THE RELATIONSHIP OF WEIGHT GAIN, CALORIC INTAKE, AND PHYSICAL ACTIVITY IN PATIENTS WITH THYROTOXICOSIS TREATED WITH RADIOACTIVE IODINE

A THESIS

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE DEGREE OF MASTER OF SCIENCE

IN THE GRADUATE SCHOOL OF THE

TEXAS WOMAN'S UNIVERSITY

COLLEGE OF NUTRITION, TEXTILES, AND

HUMAN DEVELOPMENT

BY

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DENTON, TEXAS

MAY, 1980

ACKNOWLEDGEMENTS

To the chairman of my committee, Dr. Valerie Knotts, goes my deepest appreciation for her time and guidance in the completion of this thesis. Gratitude is extended to Dr. Philip Johnson for his helpfulness and support of this study and for making it possible. Gratitude is also extended to Betty Boots, member of Dr. Philip Johnson's staff for her helpfulness and good nature.

Many thanks also go to Dr. Shirley Baird, committee member and Dr. William Duer for his assistance in the statistical analysis. I wish to thank my roommate Karen L. Yowell for her support and encouragement throughout the completion of this program. Many thanks to Pat Valadez for her help in typing this paper.

Finally, to my parents, William and Angeline Foley, for their lifetime support and encouragement of all my endeavors, I extend all my love and appreciation.

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INTRODUCTION

Thyrotoxicosis is defined as the biochemical and physiological complex that results when tissues are presented with excessive quantities of thyroid hormones (1). Thyrotoxicosis is characterized by increased basal metabolic rate, increased appetite, increased serum T_3 and T_4 values, and weight loss (1,2).

Radioactive iodine (I^{131}) has been used in the treatment of thyrotoxicosis since 1946 (3). In therapeutic doses I^{131} destroys thyrotoxic follicular cells and damages the stroma of the gland with little or no damage to surrounding tissues (4). Treatment of thyrotoxicosis with I^{131} has several advantages and disadvantages over other forms of treatment. One of the main disadvantages of I^{131} is the increasing incidence of hypothyroidism following treatment. Hypothyroidism is characterized by a decreased basal metabolic rate, decreased appetite in most cases, and weight gain. In this condition serum T_3 and T_4 values are decreased (1).

Records from one Health Care Facility revealed that two months following I^{131} treatment patients with thyrotoxicosis gained an average of 8.5 pounds with a range of two to seventeen pounds (5). The gain in weight

raised several questions. Is this weight gain related to the treatment itself or did dietary and energy expenditure factors have a relationship to the weight gain? Are the changes in body weight related to caloric intake and physical activity patterns before and after I^{131} treatment? Do these patterns change? Is the basal metabolic rate the influencing factor?

Many patients with thyrotoxicosis do not want to gain excess weight. If the weight gain is related to dietary and physical activity factors, then perhaps dietary counseling to decrease caloric intake or increase physical activity or both could help to prevent the excess weight gain.

STATEMENT OF THE PROBLEM

Patients with thyrotoxicosis notably gain weight several months after I^{131} treatment. The purpose of this study was to determine the relationship of dietary intake and physical activity patterns to weight gain in these patients. Were there changes in caloric intake and physical activity patterns before and after I^{131} treatment which were related to the weight change? Did the caloric intake of these patients increase and physical activity decrease after I^{131} treatment? Was there an increase in caloric intake without a change in physical activity? Was there decreased physical activity with similar consumption patterns after treatment as compared to before treatment? Did the caloric intake and physical activity remain relatively constant before and after I^{131} treatment? Did the basal metabolic rate change significantly two months after I^{131} treatment? Was this related to the weight change?

HISTORICAL PERSPECTIVE

There are many clinical manifestations of thyrotoxicosis. These include increased cardiac output, warm, moist skin, eye alterations, nervousness, and emotional lability (1). Other clinical symptoms include increases in appetite, basal metabolic rate (2), and gastrointestinal motility (6) with weight loss (2). Elevated serum T_3 and T_4 are evidenced in thyrotoxicosis (normal range of serum T_3 is 70-190 ng/100ml and serum T_4 is 4-12 ug/100ml) (7). Hyperkinesia, fatigue from the neck down, insomnia, and muscle weakness are also presented in thyrotoxicosis (1).

Radioiodine 131 has been available for treatment of thyrotoxicosis since 1946 (3,4). Responses of patients to selected doses of I^{131} varies widely. Some patients respond well to a selected does, others do not respond at all (8). Most Health Care Facilities administer I^{131} according to their own method of calculation. Many facilities give arbitrary doses of 140-160 uCi/g of estimated glandular weight (1). The doses vary with the individuals.

