Original Article

The Effect of Hot Water Application in Pregnant Women With Restless Legs Syndrome: A Randomized Controlled Study

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Abstract
Objectives It may be inconvenient for pregnant women to use pharmacological treatment methods. Therefore, non-pharmacological treatments are needed. This study aimed to determine the effect of hot water application on pregnant women with restless legs syndrome (RLS).
Patients and Methods: The study is a a pretest-posttest randomized controlled (NCT04887103). The sample comprised 29 (13 hot water and 16 control groups) pregnant women with RLS. Hot water application was made to the legs of the intervention group (IG) for 20 minutes before bedtime for seven days.
Results: The pregnant women's descriptive and gestational characteristics in both groups were identical (p>0.05). In pretest, IRLS score of the IG was 24.76±4.72, the control group (CG) was 22.06±5.56 and the groups were similar (p>0.05). While posttest score was 6.69 ± 7.70 in the IG and 20.62 ± 7.64 in the CG and the difference between the groups were statistically significant (p<0.001). While the presence of severe and very severe symptoms was not found in any of the pregnant women (0.00%) in the IG, it was found in 83.8% of the CG.
Conclusion: Hot water application made to the legs of pregnant women with RLS decreased the severity of RLS.
Keywords: lestless legs syndrome, pregnancy, hot water application.

Introduction

Restless Legs Syndrome (RLS) is a progressive, repetitive, chronic sensorimotor disorder that creates an irresistible sense of motion and discomfort in the legs (Picchietti et al., 2015). Symptoms start especially during long-term sedentary periods such as watching television, traveling long distances, sleeping and lying down to rest, and the severity of symptoms increases at night (Allen et al., 2003). While the prevalence of the disease varies between 0.25% and 15.3% in the general population (Allen et al., 2003; Ghorayeb et al., 2009; Nichols et al., 2003), its prevalence in Turkey was reported to be between 3-5% (Sevim et al., 2003;Yilmaz 2013). Although it can be seen at any age, RLS, the prevalence of which increases with increasing age, develops on the average two times more frequently in women (Berger et al., 2004; Phillips et al., 2000). RLS, also known as Ekbom syndrome, is seen in two forms (primary and secondary). Primary RLS develops upon genetic transmission and a hereditary defect in dopamine metabolism.

Secondary RLS can be seen secondarily in using drugs such as selective serotonin-reuptake inhibitors, caffeine intake, Parkinson's disease, thyroid, fibromyalgia, diabetes, multiple sclerosis, end-stage kidney disease, iron deficiency anemia, and pregnancy (Bayard et al., 2008). While RLS can be seen two to three times more in pregnant women than other women, this rate varies between 15.4 and 26.0 in Turkey (Cakmak et al., 2014; Sahin et al., 2007; Tunc et al., 2007). While treatment such as dopaminergic agents, opioids, anticonvulsants, antiepileptics, non-serotonergic, and oral iron therapy can be used in the pharmacological treatment of the disease, it may be inconvenient for pregnant women to use these treatment methods (Montplaisir et al., 2006; Patrick, 2007; Sahin and Akbostancı, 2008, Telstadet al., 1984; Trenkwalderet al., 2010; Walters et al., 2001). The number of studies conducted with pregnant women is limited (Yuksel, 2017; Jafarimanesh et al., 2020).

Although it is stated in the clinical practice guideline for the diagnosis and treatment of RLS during pregnancy and lactation that hot applications can be applied as an alternative method (Picchietti et al., 2015), only one study was found in which the method was applied in pregnant women (Jafarimanesh et al., 2020). Therefore, there is a need for more studies investigating the effect of hot water application on the severity of RLS in pregnant women. This study aimed to determine the impact of hot water application on the complaints of pregnant women with RLS.

Research Hypothesis: Using the immersion method, hot water application made to the legs of pregnant women with RLS affects their complaints.

Methods

Study Design: Consolidated Standard Reporting Experiments, 2010 – CONSORT, were followed to report the research. This research is a single-center, pretest-posttest randomized controlled, parallel-group study conducted in Turkey. The Clinical Trial Registration number is NCT04887103.

Participants: Assuming that the application would reduce the severity of RLS by 10 points (differences=10, power= 0.99, standard deviation=5, n2/n1 = 1), it was found that at least 11 people should be taken for each group. Considering that there will be losses during the study, 20 pregnant women were included in each group.

