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## **Unani Formulation for Conservative Treatment of Cholecystitis: An Observational study.**

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### **ABSTRACT**

In Unani system of medicine *Sharbat Bazoori Motadil* and *Majoon Dabedulward* are compound formulation is effective in the treatment of *Amraz-e- Jigar* and may be useful in the treatment of *Cholecystitis* also. So, the aim of this study is to evaluate the efficacy of Unani Formulation on scientific parameters. This study was an open observational study, carried out on 40 patients. The test drug was given in the form of decoction with 7 gm *Majoon Dabidul Ward* with 50 ml *Sharbat Bazoori Moatadil* twice a day after meal for the period of 2 months. All the patients of were assessed fortnightly on subjective parameters (0<sup>th</sup>, 15<sup>th</sup>, 30<sup>th</sup> 45<sup>th</sup> and 60<sup>th</sup> day) whereas objective parameters were assessed before and after the treatment. The outcome of intervention was analyzed using appropriate statistical methods. Subjective parameters were satisfactorily alleviated by the test drugs. Findings suggest the effectiveness of test drug in *Cholecystitis*. Subjective parameters and the findings in USG and CT scan ere also improved.

**Keywords:** *Majoon Dabidul Ward; Sharbat Bazoori Moatadil; Cholecystitis; Warm-e-Marara.*

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Received 10 September 2020, Accepted 20 September 2020

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Please cite this article Alam TA *et al.*, Unani Formulation for Conservative Treatment of Cholecystitis: An Observational study.. American Journal of Pharmacy & Health Research 2020.

## INTRODUCTION

**Prevalence:** The incidence of acute cholecystitis among people with gallstones is unknown. The incidence of acute cholecystitis is about 20% among people with biliary colic. Biliary colic occurs in 1% to 4% of people with gallstones. Of people admitted to hospital for biliary tract disease, 20% have acute cholecystitis<sup>1</sup>.

**Pathophysiology of Cholecystitis:** Over 90% of cases of acute cholecystitis result from obstruction of the cystic duct by gall stones or by biliary sludge that has become impacted at the neck of the gall bladder. Obstruction of the cystic duct causes the intraluminal pressure within the gall bladder to increase and, together with cholesterol supersaturated bile, triggers an acute inflammatory response<sup>2,3</sup>. The trauma caused by the gall stones stimulates the synthesis of prostaglandins I<sub>2</sub> and E<sub>2</sub>, which mediate the inflammatory response<sup>4</sup>. Secondary bacterial infection with enteric organisms (most commonly *Escherichia coli*, *Klebsiella*, and *Streptococcus faecalis*) occur in about 20% of cases<sup>5</sup>. Biliary sludge is a mixture of particulate matter and bile, and it may stimulate microlithiasis. If the sludge persists-for example, because the patient has already had several pregnancies or is receiving total parenteral nutrition-gall stones can form. Most patients with biliary sludge have no symptoms, but the sludge itself can cause acute cholecystitis<sup>6,7</sup>.

**Sign and Symptoms of Cholecystitis:** Signs and symptoms of cholecystitis include right upper quadrant pain, fever, and a high white blood cell count<sup>8</sup>. Pain generally occurs around the gallbladder, in the right upper quadrant of the abdomen. In cases of acute cholecystitis, the pain starts suddenly, it does not go away, and it is intense. Left untreated, it will usually get worse, and breathing in deeply will make it feel more intense. The pain may radiate from the abdomen to the right shoulder or back<sup>9</sup>.

**Other symptoms may include:**

- Abdominal bloating
- Tenderness on the upper-right hand side of the abdomen
- Little or no appetite
- Nausea
- Vomiting
- Sweating<sup>10</sup>

A slight fever and chills may be present with acute cholecystitis. After a meal, especially one that is high in fat, symptoms will worsen. A blood test may reveal a high white blood cell count<sup>11</sup>. There are various allopathic medicines available for the management of cholecystitis like ursodeoxycholic acids, NSAID, Opium derivatives etc., have various side effects<sup>12</sup>.

