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An Observational Study Among Obese Hypothyroid Dyslipidemia Clients Following an Integrated Approach Involving Nutrition and Lifestyle Counseling.

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Abstract

Background: Hypothyroidism, a clinical condition of reduced TSH, is responsible for various body changes which includes obesity and dyslipidemia. Studies show with medication and integrated approach involving nutrition and lifestyle counseling will benefit the hypothyroid clients. Possible is a research and nutrition based healthcare company providing super foods, nutritionist and Ayurveda physician consultation, health education through videos by experts and a scientifically built mobile application to track food intake and lifestyle. **Objective:** The broad objective was to assess the effect of the integrated approach involving nutrition and lifestyle counseling among the obese hypothyroid dyslipidemia clients on lipid profile and thyroid profile along with weight loss. **Methodology:** The study was ten month clinical data analysis of 101 obese hypothyroid clients with dyslipidemia. The parameters assessed were initial and final weight, BMI, biochemical parameters such as Lipid Profile and Thyroid Profile. The data analysis was carried out using SPSS 2.0 for Windows. Paired "t" test was used to test the significance before and after the program. **Results:** Mean age was 49 $\pm$ 8.85 yrs, 57.43 per cent were females. Along with obesity, hypothyroidism, dyslipidemia, other non-communicable diseases like hypertension (46.53 per cent), Knee /Joint pain (32.67) Diabetes (31.68 per cent), exists. Significant reduction in weight and BMI ($p<0.05$). The mean value of Total cholesterol (202.18; 179.85) LDL-C (129.33: 112.04), Trig (190.37:142.63) and TSH (6.33:3.32) decreased significantly ($p<0.05$) following the integrated approach involving nutrition and lifestyle counseling. **Conclusion:** Nutrition, Lifestyle counseling and health education could result in behavioral and diet modifications. Along with medications, these modifications will result in better management of dyslipidemia among hypothyroid clients.

Keywords
Hypothyroidism, Dyslipidemia, Obesity, Possible, Weight loss.

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1. INTRODUCTION:

Hypothyroidism results from reduced secretion of thyroxine (T4) and triiodothyronine (T3) from the thyroid gland. These decrease in T4 and T3 concentrations lead to hyper secretion of pituitary TSH and thus an amplified increase in serum TSH levels. This is the key laboratory finding, particularly in the early detection of thyroid failure. Hypothyroidism, a clinical condition resulting from TSH deficiency, is responsible for various body changes that may induce non-communicable chronic diseases (NCD) such as obesity and dyslipidemias [1]. Prevalence of hypothyroidism in India is around 11 per cent [2]. Serum thyroid-stimulating hormone (TSH) is also found to be associated with adverse changes of lipid metabolism as well [3]. When an individual suffers from hypothyroidism as well as subclinical hypothyroidism, without proper treatment causes elevated cholesterol in a gradual way. The link between thyroid diseases and serum cholesterol was firmly established following the classic article by Mason et al. [4] on Christmas Day of 1930, shedding light on the significance of thyroid function in cholesterol metabolism [5]. The prevalence of hypothyroidism is 1.4–13% in patients with hyperlipidemia, indicating that thyroid failure is common and may often go undetected in these patients [6]. From known hypothyroid cases, elevated cholesterol clients were identified and the present study was carried out. The present study has been undertaken to assess the effect of possible program on lipid profile of obese hypothyroid clients

Specific Objectives of the study were to:

- Assess the background details of the clients
- Assessment of the Nutritional Status of the Clients
- Assess the effect of Possible program on weight loss and biochemical parameters
- Ascertain the association between lipid profile and thyroid profile
- Effect of Possible program on the changes in medication of elevated cholesterol among the hypothyroid clients

2. METHODOLOGY:

The present study was a clinical data analysis of obese hypothyroid clients enrolled in the possible health care program for ten month. Possible is a research and nutrition based healthcare company that helps the enrolled clients to manage clinical conditions along with weight loss. These enrolled clients were provided Ayurveda physician consultation, periodic diet counseling, a kit of super foods containing functional ingredients and access to the Possible Mobile application, which is a scientifically built mobile application. The clients have to use the mobile application to log their daily food intake and their lifestyles like sleep time, physical activity type and duration. Health education videos by experts were shared through this mobile application in a regular manner to bring about behavioral modifications. The clients were also asked to share learning obtained from the health education session with nutritionists during consultation.