The study was carried out in the Perinatology Polyclinic of a University Hospital located in Central Anatolia in Turkey. Patients from many cities apply to the 1300-bed hospital; an average of 14,000 pregnant women apply to the perinatology polyclinic annually (Erciyes University Health Application and Research Center Hospital, 2020). Pregnant women who applied to the outpatient clinic between 19 September and 17 November 2019 were screened by researchers, one of whom was a perinatologist, and those with RLS symptoms were evaluated within the scope of the study. According to the RLS Severity Rating Scale, pregnant women who had RLS symptoms, had a severity of 11 and above, and were literate, at 28-32 weeks of gestation were included in the study using iron preparations. Pregnant women with primary RLS, risky pregnancy, any chronic and psychiatric disease, history or risk of deep vein thrombosis, using antipsychotics, antidepressants, antihistamines, antiemetics, anticoagulants, and drugs for RLS treatment, and those with communication barriers were not included in the study.

Randomization: During the planning process of the study, a randomization list of 40 people was prepared by the researcher (OK) (Haahr, 2021) in the computer environment. It was planned to assign the pregnant women to the groups (intervention group n=20, control group n=20) by simple randomization method by the same researcher in line with this list, by numbering according to the order of arrival for the examination. During the study period, 824 women were screened, and it was determined that 73 of the women had RLS symptoms. Thirty-three of them did not want to participate in the study. The remaining 40 eligible women agreed to participate in the study and were randomized into groups. The study was completed with 13 people in the intervention group (IG). Two gave birth prematurely, four did not apply hot water following the specified protocol (Chart 1), and one could not be reached after the

application. The control group (CG) was completed with 16 people because two could not be reached after the application, and two did not want to complete the final test (Chart 1). At the end of the study, according to the post-hoc power analysis performed in G-power, the study's power was 99%.

Intervention

Chart 1. Consort flow

Interviews were done individually by the researchers (OK, IIM) in the perinatology outpatient clinic. After informing the women about the study, written consent was obtained from those who agreed to participate. IRLSSG was applied to detect RLS symptoms. IRLS was applied to women who met the inclusion criteria. According to the randomization list, pregnant women with an RLS severity greater than 11 were numbered according to the order of arrival and assigned to the intervention (n=20) or control (n=20)

groups. Finally, the personal information form was filled.

Each woman in the intervention group was given a bucket and a thermometer. The researchers' written instructions and contact information were given to the women. The researcher explained and demonstrated the application of dipping their legs (OK) in line with the hot water application procedure (Chart 2).

Chart 2. Hot Water Application Protocol in RLS Severity Management of the Pregnant Women

Following the literature, the temperature of the water was 37-40 °C and the application time was 20 minutes for seven days (Kozier et al., 2013; Sabuncu et al., 2015). Hot water application was made before going to bed to allow the women to rest after the application since the symptoms of RLS are more intense at night (Image 1).

Image 1: Hot Water Application

On the other hand, no application was made to the control group other than the routine follow-up and maintenance of the hospital.

The application process was followed via WhatsApp, SMS, and phone calls. IRLS was applied to both groups on the eighth day.

For this purpose, the scale was sent via mobile phone, and the women sent their answers via message.

Outcome Criteria: Women in both groups completed outcome measurements one week after randomization. The forms were sent via mobile phone, and the women sent their answers to the researcher via message. The primary outcome is RLS severity as measured by the RLS Severity Rating Scale.

Data Collection Tools: Data of this study were collected using Personal Information Form IRLSSG and IRLS.

Personal Information Form: The form, prepared by the researcher, consists of questions including socio-demographic and obstetric characteristics of the women.

International Restless Legs Syndrome Study Group (IRLSSG) Diagnostic Criteria: The form was prepared in 1995 by the International Restless Legs Syndrome Study Group (IRLSSG). When all questions are answered yes in the form consisting of five questions, the diagnosis of RLS is made (International Restless Legs Syndrome Study Group, 2003). The Cronbach's alpha coefficient of the form was 0.81, and the Cronbach's alpha coefficient in this study was found to be 0.82.