Radioiodine treatment has several advantages over surgery and antithyroid drug therapy. These include ease

in administration with hospitalization being unnecessary, almost no immediate complications, and a long period of effectiveness (1,9). It is especially useful in management of patients with heart disease and those with prior thyroid surgery (9). Radioactive Iodine-131 completely restores the motor function of the gastro-intestinal tract (6).

One disadvantage of I^{131} treatment is the concern that it will cause thyroid cancer or leukemia especially to a fetus if irradiated. There is also possible irradiation to the gonads during therapy which could induce genetic damage (1). However, radiation is associated with thyroid cancer in only a small number of individuals twenty-five years of age and under (11). The major disadvantage of I^{131} in treatment of thyrotoxicosis appears to be the occurrence of hypothyroidism following treatment.

Hypothyroidism was originally thought to be a complication which occurs within the first two years following I^{131} treatment. However, a steadily increasing number of patients develop hypothyroidism many years after treatment. Thus hypothyroidism is recognized as a delayed manifestation of the treatment (12,13).

The rate of hypothyroidism following I^{131} treatment of thyrotoxicosis ranges from 7.46% to 69% after one year

(14,15,16,17,18), and 29% to 43% after ten years (14,19). Each year the incidence of hypothyroidism following I^{131} treatment increases at an estimated annual rate of 2.7% to 5.0% (15,20,21). Reasons for the wide range of post I^{131} hypothyroidism is probably due to disparity in the definition of hypothyroidism and variance in methods of calculating a selected dose (14).

The incidence of post I^{131} hypothyroidism is slightly higher in patients over forty years of age and lower in patients aged in the twenties and eighties (14). Beling and Einhorn (18) found a higher incidence of post I^{131} hypothyroidism in patients under fifty years of age. Several studies indicated sex, duration, clinical severity of the disease, and number of I^{131} doses had no significant relationship to the frequency of post I^{131} hypothyroidism (14,18). However, Beling and Einhorn (18) found that patients cured with one dose of I^{131} had the highest incidence of developing hypothyroidism. Those receiving four or more doses had a lower incidence of early or late hypothyroidism.

The size of the initial dose of I^{131} appears to be a major factor in the development of post I^{131} hypothyroidism. A low initial dose of I^{131} is associated with a lower incidence of early hypothyroidism (21,22). Douglas (21) observed this but noted that a low initial dose of I^{131} was followed by a high incidence of late

hypothyroidism. Late hypothyroidism is believed by some to be related to biological factors and the rate of cell division rather than dosage (23,24). A low serum T_4 is the most sensitive index in diagnosing post I^{131} hypothyroidism (25).

Eller et al found that in 436 thyrotoxic patients, one-third gained ten to twenty pounds, one-third gained ten pounds or less, 1% gained fifty pounds or more, and 5.7% lost weight after I^{131} treatment. Loss of weight was attributed to loss of edematous fluid in thyrocardiac patients and to deliberate weight loss by dieting (26). Wing et al found weight gain in 69 out of 74 hyperthyroid patients after anti-thyroid drug therapy. The approximate average weight gain after two months was 10.5 pounds (27).

Serum T_3 and T_4 values are frequently used as indicators of the metabolic state. Another less frequently used indicator of basal metabolic rate is Specific Weight Loss (SWL) ($mg./Kg.^{-1}/min.^{-1}$) (2). Specific Weight Loss is believed to be a more accurate method for determining BMR, however, it is not used as often due to the expense of the equipment needed.

There is little research in the area of food consumption and physical activity patterns related to thyrotoxicosis and I^{131} treatment. Grossie and Turner found that in rats of the Sprague-Dawley-Rolfsmeyer strain, the more serum T_4, the greater the food

consumption (37% increase for males, 70% increase for females). After I^{131} treatment there is clinical evidence of weight gain. Since it is well known that caloric intake and physical activity as well as basal metabolic rate play major roles in weight gain of normal individuals, it is believed that these parameters need investigation in thyrotoxic patients treated with I^{131}. This is especially true since the rate of post I^{131} hypothyroidism appears to be steadily increasing annually.

HYPOTHESES

The null hypotheses to be tested in this study were: There is no significant relationship between change in weight and 1) change in caloric intake; 2) change in physical activity; or 3) change in serum T_4 values in patients with thyrotoxicosis before and two months after treatment with I^{131}.

RESEARCH DESIGN

Methods and Procedures

Ten male and female patients with thyrotoxicosis (ages twenty-five to seventy) treated at Travis Medicine Clinic served as subjects for the study. All subjects were studies on an out-patient basis. The study was explained to the subjects by the investigator and an informed consent form was signed acknowledging the subjects' willingness to participate in the study (see appendix A).