2.1 Research design

The study was Clinical data analysis of 101 obese hypothyroid clients who also were known cases of elevated cholesterol. The clients were selected based on the inclusion and exclusion criteria. The study was conducted following the purposive sampling technique. The duration of the study was for ten months.

2.2. Possible - An Integrated Approach

Possible Healthcare Program comprises three principal functionaries which includes, a customized meal plans and Super foods, Personal Nutritionist and Ayurveda Doctors - tech based scientific analysis and constant mentoring. A kit of nutrient dense functional foods which are natural were provided every month, diet plans were provided by qualified nutritionists every 15 days once and the mobile app which helps to follow a healthy diet and lifestyle by logging as well as recording weight, sugar levels and foods consumed. Diet plan with addition of a kit containing ready to eat or prepare foods with added functional ingredients was provided to the patients. The Super food kit provided about 20 per cent of the daily diet and the rest 80 percent was prepared by the clients. Appropriate quantities were provided based on the client's weight and weekly counseling was provided by the nutritionist. The clients were asked to follow the diet plan as per the diet guidelines and were asked to log the food they have eaten for the day and need to click the finish my day daily. Every fourth or fifth day, they were asked to update the weight. The clients were asked to do 30 mins physical activity and be active throughout. The nutritionist during her weekly counseling on nutritional and lifestyle, discussed the diet plans, use of super foods in the plans, regarding the diet logs, nutrient intakes, and physical activity. Also, the learning based on health education through videos by experts was also discussed. During the follow up call by the in house Ayurveda physicians, herbs for thyroid and dyslipidemia and the dosage of medicines were checked and home based remedies wherever required.

2.3. Selection of clients:

Hypothyroid clients enrolled for the Possible Health Program were elected for the study. These clients

were taking various doses for thyroid medication. They were asked to continue the same. Based on the following inclusion and exclusion criteria, the data was collected.

Inclusion criteria -

- Age between 20 yrs to 68 yrs
- Willing to follow the program and update diet in the app
- Clients having two sets of lab reports - Thyroid profile and lipid profile
- Clients who were known case of hypothyroidism and elevated cholesterol with or without medication for elevated cholesterol

Exclusion Criteria -

- < 19.9 yrs and > 69 yrs
- People who did not volunteer to participate in the study and not willing to use mobile app
- Clients suffering from thyroid carcinoma, thyroidectomy, Chronic Kidney diseases, Liver Cirrhosis, Heart diseases
- History of heart surgery or other cardiovascular interventions , Chronic kidney diseases pregnancy and lactation
- Hypothyroid clients with normal cholesterol levels

2.4. Conduct of the Study

The Clients of the study were enrolled online; under the Possible health program. After enrolment, they were given consultation through phone. A kit of Super foods containing functional ingredients from Truweight were given monthly once and nutritionists did telephonic consultation with the clients every week. The clients were asked to continue the hypothyroid medications as well as other medications which they were taking were continuing as per their physician.

2.5. Collection of Data

2.5. A. Assessment of the background details of the Clients

Information regarding age, gender, food habits, presence of comorbidities etc were collected using a general questionnaire designed which was pre-tested and updated in the mobile app.

2.5. B. Assessment of the Nutritional Status of the Clients

The nutritional status of the Clients was assessed from anthropometric measurements, biochemical estimation, clinical profile and diet recall.

2.5. B. i. Anthropometric measurements

Standardized techniques were used for measuring the height and weight of the clients. Heights of the clients were measured using stature meter and weight using digital weighing balance. The height and weight of all clients were recorded following the methods of Jellifee (1966) [7]. BMI was calculated using the formula weight in kg / height in m^2.

2.5. B. ii. Biochemical estimation

The biochemical parameters analyzed in this study were:

a) Lipid Profile: Total Cholesterol, High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL), Triglycerides

b) Thyroid Profile: Thyroid Stimulating Hormone (TSH), T3, T4

Clients were asked to submit the said biochemical parameters. These values were submitted twice in the possible mobile app by the clients -initially at the time of enrolment and final after the ten month program.