International RLS Rating Scale (IRLS): The scale was developed by IRLSSG (37). The scale has 10 questions. The questions are rated between 0-4 points. Thus, while the minimum score obtained from the scale is 0, its maximum score is 40. The score between 1-10 refers to mild RLS, the score between 11-20 refers to moderate RLS, the score between 21-30 refers to severe RLS, and the score between 31-40 refers to very severe RLS. The validity and reliability study of the scale was conducted in our country by Ay et al. (2019), and Cronbach's alpha coefficient was found to be 0.82 (Ay et al., 2019). In this study, Cronbach's Alpha of the scale was determined as 78.7 in the pre-test and 93.3 in the post-test.

Materials used in the data collection process: TP Thermometer Immersion Probe Digital Food Thermometer and water bucket were used in this study process. The thermometer, which was used to adjust the temperature level of the water in which the women would dip their legs, could measure the temperature of all liquid or solid objects, including food and water. The dimensions of the plastic bucket used for hot water application were 42x47cm, and its total volume was 50 liters. In the study, a bucket with a base diameter in which the feet of the women could fit comfortably and a height where the water level can reach knee level was used.

Statistical Analysis: The data obtained in the study were analyzed using SPSS (Statistical Package for Social Sciences) (IBM Corp., Armonk, New York, USA) for Windows 24.0 program. Chi-square tests and descriptive statistics were used to analyze the study variables. Descriptive statistics were given as a unit number (n), percentage (%), mean±standard deviation. Normal distribution of the data related to numeric variables was assessed via the Shapiro Wilk test for normality and Q-Q plots. Two groups were compared with independent samples t-test for normally distributed variables. Cronbach's alpha coefficients were calculated for the internal consistency of the inventories. In numerical variables with normal distribution, the values of the groups before and after the procedure were evaluated with the independent sample t-test. In the comparisons, the value of $p<0.05$ was accepted as statistically significant.

Ethical Considerations: Ethics Committee approval (334) from the Clinical Trials Ethics Committee of xxx University and written permission (71259) from the hospital where the study was conducted were obtained to conduct the study. The individuals included in the study were informed about the purpose of the study, and they signed the 'Informed Consent Forms.' In the consent form, the women were informed about the study design; no emphasis was placed on the fact that hot water application would reduce the severity of RLS. It was explained that only the effectiveness of the application would be determin At every study stage, attention was paid to comply with ethical principles.ed.

Results

Socio-demographic variables between intervention and control groups

The mean age of the women participating in the study was 25.84 ± 5.95 in the IG and 29.62 ± 4.51 years in the CG. The rate of the women who received an education of 9 years or more was 53.84% in the IG and 56.25% in the CG. It was found that the women in the IG and CG were similar in terms of their descriptive characteristics ($p>0.05$). 76.9% of the women in the IG and 93.8% of the women in the CG were multiparous. The mean gestational week of the women was 29.92±1.60 in the IG and 29.81±1.64 in the CG. It was seen that the women included in the study were similar in terms of gestational properties ($p>0.05$; Table 1).

Comparison of IRLS pretest-post test mean scores between intervention and control groups

It was determined that the post-test RLS severity total score averages were significantly different between the groups (p<0.001; Table 2). In the pre-test measurements of the study, the mean total score of RLS severity was 24.76±4.72 in the IG, and 22.06±5.56 in the CG, and the total scores of the groups were similar (p>0.05; Table 2). The post-test total score was found to be 6.69±7.70 in the IG and 20.62±7.64 in the CG.

Comparison of IRLS severity pretest-posttest between intervention and control groups

It was also determined that the severity of RLS after the application was significantly different categorically in both groups. While the presence of severe and very severe symptoms was not found in any of the pregnant women (0.00%) in the hot water group, it was found in 83.8% of the CG (p<0.001; Table 3).

At the same time, no adverse situation reports were received from the women regarding hot water application to the legs.