Prior to treatment, blood was drawn and serum T_4 values were obtained from the subjects. On the first day of the study, subjects were treated with an individualized dose of I^{131} by a physician. Weight of the subjects (lbs) was measured and recorded by the investigator. Subjects were then given written and oral instructions by the investigator to keep a seven-day food diary and seven-day physical activity record beginning the day after the initiation of treatment (see appendix B).

Consumption of all food and drink for seven consecutive days was recorded on the food diaries (see appendix C). Physical activity was recorded on the physical activity records (see appendix D). Physical activity was categorized into light, moderate, vigorous, and strenuous

exercise patterned after a modification of the technique used by Stuart and Davis (29) and based on values cited by Fleck (30). Each category of exercise had the corresponding amount of calories expended for a five minute interval of that exercise. Exercise not indicated on the physical activity record was filled in by the subjects on the bottom of the form.

Data recorded by the subjects on the seven day food diaries and physical activity forms were given orally via telephone to the investigator daily during the two seven day recording periods. This was to provide accuracy in the recording process.

Two months after initial I^{131} treatment subjects were weighed using the same scale on which they were originally weighed. Blood was drawn prior to the second recording period, and serum T_4 values were recorded again at this time. The subjects were given new seven day food diaries and physical activity records with the same instructions and procedures as given during the first week. Each subject received a self-addressed, stamped envelope in which to mail their records to the investigator.

During the study interval, a twenty-four hour diet recall and twenty-four hour physical activity recall were taken three times via telephone by the investigator. This occurred every fifteen days between the first and second record keeping periods. This was undertaken to determine

if there was a specific pattern of caloric intake change and physical activity change over time.

Limitations

There were three limitations in the research design. One limitation was the record keeping tools. Although the seven-day food diary recited daily via telephone to the investigator appeared to be an accurate method in calculating caloric intake, the physical activity record was less accurate. The second limitation was that the sample size did not exceed ten. Significant results might have been obtained had the sample size been twenty-five or more. Such a sample size would have been more appropriate in meeting the assumptions for validity of the statistical analysis. The third limitation was the time element. Had the pre- and post-treatment interval been extended over a longer period of time, perhaps a greater weight gain with significant differences in dietary, physical activity, and serum T_4 values would have been observed.

Statistical Analysis

Data from the seven-day food diaries were used to calculate the daily caloric intake of each subject. Food items were given caloric values (kcal) based on Agriculture Handbook 456 (31). An average caloric intake was calculated for the seven day period and served as the initial value of caloric intake in kilocalories. The same

process was performed for the seven-day food diaries two months after I^{131} treatment.

Data from the seven-day physical activity records were used to calculate the daily energy expenditure of each subject based on the amount of kilocalories expended (refer to appendix B). The average amount of energy expenditure for the seven day period was calculated and served as the initial value of physical activity. The same process was performed for the seven-day physical activity records two months after I^{131} treatment. The average amount of energy expenditure (kcal) from these records served as the physical activity values two months post I^{131} treatment.

Changes in caloric intake, physical activity, and serum T_4 values were calculated by substracting the initial values in all cases from the values obtained two months post I^{131} treatment.

The t-Test of Difference was used to determine if there was a significant difference in weight, caloric intake, physical activity, and serum T_4 values before and after I^{131} treatment. The Pearson Product-Moment Correlation (r) was used to determine if a significant relationship existed.

RESULTS AND DISCUSSION

Ten of the subjects completed the study as proposed. Table 1 represents the initial weight and weight change two months post I^{131} treatment. There was a significant change in weight ($p < 0.01$) before and after I^{131} treatment. The average weight gain two months after treatment with I^{131} was 6.1 pounds. Only two subjects lost weight. One of these subjects had a serum T_4 value within the normal range two months after treatment while the other subject's serum T_4 value was slightly increased above the initial value. This indicated the subject was still thyrotoxic.

It should be added that because the sample size was relatively small (ten subjects) an abnormal value for any subject could influence the results. If a subject lost weight rather than gained weight as expected, the weight change might not be as significant. This is true for all of the following data.

Table 2 represents the average caloric intake during the first week after I^{131} treatment as compared to the average caloric intake two months after I^{131} treatment. There was no significant change in caloric intake before and after I^{131} treatment ($p < 0.44$). The average caloric

TABLE 1

WEIGHT CHANGE OF PATIENTS WITH THYROTOXICOSIS PRE- AND POST-TREATMENT WITH I-131

Subject	Initial Wt. (lbs)	Post Treatment Wt. (lbs)	Wt. Change* (lbs)
S_1	147	159	+ 12
S_2	115	112	- 3
S_3	149	158	+ 9
S_4	103	110	+ 7
S_5	189	198	+ 9
S_6	105	112	+ 7
S_7	168	163	- 5
S_8	156	171	+ 15
S_9	127	131	+ 4
S_{10}	179	185	+ 6

\+ = weight gain
\- = weight loss

*Significance: $\underline{t} = -3.125$ with 9 D.F., 2-tail $p < 0.01$

intake during the first week was 2086 kilocalories. The average caloric intake two months post I^{131} treatment was 1986 kilocalories. The average caloric intake change was an estimated 100 kilocalories decrease.