2.5. B. iii. Dietary Assessment

Assessment of the dietary pattern of the Clients were carried out on the basis of the diet logs they update in the mobile app. Major nutrients like carbohydrate, fats, proteins and fibre were calculated using the standard formula.

2.5. B. iv. Medication details

The hypothyroid clients who were on different medications for elevated cholesterol were taken. Initial during the start of the program and final at the end of the program.

2.7. Statistical Analysis of the data

For the present study, the data analysis was carried out using SPSS 2.0 for Windows. The data was analyzed by calculating mean, standard deviation. Paired "t" test was used to test the significance before and after the program. Pearson Correlation was used to test whether TSH, T3, T4 was correlated with TC, HDL-C, LDL-C and Triglycerides. $p > 0.05$ was considered statistically significant.

3. SALIENT FINDINGS OF THE STUDY:

The present study was a clinical data analysis of obese hypothyroid clients enrolled in the possible health care program for ten month. The results are presented here.

3.1. Background details of the Clients

In the background details, age, gender, food habit and comorbidities were analysed.

3.1. a. Age wise distribution of the Clients

Results of multiple studies pointed that, as age progresses, the chances of getting hypothyroidism increases. Table I shows the Background details of the clients.

Table I. Background details

Parameters	Mean ± SD
Age (yrs)	49 ± 8.85
Age (yrs)	**Per cent**
< 30	3.96
31 to 40	24.75
41 to 50	33.66
51 to 60	29.70
>61	7.92
Gender wise distribution	**(Per Cent)**
Female	57.43
Male	42.57
Food habits	**(Per Cent)**
Vegetarians	30.69
Non-vegetarians	51.49
Eggetarians	17.82
Presence of comorbidities	**(Per Cent)**
Hypertension	46.53
Knee Pain	32.67
Diabetes	31.68
Acidity	28.71
Constipation	8.91
Asthma and water retention	7.92

The mean ages of the selected clients were 49 ± 8.85 years. From Table.1, it was found that, around 33.66 per cent of the clients were in the age group of 41 to 50 years, 29.70 per cent were in the age group of 50 to 60 years, 24.75 per cent were in the age group of 31 to 40 years, 7.92 per cent were above 61 years and 3.96 per cent were less than 30 years. Study conducted in Guwahati reported that, the mean age of the hypothyroid individuals was 48.39 ± 10.85 [8]. This is in line with the present study. Earlier study reported that the highest prevalence of hypothyroidism (13·1%) is noted in people aged 46–54 years [9], where in the present study majority of the clients were in the age group of 41 to 50 yrs.

Assessment of the gender wise distribution of the clients reported that, around 57.43 per cent of the clients were females and 42.57 per cent of the Clients were males. An Indian multi-centric study among hypothyroid reported that 54.70 per cent were females whereas 45.30 per cent were males [9].

Food habits and culture are interrelated, i.e., beliefs, values, and social norms have a role in forming nutritional habits [10]. In this study, clients were distributed based on food habits in the following ways - vegetarian, non-vegetarian and eggetarian. Around 51.49 per cent of the clients were non-vegetarians, 30.69 per cent were vegetarians while 17.82 per cent of the clients were eggetarians. This is similar to the NFHS 2006 [11] reports which showed 64 per cent of the study population were non vegetarians.

Along with obesity, hypothyroidism and elevated cholesterol, the clients were suffering from other comorbidities such as hypertension (46.53 per cent), Knee /Joint pain (32.67) Diabetes (31.68 per cent), Acidity (28.71 per cent), Asthma and water retention (7.92 per cent), Constipation (8.91 per cent). An earlier multi centric study also reported that the hypothyroid clients selected for the study were suffering from other diseases like Hypertension (20.4%) and diabetes mellitus (16.2%) were the most common concomitant diseases observed in the study population [8].

3.2. Mean Nutrient intake of the clients

The nutrient intake of the clients was assessed from the daily diet logs. The monthly average was taken for each client. Mean and SD were calculated. The nutrients analyzed for the present study were carbohydrates, protein, fat fiber and sugar. Table II shows the Mean Nutrient intake of the clients.