Table 1. Comparison of the descriptive characteristics of pregnants in the IG and CG

| Characteristics | Groups | | Test | p value |
	IG (n= 13)	CG (n= 16)		
Age *	25.84 ± 5.95	29.62 ± 4.51	t= -1.944	0.062
Education (year) ≠				
8 years and less	6 (46.15)	7 (43.75)	x^2 = 0.897	0.596
9 years and more	7 (53.84)	9 (56.25)		
Working status≠				
Employed	1 (7.7)	1 (6.3)	x^2 = 0.879	0.704
Unemployed	12 (92.3)	15 (93.8)		
Gravida≠				
Primiparous	3 (23.1)	1 (6.25)	x^2 = 0.191	0.223
Multiparous	10 (76.9)	15 (93.75)		
Gestational age (week)*	29.92 ± 1.60	29.81 ± 1.64	t= 0.182	0.857
Weight Gain in Pregnancy *	9.92 ± 4.0	9.87 ± 9.53	t= 0.017	0.987
BMI *	28.08 ± 1.60	29.36 ± 5.24	t= -0.657	0.517

Values in parentheses show percentages.   BMI, body mass index   *Mean± standard deviation   ≠ frequency

Table 2. Comparison of IRLS total score pretest-posttest mean scores of the pregnants in the IG and CG
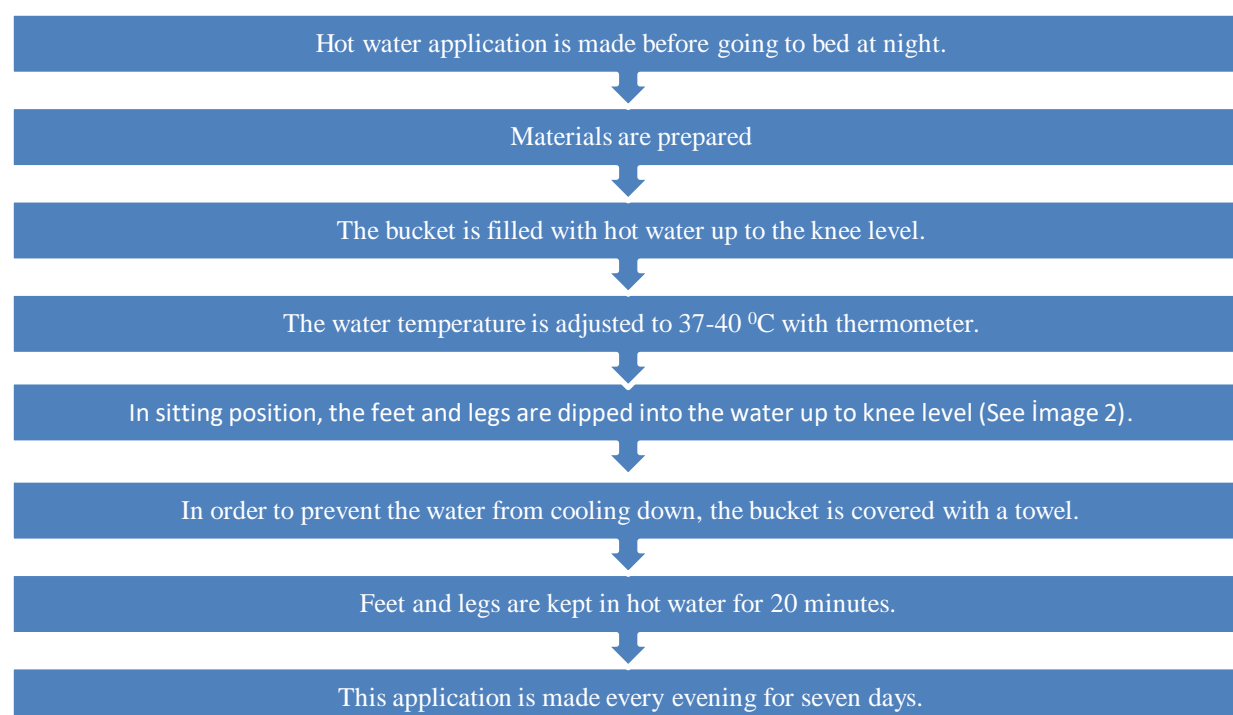
IRLS Total Score	IG (n= 13)	CG (n= 16)	t	***p value
Pretest *	24.76 ± 4.72	22.06 ± 5.56	1.391	0.176
Posttest *	6.69 ± 7.70	20.62 ± 7.64	-4.862	<0.001
Difference (score)	18.07±6.57	1.43±6.93	-6.573	<0.001
t	9.916	0.8254		
***p**	<0.001	0.422		

RLS, restless leg syndrome   Mean± standard deviation   **Paired sample t test   ***Independent sample t test