TABLE 2

CALORIC INTAKE CHANGE OF PATIENTS WITH THYROTOXIC PRE- AND POST-TREATMENT WITH I-131

Subject	Initial Caloric Intake Average (kcal)	Post-Treatment Caloric Intake Average (kcal)	Caloric Intake** Change (kcal)
S_1	2820	2499	- 321
S_2	2663	2817	+ 154
S_3	3100	2760	- 340
S_4	1474	1203	- 271
S_5	3225	2704	- 521
S_6	1707	1197	- 510
S_7	1330	1981	+ 651
S_8	2660	2666	+ 006
S_9	871	1232	+ 361
S_{10}	1007	801	- 206

\+ = increased caloric intake
\- = decreased caloric intake

**nonsignificance $\underline{t}$ = 0.816 with 9 D.F., 2-tail $p < 0.44$

Table 3 represents the physical activity in terms of kilocalories expended during initial treatment and two months later. There was no significant change in physical activity patterns before and after I^{131} treatment ($p < 0.26$). The estimated average amount of energy expended during

TABLE 3

PHYSICAL ACTIVITY CHANGE OF PATIENTS WITH THYROTOXICOSIS PRE- AND POST-TREATMENT WITH I-131

Subject	Initial Physical Activity (kcal)	Post-Treatment Physical Activity (kcal)	Physical** Activity Change (kcal)
S_1	303	303	0
S_2	411	815	+ 404
S_3	1491	1092	- 399
S_4	259	319	+ 60
S_5	635	1015	+ 380
S_6	419	1819	+1400
S_7	464	110	- 354
S_8	312	324	+ 12
S_9	609	1084	+ 475
S_{10}	244	244	0

+ = increased activity
- = decreased activity

**nonsignificance $\underline{t}$ = -1.214 with 9 D.F., 2-tail $p < 0.26$

initial treatment was 515 kilocalories. The estimated average amount of energy expended two months after treatment was 713 kilocalories. The estimated average energy expenditure change was an increase of 198 kilocalories. Most subjects appeared to slightly increase their activity

pattern even though the change was not significant. Perhaps this was because after treatment with I^{131} the subjects felt better than prior to treatment. They may have experienced less fatigue and muscle weakness due to I^{131} treatment.

The physical activity record was believed to be an inaccurate tool since most subjects were less precise in recording how much time they spent in the stated activities. The subjects often had to think back and guess at the amount of time spent in the activities. It was difficult to record daily activities in five minute intervals because it was easy to lose track of time. In contrast, the subjects always were aware of just what they had eaten that day. Phoning the subjects daily provided an accurate record of food intake. If the subjects forgot to record the quantity of food eaten that day it was easy to ask them and get the estimate. Thus to get an accurate measure of food intake when employing a seven-day food record in a study it is best to phone the subjects daily. This not only reminds the subjects to keep the record but also enables the researcher to ask any questions there might be regarding the subjects' intakes.

Table 4 represents the serum T_4 values pre- and post-I^{131} treatment. The serum T_4 values decreased significantly ($p < 0.02$) indicating a decline in the basal metabolic rate (BMR). This was believed to have the

SERUM T_4 CHANGES OF PATIENTS WITH THYROTOXICOSIS PRE- AND POST-TREATMENT WITH I-131

TABLE 4

Subject	Initial Serum T_4 (ug%)	Post-Treatment Serum T_4 (ug%)	Serum T_4* Change (ug%)
S_1	20	3.2	- 16.8
S_2	15	8.1	- 6.9
S_3	13	8.1	- 4.9
S_4	14.5	5.4	- 9.1
S_5	49	2.0	- 48.0
S_6	23	14.6	- 8.4
S_7	23	25.6	+ 2.6
S_8	19.6	13.5	- 6.1
S_9	17	4.5	- 12.5
S_{10}	18.9	4.8	- 14.1

+ = increased serum T_4
- = decreased serum T_4

*significance $\underline{t}$ = 2.924 with 9 D.F., 2 - tail $p < 0.02$

greatest effect on weight gain. In all cases the serum T_4 values were well above the normal range before I^{131} treatment. After I^{131} treatment three subjects were within normal range of serum T_4 values, two subjects were very near the normal range, two subjects were below the normal range, and three subjects were above the norm. However,

serum T_4 in two out of three subjects with higher than normal serum T_4 values had a decrease in serum T_4 after I^{131} treatment even though it did not reach normal values. Only one subject had a higher serum T_4 value after treatment than before treatment with I^{131}. This subject was one of the two who lost weight after I^{131} treatment.

