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Treating Uncontrolled Hypertension with *Hibiscus sabdariffa* When Standard Treatment Is Insufficient: Pilot Intervention

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Abstract

Objectives: To assess the use of *Hibiscus sabdariffa* (HS), known as karkade in Jordan, in cases of uncontrolled hypertension, either with or without medication, as validated by several clinical trials.

Design: A multicentric pilot clinical study.

Location: Outside a refugee camp in Jordan.

Subjects: Thirty-eight participants with blood pressure (BP) above 140/90 mmHg consumed *H. sabdariffa* tea.

Intervention: Consumption of karkade tea containing 10 g of HS/0.5 L daily. This dosage was increased to 15 g of HS/1 L and to 20 g of HS/1 L during the second and third weeks, respectively, if their BP was still high.

Outcome measurements: The primary outcome measurement was blood measurement taken once a week. Secondary outcome measurements were satisfaction, possible side effects, and interactions with other medications.

Results: Of the 38 participants, 29 finished the program, 72% of whom were taking antihypertensive medication due to uncontrolled hypertension and 28% of whom were not. *H. sabdariffa* was generally well tolerated: 38% of participants reached the target BP at the end of the study and 65% saw their systolic BP decrease by at least 10 mmHg.

Conclusion: *H. sabdariffa* (karkade) is generally well tolerated and seems to be helpful in treating uncontrolled hypertension, with or without medication.

Keywords: hypertension, *Hibiscus sabdariffa*, adjuvant therapy, Roselle, refugees, traditional medicine

Introduction

Hypertension, or high blood pressure (BP), is a common disease in which the force of the blood pushing against the artery is high.[1] About 5.7 million deaths occur yearly worldwide due to hypertension, whereas ~1 billion people have uncontrolled hypertension (i.e., high BP despite attempts to treat it).[2]

The poorest countries have a high prevalence of hypertension due to the economic and social situation, reaching 40% of total morbidity of all diseases.[2] Refugees are one population that suffers the most, with poverty and difficult access to health services among the factors that increase the prevalence of uncontrolled hypertension.

There are ~589,000 refugees in Jordan, 80% of whom are living in host communities.[3] The prevalence of noncommunicable diseases is particularly high among refugees living outside refugee camps, the most prevalent of which are hypertension and arthritis.[4] For this population, the World Health Organization and other organizations are striving to find solutions to help control the prevalence of hypertension in an easy and affordable way.[5]

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As standard treatments are not always available or have undesirable side effects, medical professionals have looked for additional solutions, including foods or food supplements that could help curb hypertension. These are especially interesting when they are accessible local resources with a good safety and effectiveness profile. This was not only a distant dream in Jordan because there is an existing traditional remedy: an herbal tea prepared from the flowers (calyces and epicalyces) of *Hibiscus sabdariffa* L. (Malvaceae). Generation after generation has used this plant—known as ''karkade'' (Arabic) in Jordan and as ''bissap'' (Wolof) in parts of western Africa.[6,7] The plant is called roselle in the European Union and simply as *Hibiscus* in the United States. In addition to its lowering BP effect, this plant also has been extensively investigated as an antioxidant and an anti-inflammatory, in lowering cholesterol levels, and as an antidepressant.[6–8]

A review of clinical trials of *H. sabdariffa* shows that it is safe and effective as an antihypertensive solution, through its diuretic effect via anti-aldosterone activity and its vasodilator effect via angiotensin-converting enzyme inhibition by anthocyanins.[8,9]

We organized a pilot clinical study to establish the feasibility of a karkade intervention and to estimate the magnitude of its effects among Syrian refugees in Jordan. This study aimed to measure the effects and safety of using karkade for 4 weeks among patients with uncontrolled hypertension.

Materials and Methods

Plant material

We bought the plant material in Amman, Jordan, and ensured its proper identification using a voucher herbarium specimen deposited at the Botanical Gardens in Geneva, Switzerland, under the number G00394517.The verification was carried out by a botanist based on macroscopic observations.

Study design and intervention

We conducted this multicenter ''before-after'' pilot clinical study in two centers in Jordan (Amman and Al-Mafraq). We instructed the patients to steep the dry *H. sabdariffa* (karkade) calyces in water and boiling for 20 min, starting with a dose of 10 g karkade in 0.5 L.

