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REVIEW

Complementary and Alternative Therapies for Pregnant Women Suffering from Constipation: A Systematic Review

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Abstract

Background: Constipation is one of the most common gastrointestinal symptoms in pregnant women.

Purpose: This study was aimed at determining the effects of complementary and alternative therapy methods on the symptoms of pregnancy-related constipation.

Search strategy: The authors performed a systematic search according to PRISMA guidelines. The database Web of Science, Scopus, EMBASE, CENTRAL, national databases were screened to reach studies published from January 2010 to March 2020 with restriction to human studies in English or Turkish language. The quality of the studies included in the study was assessed with the measurement tool proposed in the JADAD, JBI, and Observational Open-Label Studies scales.

Inclusion criteria: Electronic searches were conducted in PubMed using the keywords constipation “pregnancy” or pregnant woman and “acupuncture” or “acupressure” or “massage” or “herbal medicine” or “aromatherapy” or “music therapy” or “homeopathy” or “hypnosis” or “meditation” or “reflexology” or “moxibustion” or “ayurvedic Medicine” or “ayurveda” or “Traditional Iranian Medicine

Data extraction and analysis: Selection of included articles, data extraction and methodological quality assessments were respectively conducted by two review authors.

Findings: 14536 studies were selected and 706 studies were screened based on their titles and abstracts. Seventy-three studies were analyzed in detail to assess whether they were suitable. In order to find a larger number of original articles, of the studies in the reference lists of these studies, those found in the electronic environment were screened, but no studies were found to meet the inclusion criteria. Finally, 3 studies were included in the study.

Conclusions: The results demonstrated that herbal medicine and foot reflexology reduced constipation complaints during pregnancy without any side effects. Because the number of studies conducted to investigate the efficacy and safety of different types of complementary and alternative medicine methods in pregnant women with constipation is very few, more studies should be carried out on the issue.

Key words: Complementary and Alternative Medicine, Pregnancy Care, Constipation

What is already known about the topic: One of the leading complaints during pregnancy is constipation. In recent years, the use of complementary and alternative medicine instead of pharmacological drugs for the alleviation of such complaints has drawn more attention.

What do the results of this study add: Performing a larger number of randomized controlled studies to assess the effects of Complementary and Alternative Therapy methods on pregnancy-related constipation may be effective in reducing the need for pharmacological methods to be used during pregnancy.

What are the implications of these findings for clinical practice and or further research:

Complementary and Alternative Therapies are easy to apply and cost-effective methods and play a significant role in reducing constipation. Performing more studies on the use of CAM methods will provide an alternative option for pregnant women who do not want to resort to pharmacological methods.

INTRODUCTION

Constipation is one of the most common symptoms of gastrointestinal complaints in pregnant women.^{1,2} Pregnancy-related constipation affects the daily life of women negatively.¹ In Rungsiprakan et al.’s systematic review (2015), the rate of constipation

during pregnancy ranges between 11% and 44%.³ According to the results of studies conducted in Turkey, the rate of constipation in pregnant women varies between 38.8% and 47%.^{4,5} The etiology of constipation that occurs during pregnancy is

multifactorial. One of these factors is that the pelvic organs and the structures supporting the urethra (levator ani muscle and anal sphincters) that are primarily responsible for the defecation process undergo changes due to the increase in the internal abdominal pressure during pregnancy.² Another factor is the decrease in bowel movements caused by the increase in the hormone progesterone level during pregnancy. In addition, the enlargement of the uterus, a decrease in the activities of daily living of the mother, stress, taking iron and calcium preparations, inadequate fluid consumption and changes in diet cause constipation more frequently during pregnancy.^{1,6-8} The review of the literature demonstrated that pregnancy-related constipation (both difficult defecation and the feeling of not being able to empty fully) is common in every trimester of pregnancy.⁹⁻¹¹