Although there was a significant change in weight (increase) and a significant change in serum T_4 values (decrease) the Pearson Product-Moment Correlation (r) revealed no significant relationship between these two variables (see table 5). The correlation coefficient of -0.345 showed a slight negative correlation (between weight change and serum T_4 change) even though it was not significant. A higher negative correlation coefficient was expected which would have strengthened the relationship. However, other factors might have accounted for the weak correlation. Ingestion of natural or synthetic estrogens and most contraceptive steroid preparations increased the serum T_4-binding activity of the principal T_4-binding protein, thyroxine-binding globulin (TBG). This produces an increase in serum T_4 (33). Prolonged use of tranquilizers (phenothiazines), congenitally high levels of TBG, analbuminemia, and massive doses of corticosteroids can also increase serum T_4 (34). This would influence the correlation coefficient had any of the subjects experienced the above factors which tend to increase serum T_4. Thus,

TABLE 5

WEIGHT CHANGE VS. SERUM T4 CHANGES
IN PATIENTS WITH THYROTOXICOSIS

Subject	Weight Change (lbs)	Serum T_4 Change (ug%)
S_1	+ 12	- 16.8
S_2	- 3	- 6.9
S_3	+ 9	- 4.9
S_4	+ 7	- 9.1
S_5	+ 9	- 48.0
S_6	+ 7	- 8.4
S_7	- 5	+ 2.6
S_8	+ 15	- 6.1
S_9	+ 4	- 12.5
S_{10}	+ 6	- 14.1

+ = increased values
- = decreased values

Pearson's r = -0.345 $p < 0.33$

other factors besides thyrotoxicosis can increase serum T_4 and may account for the low negative correlation of weight change and serum T_4 change.

To see if the data would have produced significance had other statistics been employed, a Kendall's tau and

Spearman's rho were used with the same data as presented in table 5. There was no significant relationship between weight change and serum T_4 change when using these statistics. The correlation coefficients for Kendall's tau and Spearman's rho were -0.205 ($p < 0.41$) and -0.258 ($p < 0.47$) respectively. Thus, there was even a weaker correlation using these statistics than when using Pearson's Product-Moment Correlation.

The twenty-four hour recall of physical activity and food intake taken every fifteen days between the recording periods demonstrated an inconsistent pattern of food intake and physical activity patterns (see table 6). From these data future trends could not be predicted. However, the validity of the twenty-four hour diet recall has been questioned over the years (32). Seven-day food diaries were considered more accurate. When used in combination with daily phone calls to obtain the data needed the seven day food diaries provided an accurate account of food intake.

Even though there were no significant changes in physical activity and food intake patterns pre- and post-I^{131} treatment, it was beneficial to look at these values on an individual basis. Table 7 represents the weight change related to the caloric intake change. Six out of ten subjects gained weight while their caloric intake

TABLE 6

CONSECUTIVE 24-HOUR DIET AND PHYSICAL ACTIVITY RECALLS OF PATIENTS WITH THYROTOXICOSIS

Subject	24-Hour Diet Recalls (kcal)	24-Hour Physical Activity Recalls (kcal)
S_1	2982	763
	2344	350
	2422	73
S_2	2380	78
	2025	840
	2490	620
S_3	2668	2027
	3568	2262
	3779	1962
S_4	2275	240
	1498	240
	1334	240
S_5	3940	1200
	2933	1453
	3276	1440
S_6	1546	1818
	1232	2496
	826	1716
S_7	1813	240
	1351	0
	1665	78
S_8	1679	336
	1778	52
	1964	180
S_9	455	1632
	2375	2394
	953	1794
S_{10}	946	559
	939	541
	842	312

TABLE 7

WEIGHT CHANGE VS. CALORIC INTAKE CHANGE
OF PATIENTS WITH THYROTOXICOSIS

Subject	Weight Change (lbs)	Caloric Intake Change (kcal)
S_1	+ 12	- 321
S_2	- 3	+ 154
S_3	+ 9	- 340
S_4	+ 7	- 271
S_5	+ 9	- 521
S_6	+ 7	- 510
S_7	- 5	+ 651
S_8	+ 15	+ 6
S_9	+ 4	+ 361
S_{10}	+ 6	- 206

+ = increased values
- = decreased values

decreased. One subject gained weight with little change in caloric intake. Two subjects lost weight while their caloric intake increased. This was not what was expected as most increased weight with a decreased caloric intake. This strengthens the opinion that the BMR played the major role in the weight gain.