Participants

We included all participants between 30 and 75 years of age with uncontrolled hypertension, whether taking antihypertensive medications or not, in the study based on the following criteria:

(1) Inclusion criteria

- Aged >18 years
- Systolic BP between 140 and 175 mmHg and/or diastolic BP between 90 and 110 mmHg.
- No evidence of cardiovascular, renal, or retinal complication
- Patients with high BP even while taking ongoing antihypertensive medication were encouraged to participate

(2) Exclusion criteria

- Hypertensive crisis requiring urgent medication
- Overt kidney failure (serum creatinine ≥1.4 mg/dL)
- Women who were pregnant or lactating (excluded as a rule although there is no evidence of any problems encountered with the tested food product)
- Previous adverse reaction to karkade

Methodology

The first encounter was a health awareness lecture on the management of hypertension and the potential benefits of using *H. sabdariffa* (karkade) to lower BP. Following this lecture, participants received enough karkade tea to treat their hypertension for more than 1 month.

At the second visit, after a week, participants who did not reach the target BP of 140/90 were told to increase the dose to 15 g of karkade in 1 L of boiled water. At the third visit, after 2 weeks, if the BP was still too high, we increased the recommended dose of karkade to 20 g steeped in 1 L of boiled water.

Measurement procedures

During the 4 weeks of this study, we assessed the participants once a week to measure their BP and enquire about other treatments, treatment adherence, and side effects.

We measured arterial pressure using automatic arterial pressure measurement devices on both arms after 5 min of rest. In most cases, we kept the mean value between both arms for the analysis. In cases of a discordance of >5 mmHg, we repeated the measurements up to three times per arm. In our study, we always found a between-arm difference of ≤5 mmHg. We also asked participants about their treatment compliance, new symptoms (classified as unlikely, possible, or probable side effect), and the eventual intake of other medications since the last consultation. One side effect was expected: *Hibiscus* is known to be slightly laxative.

If any participant missed a consultation, we called them by phone to set up a new meeting as soon as possible. If participants experienced a rupture in treatment of >15 days, we excluded them from their current follow-up and, if possible, reincluded a new participant.

We collected all data and registered them in a local treatment register, which we then transferred to Excel data sheets.

Intervention

We obtained *H. sabdariffa* (karkade) from a reputable herbal shop in Amman bazaar. The karkade available in Jordan comes mainly from Egypt, Sudan, and Nigeria. We decided to use the Nigerian product because Nigeria is geographically closer to Senegal, where Seck et al.[8] conducted a study on *Hibiscus*. Nigerian product was also among the cheapest ones in the market and we wanted to test the most affordable source of tea available. Participants took the karkade tea daily, either in the morning or early afternoon because of its diuretic effects.

Ethical issues

We conducted this study within the framework of the Jordan Red Crescent. We informed all participants about the

study's protocol and the ingredient used. Because this study focused on a locally well-known food product, no ethical committee clearance was required; measurements were restricted to what is done as a matter of course in clinical care in such cases.

Outcome measurements

The primary outcome measurements were systolic and diastolic BP, the difference between before and after, and the number of weeks participants consumed the karkade tea.

Secondary outcome measurements were satisfaction, compliance, adherence to the treatment proposed, possible side effects, and interactions with other medications.

Analysis

We used R statistical software to calculate mean values, median values, and percentages, and to compare the results from the first week of taking karkade to the fourth week through a line graph. We created all graphics using GraphPad Prism version 5.01.

Results

Recruitment

Between July and September 2018, 1 pharmacist, and 2 assistants screened 50 participants known for uncontrolled hypertension in Jordan. Among these participants, 38 were included in the study, as the rest of participants did not meet the inclusion criteria (Fig. 1).

Twenty-one participants were in Amman and 17 participants were in Al-Mafraq; among them, 24 participants (63%) were taking antihypertensive medications and 14 participants (37%) were not. The age of participants ranged from 30 to 75 years; 55% were women and 45% were men.

