Hibiscus sabdariffa L: Safety and Efficacy during Pregnancy and Lactation

Abstract

Aim of the study: The present study was aimed to review the literature for evidence on the use, safety, efficacy and pharmacology of Hibiscus sabdariffa during pregnancy and lactation.

Background: The flowers, calyx and seeds of Hibiscus sabdariffa L. (Malvaceae) are used in traditional medicine for management of edema, cancer, constipation, hypertension, fever, liver and nerve diseases. In Nigeria, a decoction of the seeds is used in folk medicine to enhance or induce lactation in cases of poor milk production. But its potential for toxicity when administered during pregnancy, lactation and breast feeding has not been completely investigated.

Method: Seven electronic databases including the Napralert database were searched. Data were compiled based on the grade and evidence found.

Results: There were no scientific evidence to support the use of Hibiscus sabdariffa during pregnancy and lactation. However, there is in vitro evidence from animal studies that the seeds of Hibiscus sabdariffa have lactogenic effect. Animal studies have also shown that there is a delayed puberty, elevation of body weight and BMI in female rats that consumed extracts of Hibiscus sabdariffa.

Implications for nursing: Findings can be utilized by community health nurses and policy makers to advice on the use of Hibiscus sabdariffa during pregnancy and lactation.

Conclusion: Caution should be exercised with the use of Hibiscus sabdariffa during pregnancy and lactation till human research is conducted to determine its safety. There is a need to be cautious when using medications with Hibiscus sabdariffa.

Keywords: Hibiscus sabdariffa L; Zobo drink; Safety; Efficacy; Pregnancy; Lactation

Background

Medicinal plants play a major role in the health care system of developing countries such as Nigeria. Despite their huge use, most of these plants lack information on standardization, active chemical constituent, quality, clinical studies, safety and efficacy. Hibiscus sabdariffa is an herb belonging to the genus Malvaceae or Mallow family. In English speaking countries, it is called “Red Sorrel” [1]. It is originally from Angola. It is also found in tropical and subtropical regions, especially Sudan, Egypt, Thailand, Mexico and China. Historically, the generic name is derived from the Greek word (híbískos), which was the name Dioscorides (ca. 40-90) gave to Althaea officinalis or Marshmallow. Hibiscus species are used to represent nations: Hibiscus syriacus is the national flower of South Korea, and Hibiscus rosa-sinensis is the national flower of Malaysia. In Hindu worship, Hibiscus is used as an offering to goddess Kali and Lord Ganesha (Gaia herbs). Flowers of Hibiscus contain various polyphenols including anthocyanins, proanthocyanidins, flavonols, and other pigments [2], oxalic, malic, citric, stearic, tartaric acids, and 15 to 28% of hibiscic or hibiscus acid (lactone of hydroxycitric acid). The seed and seed oil of Hibiscus sabdariffa, contain a mixture of more than 25 volatile compounds, mainly unsaturated hydrocarbons, aldehydes, and alcohols [2], gamma tocopherol [3], saturated fatty acids (palmitic and stearic), unsaturated fatty acids (oleic and linoleic) [2]. The seed has high amounts of protein, crude oil, ash, carbohydrate [4]. The proteins isolated from the seeds are rich in arginine, aspartic acid, and glutamic acid. The seeds and flowers contain high amounts of protein, crude oil, ash, and carbohydrate [5,6].

Hibiscus sabdariffa has been used for centuries for a variety of traditional use including hypertension [7], edema, constipation, cancer, cardiac, fever, nerve and liver disease [8-10]. Extract from this plant has been used to enhance lactation [7].

In Nigeria, it is commonly produced, sold and consumed by adults and children without caution by both males and females, as a common local drink popularly known as zobo [10]. “Zobo” drink is a sweetened water extract of the dry petals of Hibiscus sabdariffa. The demand for zobo drink is higher than carbonated drinks due to the low cost and availability of Hibiscus sabdariffa [11]. Some people have been observed consuming zobo drink during lactation [7].

There is few traditional use of Hibiscus sabdariffa for women’s health issues. One report shows that the seed extract of Hibiscus sabdariffa, is used traditionally as a galactogogue, and to enhance or induce lactation when there is poor milk production, poor letdown and maternal mortality [7,10]. However, due to its
common use as a local drink, there is a possibility it will be used by women of reproductive age and women who may be pregnant. Its use by women during lactation calls for an in-depth understanding of its efficacy and potential for harm during pregnancy and lactation. One of the ways to address these issues is to do a systemic review of the literature. In this paper, we will review the effectiveness of *Hibiscus sabdariffa* with emphasis on issues related to pregnancy, lactation and breast feeding. This paper is the first on the evaluation of the efficacy and safety of a series of commonly used Nigerian plants during pregnancy and lactation.

**Methods**

AHMED, CINAHL, Cochrane CENTRAL, Cochrane Library, Medline, Internet journals, Napralert database, Natural Medicines comprehensive database, and Natural standard were reviewed from inception to March 2013 for information on *Hibiscus Sabdariffa* as it relates to its use on “pregnancy”, “lactation”, and “breastfeeding”. The Latin and common name of *Hibiscus sabdariffa* were also used as keywords in the search.