Unani Scholars also described about *Amraze Mararah*, under the caption of *Amraze Jigar*, they also mentioned that inflammation occurs in the *mararah* is due to *Ghaleez wa fasid ghiza, ehtebas ghair tabayi*<sup>13</sup>. Most of the great Unani scholars like *Hippocrates, Galen, Zakaria Rhazi, Ali Ibn Abbas Majusi, Ibn-e-Sina, Ismail Jurjani, Ibn-e-Hubal Baghdadi* etc., are described about the pathophysiology of this disease and also their treatment method by *Mufarrad wa Murakkab Drugs like; Kasni, Mako, Karafs, Tukhm Soya, Khare Khasak, Hajrul Yahud, Afsanteen, Duqu, Habbul Qilt, Sirka, Arque Kasni, Arque Mako, Arque Ajwain, Majun Hajrul Yahood* etc<sup>14</sup>. Currently most of them are scientifically proved for their lithotripsy, analgesic, hypolipidemic activities<sup>15</sup>. So, this study was conducted as a clinical trial using Unani formulation title as “Clinical or Surgical Study of *Warm-e- Marara* (Cholecystitis)” on scientific parameters.

After obtaining ethical clearance from Institutional Ethical Committee, Deoband Unani Medical College, Hospital & Research Centre, Deoband, as an open labeled interventional without control pre and post analysis study, Sample size was 40 (both male & female) only interventional group, Diagnosed case *Cholecystitis* and Patients who have agreed to sign the informed consent form and follow up the protocol, Patients were kept under strict observation and advised to come fortnightly in OPD for the assessment of study till the completion of study. Sixty days study was divided into four visits of follow up, which were made at an interval of 15 days. At every visit, patients were asked about the progression or regression in their symptoms and subjected to assess the clinical findings.

The study outcome measures of baseline are compared with each follow ups in terms of subjective and objective parameters as per protocol. A total of 80 patients were screened, out of which 40 cases fulfilling the inclusion criterion based on thorough history, clinical examinations. Certain investigations were carried out with the aim to exclude the patients with pathological conditions mentioned under exclusion criteria and to assess the efficacy of treatment group and to establish the safety of the test drug.

#### **Line of treatment (*Usul-e-Ilaj*) of Cholecystitis:**

- Removed the real cause of disease
- Avoid from fatty, oily and Ghizae Kaseef
- Use warm water for drinking purpose
- Be regular aerobic exercise
- At the time of pain used *Arq Mako* and *Arq Kasni* 6 Tola each
- Dry Hammam is effective
- Correct the sue *mizaj* of *Kabid*

- *Islahe Jigar*
- Use of hepatoprotective Drugs<sup>16</sup>

### **Unani Pharmacotherapy for Cholecystitis:**

Basically, two types of drugs are being used for the management of *warme marara* i.e. single and Compound drugs. Single Drugs like- *Mako, Kasni, Khare Khasak, Jawakhar, Habbul Qilt, Hajrul Yahood, Chobchini, Kutki* etc whereas compounds are- *Arque Mako, Arque Kasni, Habbe Kabid Naushadri, Majoon Dabidul ward, Sharbate Ward, sharbate Jigar, Sharbate Deenar, Dawaul Kurkum* etc are highly effective for the management of *Amraze Kabid wa mararah*.<sup>14,17,18</sup>

### **Objective of the Study**

To evaluate the efficacy of Unani formulation in *Warm-e-Marara* (Cholecystitis) as conservative treatment.

### **Methodology**

So, this study was conducted as a clinical trial using Unani formulation title as “Clinical or Surgical Study of *Warm-e- Marara* (Cholecystitis)” on scientific parameters. After obtaining ethical clearance from Institutional Ethical Committee, Deoband Unani Medical College, Hospital & Research Centre, Deoband, as an open labelled interventional without control pre and post analysis study, Sample size was 40 (both male & female) only interventional group, Diagnosed case Cholecystitis and Patients who have agreed to sign the informed consent form and follow up the protocol, Patients were kept under strict observation and advised to come fortnightly in OPD for the assessment of study till the completion of study. Sixty days study was divided into four visits of follow up, which were made at an interval of 15 days. At every visit, patients were asked about the progression or regression in their symptoms and subjected to assess the clinical findings.