After the first week of karkade tea consumption, 13 participants (34%) reached the target BP, whereas 25 participants (65%) did not and their recommended dose increased to 15 g of karkade dissolved in 1 L of boiled water. Nobody dropped out of the study. After the second week of karkade tea consumption, 14 participants reached the target BP and 5 participants increased the dose of karkade to 20 g dissolved in 1 L of boiled water; 4 participants dropped out of the study (one due to stomach pain and the others lost to follow-up). In the last week, the total number of participants who reached the target BP was 11 (38%), 5 participants dropped out of the study, 2 of them due to dyspnea (see ''Discussion'' section), whereas the others were lost to follow-up.

In the first week of the study, the mean systolic BP was 149 ± 18.6 and diastolic BP was 98 ± 12.5 before karkade tea consumption, while the mean systolic BP and diastolic BP reached 133 ± 18 and 92 ± 11.5, respectively, after 4 weeks of tea consumption, each participant receiving an individualized dose in accordance with their progress.

Globally, 22 of the 29 participants (76%) who finished the study saw their systolic BP decrease by at least 5 mmHg; 19 (65%) participants saw a decrease of at least 10 mmHg in systolic BP; 15 (51%) participants saw their systolic BP decrease by 15 mmHg; and 14 (48%) participants saw their systolic BP decrease by 20 mmHg after the fourth week of karkade tea consumption.

Among the participants who did not reach the target BP, 9 of 13 (69%) saw their systolic BP decrease by 10 mmHg and 4 of 13 (30%) had a 20 mmHg drop in systolic BP at the end of the project.

Based on the satisfaction questionnaires that cover various aspects of this treatment, we found that three participants suffered from a new symptom—one had stomach pain and two had dyspnea—whereas the others were highly satisfied with the treatment and the results obtained.

During the 4 weeks of the pilot study, treatment adherence was satisfactory as all the participants consumed the

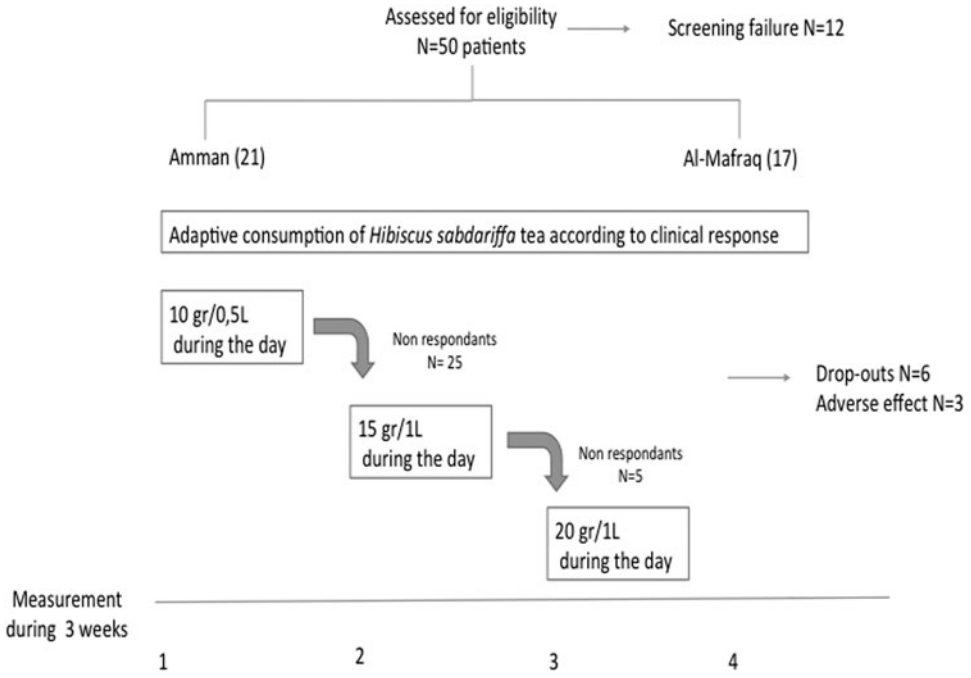

FIG. 1. Protocol procedure and dose adaptation according to the clinical response after *Hibiscus sabdariffa* consumption.

karkade tea regularly as advised. Nine participants dropped out of the program during the 4 weeks (23%) either because they did not come for the weekly measurement or due to some new symptoms. Ninety percent of participants did not experience any side effects from the karkade tea during this program; three participants (10%) experienced mild side effects in the form of stomach pain, which disappeared rapidly after stopping treatment; despite thorough clinical examination, we were unable to determine whether it was a food intolerance or an interaction with or an unexpected problem related to other medications.

