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Dietary and Serum Lycopene Levels in Prostate Cancer Patients Undergoing Intensity-Modulated Radiation Therapy

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ABSTRACT Tomato products, good sources of lycopene, may lower the incidence of prostate cancer, but data on the effectiveness of lycopene supplementation during radiation therapy are lacking. This study aimed to evaluate the tolerance and acceptance of three different amounts (4, 8, or 12 oz) of tomato juice (TJ) and their effect on serum lycopene during radiotherapy in 20 men with localized prostate cancer. Participants were randomized into a control group or one of three intervention groups who consumed TJ daily during treatment. Dietary lycopene intake was estimated using the National Cancer Institute (NCI) Diet History Questionnaire, and gastrointestinal tolerance of TJ was evaluated using the NCI Cancer Therapy Evaluation Program: Common Toxicity Criteria v 2.0. Serum and TJ lycopene levels were measured by liquid chromatography-mass spectrometry. TJ was well tolerated without any gastrointestinal side effects, and increased serum lycopene levels were observed in the 8 and 12 oz groups from baseline to endpoint. No correlation between serum and dietary lycopene was detected. Despite no reported change in dietary intake, non-significant weight loss was observed in the control group but not the intervention group participants. A significant positive correlation between serum lycopene, weight, and body mass index, and a negative correlation between serum lycopene and piror nutritional supplement use was detected. Weight change should be monitored and evaluated during treatment. Larger clinical trials are needed to validate the use of TJ to increase serum/dietary lycopene intake and correlate with side effects during radiotherapy in men with prostate cancer.

KEY WORDS: • *lycopene* • *prostate cancer* • *radiation therapy* • *tomato juice*

INTRODUCTION

DIETARY PHYTOCHEMICALS MAY HALT carcinogenesis by suppressing inflammation, cancer cell proliferation, expression of anti-apoptotic proteins, inhibiting growth factor signaling, signal transducers, and activators of transcription protein pathways and angiogenesis.[1] The phytochemical lycopene may decrease the incidence of prostate cancer[2,3] and has shown a therapeutic role in men with prostate cancer.[4–6] A significant increase in serum lycopene[4,7,8] and reduction in prostate specific antigen[4,8] and tumor size[4] was shown with daily lycopene supplements or intake of lycopene-rich foods (*e.g.*, tomato products) in men during various stages of prostate cancer. However, data on the effectiveness of lycopene supplementation during radiation therapy are lacking.[9,10]

Radiotherapy may decrease tissue antioxidant levels, thereby increasing oxidative stress,[11] and may worsen existing subclinical or clinical nutrient deficiencies.[12] Chemopreventive agents (either alone or as adjuncts) can be used to halt progression, prevent secondary cancers, or reduce treatment toxicities.[12] Consequently, we were interested in determining the level of serum lycopene without and with three different amounts of tomato juice (TJ) administered daily and its tolerance in men with localized prostate cancer undergoing radiation therapy.

MATERIALS AND METHODS

Study design

This randomized controlled trial conducted in men newly diagnosed with localized prostate cancer and scheduled to undergo intensity-modulated radiation therapy (IMRT) consisted of four study arms. All participants consumed their normal diets, and intervention groups additionally received 4 oz (118 mL), 8 oz (237 mL), or 12 oz (355 mL) of TJ (Table 1). Participants were instructed not to change their diet or consume any dietary/nutritional supplements during the study. For participant convenience, all assessments, blood draws, and TJ administration were scheduled to coincide with each patient's physician appointment, procedure planning, or radiation therapy times.

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Table 1. Nutrition Contribution from Crackers and Tomato Juice Provided to Intervention Group Participants Daily During Intensity-Modulated Radiation Therapy

	4 oz (n = 4)	*8 oz (n = 5)*	*12 oz (n = 3)*
Tomato juice			
Calories (kcal)	25	50	75
Sodium (mg)	340	680	1020
Potassium (mg)	215	430	645
Total calories[a] (tomato juice + crackers)	121	146	171

Metric units: 4 oz = 118 mL, 8 oz = 237 mL, and 12 oz = 355 mL.

[a]With each serving of tomato juice, intervention group participants consumed six crackers providing 96 kcal, 5.4 g of fat, 162 mg sodium, and 12 mg potassium.