Table II Mean Nutrient intake of the clients

	Carbohydrates (g)	Protein (g)	Fiber (g)	Sugar (g)	Fat (g)
Mean Intake	162.04 ± 22.31	48.81 ± 8.10	35.16 ± 6.51	36.04 ± 7.40	28.16 ± 10.75

As per Table. II, the mean nutrient intake of the clients was 162.04 ± 22.31, 48.81 ± 8.10, 35.16 ± 6.51, 36.04 ± 7.40, 28.16 ± 10.75 respectively for carbohydrates, protein, fiber, sugar and fat.

3.3. Comparison of mean Initial and Final weight and BMI among the clients.

Table III. Comparison of mean levels of initial and Final weight, BMI among Clients

	Initial	Final	
Weight (kg)	89.34 ± 15.44	79.96 ± 13.60	0.938776**
BMI	32.78 ± 5.13	29.35 ± 4.55	0.918945**

** 1% significant

Table III depicts the comparison of mean levels of Initial and Final weight and BMI of the clients. Possible program resulted in 9.36 ± 5.41 kg weight loss in ten month duration the initial weight was 89.32 ± 15.46 kg and final weight was 79.96 ± 13.60 kg. In ten month BMI also reduced from 32.78 ± 5.13 to 29.36 ± 4.55. It was found that there was a significant reduction in mean weight loss and BMI levels among the hypothyroid clients at 1% level of significance in a span of ten month. There was a mean total weight loss of 9.40 ± 5.33 kg in ten months. Earlier studies also pointed that even a weight loss of ≤10% has been shown to have beneficial health effects [12].

3.4. Comparison of mean Initial and final Biochemical Parameters of the clients

The Biochemical Parameters analyzed for the study were Total lipid profile which includes Total Cholesterol, HDL-C, LDL-C and Triglycerides and Thyroid Profile which includes TSH, T3 and T4.

Fig I. Changes in the biochemical parameters of the clients

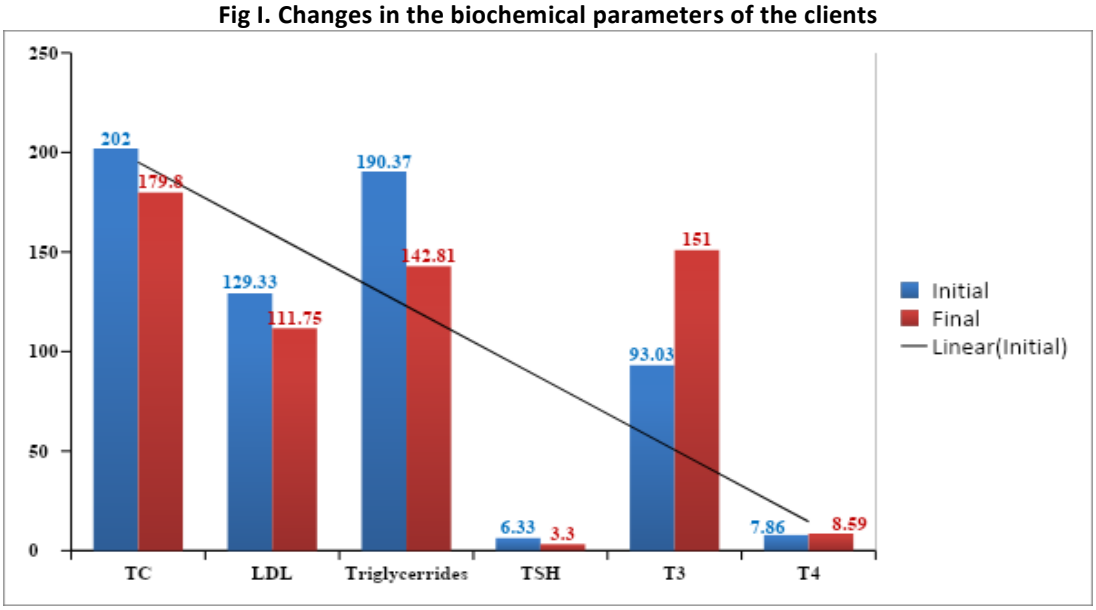

Fig.I. shows the mean levels of Initial and Final Biochemical Parameters. TSH reduced from 6.33 ± 5.9 to 3.33 ± 2.23, Total cholesterol reduced from 202.18 ± 39.16 to 179.85 ± 38.89, LDL-C reduced from 129.23 ± 39.15 to 112.04 ± 38.03 and Triglycerides decreased from 190.37 ± 105.68 to 142.63 ± 48.06.

