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CLINT PUBLICATIONS

The Effect of Daily Ingestion of 100 mg Iodine Combined with High Doses of Vitamins B₂ and B₃ (ATP Cofactors) in Five Subjects with Fibromyalgia

by Guy E. Abraham, MD and Jorge D. Flechas, MD

Introduction

Fibromyalgia is a common clinical syndrome of generalized musculoskeletal pain, stiffness, and chronic aching, characterized by reproducible tenderness on palpitation of specific anatomical sites, called tender points.¹ Fibromyalgia is nine times more common in middle-aged women (between the ages of 30 and 50) than in men. The association of fibromyalgia with chronic fatigue syndrome has been reported.²

We previously proposed that fibromyalgia is caused by deficiencies of substances needed for ATP synthesis.³ The vitamins B₂ and B₃, as precursors of the cofactors FADH₂ and NADH, play a key role in ATP synthesis⁴ and in the generation of intracellular hydrogen peroxide.⁵ Hydrogen peroxide formation is the rate-limiting step in the oxydation of iodide to iodine by iodoperox-idases, including thyroid peroxydase (TPO). The oxydation of intrathyroidal iodide to iodine by TPO is the first and key step in the synthesis of thyroid hormones.

The role of iodine in ATP synthesis and in normal functions of striated muscles is presently unknown. In severely iodine-deficient individuals, the thyroid gland takes the lion's share of the total body iodine pool. However, in iodine-sufficient individuals, the maximum iodine content of the thyroid gland (50 mg) represents only 3% of the total body iodine of 1,500 mg⁶ and striated muscles contain 33% of the total body iodine.⁷

During a study on the bioavailability of an oral dosage form of Lugol solution at 100 mg of elemental iodine a day for six weeks in six female volunteers, one of them reported significant improvement of fibromyalgia (FM) pain and associated discomfort. She decided to continue the ingestion of 50 mg iodine/day for another 40 weeks. Further evaluation of this subject revealed an inability to retain ingested iodine which was corrected with iodine supplementation at 50-100 mg/day. Further improvement of FM symptoms, including increased energy level and decreased pain post exercise, occurred following the addition of vitamin B₃ at 1000 mg/day in the form of inositol hexanicotinate for eight weeks.⁸

Further studies revealed that the potentiating effects of ATP cofactors vitamin B₂ and B₃ on orthiodosupplementation in FM patients was not observed until the daily amounts were increased to 1,000 mg B₃ and 200 mg B₂, and that B₃ alone at 1,000 mg/day was not as effective as in combination with vitamin B₂ at 200 mg/day. In order to evaluate further the effect of iodine/iodide alone at 100 mg a day and in combination with the ATP cofactors, vitamins B₂ (riboflavin) and B₃

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Table 1

Clinical Data on 5 Female Subjects with Fibromyalgia

SS#	Age (Years)	Height (Inches)	Weight (Pounds)	BMI*	Menstrual Status	Duration of FM	Severity of FM (FIQ** Score)
1	41	53	140	28.3	Premenstrual	6 months	Moderate (54)
2	54	63	132	23.4	Postmenstrual	4 years	Severe (74)
3	47	64	204	35	Premenstrual	3 years	Severe (86)
4	43	68	227	34.5	Premenstrual	12 years	Moderate (60)
5	37	70	180	25.8	Premenstrual	8 years	Severe (83)
±	44.4	64.8	177	28			
SD	6.5	4.3	41	4.8			

* BMI = Body Mass Index

** FIQ = Fibromyalgia Impact Questionnaire: 50-60 = Moderate; 60-70 = Moderate to Marked; >70 = Severe

Table 2

Clinical Evaluation, Laboratory tests, and Questionnaires Performed on the 5 FM Subjects

Tests & Evaluation	Pre-Intervention	Post-Phase I	Post-Phase II
Physical Exam + Vital Signs	X	X	X
Body Composition	X	X	X
Ghent Score	X		X
Pressure Threshold (Dolorimetry)	X	X	X
Fibromyalgia Impact Questionnaire	X	X	X
Zung's Depression Scale	X	X	X
CBC	X	X	X
Urinalysis	X	X	X
Blood Chemistry	X	X	X
Thyroid Function Tests + TPO Ab	X	X	X
Thyroid Ultrasonometry	X		X
Serum 25-OH-D ₃	X	X	X

(niacin), at daily doses of 1,000 mg B₃ and 200 mg B₂, five female subjects with FM were evaluated before treatment; after six weeks on 100 mg iodine/iodide alone (Phase I) and after six weeks of 100 mg iodine/iodide combined with the B₂ and B₃ complex (Phase II). Phase II followed Phase I without interruption. This study was performed under contract at the Flechas Family Practice Clinic and funded with a grant from Optimox Corporation.