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### **DRUG REVIEW**

***Sharbat Bazoori Moatadil (SBM)***: It is a polyherbal Unani formulation which consists of five ingredients and one base (sugar). This formula differs from pharmacopeia to pharmacopeia. Mizaj of this syrup is moderate hence name it. *Sharbat* are those medicinal preparations which are made

either by preparing the decoction from the plant, animal and mineral origin drugs or by taking juice of the fruits from different plants and mixed with Sugar and boiled to the required consistency.

S. No	Common Name	Scientific Name	Weight
1	<i>Tukhm Kasni</i>	<i>Chicorium intybus</i>	25.0 gm
2	<i>Tukhm Kheera</i>	<i>Cucumis sativus</i>	25.0 gm
3	<i>Tukhm Kakri</i>	<i>Cucumis melo</i>	25.0 gm
4	<i>Tukhm Kharbuzah</i>	<i>Cucumis melo</i>	25.0 gm
5	<i>Bekh Kasni</i>	<i>Chicorium intybus</i>	50.0 gm
6	<i>Shakkar</i>	<i>Saccharum officinarum</i>	1.0 Kg

#### Method of Preparation:

Soak the drugs in water for 24 hours. Make decoction of all drugs in water and obtain filtrate, then mix sugar in filtrate and make *Qiwam* (Basic Solution of Particular consistency).

**Dose:** 25-50 ml

**Action:** It eliminates the waste products of *Gurda* (kidney), *Jiger* (liver), and *Rahem* (uterus) etc.

#### Medicinal Uses:

*Mufattite Hissat, Muduirre Baul, Daffe Taffun, Dafe Humma, Dafe Sudda, Dafe Hiddat, Dafe Suda, Musakkine Alam* etc.<sup>19,20</sup>

#### Majoon-e-Dabeedul-Ward (MDW):

It is a semi-solid preparation made of ingredients in quantity given below.<sup>19,20</sup>

S. No	Common Name	Scientific Name	Weight
1.	<i>Sumbul-ut-Teeb</i>	<i>Nardostachys jatamansi</i>	10 gm
2.	<i>Mastagi</i>	<i>Pistacia lentiscus</i>	10 gm
3.	<i>Zafran</i>	<i>Crocus sativus</i>	10 gm
4.	<i>Tabasheer</i>	<i>Bambusa bambos</i>	10 gm
5.	<i>Darchini</i>	<i>Cinnamomum zeylanicum</i>	10 gm
6.	<i>Izkhar</i>	<i>Cymbopogon citratus</i>	10 gm
7.	<i>Asaroon</i>	<i>Asarum europaeum</i>	10 gm
8.	<i>Qust Shirin</i>	<i>Saussuria hypoleuca</i>	10 gm
9.	<i>Gul-e-Ghafis</i>	<i>Gentiana olivierii</i>	10 gm
10.	<i>Tukhm-e-Kasoos</i>	<i>Cuscuta reflexa</i>	10 gm
11.	<i>Majeeth</i>	<i>Rubia cordifolia</i>	10 gm
12.	<i>Luk Maghsul</i>	<i>Lacifer lacca</i>	10 gm
13.	<i>Tukhm-e-Kasni</i>	<i>Cichorium intybus</i>	10 gm
14.	<i>Tukhm-e-Karafs</i>	<i>Apium graveolens</i>	10 gm
15.	<i>Zarawand Taweel</i>	<i>Aristolochia longa</i>	10 gm
16.	<i>Habb-e-Balsan</i>	<i>Commiphora opobalsamum</i>	10 gm
17.	<i>Ood Hindi</i>	<i>Aquilaria agallocha</i>	10 gm
18.	<i>Qaranfal</i>	<i>Syzygium aromaticum</i>	10 gm
19.	<i>Heel Khurd</i>	<i>Elettaria cardamom</i>	10 gm
20.	<i>Gul-e-Surkh</i>	<i>Rosa damascena</i>	200 gm
21.	<i>Usl</i>	<i>Apis indica</i>	600 gm

**Therapeutic uses:** <sup>19,20</sup> *Istisqa* (Dropsy), *Zof-e-Kabid* (Weakness of Liver), *Waram-e-Kabid* (Hepatitis), *Waram-e-Rahem* (Uteritis), *Faqr-ud-Dam* (Anaemia).