Table 3. Comparison of RLS severity pretest-posttest of the women in the IG and CG

	IG (*n*= 13) (n%)		CG (*n*= 16) (n%)		**P value Before intervention in groups	**P value After intervention in groups
No	0 (0)	2 (15.4)	0 (0)	0 (0)	0.514	<0.001
Mild	0 (0)	6 (46.2)	0 (0)	1 (6.3)		
Moderate	3 (23.1)	5 (38.5)	7 (43.8)	8 (50.0)		
Sever	9 (69.2)	0 (0)	7 (43.8)	6 (37.5)		
Very sever	1(7.7)	0 (0)	2 (12.5)	1 (6.3)		
***P value**	<0.001		0.216			

*Paired sample t test

Hot water application is made before going to bed at night.

↓

Materials are prepared

↓

The bucket is filled with hot water up to the knee level.

↓

The water temperature is adjusted to 37-40 ^{0}C with thermometer.

↓

In sitting position, the feet and legs are dipped into the water up to knee level (See İmage 2).

↓

In order to prevent the water from cooling down, the bucket is covered with a towel.

↓

Feet and legs are kept in hot water for 20 minutes.

↓

This application is made every evening for seven days.

Figure 1. Hot Water Application Protocol in RLS Severity Management of the Pregnant Women

Discussion

RLS, which is common in the community, can be seen four to six times more frequently in pregnant women (Cakmak et al., 2014; Sahin et al., 2007; Tunc et al., 2007). The prevalence and severity of RLS in pregnancy can increase in older ages, in advanced gestational weeks (Cakmak et al., 2014; Yuksel, 2017), and in direct proportion to pregnancy BMI (Cakmak et al., 2014; Gao et al., 2009).

RLS severity of the IG after hot application decreased approximately 2.5 times compared to the control group (p<0.001). RLS severity of the IG decreased by 18.07 points after the application compared to the pre-application and decreased to a mild level. According to this result, it can be said that hot water application to pregnant women with RLS reduces the severity of RLS by 70%.

In the CG, there was no significant change between the RLS pretest and post-test total

scores ($p>0.05$). According to this result, it was seen that hot water application made to legs of women with RLS could effectively reduce the RLS severity and the hypothesis that "Hot water application made to the legs of pregnant women with restless legs syndrome by using immersion method affects their complaints" was accepted.

Although no definite information can be provided about the pathophysiology of RLS, it is assumed that it may be associated with decreased oxygenation in the limbs. The partial reduction of symptoms when the person moves their limbs is explained because muscle contractions provide circulation and increase oxygenation (Lettieri and Eliasson, 2009). Hot water application causes vascular vasodilation by providing heat to deliver more oxygen and nutrients to the tissues. In addition, skin heat receptor stimulation can alleviate the severity of RLS by reducing acute and chronic muscle responses (Kozier et al., 2013; Sabuncu et al., 2015). Therefore, applying hot water to the legs of pregnant women may have decreased the severity of RLS by increasing oxygenation. In the literature, only one study was found in which hot water application was used to reduce the severity of RLS in pregnant women (Jafarimanesh et al., 2020). In this study, Jafarimanesh et al. (2020) applied thermotherapy and cryotherapy to reduce symptoms in pregnant women with RLS. According to their group, the women applied hot (40-45 °C) and warm (20-25 °C) water to their legs for 10 minutes, half an hour before sleep for two weeks. It was found that there was a decrease in the mean total score of the pregnant women in the RLS severity rating questionnaire compared to the pre-application. Still, there was no change in the RLS severity, and it continued at a moderate level. According to the results obtained, it is seen that the application of warm water to the legs affects reducing the severity of RLS during pregnancy. However, despite the application of similar techniques, there was a more significant decrease in RLS severity scores in our study compared to this study. It is thought that this difference may be due to the application temperature and application time.

In a thesis study (Jeppson, 2019), Jeppson examined the effect of hot water treatment on sleep quality and RLS symptoms in a 29-year-old female patient with moderate RLS. It was found that individual and therapist-supported water therapy sessions at 40 °C three times a week for five weeks were effective in reducing RLS severity in women ($p<0.05$).