Among the pharmacological methods used for constipation are the use of stool softeners, prokinetic agents, osmotic agents and stimulant laxatives.^{1,12} These pharmacological methods used during pregnancy can negatively affect the health of both the mother and the fetus.^{1, 13-15} According to clinical guidelines, no clinical recommendations have been made for the treatment of constipation during pregnancy.^{1,12} Today, the choice of treatment for the pregnancy-related constipation remains a challenging clinical problem. The National Center for Complementary and Integrative Health (NCCIH) defines the Complementary and Alternative Medicine (CAM) as a healthcare approach not considered as a part of the general Western or traditional medicine.¹⁶ While the term 'complementary medicine' refers to treatments used together with conventional medical treatments, the term 'alternative medicine' refers to treatments used instead of conventional medical treatments.¹⁶ In many parts of the world, the use of CAM to reduce such problems as nausea, vomiting, labor pain, low back pain, pelvic pain, anxiety etc. occurring during pregnancy is very common. Among the most widely used CAM methods are herbal medicine, acupuncture, acupressure, relaxation therapies, aromatherapy, moxibustion, massage, reflexology and homeopathy.¹⁷⁻²² Although data in the literature on the rates of using CAM in reducing constipation during pregnancy is very limited, the rates of CAM use in pregnancy-related problems are reported to be quite common in developed countries such as America (69%), the United Kingdom (57%) and Germany (51%).²³⁻²⁵ Performing research to reveal the efficacy and safety of CAM methods in reducing

the symptoms of pregnancy-related constipation is a realistic and urgent need.

Many women experience constipation during their pregnancy. Nowadays, interest in non-pharmacological methods has increased, rather than pharmacological methods, in reducing this constipation that develops due to pregnancy. Especially, it is very important for midwives in every period of women's life to know what CAM methods are. That's why in this systematic review, it was aimed to focus on articles analyzing the effectiveness of CAM methods used to reduce symptoms pregnancy-related constipation.

MATERIALS AND METHODS

Design

This study is a quantitative systematic review in which the PRISMA guidelines were used for the analysis of the studies.²⁵ These guidelines ensure a clear and transparent review of the articles included in the study in terms of their integrity. This study focused on articles analyzing the effectiveness of CAM methods used to reduce symptoms pregnancy-related constipation.

After the duplicate articles were removed, the study was carried out through a three-stage inclusion process:

1. Screening relevant articles according to their titles and abstracts,
2. Selection of articles based on the reading of the entire text,
3. Analysis of the texts

These 3 stages were analysis by at least two of the three referees independently of each other, one of whom not included in the study (AŞK, SD, NÇD)

Search methods

The study was carried out between January 2010 and March 2020 by retrospectively screening the publications that analyzed the effectiveness of CAM methods used to reduce pregnancy-related constipation. For this purpose, the databases were screened over the internet access networks of Kocaeli University and Kırklareli University using the following keywords: constipation [MeSH Terms and free text terms] and (pregnancy [MeSH Terms and free text terms] or pregnant woman [MeSH Terms and free text terms] and ("Acupuncture" or "Acupressure" or "Massage" or "Herbal medicine" or "Aromatherapy" or "Music therapy" or "Homeopathy" or "Hypnosis" or "Meditation" or "Reflexology" or "Moxibustion" or "Ayurvedic Medicine" or "Ayurveda" or "Traditional Iranian Medicine") .

Search outcomes

Original studies which met the following inclusion criteria were included in the study:

1- Randomized design, quasi-randomized trial, non-controlled and non-randomized prospective studies

2- Published in English or Turkish

3- Published between January 2010 and March 2020

4-Interventions pregnancy-related constipation associated with one of the aforementioned CAM methods

5- Outcome measure which was focused on changes in constipation with one of the aforementioned CAM methods

Quality appraisal

The quality appraisal of the studies was performed in accordance with the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green, version 5.1.0, updated in March 2011).²⁷. Therefore, after the selection of each study, the quality of the studies was rated using different methods to evaluate different study designs.

Assessment of the risk of bias is part of conducting and reporting of any systematic review. In this context, the JADAD checklist was used to assess the risk of bias and the quality of randomized controlled trials in each study.²⁸ This scale consists of 3 items: describing randomization, blinding and accountability (dropouts and withdrawals).

Scoring: If randomization was mentioned in the study, it was given 1 point and if the study was consistent with the randomization method, it was given 1 point. However, if the study was not consistent with the randomization method, 1 point was subtracted.