Table 8 represents the weight change related to the physical activity change. Five out of ten subjects gained weight with increased physical activity. Two subjects gained weight with no change in physical activity. One subject gained weight with a decrease in physical activity and two subjects lost weight. In those losing weight, one had an increase in physical activity and the other had a decrease in physical activity. This also was not what was expected as most subjects gained weight with an increase in physical activity. Again the subjects may have engaged in more activities due to better physical well-being after treatment, but the BMR appeared to be the most important factor.

Table 5 represents the weight change related to the serum T_4 change. On an individual basis eight out of ten subjects gained weight while serum T_4 decreased, and two subjects lost weight. Of the two subjects who lost weight, one subject's serum T_4 value increased after I^{131} treatment while the other subject's serum T_4 decreased. Thus, the weight gain appeared to be related mainly to the BMR more than any other variable. However, the data support the null hypotheses that there was no significant relationship between change in weight and 1) change in caloric intake; 2) change in physical activity; or 3) change in serum T_4 values in patients with thyrotoxicosis before and two months after treatment with I^{131}.

TABLE 8

WEIGHT CHANGE VS. PHYSICAL ACTIVITY CHANGE OF PATIENTS WITH THYROTOXICOSIS

Subject	Weight Change (lbs)	Physical Activity Change (kcal)
S_1	+ 12	0
S_2	- 3	+ 404
S_3	+ 9	- 399
S_4	+ 7	+ 60
S_5	+ 9	+ 380
S_6	+ 7	+1400
S_7	- 5	- 354
S_8	+ 15	+ 12
S_9	+ 4	+ 475
S_{10}	+ 6	0

+ = increased values
- = decreased values

If the average weight gain of 6.1 pounds two months after I^{131} treatment could be projected into the future, then approximately as much as 36 pounds could be gained in one year after I^{131} treatment. Because this is excessive weight gain for many individuals, it is important to look at the variables more closely. The weight change seems to be most closely associated with a change

in the BMR due to the treatment and not dietary and physical activity patterns, before and after treatment. However, changing these variables of dietary intake and physical activity might have some effect on the weight change. If after I^{131} treatment, patients with thyrotoxicosis decrease their caloric intake or increase their physical activity or both as soon as weight gain becomes evident, then perhaps not as much weight would be gained. Decreasing caloric intake is believed to have the stronger effect in limiting weight gain as compared to increasing physical activity. Dietary counseling might benefit these patients who do not wish to gain weight by helping them to identify their eating habits and by providing them with information on how to watch their weight.

CONCLUSIONS

No significant changes in caloric intake and physical activity patterns were found before and two months after I^{131} treatment in thyrotoxic subjects. Significant changes in weight and serum T_4 values were found before and after I^{131} treatment. Although weight increased significantly and serum T_4 values decreased significantly, the relationship between weight gain and serum T_4 values was not significant.

Error was introduced to the study by the lack of consistency in reporting amounts of physical activity on the physical activity forms. This was the only method used to determine physical activity. Subject availability was limited and the sample size was small (ten subjects) which influenced the results of the study.

The seven-day food record proved to be an accurate tool to measure food intake when combined with daily telephone calls to the subjects. In this way subjects were reminded to keep the records, and if any questions arose, they could be answered quickly.

There was a significant change in weight (increase) and a significant change in BMR (decrease) as indicated by serum T_4 values with no significant changes in food intake

or physical activity patterns pre- and post-treatment with I^{131}. This suggested that altering the variables of food intake (decreasing it) and physical activity (increasing it) or both after I^{131} treatment may have aided in preventing unwanted weight gain.

IMPLICATIONS FOR FURTHER RESEARCH

Although 6.1 pounds did not appear to be an excessive amount of weight gain in two months after I^{131} therapy, personal contact with thyrotoxic patients treated previously with I^{131} revealed that as time went on more weight was gained. In many cases this weight was an excessive amount and dietary counseling was introduced. The fact that hypothyroidism following I^{131} treatment is increasing annually also adds to the alarm of excess weight gain.

Further investigation is needed using a larger sample size and more precise measuring devices to determine if dietary and physical activity patterns change before as compared to after I^{131} treatment. A longer period than two months could be beneficial in determining if weight gain steadily increased after treatment. Further investigation is required to determine if dietary counseling would actually help these patients to lose weight. To improve accuracy, it is recommended that future studies using food diaries in the design incorporate daily telephone calls to obtain the needed data.