Table IV. Comparison of mean levels of Initial and Final Biochemical Parameters among the clients

Biochemical Parameters	Reference Range	Initial	Final	Significance of Paired t value
TSH (µIU/ml)	0.3-5.5 #	6.33 ± 5.9	3.33 ± 2.23	5.705**
T3 (ng/dl)	60-200 #	93.03 ± 40.36	151.58 ± 30.50	0.340^{NS}
T4 (µg/dl)	4.5-12 #	7.86 ± 3.55	8.59 ± 11.19	- 0.681^{NS}
Total Cholesterol (mg/dl)	<200*	202.18 ± 39.16	179.85 ± 38.89	6.972**
LDL (mg/dl)	<130*	129.23 ± 39.15	112.04 ± 38.03	5.645**
Triglycerides mg/dl	<150*	190.37± 105.68	142.63 ± 48.06	4.740**

**** 1 % Significant, NS Not Significant**

Guidelines of American Thyroid Association for the Diagnosis and Management of Thyroid (2011)

*Reference ranges as per NCEP ATP III guidelines

Table IV shows the comparison of biochemical parameters initial and final along with the reference ranges. Following the Possible program for 10 months significantly improved the Thyroid and Lipid profile along with weight loss. The mean value of Total cholesterol (202.18; 179.85), LDL-C (129.33: 112.04), Triglycerides (190.37: 142.63) and TSH (6.33: 3.32) decreased significantly ($p<0.05$) after intervention. As anticipated, Paired t-test showed a significant difference between the before and after intervention values of TC, LDL-C, Triglycerides and TSH among the clients, whereas not significant in T3 and T4. This is similar to the results of the Guwahati study [8].

In the present study, the association between reduction in Lipid profile and thyroid profile did not show any significant relationship. Earlier studies reported when the TSH is >10, there is significant association between lipid profile and thyroid profiles. In the present study as the mean of the TSH is 6.33, could be the reason for non-significance. This is line with the earlier study

3.5. Effect of Possible program on the medication of elevated cholesterol initial and final

Possible program involve lifestyle changes through super foods, health education through videos by experts, telephonic consultation by nutritionists and Ayurveda Physician consultation. These results in healthy eating, lifestyle modifications which will gradually result in reducing weight as well as improvement in biochemical parameters. Fig. II. shows Change in the Medication of elevated cholesterol /dyslipidemia before and after Possible

Fig. II. Change in the Medication of elevated cholesterol /dyslipidemia before and after Possible.

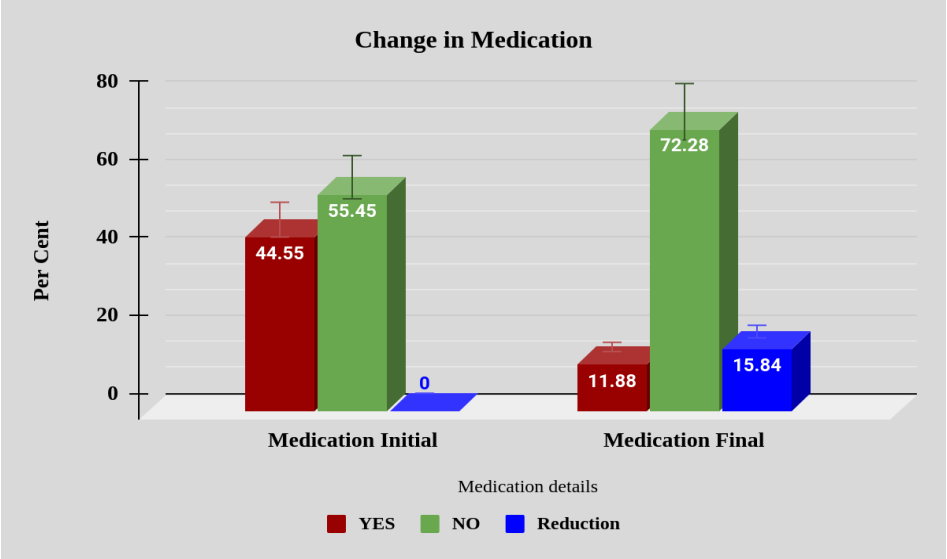

Fig. II. Shows the change in medication of dyslipidemia among the hypothyroid clients after following Possible. Initially 44.55 per cent of the clients were on medication for dyslipidemia and 55.45 per cent of the clients were not taking medicines for dyslipidemia. After following Possible for 10 months, there was a reduction in medications for dyslipidemia. Around 72.28 per cent of the client stopped medication and 15.84 per cent clients reduced the dosage for lipid medication.