Subjects and Methods

Female subjects with FM (criteria of reference 1 used in screening) were recruited from the private practice of one of the authors (JDF). They were ambulatory, clinically euthyroid, and off all medications one week prior to this study. Informed consent was obtained from all subjects. The clinical data on these subjects are displayed in Table 1. The self-administered questionnaires, as well as the clinical and laboratory tests performed on these subjects, are listed in Table 2. The body mass index (BMI) is the ratio of body weight divided by height squared, using the metric units of kilograms (kg) for weight and meters (m) for height. The normal range is 18.5-24.9 kg/m², with less than 18.5 as underweight; between 25-29.9 as over weight and 30

and above as obese. Based on this classification, one subject was within the normal range, two were overweight, and two were obese. A BioImpedance Analyzer Model 450 from BioDynamics, Seattle, WA was used to measure muscle mass, fat mass, and total body water.

After initial evaluation, each was supplied with Iodoral[®] 50-mg tablets and instructed to ingest two tablets a day for six weeks (Phase I) and to report any adverse effects. At their return visit at the end of Phase I, they received bottles of ATP cofactors containing 100 mg riboflavin and 500 mg niacin as inositol hexanicotinate per tablet. They were instructed to ingest two tablets daily for six weeks in addition to the 100 mg elemental iodine.

The following clinical and laboratory evaluations were performed prior to treatment; after 6 weeks on iodine 100 mg /day (Phase I); and after 12 weeks on iodine plus six weeks on vitamins B₂ and B₃ (Phase II):

- Urine analysis was performed at the clinic with Multistix 10SG reagent strips and read on a Clinitek 100 that was calibrated daily.
- Complete blood count (CBC), the metabolic panel,

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thyroid profile, TPO antibody titer and serum 25-OHD₃ levels were performed by Lab

Corporation of America.

- Thyroid ultrasonometry was computed by a registered sonographer using a portable Biosound Esaote Megas System unit with a frequency of 7.5 MHz.

The volume of each lobe of the thyroid gland was calculated as previously described:⁹ $V \text{ (mL)} = W \text{ (cm)} \times D \text{ (cm)} \times L \text{ (cm)} \times 0.52$. The thyroid volume was the sum of the volumes of both lobes, taking 18 mL as the upper limit for normal thyroid volume in women living in a non-endemic goiter area.⁹

Two questionnaires were completed by the subjects before intervention, post-Phase I and post-Phase II: The FM Impact Questionnaire (FIQ)¹⁰ and the Zung Depression Scale.¹¹ FIQ has been designed to measure the components of health status that are most affected by FM. A higher score indicates a greater impact of FM on the patient. The maximum score is 100. Most FM patients with mild to moderate FM scored in the 50s; with moderate to marked symptomatology in the 60s. Severely affected patients scored in the 70s and above. Klerman, *et al*,¹² reported FIQ scores of 19 ± 5.5 in 12 healthy premenopausal American women in their 30s, compared to 71 ± 5.0 for 10 American women with FM.

Normal women from Mexico and Spain¹³ scored lower on the FIQ test: 5.9 ± 6.3 for 33 Mexican women and 1.6 ± 2.5 for 80 Spanish women. The Zung's Depression Scale is a measure of the severity of depression with scores of 50-59 as mild to moderate depression, 60-69 as moderate to marked depression; and greater than 70 as severe depression.