Among the 29 participants who finished the program, 8 had diabetes, 21 (72%) were taking antihypertensive medication, and 8 (28%) were not taking antihypertensive medication. Eleven of the 29 participants (38%) reached the target BP (Figs. 2 and 3).

Discussion

This study assessed the feasibility of a program supplying a food product, *H. sabdariffa* (karkade), as an adjuvant in the treatment of hypertension. For the first time in the literature, a large proportion of participants (75%) were using ongoing standard hypertensive medication. The participants showed improvement after the first week of karkade tea consumption, as determined by weekly BP measurements.

Karkade was generally safe and well tolerated except in three participants who developed new symptoms during the consumption of karkade tea, such as dyspnea and stomach pain. Although we could not attribute the symptoms with certainty to the plant, its attribution is plausible, as *H. sabdariffa* tends to be acidic: it contains a high percentage of organic acids like malic acid, citric acid, and tartaric acid.[8] We were unable to determine if it was food intolerance or an interaction with or unexpected problem related to another medication, as two of the three patients were also taking hypothyroid medication (the two with dyspnea). A question is whether a new batch of thyroid medicine might have had a quality problem. A review of the literature shows that, in general, the combination of *Hibiscus* with other sorts of medication is well tolerated; the only interaction found with karkade is with hydrochlorothiazide as the former increases the action of the latter.[10]

In this pilot study, we observed a decrease in systolic BP ($149 \pm 18.6/133 \pm 18$) and diastolic BP ($98 \pm 12.5/92 \pm 11.5$); and 65% of participants had a decrease of at least 10 mmHg in their systolic BP after consuming karkade tea, with the dose adapted to their individual clinical response. In a similar situation without the adaptation of the dose, Herrera-Arellano et al.[11] found a similar decrease in systolic BP ($139.05 \pm 7.23/123.37 \pm 12.10$ mmHg) and diastolic BP ($90.81 \pm 2.19/79.52 \pm 7.25$ mmHg) by giving 10 g of *H. sabdariffa* steeped