Participants

Our convenience sample was accrued at the Hayworth Cancer Center at High Point Regional Health System (HPRHS) between April 2009 and October 2010. Participant screening was conducted in two stages: A preliminary screening was conducted by the radiation oncologist at the time of initial consult based on treatment area, type, and dose, that is, men receiving ≥ 72 Gy of IMRT to the prostate alone or prostate and seminal vesicles. Patients meeting preliminary screening criteria signed a Health Insurance Portability and Accountability Act form granting access to their medical information for detailed medical record review and interview with the principal investigator (PI). The Institutional Review Boards at the University of North Carolina–Greensboro (UNCG) and HPRHS approved the study protocol. All participants provided written informed consent before study enrollment.

The eligibility criteria included histologically confirmed localized prostate adenocarcinoma without lymph node involvement or metastasis; normal immune, liver, and renal function; and Eastern Cooperative Oncology Group performance score of ≤ 1. Exclusion criteria included prior treatment for prostate cancer, receiving hormone therapy or participating in other treatment-based clinical trials concurrently with IMRT; allergy to tomato products; preexisting uncontrolled gastroesophageal reflux disease, malabsorptive disorders, or hyperkalemia; or routine consumption of fiber, saw palmetto, lycopene, omega-3 fatty acids/fish oil, eicosapentaenoic acid/docosahexaenoic acid, and vitamins C, E, A; β-carotene, flaxseeds, and flaxseed oil supplements and unwilling to stop these supplements during treatment. Participants consuming these supplements at initial interview were asked to discontinue them until the end of the treatment. This allowed for a wash-out period of several weeks before radiation treatment commenced. Verbal confirmation was obtained on the first day of treatment to ensure that the participants had discontinued use of supplements as previously instructed.

TJ supplementation, diet history, and weight

TJ was purchased in bulk at the beginning of the study. TJ supplementation began 2 days before the first dose of IMRT, and continued daily until the last day of treatment. On treatment days, participants were asked to consume their assigned volume of TJ and crackers (providing at least 5 g of fat; Table 1) after their radiation treatment in the presence of the PI before leaving the cancer center. Assigned volume of TJ was provided to intervention group participants for consumption during weekends and holidays. Verbal confirmation of TJ consumption was obtained at the subsequent treatment day. Participants were instructed to consume TJ with either a meal or a snack containing at least 5 g of fat to facilitate lycopene absorption. Snacks containing at least 5 g of fat were discussed with participants.

We used the National Cancer Institute (NCI) Diet History Questionnaire (DHQ)[13] to obtain each participant's diet history and calculate routine dietary lycopene intake once during the study. The DHQ was given to the participants before starting radiation therapy, and intervention group participants were reminded not to include their study-related TJ intake when completing the DHQ. Participants were weighed by the nursing staff or PI on the first day of treatment (baseline) and then once a week during treatment on a stationary platform scale in the radiation therapy department at HPRHS.

Toxicity assessment

To evaluate gastrointestinal tolerance of TJ, the NCI Cancer Therapy Evaluation Program: Common Toxicity Criteria (CTC) v 2.0[14] was used. The CTC evaluates adverse events on a scale of 0–5. A toxicity grade ≥ 3 would result in participant withdrawal from the study by the researchers.

Intensity-modulated radiation therapy

Participants received IMRT using a Linear Accelerator 2100 iX device (Varian Medical Systems, Palo Alto, CA, USA) according to a standardized planning and filming protocol. The prescribed radiation dose ranged between 72.50 and 79.20 Gy, and treatment days ranged from 29 to 44 days.

Lycopene measurements

Participants provided blood samples at three time points in this study: baseline, midpoint (end of 3 weeks of treatment), and on the last day of treatment (endpoint). Whole blood was collected in three aluminum-covered vacutainer tubes (7 mL each), and transported on ice to the laboratory at UNCG, where blood samples were processed under a yellow light to minimize lycopene loss. After centrifuging (3000 rpm $\times$ 20 min at 4°C [Jouan GR412]) whole blood, the separated serum was divided into aliquot tubes, labeled with the patient ID and blood draw time point (baseline, midpoint, or endpoint), and stored at -80°C until analyzed. At the end of the study, serum and TJ samples were shipped under dry ice to Dr. Wei Jia's laboratory at the North Carolina Research Campus (Kannapolis, NC, USA) for lycopene

analysis using liquid chromatography/mass spectrometry (LC-MS). Lycopene standard for the LC-MS was purchased from Sigma-Aldrich (St. Louis, MO, USA).