During all three visits, the Pressure Tolerance of each tender point of both sides of the body was performed. The pressure tolerance meter model PTO from Pain Diagnostics and Thermography, Great Neck, New York, was used at all 18 tender points to assess the pressure threshold in kg/cm^2 .¹⁴ Pressure Threshold (PT) is the minimum force which induces pain. In seven normal women, which we used as controls, the sums of PTs of all tender points had mean \pm SD of 140 ± 30 with a 95% confidence limit of 113-168 kg/cm^2 . During breast examination, the Ghent score was used to assess the severity of fibrocystic disease of the breast (FDB) in those five subjects.¹⁵ The maximum score is 40 for both breasts. A score of 7 or less is considered normal. Paired data analysis was used to compare the mean values obtained between pre- and post-intervention within these subjects; with the SPSS software version 14.

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Table 3

Effect of Iodine/Iodide Alone or in Combination with Vitamins B₂/B₃ on Some Clinical Parameters in 5 Subjects with FM

	Pre-Intervention	Post-Phase I	Post-Phase II
	$x \pm SD$	$x \pm SD$	$x \pm SD$
Systolic BP	116 ± 1.1	118 ± 11	$113 \pm 8^*$
Diastolic BP	78 ± 8	81 ± 5	$74 \pm 8^*$
Body Weight (lbs)	177 ± 41	178 ± 39	180 ± 39
Body Temp (°F)	97.8 ± 0.25	97.8 ± 0.21	$98 \pm 0.29^*$
Basal Med Rate (cal/24hrs)	1505 ± 275	1505 ± 235	1516 ± 272
Lean Mass (lbs)	107 ± 20	106 ± 17	106 ± 20
Fat Mass (lbs)	70 ± 24	71 ± 24	71 ± 22
Total Body Water	71 ± 3	70 ± 2	71 ± 3

* $0.05 < p < 0.1$

Table 4

**Effects of a Daily Dose of 100 mg Iodine/Iodide with and without
Vitamins B₂ and B₃ on Thyroid Function Tests in 5 Subjects with Fibromyalgia**

	TSH (mIU/L)	Total T4 (µg/dl)	Free T4 (ng/dl)	Total T3 (ng/dl)	Free T3 (pg/ml)
	X ± SD	X ± SD	X ± SD	X ± SD	X ± SD
Pre-Intervention	1.35 ± 0.26	7.4 ± 2.7	1.1 ± .21	149 ± 35	3.1 ± .29
Post-Phase I	4.1 ± 1.4	6.6 ± 2.3	.93 ± .12	126 ± 24	2.9 ± .46
Post-Phase II	5.2 ± 2.1	7.1 ± 2.4	0.96 ± .18	151 ± 42	3.0 ± 0.5
Pre vs Post-Phase I p Value	<0.05	<0.05	NS	<0.05	NS
Pre vs Post-Phase II p Value	<0.05	NS	NS	NS	NS

Results

No side effects were reported by the subjects during the study period and the intervention with iodine 100 mg/day and the B₂/B₃ complex was uneventful. Comparing pre-intervention with post-Phase I and post-Phase II, no statistical significance was observed for urinalysis, blood chemistry, hematology, and body composition. The values for the above parameters were within the normal range before and after intervention. Near significance ($0.1 > p > 0.05$) for the following parameters was observed between pre-intervention and post-Phase II (See Table 3): decreased systolic and diastolic blood pressure and increased basal body temperature.

Pre-intervention, the thyroid volumes ranged from 9.0-13.3 ml with a mean of SD of 9.5±2.3 ml. Post-Phase II values ranged from 7.4-12.8 ml with a mean of SD of 10.3±2.4 ml. There was no significant difference between pre- and post-intervention mean thyroid volumes. The data on the thyroid panel are displayed in Table 4. Mean serum TSH levels increased significantly ($p < 0.05$) above baseline following Phase I and Phase II interventions. The means of all four thyroid hormones decreased following Phase I, with significant differences ($p < 0.05$) observed for total T4 and total T3. However, the mean levels of total T4, total T3, free T4, and free T3 increased following Phase II to reach pre-treatment levels, and there was no significant difference for the mean values of all four thyroid hormones between pre-intervention and post-Phase II.