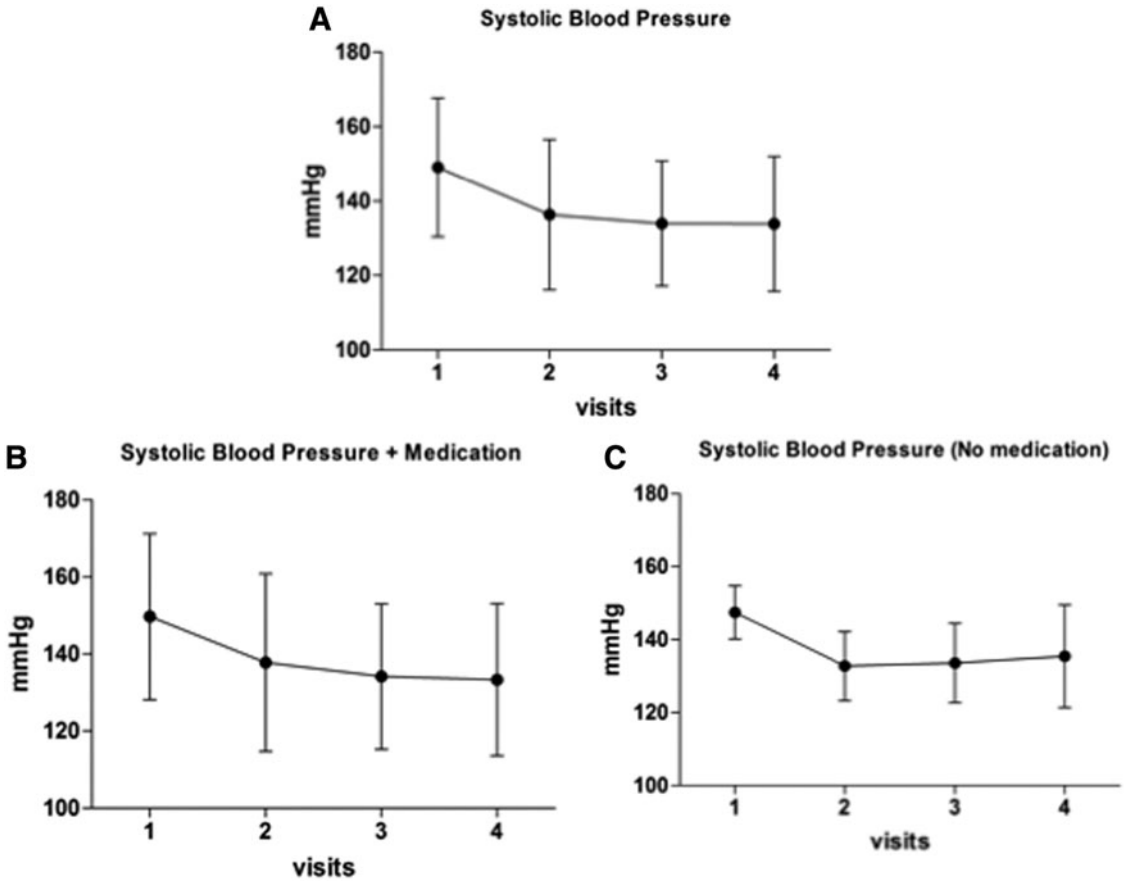

FIG. 2. Systolic blood pressure measurement. **(A)** Systolic blood pressure measurement of all patients who followed the treatment until the end ($n = 29$). **(B)** Systolic blood pressure measurement of patients consuming *H. sabdariffa* + a classical antihypertensive medication ($n = 21$). **(C)** Systolic blood pressure measurement of patients consuming *H. sabdariffa* without classical antihypertensive medication ($n = 8$).