Stock solution for the lycopene standard was prepared by dissolving 1 mg of the standard in 1 mL of chloroform and stored at −80°C. Fresh calibration solutions were prepared each day from the stock solution. Calibration curves were obtained using freshly prepared lycopene standard solutions in the range of 0.005–10 μg/mL in acetonitrile/methyl *tert*-butyl ether (MTBE; 1:1, v/v). Aliquots of 10 μL of each standard solution were injected onto the column for LC analysis, and calibration curves were constructed by linear regression analysis of the area versus the concentration of lycopene.

Lycopene from TJ was extracted with an extraction mixture (hexane, methanol, and acetone, 2:1:1, v/v/v, containing 2.5% butylated hydroxytoluene [BHT]). TJ (200 μL) was extracted with the extraction mixture (600 μL). Samples were vortexed for 1 min and then centrifuged (13,000 rpm × 5 min at 4°C [Jouan GR412]). Aliquots of 10 μL of the supernatant were diluted to 1 mL with the mobile phase for the high-performance liquid chromatography (HPLC) injection. To prepare serum for lycopene analysis, 300 μL serum was mixed with the same amount of ethanol. The mixture was extracted twice with 600 μL of hexane containing 100 mg/L BHT. The hexane extracts were collected after being centrifuged (13,000 rpm × 5 min at 4°C [Jouan GR412]), combined, and evaporated to dryness under vacuum. The extract was reconstituted in 100 μL of acetonitrile/MTBE (1:1, v/v). An aliquot of 10 μL was injected onto the LC for lycopene measurement. An Agilent HPLC 1200 system equipped with a binary solvent delivery manager and a sample manager (Agilent Corporation, Santa Clara, CA, USA) was used with chromatographic separations performed on a 4.6 mm × 150 mm, 5 μm Agilent ZORBAX Eclipse XDB-C18 chromatography column. The flow rate was 1 mL/min. Elution solvent A was acetonitrile, and solvent B was MTBE. The LC elution conditions were optimized with isocratic acetonitrile/MTBE (45:55, v/v). The column was maintained at 20°C. The detection wavelength was set at 472 nm. A 10 μL aliquot reference standard and 10 μL samples were injected onto the column, respectively. This methodology was adapted from Fang *et al.*[15] and Rao *et al.*[16]

Statistical analysis

Descriptive statistics were used to analyze key participant and cancer-related characteristics. Between-group differences were detected using Wilcoxon rank-sum analysis. Spearman's correlation was used to determine associations between dietary and serum lycopene levels and select lifestyle characteristics, and stepwise regression was used to detect the strength of this relationship. Repeated-measures analysis of variance was used to evaluate within-group change over time. One-sided level of significance was established at $P \leq .05$.

RESULTS

Participant lifestyle characteristics

Seventeen men between the ages of 61 and 77 years completed this study. Participant physical and demographic

Table 2. Study Participant Characteristics

		Tomato juice intervention groups		
	Control (n = *5*)	*4 oz* (n = *4*)	*8 oz* (n = *5*)	*12 oz* (n = *3*)
Age (years)	69.40 ± 1.91	66.25 ± 1.89	68.20 ± 2.22	72.33 ± 3.28
Height (inches)[a]	66.40 ± 0.87[a]	70.50 ± 1.44	70.60 ± 1.36	71.17 ± 0.93[a]
Weight (pounds)	167 ± 13.11	193 ± 14.61	221 ± 30.74	168 ± 28.41
BMI (kg/m^2)	27 ± 1.97	27 ± 1.30	30 ± 3.22	23 ± 4.10
Ethnicity				
African American	2 (40)	1 (25)	1 (20)	0
Caucasian	2 (40)	3 (75)	4 (80)	3 (100)
Other	1 (20)	0	0	0
Education				
Less than high school	1 (20)	2 (50)	2 (40)	0
High school	3 (60)	1 (25)	1 (20)	2 (67)
More than high school	1 (20)	1 (25)	2 (40)	1 (33)
Marital status				
Married	4 (80)	4 (100)	4 (80)	2 (67)
Divorced	1 (20)	0	1 (20)	1 (33)
AJCC tumor stage				
T1c N0 M0	4 (80)	3 (75)	3 (60)	2 (67)
T2a N0 M0	1 (20)	1 (25)	0	1 (33)
T2b N0 M0	0	0	1 (20)	0
T2c N0 M0	0	0	1 (20)	0

Data are reported as mean ± standard error of the mean or number (%). Metric units: 4 oz = 118 mL, 8 oz = 237 mL, and 12 oz = 355 mL.