**Actions:** *Mudirr-e-Baul* (Diuretic), *Mohallil-e-Waram* (Anti-inflammatory), *Mowallid-e-Dam* (Haematogenic). <sup>19,20</sup>

**Dose:** <sup>19,20</sup> 5-10 gm.

**Mode of administration:**

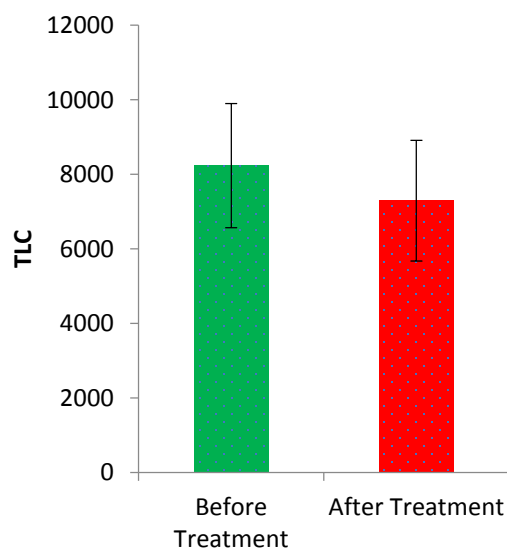
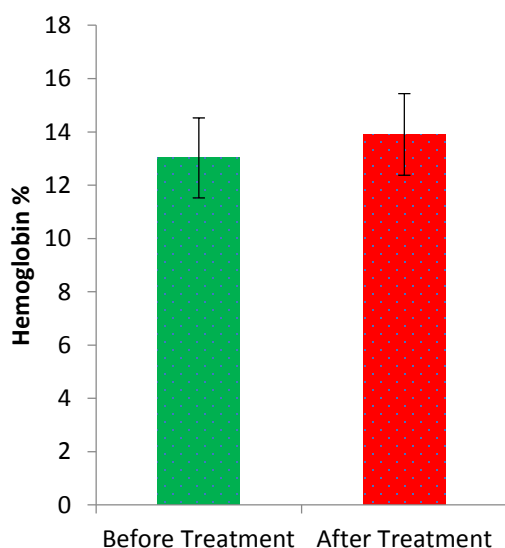
With water twice a day after meal.