Blinding: One point was given if blinding was mentioned. Another 1 point was given if it was consistent with the blinding method. If not, 1 point was subtracted.

Finally, we assigned 1 point if the accountability was known; if there were no data, the reason should have been stated. In the Jadad rating, scoring ranges between 0 and 5 points. If the Jadad score was ≥ 3 points, the study was considered a high-quality study, and if it was ≤ 2 points, the study was considered a low-quality study.²⁸⁻³¹

Similarly, the CONSORT checklist was used to assess the quality of study report. This quality assessment includes the following: identification of the structured abstract and title to find out whether the study was a randomized study, the rational and scientific background and description of the goals or hypothesis, the definition of research design and important changes, the criteria for the compliance

with participants and the study environment, interventions including replication details for each group, results and changes in the results, sample size and interim analysis and stop guides, explanation of randomization, blindness and similarity of interventions, statistical methods and additional analyses, participant flow, losses and exclusions, recruitment and reasons for stopped trial, basic data, numbers analyzed, results, estimation and binary outcomes, subsidiary analysis, losses, limitations, generalization and interpretation. Studies that did not meet at least 70% of the items included in the CONSORT checklist were considered to contain significant methodological flaws.

In this systematic review, the quality of quasi-randomized trial was assessed using the JBI Checklist.⁴³ This measuring tool consists of 10 items. The JBI checklist is used to assess whether the following criteria are met in studies: cause and effect relationship, presence of a control group, whether the treatment and control groups undergo the same application, the number of variables examined before and after the intervention, exact definition of the follow-up process, whether the variables in the two groups are evaluated with the same measurement method, same measurement methods for the variables in the two groups, whether the appropriate statistical tests are used and whether the overall assessment is made. Whether the criteria are met or not is determined with the following options: "Yes", "no", "unclear" and "not applicable".

In addition, because there is no quality assessment scale to rate non-randomized, non-controlled and prospective observational studies, a scale was developed to assess the quality of the studies based on the criteria list proposed by the Observational Open-Label Studies scale. The scale consists of 12 items. Whether the criteria were met or not was assessed with the "yes", "no" or "unclear" options. If a study met 9 or more of the 12 criteria, the study was considered to have a low risk of bias (RoB) and to be a high-quality study. If 6 to 8 of the 12 criteria were met, the study was considered to have a moderate RoB and to be a medium quality study. If only 5 or fewer of the criteria were met, the study was considered to have a high RoB and to be a low quality study.

Data extraction

The document included the following data: type of the CAM, name of the study, authors / publication year of the study, country where the study was conducted, type of study, place of study, inclusion criteria for the study and participants' age and gestational age,

sample size, data collection tools, details of the intervention, and results.

RESULTS

Study selection

For the review, 14536 studies were selected. Of hem, 706 were excluded because they were not in English or Turkish, or they were duplicates. As a result, 706 studies were screened based on their titles and abstracts. Seventy-three studies were analyzed in detail to assess whether they were suitable by two of the authors. They determined whether the title and abstract met the inclusion criteria.

In order to find a larger number of original articles, of the studies in the reference lists of these studies, those found in the electronic environment were screened, but no studies were found to meet the inclusion criteria. In case of disagreement between the authors, the referees reached a decision after discussing the matter. In case they did not reach a decision, the opinion of the third referee who was not involved in the study was asked.

Finally, 3 studies were included in the study. The process was illustrated in a flow diagram in Figure 1. Detailed information of these 3 studies was summarized in Table 1.