[a]$P < .05$ (one sided).

BMI, body mass index; AJCC, *American Joint Committee on Cancer Cancer Staging Manual*.

Table 3. Supplement Use Among Study Participants

	Control (n = 5)	Tomato juice intervention groups: 4 oz (n = 4)	8 oz (n = 5)	12 oz (n = 3)
Routine use of supplements				
Yes	4 (80)	3 (75)	4 (80)	1 (33)
No	1 (20)	1 (25)	1 (20)	2 (67)
Supplements evaluated				
Fiber[a]	0	0	2 (40)	0
Multivitamin[a]	3 (60)	1 (25)	4 (80)	1 (33)
Saw palmetto[a]	0	0	1 (20)	0
Vitamin C[a]	0	1 (25)	1 (20)	0
Vitamin D[a]	2 (40)	0	1 (20)	0
Vitamin E[a]	0	0	1 (20)	0
Omega-3 fatty acids/fish oil[a]	1 (20)	1 (25)	3 (60)	0
Flax seeds or flaxseed oil[a]	0	1 (25)	0	0
Coenzyme Q10[a]	0	1 (25)	0	0
Eye vitamin[a]	0	0	2 (40)	0

Data are reported as mean ± standard error of the mean or number (%). Metric units: 4 oz = 118 mL, 8 oz = 237 mL, and 12 oz = 355 mL.

[a]Indicates affirmative responses from participants using these supplements.

characteristics are reported in Table 2. Height was statistically different between the control group and 12 oz group participants ($P = .026$); however, no differences were detected among groups for weight or body mass index (BMI).

The most frequent co-morbid medical conditions at the time of study enrollment were hypercholesterolemia and hypertension (88% each), followed by coronary artery disease and diabetes (35% each). One participant reported smoking and 11 reported consuming alcohol (data not shown). Nutritional supplements consumed by participants before study enrollment are reported in Table 3. Overall, 71% of participants reported consuming one or more over-the-counter herbal/nutritional supplements during the initial interview. A multivitamin was the most commonly consumed supplement (53%), followed by fish oil/omega-3 fatty acid (29%). All participants reported discontinuing supplements for the duration of the study.

TJ supplementation, DHQ, and weight history

Intervention group participants tolerated the TJ well with no reported gastrointestinal side effects (nausea, vomiting, or heartburn) (data not shown). Each ounce of TJ provided ~2 mg lycopene. Based on the DHQ analysis, although a large variation in the reported energy intakes among the four groups was noted, only caloric intake between the control and 8 oz groups was statistically significant (1634 ± 277 vs. 3015 ± 668 kcal; $P = .048$). Consequently, nutrients from the DHQ were standardized per 1000 kcal consumed. No significant between-group differences were detected in reported nutrient intakes (Table 4). Significant differences in unadjusted dietary lycopene intake between the control and 12 oz groups ($P = .036$) and 4 and 12 oz groups ($P = .029$) were detected. In addition, men with a higher education consumed more dietary lycopene ($r = 0.517$; $P = .017$).

Serum lycopene

Baseline serum lycopene levels ranged between 0 and 1.04 μg/mL with the highest baseline lycopene levels (0.51 ± 0.17 μg/mL) measured in the 8 oz group. Two participants in both 4 and 12 oz groups had no detectable serum lycopene at baseline, but serum lycopene was detectable at midpoint and endpoint in all participants. We detected a significant decrease in serum lycopene levels among control and 4 oz group participants and an increase in 8 and 12 oz groups throughout treatment. Significant between-group differences in serum lycopene were detected at several time points (Table 5). A significant positive correlation was detected between serum lycopene, weight ($r = 0.525$; $P = .015$), and BMI ($r = 0.541$; $P = .012$), and in the final stepwise regression model, BMI (but not weight) and smoking explained 56% of the variance [F (2, 14) = 8.833, $P = .003$] in serum lycopene level.