The Ghent score for severity of FBD decreased significantly ($P = 0.02$) post-Phase II, with mean values ±

SD of 14.6±9 pre-intervention and 5.4±3.3 post-Phase II (Table 5). The means of pressure threshold of tender points (kg/cm²) were pre-intervention — 51±3.6; post-Phase I — 63±14 (NS); and post-Phase II — 72±26 ($p = 0.07$). There was no significant difference between pre-intervention and post-Phase I and post-Phase II for the mean values of the FIQ: pre-intervention — 74±14; post-Phase I — 70±18; post-Phase II — 65±17. The Zung Depression Scale showed a near significant decrease ($p = 0.08$) post-Phase II. The mean ± SD were pre-intervention — 64±14; post-Phase I — 62±7; and post-Phase II — 56±4.8.

The levels of serum 25-OH-D₃ (ng/ml) are displayed in Table 6. The mean ± SD for pre-intervention, post-Phase I and post-Phase II were respectively: 31±16; 28±15; and 19±3. There was a non-significant drop in the mean serum 25-OH-D₃ level following Phase II.

Discussion

Chronic pain is one of the most common complaints for which patients seek medical advice and FM is the most common etiology for non-localized and diffused myalgias.¹⁴ We have evaluated five subjects who fulfill the criteria set by The American College of Rheumatology¹ for the classification of fibromyalgia. Several clinical and laboratory data were collected before intervention; post six weeks on iodine at 100 mg/day and post six weeks on at 200 mg B₂ and 1000 mg B₃ per day for six weeks concomitant with the administration of iodine 100 mg/day. Because of the small number of participants, trends were observed that

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did not reach statistical significance at $P < 0.05$. These trends need to be confirmed with a larger group of FM sufferers.

Clinical Response: The near significant decrease in systolic and diastolic blood pressure between pre-intervention and post-Phase II, combined with the near significant increase in basal body temperature, deserves further evaluation. The participants reported feeling warmer after the addition of the B vitamins to the iodine supplementation. A marked and significant ($p = 0.02$) drop in mean Ghent score occurred following 12 weeks of supplementation. Using iodine alone, we have usually observed such a response in the Ghent score after a longer period on this supplement.

As a group, there was no significant improvement in the FIQ score, Zung's Depression Scale, and Pressure Threshold (Table 5). However, subject #5 responded extremely well (Table 7). The original pretreatment scores for depression and impact of fibromyalgia were rated as severe in this subject. Following 12 weeks on the iodine and B complex supplement, her scores improved to the level rated as mild depression and slight impact of Fibromyalgia. The FIQ score decreased markedly from a pre-intervention of 83 (severe) to a low value of 42 (mild) following 12 weeks of iodine and B vitamin supplementation. Using Klerman's FIQ scores for normal American women with mean \pm SD of 19 ± 5.5 , the upper normal limit would be $19 + 2(5.5) = 30$.

Because of the marked difference in FIQ scores for normal women from different locations, upper normal limits for each FM group studied should be computed using normal women from the same population. For

example, upper normal FIQ scores would be 18.5 for Mexican women, 6.6 for Spanish women,¹³ and 30 for American women.¹²

The 95% confidence limits for pressure threshold in our seven normal women were 113-168 kg/ml. Pressure threshold in subject #5 improved markedly from a pre-treatment of 50 kg/cm² to a normal value of 119 kg/cm² following 12 weeks of intervention. However, as a group, the pressure threshold of five FM subjects did not reach statistical significance of $p < 0.05$ following intervention, with a $p = 0.07$ following Phase II. Following the end of the study, subject #5 decided to continue on the program, but she decreased the daily intake of iodine to 50 mg, while continuing the ATP cofactors. Fibromyalgia and associated discomfort returned in full force within 2 days. One day after increasing the iodine intake to 100 mg, she noticed a marked improvement of her symptoms to reach the level of well-being she experienced post-Phase II.