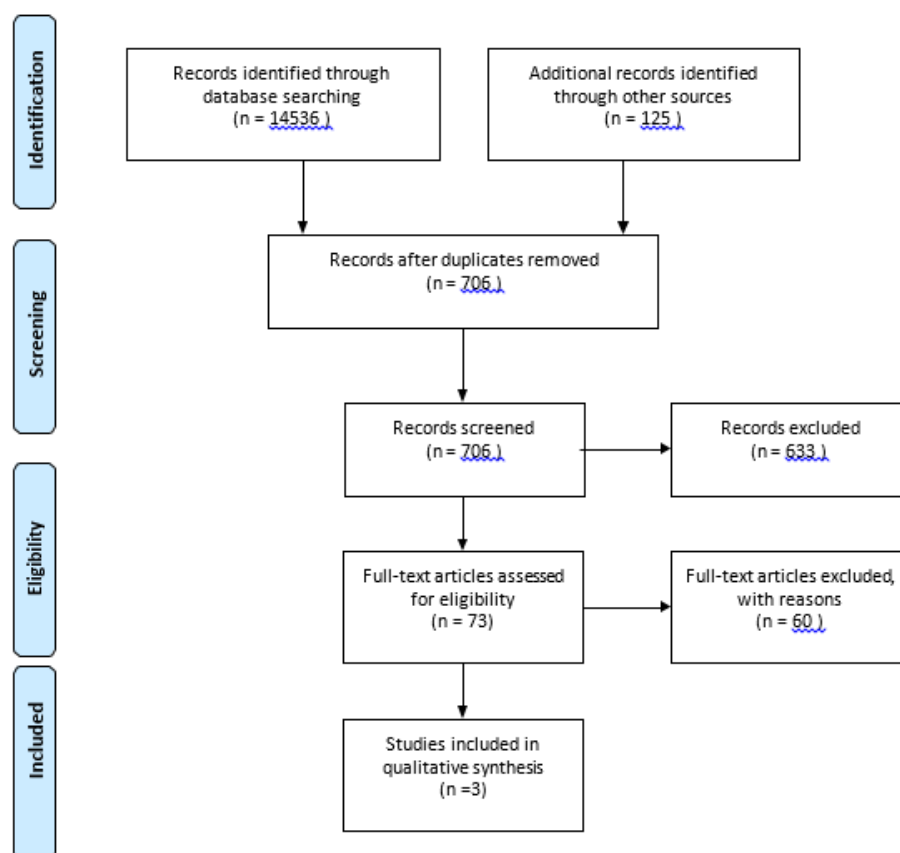


Figure 1. Study selection process.

Study characteristics

We reached the final stage on these 3 studies conducted between January 2010 and March 2020 to investigate the effects of CAM methods on women suffering from constipation during pregnancy. These studies were a randomized controlled trial (RTC), a quasi-experimental studies and non-randomized, non-controlled and prospective observational study conducted on herbal medicine (n = 2) and reflexology (n = 1). The number of the participants in the samples of the studies varied between 20 and 74. The ages of the pregnant women participating in them ranged between 16 and 45.

One of the 3 studies was a RTC whose quality was assessed using the JADAD checklist. The score range of this study was ≥ 3 . One of the remaining 2 studies was a quasi-experimental study. Its quality was assessed using the JBI checklist. The third study was a non-randomized, non-controlled and prospective observational study. Its quality was assessed using the Observational Open-Label Studies Scale. The study met 11 of the 12 criteria. Therefore, it was considered a high quality study because its RoB was low. All the 3 studies were included in the study according to the items studied.

Table 1. Complementary and alternative therapies for pregnant women suffer from constipation: a systematic review.

Complementary and alternative therapies for pregnant women suffer from constipation: results of a systematic review of randomized trials										
Type of CAM	Title of manuscript	First Author Year	Country	Type of study	Place	Gestational weeks/ Included criteria	Age	Sample size	Tools of data	Treatment arm
Herbal Medicine (Daikenchuto)	Efficacy and safety of daikenchuto (TJ-100) in pregnant women with constipation	Tsuda et al., 2016 [31]	Japon	Prospective Observational Open-label trial (A prospective interventional one-arm study)	Hospital	-14-28 w - Suffering with constipation during pregnancy period.	-Unclear	20	Constipation assessment scale (CAS)	The patients received 7.5 g/day of daikenchuto for 28 days from the day of registration.
Herbal Medicine (Glucamana)	The effect of glucomannan on pregnancy constipation	Janani and Changase , 2018 [32]	Iran	Non randomized control study	Hospital	- Unclear gestational weeks - Suffering with constipation during pregnancy period.	-Unclear	64	Questionnaire (demographi reproductive characteristic, information about constipation).	-4 g of powdered glucomannan in two divided doses of morning and night with a glass of water.
Foot Reflexology	The effect of short-term foot reflexology in improving constipation symptoms during pregnancy: A two-armed, randomized controlled trial	Sebbati et al., 2020 [33]	Iran	Randomized blinded control trial study	Health care centers	-23-28 w -Having a score of 9 to 16 based on a CAS	16-45 years of age	74	-Constipation Assessment Scale (CAS). - State-Trait Anxiety Inventory (STAI)	-Foot reflexology was performed for a short period of time for 6 weeks for 12 minutes.