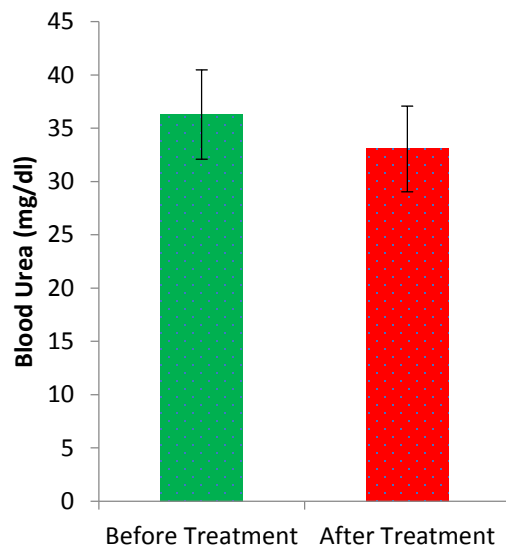
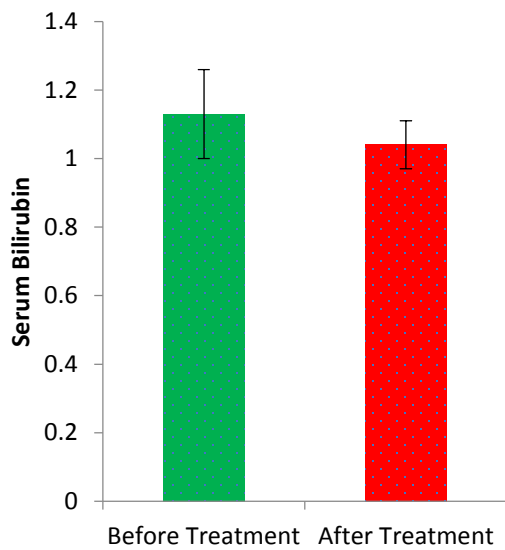
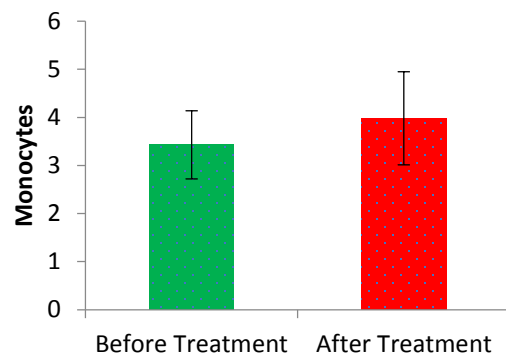
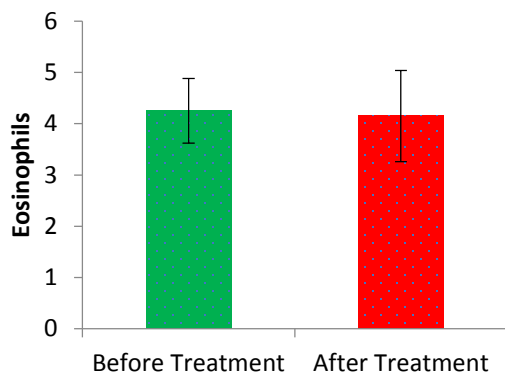
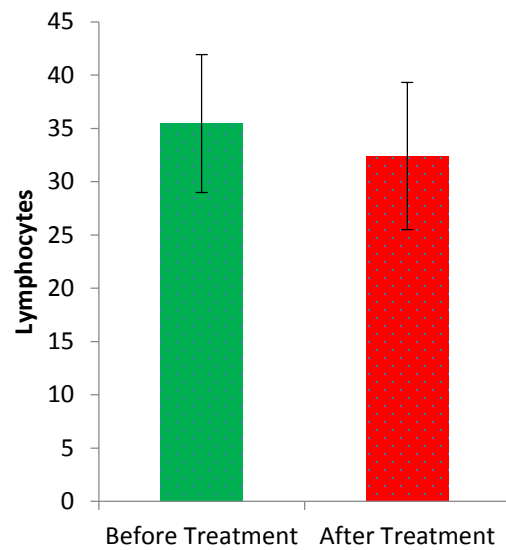
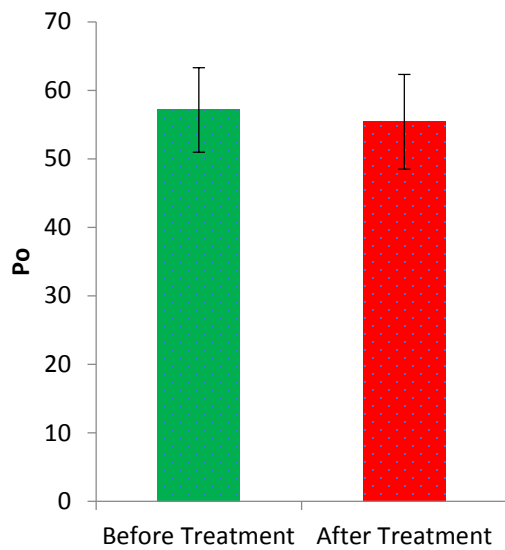
## RESULTS AND DISCUSSION