Laboratory Results: Thyroid function tests included TSH, T4, free T3, free T4, and TPO antibody titer. Serum TSH increased significantly following iodine supplementation for six weeks. This increase persisted following the addition of the B vitamins. We have observed increased TSH levels following orthiodosupplementation, but these levels usually return to the normal range within 6-12 months.⁸ There was a decrease in the main values of all thyroid hormones measured, with significance at $p < 0.05$ for total T4 and total T3 following Phase I. However, supplementation with the B vitamins resulted in the reversal of this trend for all four thyroid hormones which

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Table 5

Pressure Threshold, Ghent's Score, and Results of 2 Self-Administered Questionnaires in 5 Female Subjects with Fibromyalgia before and after Intervention

	Pre-Intervention	Post-Phase I		Post-Phase II	
	x \pm SD	x \pm SD	p Value	x \pm SD	p Value
Fibromyalgia Impact Questionnaire	71 \pm 14	70 \pm 18	NS	65 \pm 17	NS
Zung Depression Score	64 \pm 14	62 \pm 7	NS	56 \pm 4.8	0.08
Pressure Threshold (kg/cm²)	51 \pm 3.6	63 \pm 14	NS	72 \pm 26	0.07
Ghent's Score	14.6 \pm 9			5.4 \pm 3.3	0.02

Table 6

Serum 25-OH-D₃ Levels (ng/ml) Pre- and Post-Intervention in 5 Female Subjects with FM

SS#	Pre-Intervention	Post-Phase I	Post-Phase II
1	25.10	35.60	24.00
2	26.30	21.60	18.20
3	15.10	16.50	16.80
4	57.20	16.50	16.40
5	29.50	51.20	19.70
X	31	28	19
SD	16	15	3
p Value		0.84	0.2

increased to pre-treatment levels following Phase II. There was no statistically significant difference between pre-supplementation and post-Phase II mean levels of thyroid hormones (Table 4). An increased organification of thyroidal iodide for the synthesis of thyroid hormones by the ATP cofactors could explain this effect on thyroid hormones.⁸ Low titer of TPO antibodies were present in three subjects, ranging from 11-37. There was no increase in titer following the program. In fact, the titers decreased in all three subjects: from 11 to less than 10 in one subject; from 37 to 15; and from 25 to 16 in the other 2 subjects.

Serum 25-OH-D₃ levels pre- and post-supplementation are displayed in Table 7. According to Grant and Holick,¹⁶ serum 25-OH-D₃ levels lower than 20 ng/ml are evidence of vitamin D deficiency; levels between 20 and 32 ng/ml are evidence of insufficiency; and 32-100 as sufficiency. Based on this classification, only subject #4 had vitamin D sufficiency at baseline. However, her serum 25-OH-D₃ levels decreased to 16.4 ng/ml post-Phase II.

Whether or not vitamin D deficiency plays a role in FM is debatable at this time.^{17,18} Block and Gratwick¹⁹ reported that out of six FM patients with serum 25-OH-D₃ levels below 10 ng/ml, who received 50,000 IU vitamin D weekly for eight weeks, only one patient believed that vitamin D therapy was helpful and the other five patients found the vitamin D therapy of no benefit for their pain. In subject #5 of our study, who showed the best response to intervention, the post-intervention serum 25-OH-D₃ was 19.7 ng/ml, a level

classified as deficient vitamin D.

There was a non-significant drop of 40% in the mean serum 25-OH-D₃ levels of the five FM subjects evaluated following the addition of the ATP cofactors to iodine supplementation. The mean values were 31 ng/ml pre-supplementation; 28 ng/ml after six weeks on iodine; and 19 ng/ml post B vitamin administration. If this trend of decreasing serum 25-OH-D₃ is confirmed in a larger group of FM sufferers and becomes statistically significant, understanding its physiological significance and the mechanisms involved would require further investigation. A decrease in serum 25-OH-D₃ could be due to either decreased synthesis by the liver from vitamin D or increased metabolism of 25-OH-D₃ to calcitriol by target cells such as the kidney and other organs possessing 1-hydroxylase activity for 25-OH-D₃.