APPENDIX A

INFORMED CONSENT

PROJECT TITLE: The relationship of weight gain, caloric intake, and physical activity in patients with thyrotoxicosis treated with radio iodine.

PRINCIPAL INVESTIGATOR: Sharon P. Foley, Dietetic Intern
Graduate Student

ASSOCIATED INVESTIGATORS: Philip Johnson, M.D.

INSTITUTION INVOLVED: The Methodist Health Care Center

PARTICIPANT'S NAME_____

I, _____, give my permission to be enrolled as a participant in this study and realize there is NO monetary compensation involved. I understand that the subjects selected must perform the following tasks:

1. On the first visit to the clinic, have my height and weight recorded. After two months past the initial visit to the clinic, have my weight recorded.
2. Maintain a 7-day food diary beginning the day after the initial visit to the clinic, and the day after my visits two months past the initial visit. This would necessitate my documenting all foods and beverages I consume for each seven day time period.

I agree to do this in such detail as to include the type and quantity of each item consumed.

3. Maintain a 7-day physical activity record beginning the same day the food diaries are kept. This would necessitate my documenting the amount of physical exercise performed on a daily basis for the seven day time periods.
4. I agree to elicit the information recorded on my 7-day food diaries and 7-day physical activity records to Sharon Foley each night during the recording periods when Sharon Foley will telephone me.
5. I agree to elicit a 24-hour dietary recall and 24-hour physical activity record to Sharon Foley three times during the two month interval. This will be accomplished via telephone when Sharon Foley calls me.
6. I agree to return the initial 7-day food diary and physical activity records to Sharon Foley upon my next visit to the clinic. I will mail the 7-day food diary and physical activity records recorded after my two month visit to the clinic to Sharon Foley. I will receive a stamped, self-addressed envelope to Sharon Foley in order to do this.

I understand that I will receive detailed instructions concerning completion of the 7-day food diary and physical

activity record, and that Sharon Foley will be available to answer any questions I may have during the course of the study. The procedure described above involves the following possible risks or discomforts:

- A small portion of my time for two-seven day periods.
- The delivery of the 7-day food diary and physical activity records to the clinic. These may be brought in directly to the Health Care Center or mailed.
- Possible public embarrassment if subjects' names are accidently released.

The possibility of public embarrassment will be carefully controlled for as a code number will be assigned to each subject. Only the investigators of this study will know the key to this code.

I understand that the information gained in this study may benefit future patients with thyrotoxicosis having problems with weight gain after treatment with radio iodine.

An offer to answer all of my questions regarding the study has been made. I understand that I may terminate my participation in the study at any time.

Date:_____ _____
Participant's Legal Signature

Printed Name:_____

Mailing Address:_____

Phone:_____
Home Office

APPENDIX B

GENERAL INSTRUCTION SHEET

1. A daily food diary should be completed for two seven day periods. The first should begin the day immediately following your initial treatment with radio iodine. The second should begin the day immediately following your two month check-up to the Health Care Center. In order to identify your eating habits it is necessary to keep an accurate record of what you eat, how much you eat, and when you eat. You can do this on the food record forms provided, keeping in mind the following points.

   Write your name and the date at the top of the food record. In the first column, Time, write down the exact time you consume any food or drink (except plain water). For example, if you have breakfast at 8:00 a.m., write down "8:00 a.m."

   The next two columns are for listing the amount and a description of each food and beverage you consumed. For example, 1/2 cup orange juice, 2 pancakes, 4 tablespoons maple syrup, 6 oz. coffee, 1 tsp. sugar, etc. A complete description of each food item, including preparation, is extremely important. "Chicken breast, skinned, coated with flour and fried

in oil "tells what you really ate."

It is a good idea to measure foods to get some idea of what 1/2 cup of something looks like, even though you may not measure every item every time. If not sure of the amount of something you cannot measure, describe its size, such as 6 in. x 4 in. x 1/2 in. slice round steak, baked with nothing added.

Everything except plain water must be written down. Remember to include coffee, tea, diet drinks, and snacks. Do not forget the sugar and cream in the coffee, the margarine on the bread, or the dressing on the salad-- and the amount of each. If you eat a casserole dish, describe the amount consumed. Example, 1/2 cup broccoli casserole. List the ingredients giving an estimate of the amounts. Example, 1/3 cup broccoli, 1 tbsp. rice, 2 tbsp. cheddar cheese.

Two last points: the best time to do the food record is right after you eat. Do not wait until evening to fill out your food record. And please be as accurate as possible.