Information on the safety of this herb was searched for in the Complete German Commission E Monographs compiled by the American Botanical Council and Global Information Hub on Integrated Medicine (GLOBinMED), Natural standard monograph, and Natural Medicines, comprehensive database. Also, the safety of the active constituent of the herb was also searched. The pertinent journals were collected and the results tabulated as grade for indications of use, level for safety of consumption during pregnancy and safety of consumption during lactation. The level of evidence for therapeutic use and evidence for harm were evaluated based on ‘Grades for evidence for efficacy’ and ‘levels for evidence for harm’ as displayed in Table 1 & 2 respectively [12-14].

**Table 1: Grades for the evidence for efficacy.**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Evidence</th>
</tr>
</thead>
</table>
| A     | Very Strong Scientific Evidence  
Statistically significant evidence of benefit from one or more systemic reviews/meta-analysis |
| B1    | Strong Evidence  
Statistically significant evidence of benefit from one or more properly conducted random control trials (RCTs). |
| B2    | Good Scientific Evidence  
Statistically significant evidence of benefit from one or more RCTs. The RCTs, however, are either of small sample size OR have discrepancies in their methodologies |
| C     | Fair Scientific Evidence  
Statistically significant evidence of benefit from one or more cohort studies OR outcome studies. |
| D     | Weak Scientific Evidence  
Evidence from case series |
| E     | Indirect and/or Clinical Evidence  
Evidence from case reports OR expert opinion OR laboratory studies |
| F     | Historical or Traditional Evidence  
Historical or traditional use by medical professionals, herbalists, scientists, or aboriginal groups. |

**Table 2: Level for evidence for harm.**

<table>
<thead>
<tr>
<th>Level</th>
<th>Evidence</th>
</tr>
</thead>
</table>
| 1a    | Strong Scientific Evidence  
Statistically significant evidence from one or more systematic reviews or RCTs. |
| 1b    | Good Scientific Evidence  
Statistically significant evidence from one or more cohort studies OR control study. |
| 1c    | Weak Scientific Evidence  
Evidence from one or more case series. |
| 2     | Very Weak Scientific Evidence  
Evidence based on case reports. |
| 3     | In Vitro Scientific Evidence  
Evidence based on scientific studies conducted on animals, insects or microorganisms OR laboratory studies on human cells. |
| 4     | Indirect Evidence  
Evidence based on scientific theory OR expert opinion. |
| 5     | Unknown  
No available information. |
Synonyms/Common Names/Related Substances


Indications for Use

Acute toxicity studies were done in rats using the ethanolic extract of Hibiscus sabdariffa. The result based on Lorke method showed that Hibiscus sabdariffa has an acute toxicity (LD50) of above 5000 mgkg\(^{-1}\) [7]. The authors concluded that Hibiscus sabdariffa is safe for human consumption even when consumed for a long time [7].

Safety of Consumption during Pregnancy

A number of studies conducted on Spragu-Dawley rats, showed that exposure to extracts of Hibiscus sabdariffa during pregnancy and lactation, caused an increase in postnatal weight, delayed onset of puberty and increased body mass index at onset of puberty in the offspring of the rats [22]. The delayed puberty and increased body mass index in the rat offspring’s are associated with an increase in corticosteroid and a decrease in leptin in the maternal’s breast milk [16].

Safety of Consumption during Lactation

A study was conducted where dams were exposed to extract of Hibiscus sabdariffa during lactation. The extract of Hibiscus sabdariffa, caused a decrease in maternal fluid and food intake [11,23]. There is no clinical evidence to suggest that the delayed puberty and accelerated growth found in animal studies may also occur in humans. However, it is suggested that Hibiscus sabdariffa, should be avoided during pregnancy and lactation (GlobInMed). Hibiscus sabdariffa ethanolic seed extract has a lactogenic effect [7]. Albino rats were given ethanolic extract of the seed of Hibiscus sabdariffa at different doses for six days. At the end of the studies, it was found that there was a dose dependent increase of serum prolactin levels. There were no significant differences between Hibiscus sabdariffa and Metoclopramide in producing prolactin. Its effect on prolactin production, explains its ethno medicinal use as a galactogogue.

Table 3: Indications for Use.

<table>
<thead>
<tr>
<th>Indication</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity [15,16].</td>
<td>B1</td>
</tr>
<tr>
<td>Hypertension [17].</td>
<td>B1</td>
</tr>
<tr>
<td>Effect on lipid profile, creatinine and serum electrolytes [15].</td>
<td>B1</td>
</tr>
<tr>
<td>Hypocholesterolemic [16].</td>
<td>B1</td>
</tr>
<tr>
<td>Antioxidant [19].</td>
<td>B2</td>
</tr>
<tr>
<td>Metabolic syndrome [20].</td>
<td>C</td>
</tr>
<tr>
<td>Diuretic effect [21].</td>
<td>E</td>
</tr>
<tr>
<td>Decreased fluid and food intake-calyces [11].</td>
<td>E</td>
</tr>
<tr>
<td>Muscle relaxant [25].</td>
<td>E</td>
</tr>
</tbody>
</table>

Table 4: Safety of Consumption during Pregnancy.