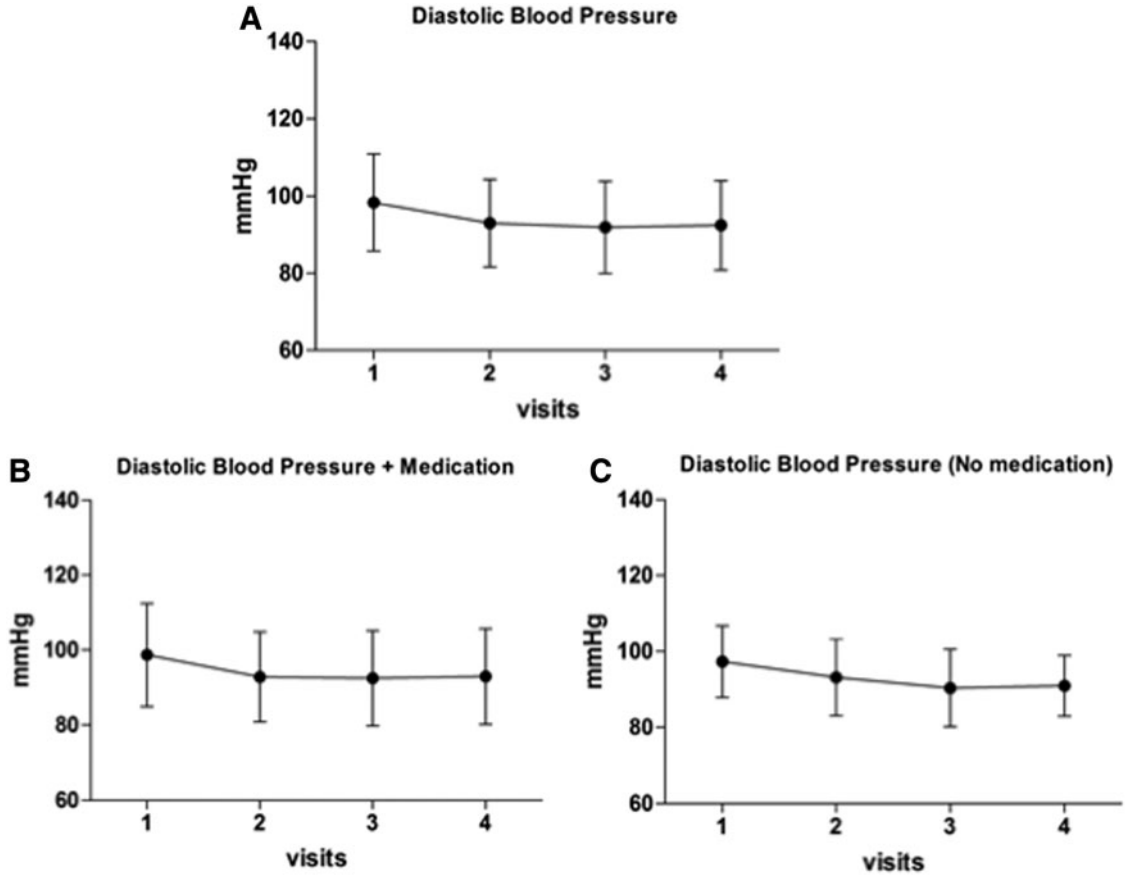

FIG. 3. Diastolic blood pressure measurement. **(A)** Diastolic blood pressure measurement of all patients who followed the treatment until the end ($n=29$). **(B)** Diastolic blood pressure measurement of patients consuming *H. sabdariffa* + a classical antihypertensive medication ($n=21$). **(C)** Diastolic blood pressure measurement of patients consuming *H. sabdariffa* without classical antihypertensive medication ($n=8$).

in 0.5 L water to hypertensive patients without any other antihypertensive treatment during 1 month. In another trial, McKay et al.[12] gave a solution of 3.75 g (three bags containing 1.25 g each) of *H. sabdariffa* steeped in 0.24 L of water a day to patients with mild hypertension without ongoing antihypertensive medication for 6 weeks. Their results showed a greater decrease in systolic BP ($129 \pm 4.8/122.3 \pm 10.3$) with *Hibiscus* than with a placebo, but no difference in diastolic BP ($78.8 \pm 7.7/75.8 \pm 8.6$). The daily dose of tea (3.75 g) was smaller than in our trial; therefore, the clinical response is less remarkable. In both studies, participants had a lower BP at the beginning of the study as compared with ours.

In most trials assessing the efficacy of *H. sabdariffa*, patients did not use standard antihypertensive medication and in all studies a clear pharmacological effect was observed, although most frequently the BP at the beginning of the study was below 140/90[13,14] and very few above this level.[15,16] The only trial in the literature that used karkade tea among patients with antihypertensive medication used a different protocol, measuring the BP right after tea consumption at days 4, 8, 12, and the third day after stopping tea consumption; however, the patients in that study only consumed the tea during the observation period, interrupting their antihypertensive medications.[17]

In our study, we measured BP once a week over 1 month without specifying the time at which to measure the BP—before or after drinking karkade tea—and the participants in the trail continued to take their antihypertensive medication during the observation.

The impact of a 10 mmHg (systolic) or 5 mmHg (diastolic) decrease in BP can lead to a 22% reduction in coronary heart disease and a 41% reduction in strokes, regardless of the use of a pretreatment to lower the BP to 110 mmHg systolic and 70 mmHg diastolic.[18] Therefore, the effects observed in 65% of participants that saw their systolic BP decrease by at least 10 mmHg in our study is remarkable although only 38% reached the target BP.

In summary, *H. sabdariffa* (karkade) seems to be useful in controlling high BP among a significant proportion of patients, with or without antihypertensive medications. As with classical antihypertension medications, no one solution fits all. However, it appears to be worth trying karkade in cases of uncontrolled hypertension.

Limitations

This evaluation presents some limitations, as it is a small pilot study with a low number of participants and there was no placebo control group. The follow-up period was short, so a longer follow-up period would be necessary to see if the promising results observed are sustained and whether the participants will maintain their motivation to prepare the karkade tea.

Conclusions

This evaluation found that *H. sabdariffa* (karkade) with adapted doses (10, 15, and 20 g daily according to clinical response) for 4 weeks was associated with an improvement in both systolic and diastolic BP even in patients taking ongoing antihypertensive medications. These results could encourage refugees, even those who live outside organized camps in Jordan, to use karkade tea to help control their BP, as it is an affordable, locally available, and scientifically validated product.

Acknowledgments

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Author Disclosure Statement

Antenna Foundation has commercialized dried *Hibiscus* calyx in the form of tablets in Switzerland to help fund future research projects on local resources for health.

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