DISCUSSION

We evaluated tolerance of consuming three different volumes of TJ daily and serum lycopene levels with and without TJ supplementation in men undergoing IMRT for localized prostate cancer. Intervention group participants

Table 4. Reported Nutritional Information Estimated Using the Diet History Questionnaire

	Control (n = 5)	Tomato juice intervention groups: 4 oz (n = 4)	8 oz (n = 5)	12 oz (n = 3)
Energy (kcal)	1634 ± 276.8[a]	2202 ± 496.3	3015 ± 668.2[a]	2296 ± 969.4
Carbohydrates (g/1000 kcal)	127.35 ± 11.71	133.80 ± 4.48	98.84 ± 13.77	124.40 ± 10.67
Protein (g/1000 kcal)	35.57 ± 2.35	38.42 ± 2.97	31.91 ± 7.22	32.25 ± 1.99
Total fat (g/1000 kcal)	38.89 ± 3.82	37.100 ± 1.52	35.34 ± 7.62	33.86 ± 4.99
Cholesterol (mg/1000 kcal)	118.85 ± 19.35	112.15 ± 21.78	126.57 ± 30.59	76.67 ± 8.39
Dietary fiber (g/1000 kcal)	10.93 ± 2.88	10.66 ± 2.16	7.31 ± 1.14	10.82 ± 1.00
Sodium (mg/1000 kcal)	1662.27 ± 216.15	1584.40 ± 117.45	1318.26 ± 261.52	1730.30 ± 358.15
Potassium (mg/1000 kcal)	1500.64 ± 328.20	1703.81 ± 183.49	1508.40 ± 268.12	1916.69 ± 193.62
Dietary lycopene (mg/1000 kcal)	3.64 ± 1.65	2.07 ± 0.57	3.29 ± 1.21	13.15 ± 10.15

Data are reported as mean ± standard error of the mean. Metric units: 4 oz = 118 mL, 8 oz = 237 mL, and 12 oz = 355 mL.

[a]Between-group differences: $P < .05$.

Table 5. Measured Serum Lycopene Levels

		Tomato juice intervention groups		
	Control (n = 5)	*4 oz (n = 4)*	*8 oz (n = 5)*	*12 oz (n = 3)*
Measured serum lycopene (μg/mL)				
Baseline	0.209 ± 0.07	0.295 ± 0.21	0.514 ± 0.17[a]	0.082 ± 0.08[a]
Midpoint	0.137 ± 0.05[b]	0.272 ± 0.08[c]	0.534 ± 0.09[bcd]	0.069 ± 0.01[d]
Endpoint	0.167 ± 0.07[e]	0.257 ± 0.07	0.622 ± 0.25[e]	0.253 ± 0.20

Data are reported as mean ± standard error of the mean. Metric units: 4 oz = 118 mL, 8 oz = 237 mL, and 12 oz = 355 mL

Between-group differences in comparison to the 8 oz group: [a]$P < .05$ (baseline, vs. 12 oz), [b]$P < .005$ (midpoint, vs. control), [c]$P < .01$ (midpoint, vs. 4 oz), [d]$P < .05$ (midpoint, vs. 12 oz), and [e]$P < .03$ (endpoint, vs. control).

tolerated daily consumption of TJ with no reported gastrointestinal side effects (heartburn, nausea, or vomiting). Serum lycopene levels decreased in the control group without additional TJ, and increased with daily consumption of 8 and 12 oz TJ, but not 4 oz.

We did not observe an association between dietary and serum lycopene. Some researchers have reported an association between serum and dietary lycopene intake,[17] while others have not.[18,19] Inaccurate reporting of dietary lycopene food sources, poor digestion, and absorption could account for the poor correlation between dietary intake and serum lycopene.[20] Heat processing tomato products and co-ingestion of fat improve, whereas dietary fibers (*e.g.*, pectin) decrease lycopene absorption.[21,22] In order to facilitate absorption of lycopene, we selected a heat-processed food source (TJ), administered the TJ with crackers that contained 5 g fat, and discontinued use of fiber supplements for the duration of the study.[22–24] Unadjusted dietary fiber intake was between 19 and 23 g/day (less than the recommended intake of 30 g/day). Serum cholesterol is also a strong predictor of serum lycopene, a fat-soluble carotenoid,[17,19] and since 88% of our participants were hypercholesterolemic and receiving antihypercholesterolemic medication, this may explain some of the inconsistent serum lycopene levels we obtained. Inter-individual differences may also reflect a varying rate of tissue lycopene uptake,[25] compounded by the oxidative stress created by radiation therapy, which may decrease tissue antioxidant levels.