Lipid levels increase in a graded fashion as thyroid function declines, while patients with TSH values between 5.1 and 10 mIU/L have significantly higher mean total cholesterol (TC) and low-density lipoprotein-cholesterol (LDL-C) levels. This could be due to the fact that thyroid hormones regulate the activity of some key enzymes in the transportation of lipoprotein and during hypothyroidism; there will be change in the lipoprotein levels. The primary mechanism for hypercholesterolemia in hypothyroidism is accumulation of LDL cholesterol due to a reduction in the number of cell surface receptors for LDL [13].

LIMITATIONS AND FUTURE RECOMMENDATIONS:

This study included several sources of bias. First, the design of the study is single arm, open and not blinded. Secondly, there was no control group. Thirdly the sample size was small and No categorization of Overt and Sub clinical hypothyroidism.

In the future research, a large comparative study with categorization of overt and sub clinical hypothyroidism will be considered.

CONCLUSION:

The study concludes that hypothyroidism and obesity results in other comorbidities including dyslipidemia, diabetes and hypertension. Middle ages as well as females are mostly affected. Following an integrated approach will result in losing weight as well as improving TSH and Lipid profile levels among known hypothyroid clients thereby reduction in dyslipidemia medication. With inclusion of super foods rich in micronutrients and diet with adequate macronutrients, along with medication will result in weight loss, better management of comorbidities among hypothyroid clients.

Author Contributions

- Dr.Shunmukha Priya, S - Methodology, writing, original draft preparation
- Suhasini Mudraganam - Conceptualization and supervision
- Dr.Trusha Abhyankar - Investigation, reviewing
- Vishnu Saraf - project administration

Abbreviations

- NCEP – ATP III : National Cholesterol Education Program Adult Treatment Panel III
- LDL-C : Low density lipoprotein cholesterol
- HDL-C : High density lipoprotein cholesterol
- TSH : Thyroid Stimulating Hormone
- T3 : TOTAL TRIIODOTHYRONINE
- T4 : TOTAL THYROXINE
- TC : Total Cholesterol

Glossary

- **Client** - A person or an individual enrolled in the Possible for health management
- **Counseling** - The nutritional counseling process consists of establishing and monitoring dietary and behavioral goals in a stepwise manner, with the application of counseling strategies to help the patient expand his or her diet
- **Nutritionist** - A qualified health professional provides nutrition guidance and goes beyond the scope nutrition to motivate clients to make positive lifestyle changes
- **Super foods** - Oxford Dictionary defines super foods as a nutrient-rich food considered to be especially beneficial for health and well-being.
- **Possible** - Possible is a research and nutrition based healthcare company that helps people deal with obesity & obesity related disorders
- **Hypothyroidism** - According to American Thyroid Association, Hypothyroidism means that the thyroid gland can't make enough thyroid hormone to keep the body running normally. People are hypothyroid if they have too little thyroid hormone in the blood.
- **Dyslipidemia** - National Cholesterol Education Programme (NCEP) guidelines [14] were used for definition of dyslipidemia as follows:
- **Hypercholesterolemia** - serum cholesterol levels ≥200 mg/dl (≥5.2 mmol/l).
- **Hypertriglyceridemia** - serum triglyceride levels ≥150 mg/dl (≥1.7 mmol/l).
- **Low HDL cholesterol** - HDL cholesterol levels <40 mg/dl (<1.04 mmol/l) for men and <50 mg/dl (<1.3 mmol/l) for women.
- **High LDL cholesterol** - LDL cholesterol levels ≥130 mg/dl (≥3.4 mmol/l) calculated using the Friedewald equation.

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There are no conflicts of interest.

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