General Discussion

Based on whole body sufficiency for iodine, the US population is severely deficient in this essential element, requiring at least 100 times the RDA to achieve sufficiency.^{5,9,20,21} If iodine plays a role in vitamin D metabolism and has a modulating effect on target organ response to calcitriol, the normal range of serum 25-OH-D₃ would need re-evaluation in whole body iodine sufficient individuals. Vitamin D is essentially a steroid and iodine affects receptor responsiveness to estrogens and other steroids.^{22,23}

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The classification of vitamin D deficiency according to serum 25-OH-D₃ levels is based on data obtained in severely iodine-deficient individuals, consuming the very low US RDA amount of iodine. This classification will need re-evaluation following published studies looking at the effect of whole body iodine sufficiency on the conversion of 25-OH-D₃ to the active hormone calcitriol. For example, magnesium increases the 1-hydroxylase activity of the kidney.²⁴ Therefore adequate magnesium intake would lower the serum 25-OH-D₃ levels required for adequate calcitriol synthesis. One would expect a magnesium sufficient individual to achieve normal calcitriol levels with lower serum 25-OH-D₃ than in a magnesium deficient individual.

Standardizing the levels of serum 25-OH-D₃ would require a careful screening of subjects participating in this standardization program. Ideally, these subjects should be supplied with adequate amount of magnesium and iodine to achieve whole body sufficiency for these two important nutrients. Magnesium deficiency is common in the US population as well as the rest of the world.²⁵⁻²⁸ Red blood cell (RBC) magnesium levels were below the normal range in all nine normally menstruating pre-menopausal American women evaluated by one of the authors (GEA) 25 years ago.²⁹ Vitamin B₆, at an oral daily dose of 200 mg in these nine women increased markedly the RBC magnesium with mean values more than twice the baseline levels. The B vitamins require phosphorylation to become biologically active and magnesium is required for this phosphorylation.³⁰ Vitamin B₆ enhances cell membrane transfer of magnesium.²⁹ Riboflavin is required to oxidize pyridoxine (B₆) phosphate to the active form, pyridoxal-5-phosphate.³⁰

It is obvious that a complete nutritional program emphasizing magnesium instead of calcium would be required in order to standardize optimal levels of

physiological parameters in optimally healthy individuals. In one of the author's (GEA) experience, megadosing with calcium (2,000-3,000 mg/day) has been the most common cause of poor response to orthiodosupplementation. Physicians and other health care professionals need to be informed about the toxicity of excess calcium,³¹ and the importance of adequate magnesium intake³¹⁻³⁶ for optimal health and strong bones.

The effect of a magnesium-emphasized complete nutritional program combined with orthiodosupplementation and high doses of B₂/B₃ will be evaluated in our next study of FM sufferers. The measurement of red blood cell ATP levels, serum calcitriol, and PTH will be added to the laboratory tests in order to achieve a better understanding of the effect of the program on ATP synthesis and the interaction between the serum 25-OH-D₃ levels and the biologically active hormone calcitriol.

About the Author

Guy E. Abraham, MD, is a former Professor of Obstetrics, Gynecology, and Endocrinology at the UCLA School of Medicine. Some 35 years ago, he pioneered the development of assays to measure minute quantities of steroid hormones in biological fluids. He has been honored as follows: General Diagnostic Award from the Canadian Association of Clinical Chemists, 1974; the Medaille d'Honneur from the University of Liege, Belgium, 1976; the Senior Investigator Award of Pharmacia, Sweden, 1980. Dr. Abraham's current research interests include the development of assays for the measurement of iodide and the other halides in biological fluids and their applications to the

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Table 7

Response of Subject #5 to Intervention

	Pre-Intervention	Post-Phase I	Post-Phase II
Ghent's Score	13		3
Fibromyalgia Impact Questionnaire	83	61	42
Zung Depression Score	75	64	55
Pressure Threshold (kg/cm²)	53	76	119

implementation of orthiodosupplementation in medical practice. The applications of Dr. Abraham's techniques to a variety of female disorders have brought a notable improvement to the understanding and management of these disorders.

Jorge D. Flechas, MD MPH, is the medical director of Flechas Family Practice in Hendersonville, North Carolina, specializing in hormonal therapy for treatment of fibromyalgia and chronic fatigue and immune dysfunction syndrome (CFIDS) since the late 1980s. He has developed a new protocol for treatment of these illnesses using oxytocin (OT), dehydroepiandrosterone (DHEA) and some natural nutrients. He feels both diseases are most likely due to a neuroendocrine/metabolic disorder with chronic hypoxia, which causes abnormalities in the biochemistry of patients. Dr. Felchas also specializes in iodine therapy for hypothyroidism and fibrocystic breast disease.

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