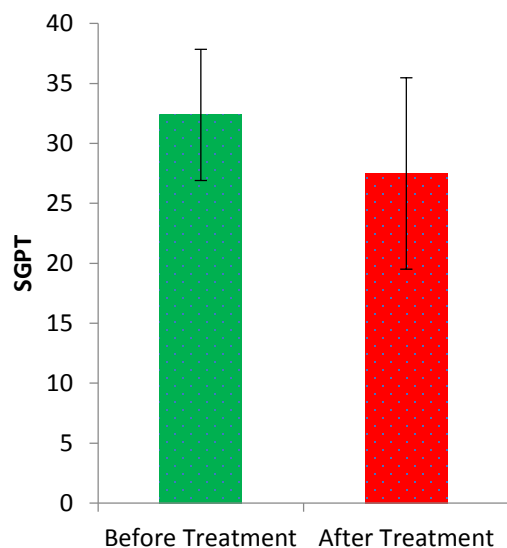
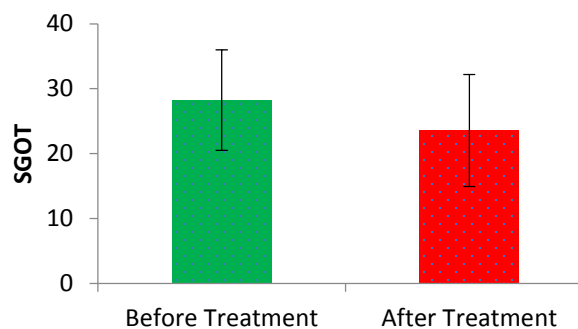
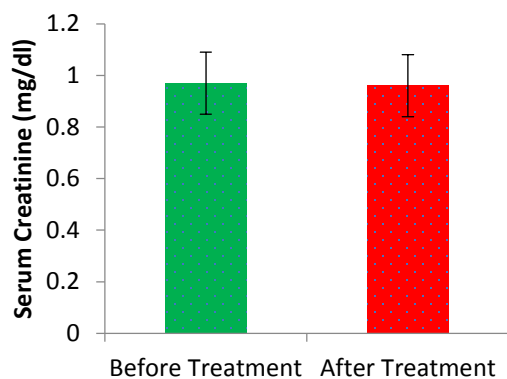
### Comparison of clinical variables before and after treatment of patients studied

Variables	Before Treatment	After Treatment	differenc e	t value	P value
Hemoglobin %	13.02±1.50	13.90±1.53	-0.880	-4.468	<0.001**
TLC	8232.50±1669	7290.00±1619	942.500	3.197	0.003**
Polymorphs	57.13±6	55.40±6.90	1.725	1.705	0.096+
Lymphocytes	35.45±6	32.40±6.91	3.050	3.416	0.001**
Eosinophils	4.25± 1.0	4.15±0.89	0.100	0.539	0.593
Monocytes	3.43±1.0	3.98±0.97	-0.550	-2.527	0.016*
Serum Bilirubin	1.13±0.13	1.04±0.07	0.090	3.636	0.001**
Blood Urea (mg/dl)	36.28±4.19	33.05±4.03	3.225	4.038	<0.001**
Serum Creatinine (mg/dl)	0.97±0.12	0.96±0.12	0.015	1.183	0.244
SGOT	28.25±7.75	23.55±8.64	4.700	4.603	<0.001**
SGPT	32.38±5.47	27.50±7.98	4.875	4.481	<0.001**

Student t test (Two tailed, Dependent)







### Significant figures:

+ Suggestive significance (P value:  $0.05 < P < 0.10$ )

\* Moderately significant (P value:  $0.01 < P \leq 0.05$ )

\*\* Strongly significant (P value :  $P \leq 0.01$ )

**Statistical software:** The Statistical software namely SPSS 18.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

### CONCLUSION

The findings about the parameters suggest that the test drug was effective in *Cholecystitis* and the cure was substantial. The effect was due to various drugs present in the *Joshanda*, *Sharbat Bazoori* *Motadil* and *Majoon Dabeedul Ward*. SBM is established diuretic and the ingredients have documented anti-inflammatory activity. Moreover, MDW has been documented as liver tonic, anti-oxidant and anti-cancer drug. Since Gall bladder is considered as part of liver in Unani and

presently it has the function of concentrating bile salts, the above drugs may have acted upon the inflammation in the similar way as in Hepatitis.

The subjective parameters of pain in abdomen, nausea & vomiting, dyspepsia and loss of appetite, were satisfactorily alleviated by the test drugs and all the findings found in USG and CT scan were also seen to subside with in the protocol duration. The findings about the parameters suggest that the test drug was effective in *Cholecystitis* and the cure was substantial. It reduced the subjective parameters as well as the findings in USG and CT scan of the *Cholecystitis* patients. The study is observational one with 40 patients. It had inherent limitation of confounding. Further research is needed in large number of patients with suitable control group to fine tune the results obtained from present study.

## ACKNOWLEDGEMENT

Authors acknowledge all the scholar, writer and scientist whose reference has been cited in this review article.

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