Studies on reducing the severity of RLS during pregnancy are minimal. For this reason, the results obtained are also discussed with studies using a hot application in other patient groups with RLS. For example, a hot water bag was applied to hemodialysis patients with RLS, and the severity of RLS after the application was found to be lower than the initial value ($p<0.05$) (Nasiriani and Eftekhari, 2016). In another study, hot massage from feet to knees was applied to DM patients with RLS for five days. Similarly, hot massage was found to be effective in reducing the severity of RLS ($p<0.05$) (41). In his pilot study, Park et al. (2020), to determine the effect of foot massage and heat therapy on the severity of RLS, participants were given an electric heat pad and asked to place it on their thighs. As a result of the hot application of the participants for 30 minutes before going to bed every day for four weeks, it was determined that although the hot application decreased the severity of RLS, this decrease was not significant ($p>0.05$) (Park et al., 2020). The study was conducted with 28 people randomized into four groups. For this reason, it is thought that this result may be due to the insufficient number of samples. In these studies, it is seen that hot applications can be made in different ways, such as a water bag, massage, pad, or dipping the legs in the water. Although the methods were different, it was determined that the hot applications effectively reduced the severity of RLS symptoms.

Special attention should be paid to protect and promote the health of pregnant women within the scope of safe motherhood services. In line with this service, healthcare professionals, especially nurses and midwives, are expected to evaluate the complaints of pregnant women (T.C. Ministry of Health, Turkish Public Health Institution, 2014). In addition to problems arising during pregnancy such as nausea-vomiting, constipation, and heartburn, it is important to identify complaints about RLS and manage them effectively. Unless

involuntary repetitive movements are treated, the sleep quality of pregnant women is distorted, their thought process is negatively affected and it can impair the quality of life by preventing the realization of ADLs. RLS can also cause prolonged labour in pregnant women and increase the rate of caesarean delivery. Therefore, early diagnosis and treatment are important in terms of healthy pregnancy and supporting the development of the fetus (Abetz et al., 2004; Akbas, 2017; Allen and Earley, 2001; Allen at al., 2002; Donmez, 2017). Midwives and nurses have important roles and responsibilities in the follow-ups of pregnant women (44. Regulation on Determination of Minimum Education Conditions for Doctorate, Nursing, Midwifery, Dentistry, Veterinary, Pharmacy and Architecture Education Programs, 2008). The most important aim in the care and treatment of RLS is to provide the maximum benefit with the lowest risk. By looking at the results of this study; Midwives and nurses can easily recommend to pregnant women with RLS complaints, as it is a practical, reliable, and low-cost application.

Strengths and Limitations of the Study

This reserch presents several strengths. This reserch is one of the limited studies conducted to reduce the severity of symptoms in pregnant women with RLS. The results obtained provide evidence for the suggestion that hot water may be effective in reducing RLS symptoms in pregnant women. In the literature, there is only one study investigating the effectiveness of hot water to reduce the severity of RLS in pregnant women. However, in our study results, hot water was found to be more effective in reducing the severity of RLS. It was thought that this effect was caused by different application time and water temperature. In other words, with this study, a more effective protocol was determined regarding the application time and temperature, as well as the effectiveness of hot water application. Other strengths of the study are that it is an easy-to-apply, effective and reliable method that can be used to reduce the severity of RLS symptoms in pregnant women. This method, whose effectiveness has been proven, provides an opportunity for pregnant women to become independent in symptom management.

Limitations include the lack of blinding during the study, the absence of a neurologist in identifying RLS symptoms, the study design not being placebo-controlled, not evaluating the bathroom habits of pregnant women, and the fact that it was studied with a small group. Despite these limitations, the study provides essential information for future studies.

Clinical Application

Applying hot water to the legs of pregnant women with RLS decreased the severity of RLS. At the same time, considering that there are no adverse reports about the application of hot water to the legs, hot water application is an effective, safe, and low-cost application in pregnant women. Therefore, it may be an excellent option for RLS symptom management in pregnant women in line with evidence-based practices. With this application, the dependency of pregnant women in symptom management will decrease, and the frequency of hospital visits will decrease as they manage their symptoms themselves.

Conclusion: After application, the RLS severity total score and categorical severity between the two groups were statistically different. While severe and very severe symptoms were not found in any of the pregnant women in the hot water group, it was present in 83.8% of the CG. As a result, applying hot water to the legs of pregnant women with RLS decreased the severity of RLS.

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