An optimum time (before or after radiation exposure) for initiating an antioxidant supplement has not been identified.[26] Lycopene reaches maximum serum concentrations within 15–48 h after consumption.[27,28] Consequently, in order to ensure presence of lycopene in the serum, we chose to initiate the TJ 2 days before the first IMRT treatment. This was significant, as serum analysis at the end of the study showed lycopene levels below detection at baseline in two participants in both 4 and 12 oz groups. Interestingly, compared with baseline, midpoint serum lycopene levels appear to decrease in the 12 oz group. However, only one participant had detectable serum lycopene at baseline, compared with all three participants at midpoint.

Dietary lycopene intake was estimated using the DHQ only once during the study. Mean reported dietary lycopene intake among participants was 7.24 ± 1.48 mg/day (range 1.56–23.59 mg/day), consistent with previously reported intake.[29,30] Most participants completed their DHQ within the first few weeks of treatment and since participants were instructed to omit their study-related TJ consumption while completing their DHQ, we do not believe that the TJ supplement accounts for the differences in estimated dietary lycopene consumption reported by participants. Although TJ increased total daily sodium and potassium intake for the intervention groups, all participants were asked to increase their fluid intake during treatment to minimize their dysuria. Higher sodium intake may worsen blood pressure that is not controlled by medication. All hypertensive participants were on anti-hypertensive medication before study enrollment. In addition, TJ is a rich source of potassium, a vasoactive nutrient that can lower blood pressure. Future trials should evaluate TJ's effect on blood pressure in study participants.

We found a positive correlation between education and dietary lycopene intake, indicating that participants with higher education included more fruits and vegetables in their diet. Intervention groups either maintained or gained weight, whereas control groups lost weight (non-significant). Participants in the intervention groups received additional 121 kcal (4 oz), 146 kcal (8 oz), and 171 kcal (12 oz) daily (Table 1), which accounts for a 1.47, 1.61, and 1.89 pound weight gain in the 4, 8, and 12 oz groups, respectively, if they maintained their usual dietary intake. Since we did not routinely monitor dietary intake during the study, we cannot determine whether weight change was related to fluid shifts/changes or variations in caloric density of foods consumed during the study period. Similar trends in weight change have been reported in animal studies.[31] Although control group participants did not report any changes in appetite, other factors such as fatigue or biochemical changes (cytokine expression)[32] may have contributed to weight loss and should be monitored in future trials. In addition, in future studies, an isocaloric beverage with same amount of crackers could be provided to the placebo group participants to control for caloric and volumetric intake.

This study has several strengths. The study design was strengthened by continuous enrollment and random patient assignment. Lycopene intake was estimated using the DHQ, a tool that has been validated for use in older adults[33] and since it estimates intake patterns over 12 months, daily variations are

included in the estimated amounts. Since we used a whole food approach instead of an isolated nutrient, there is a potential for greater beneficial effects due to the synergistic effect of all nutrients present[34] in TJ. We chose TJ as a vehicle for lycopene delivery, because it is readily available and convenient to administer and consume. In addition, it is a safe and effective way to increase consumption of vegetable intake among a population of men who typically have poor reported intake of fruits and vegetables.

This study had several limitations as well. These include a small sample size, which may have prevented us from detecting statistical significance and limits generalizability of these results. Due to variations in scheduling radiation treatments, blood was not drawn from fasted participants. Serum lycopene levels may be influenced by lycopene intake in a recent meal; however, researchers have demonstrated that the serum concentration of carotenoids does not change significantly for approximately 4 h after a meal.[35,36] We measured dietary intake only at the beginning of the study. Even though participants denied any change in eating patterns, we may have missed dietary changes (*i.e.*, change in caloric content of foods) during treatment, which may have contributed to the weight change observed in our study. In addition, we measured only total lycopene content in the serum. Cis and trans isomers of lycopene should also be evaluated to determine clinical correlates in future studies.

We believe this is the first study to supplement TJ to evaluate change in serum lycopene levels in men with prostate cancer undergoing radiation therapy. This study provides preliminary data on the tolerance of TJ in men with prostate cancer undergoing IMRT and also highlighted some areas of concern, that is, monitoring blood pressure and weight change in the intervention group participants which should be investigated in future trials. In addition, 1 serving (4 oz) of TJ may be insufficient maintain serum lycopene levels during radiation therapy. Future studies should also evaluate the relevance of serum lycopene levels during radiation therapy with clinical outcomes and quality-of-life indices.

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AUTHOR DISCLOSURE STATEMENT

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