 35 good results and 6 poor results. Of the 78 patients treated for congestive

failure there were 41 excellent results, 22 good results and 15 poor results. In the group of 59 patients treated for both angina pectoris and congestive failure, there were 28 excellent results, 19 good results, and 12 poor results.

Chapman (21) in 1952 reported treating 23 euthyroid cardiac patients with radioactive iodine.

The 23 patients in his series had received single doses of 20, 25, and 30 millicuries of radioactive iodine except one patient who had received 35 millicuries. Most of the patients were given roughly 500 to 600 microcuries per gram of thyroid tissue.

There was one case of chronic congestive failure associated with severe rheumatic heart disease. After radioiodine therapy she went into a hypometabolic state which was almost myxedema and her congestive failure improved. While the doctors in charge of her case were debating whether to give her thyroid, she went into severe congestive failure and died. Autopsy showed the gland to be almost completely eradicated. This was considered to be myxedema heart disease. Chapman concluded that the greatest benefit to patients with heart disease came from producing not myxedema but a degree of hypothyroidism with a

BMR of -20% to -25%, a PBI of 2 to 3 gamma %, and a radioactive iodine uptake of 10% to 20% in 48 hours.

Of the 23 patients in Chapman's series, 7 died. Of the remaining 16, there were 9 angina pectoris patients and 7 chronic congestive failure patients. Definite improvement was seen in 4 of the angina pectoris patients and in 4 of the congestive failure cases.

Dr. Paul D. White (22) stated several points which he deemed important in regard to radioactive iodine treatment of cardiac disease. First he thought this treatment should be used only for angina pectoris patients with recurrent severe attacks over a period of 1 year, and for intractable severe congestive failure patients. Secondly he pointed out that this was symptomatic treatment only. Thirdly he suggested that angina pectoris could improve spontaneously after months or years because of a natural development of a greater collateral coronary circulation, so that results were not so easily evaluated as those in patients with chronic congestive failure. Lastly he said that this treatment was a great help in patients with congestive failure, as well as in those with severe coronary insufficiency.

TABLE I

RESULTS	ANGINA PECTORIS				
	Jaffe	Blumgart	Serber	Wolferth	Chapman
Excellent	56%	<u>35%</u>	31%	67%	..
Good	<u>37%</u>	<u>38%</u>	<u>23%</u>	<u>22%</u>	..
Total improved	93%	73%	54%	89%	45%
No improvement	<u>7%</u>	<u>27%</u>	<u>46%</u>	<u>11%</u>	<u>55%</u>
Total cases.	94	26	13	18	9

RESULTS	CONGESTIVE HEART FAILURE			
	Jaffe	Blumgart	Serber	Chapman
Excellent	53%	31%
Good	<u>28%</u>	<u>15%</u>	<u>18%</u>	..
Total improved	81%	46%	18%	57%
No improvement	<u>19%</u>	<u>54%</u>	<u>82%</u>	<u>43%</u>
Total cases	78	13	11	7

Radiiodine Treatment of Severely Ill, Euthyroid, Cardiac Patients. Comparison of Results in the Literature. Jaffe (20)..

TABLE II

ANGINA PECTORIS

	No.	%
No. Evaluated	<u>720</u>	<u>100%</u>
No. Followed More than 1 Yr.	<u>427</u>	<u>59%</u>
Excellent	284	39%
Results Good	257	36%
Not Worthwhile	179	25%

CONGESTIVE HEART FAILURE

	No.	%
No. Evaluated	<u>350</u>	<u>100%</u>
No. Followed More than 1 Yr.	<u>193</u>	<u>55%</u>
Excellent	80	23%
Results Good	137	39%
Not Worthwhile	133	38%

Results of Radioactive Iodine Treatment in 1,070
Euthyroid Cardiac Patients. Blumgart (14).

Jaffe (20) in 1955 summarized the results of several workers who had used radioactive iodine for the treatment of angina pectoris and congestive heart failure, and this is shown in table I. In general, it can be seen that the results are favorable.

In 1955 Blumgart (14) summarized the results of 1,070 patients with angina pectoris or congestive who had been treated in 50 clinics. The results were evaluated as excellent, good and not worthwhile as shown in table II. An excellent result meant that the patient was markedly improved with either no recurrence or a great decrease in the frequency and severity of symptoms despite greatly increased activity. A good result implied a decrease in frequency or severity of symptoms on the same amount of activity as before therapy. There were 720 patients with angina pectoris of which 200 also had congestive heart failure and 350 patients with congestive heart failure. Of the angina pectoris patients 75% were improved and of the congestive failure patients 62% were improved.

SUMMARY

An observation made by Samuel Levine in 1927 opened the way to an entirely new manner of treatment of cardiac disease in euthyroid patients. A cardiac

patient thought to have hyperthyroidism causing his cardiac symptoms had a subtotal thyroidectomy after which the gland was found to be normal. Cardiac symptoms were greatly improved also. It was thought that a state of beneficial hypothyroidism had been produced and that by lowering the total body metabolism the heart had less work to do.

Following this observation subtotal thyroidectomys were performed in euthyroid patients with angina pectoris and congestive failure, but found inadequate because the thyroid tissue regenerated in a short time.

Total thyroidectomy was then tried with better results. A correlation was found between the degree of induced hypothyroidism and the amount of clinical improvement. Results were 60% good for congestive failure and 80% to 90% good for angina pectoris. The popularity of the procedure soon waned however because of the magnitude of the operation, the complications which followed it and the continued progression of the underlying disease.

When thiourea derivatives became available they were utilized in euthyroid cardiac patients to produce a medical total thyroidectomy. These drugs however

did not work in some patients. Also to maintain the hypometabolic state, the drug had to be administered to the patient for the remainder of his life. Drug reactions developed at various intervals of time following the onset of treatment including skin rash, fever, and agranulocytosis.

When work was still being done with thiourea derivatives, radioactive iodine became available and work with it was begun in 1947. In general, patients selected for treatment were those with severe angina pectoris and severe congestive heart failure who were euthyroid and refractory to all of the accepted forms of treatment. It was found by experience that small multiple doses of radioiodine were just as effective for treatment as large doses and produced fewer toxic symptoms than large doses. These small doses varied with the individuals directing the therapy, from 30 millicuries in 5 weekly divided doses to a single dose of 10 or 20 millicuries with more to follow if necessary. Large doses up to 53 millicuries produced unwanted effects as transitory hyperthyroidism and thyroiditis. In no case were radiation sickness or toxic effects on blood, kidney, or parathyroid reported and in no case was radioiodine incriminated

as the cause of death of a patient. Following destruction of the gland by the radioiodine 1/10 to 1/2 grain of thyroid had to be administered to most patients to maintain a BMR above myxedema level but still in hypothyroid range. Results of 1,070 euthyroid patients with angina pectoris or congestive failure treated in 50 clinics were reported in 1955. Of 720 patients with angina pectoris, 541 or 75% were improved. Of 350 patients with congestive heart failure, 217 or 62% were improved.

CONCLUSION

In selected patients with either angina pectoris or congestive heart failure who have been found refractory to ordinary methods of treatment, it has been determined that lowering the total body metabolism will decrease the work which the heart must do and thus improve the patient symptomatically. Radioactive iodine administration has to date proved to be the most successful manner of doing this as the complications and side effects are fewer than with total thyroidectomy or with thiouracil treatment. It has been found that such treatment is quite successful in 75% of selected angina pectoris patients and in 62% of selected congestive failure patients. It will

now require only a passage of time before this form
of therapy can be more fully evaluated..

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