2. The amount of exercise performed should be recorded for the same two-seven day periods as stated above on the physical activity records (enclosed). Each box on the record represents a five minute time interval; heavy lines represent fifteen minute intervals, and each row represents one hour. Put a check mark in the box(es)

which correspond to the amount of time spent in the particular activity listed. If you engage in activities not included in the list indicate the activity and the time spent on this activity on the bottom of the sheet. You need not include every minute of the day. Just periods of physical activity exerted. If your job includes heavy manual labor, please describe your duties such as lifting boxes, carrying metal cases, etc., and the hours spent on these.

Thank you for being a part of this study. Please be advised that all information will be kep confidential. If you should have nay questions at any time during the study, please don't hesitate to call me (collect if necessary).

Sharon P. Foley
(713) 669-0206

APPENDIX C

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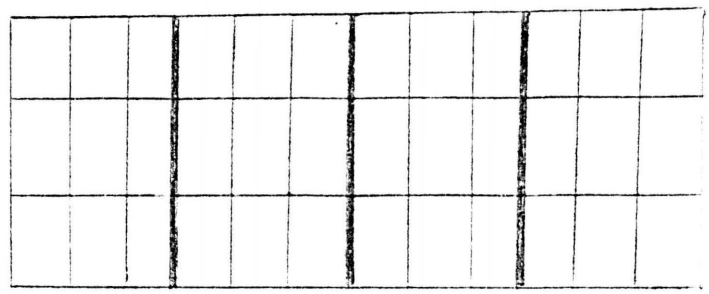
APPENDIX D

PHYSICAL ACTIVITY RECORD

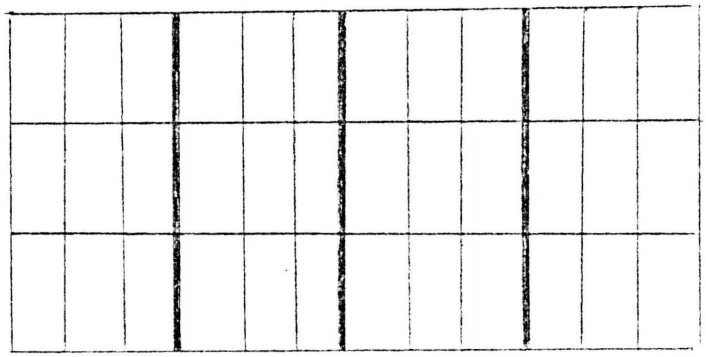
Light exercise-each box = 5 minutes = 13 calories

Preparing/cooking food
Washing dishes
Dusting
Hand washing small articles
Ironing
Walking (3 miles/hour)
Rapid typing (50 words/min.)
Officework done standing



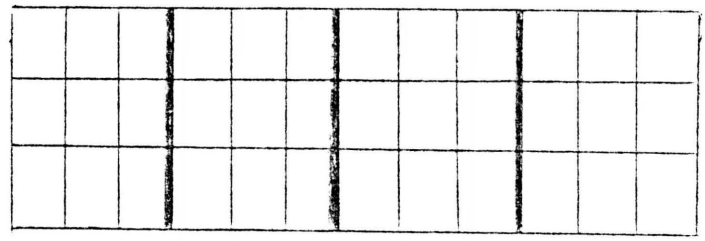
Moderate exercise-each box = 5 minutes = 20 calories

Making beds
Mopping/scrubbing/sweeping
Light polishing/waxing
Laundering by machine
Light gardening
Light carpentry
Walking (5 miles/hour)
Badminton
Volleyball
Activities while standing
which require moderate
arm movement



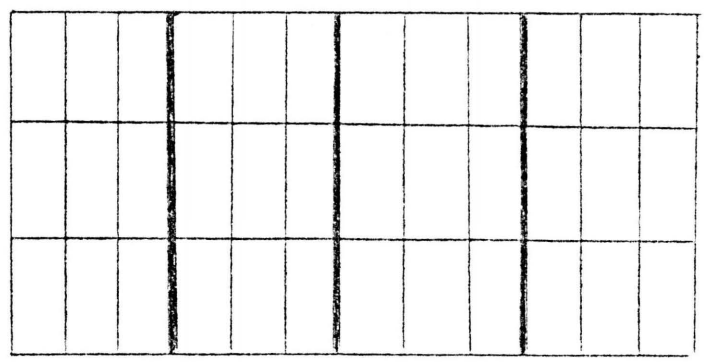
Vigorous exercise-each box = 5 minutes = 30 calories

Heavy scrubbing/waxing
Hanging out clothes
Stripping beds
Bowling
Golfing
Gardening



Strenuous exercise-each box = 5 minutes = 50 calories

Swimming
Tennis
Jogging/running (5.5 miles/hour)
Bicycling
Dancing
Skiing
Football
Baseball
Handball
Racquetball



Other Activities Not Listed:

Activity

Time Spent on Activity

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