<table>
<thead>
<tr>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase in postnatal weight gain [11].</td>
</tr>
<tr>
<td>Delayed onset of puberty in offsprings [11].</td>
</tr>
<tr>
<td>Elevated body mass index at onset of puberty in the offspring [32].</td>
</tr>
<tr>
<td>Low toxicity [7].</td>
</tr>
<tr>
<td>Minimal risk (taken as food) [11].</td>
</tr>
</tbody>
</table>
Table 5: Safety of Consumption during Lactation.

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Decreased maternal fluid and food intake in mother [23].</td>
</tr>
<tr>
<td>3</td>
<td>Increase in postnatal weight gain [11].</td>
</tr>
<tr>
<td>3</td>
<td>Low toxicity [7].</td>
</tr>
<tr>
<td>3</td>
<td>Increase in prolactin level [10].</td>
</tr>
<tr>
<td>5</td>
<td>Induce lactation [12].</td>
</tr>
</tbody>
</table>

Parts used

Leaves, fleshy calyx, seed of Hibiscus sabdariffa

Chemistry

Cyanidin-3-O-sambubioside, delphinidin-3-O-sambubioside, gossypetin, glucoside, hibiscin, Hibiscus protocatechuic acid, vitamin A, vitamin C [10,24-26].

Interactions

Hibiscus sabdariffa interacts with chloroquine, acetaminophen, diclofenac [2,27,28].

Pharmacology

Hibiscus sabdariffa lowers blood pressure and blood cholesterol. A randomized study was done on Hibiscus sabdariffa with sour tea of Hibiscus sabdariffa and black tea in type II diabetics with mild high blood pressure. Results showed that the hibiscus tea extract, lowered the average systolic blood pressure (SBP) from 13.4 ±11.8 mmHg to 112.7±5.7 mmHg while the black tea, lowered the average SBP from 118.6 ±14.9 to 127.3 ± 8.7 mmHg [29].

In a double blind and controlled clinical trial that compared the effectiveness, safety and tolerability of Hibiscus sabdariffa extract to pravastatin showed that there was a decrease in triglycerides with a high percentage of safety and tolerability [16,30].

In a randomized, controlled, double-blind clinical study which compared of Hibiscus sabdariffa extract with pravastatin on men and women with hypercholesterolemia ≥220 mg/dL and over for 30 years without previous treatment. Group I, received Hibiscus extract standardized to 10 mg of anthocyanins while group II received Hibiscus extract standardized to 20 mg of anthocyanins for 12 weeks. The control group received 20 mg of pravastatin. 104 participated in the study. The result showed that the experimental I group reduced triglycerides (p ≤0.0001), the control treatment reduced triglycerides, total cholesterol and its fractions (p = 0.02), and finally, the experimental treatment II reduced triglycerides (p = 0.0001). The three treatments showed high percentages (> 96) of safety and tolerability, without showing significant differences (p ≥ 0.57). The control treatment showed the greatest effect on lowering total cholesterol and fractions compared to experimental treatments [16,30].

The level of evidence on the use of Hibiscus sabdariffa during pregnancy and lactation is limited to invitro studies and ethnomedical use. The effect of Hibiscus sabdariffa on reproduction are conflicting, with anecdotal evidence that the plant is an aphrodisiac, while others report that it is estrogenic, and adversely affects spermatogenesis in rats [31]. In some studies H. sabdariffa exerts no adverse effect on the male reproductive system [31].

Consumption of aqueous extracts of Hibiscus sabdariffa, delays the onset of puberty in rats if taken during Juvenile-Pubertal period and lactation [32]. The delayed puberty is proposed to be through increased corticosterone and decreased leptin delivery through breast milk.

Discussion

The seed and calyces of Hibiscus sabdariffa have been shown to possess some beneficial therapeutic effect. There is no strong clinical evidence supporting the use of Hibiscus sabdariffa in pregnancy or during lactation. Based on invitro studies, the aqueous seed extract of Hibiscus sabdariffa produced an increase in serum prolactin in a dose dependent manner in lactating rats. At a dose of 1600 mg/kg the extract, produced a similar lactogenic activity as compared to Metoclopramide treated group (5mg/kg). Studies have shown that the increase in prolactin is due to the presence of steroidal saponins, tannins, alkaloids and flavonoids constituents in the extract [10]. The proposed mechanism through which Hibiscus sabdariffa exerts its lactogenic effect is proposed to be through the dopaminergic pathway [10]. Hibiscus Sabdariffa should be used with caution during lactation. In rats, consumption of the aqueous extract of Hibiscus sabdariffa calyces, during lactation, (P<0.05), caused a decreased maternal fluid and food intake, increased postnatal weight gain and delays the onset of puberty in the female offspring of Sprague-Dawley rats.

No risk has been reported on the use of this herb through its traditional or common use. A more rigorous and well controlled-clinical research is needed before this herb can be used during pregnancy and lactation. The latter is so important in the developing tropical countries where chloroquine is used for the management of malaria.
References