Interventions characteristics

Of the CAM methods, herbal medicine was used in two of the 3 studies included in the study, and reflexology was used in the third one.

Herbal medicine Intervention

Two of the 3 studies included in our review were on herbal medicine interventions. One of them was a Prospective Observational Open-label trial (A prospective interventional one-arm study) conducted by Tsuda et al. (2016), in which Daikenchuto (TJ-100), a traditional Japanese herbal medicine, was used.³² The sample of this study performed in Japan comprised 20 pregnant women whose gestational age ranged between 14 and 28 weeks. The “Constipation assessment scale” (CAS) was used to assess constipation in the participating women. Daikenchuto (7.5 g / day) was administered to the participating pregnant women for 28 days. At the end of the study, Daikenchuto was determined to be effective and reliable in reducing the symptoms of constipation during pregnancy. The study was rated using the Observational Open-Label Studies scale and was given 11 points out of 12.

The other 2 studies in which herbal medicine interventions were used was a non-randomized control study conducted by Janani and Changae (2018).³³ They administered a plant called Glucomannan used in various diseases to the patients. In this study conducted with 64 pregnant women in Iran, the questionnaire (demographic and reproductive characteristics of the participants, information about constipation) created by the researchers was used to assess constipation in pregnant women. In the study, the participants in the experimental group drank a glass of water including glucomannan. The total dose (4 g / day) of glucomannan was divided into two and administered twice a day in the morning and in the evening for one month days. The participants in the control group were given 1 tablespoon of magnesium hydroxide every night for one month. At the end of the study, it was stated that glucomannan was quite effective in the treatment of pregnancy-related constipation with no serious complications. The study was rated using the JBI checklist and was given 5 points out of 9.

Reflexology intervention

The third of the 3 studies reviewed was a study of foot reflexology. The study conducted by Sehhatti et al. (2020) is a randomized blinded control trial study.³⁴ The study sample comprised 74 Iranian pregnant women aged between 16 and 45 year. Their gestational age ranged between 23 and 28 weeks. In the study, the Constipation Assessment Scale (CAS) and State-Trait Anxiety Inventory (STAI) were used

to assess constipation and other symptoms suffered by the participants. Those with a CAS score of 9-16 were especially included in the study. The participants in the experimental group underwent a 12-minute foot reflexology session per week for 6 weeks. The participants in the control group were given standard care. At the end of the study, foot reflexology was determined to decrease pregnancy-related constipation and anxiety. The study was rated using the JADAD checklist and was given 4 points out of 5.

DISCUSSION

This systematic review was conducted to determine the effects of CAM methods such as herbal medicine and reflexology on reducing constipation during pregnancy. Our review included 3 studies conducted in 2 countries between January 2010 and March 2020 with 158 pregnant women suffering from constipation. Of the 3 studies, 1 was about the use of foot reflexology and 2 were about the use of herbal medicines.

In one of the 2 studies about the use of herbal medicines, Daikenchuto (TJ-100), a traditional Japanese herbal medicine, was administered. This herbal extract consists of four active ingredients, including processed ginger, ginseng, Japanese zanthoxylum bark and koi (maltose powder). In the literature, Daikenchuto plant is known to affect gastrointestinal motility and microcirculation and to have anti-inflammatory effect.^{35,36} In a prospective randomized controlled study conducted with 39 patients with esophageal cancer in Japan, treatment with Daikenchuto was found to improve gastrointestinal motility after esophageal cancer resection.³⁶ According to Hosaka et al.’ meta-analysis (2019), daikenchuto, administered to patients with gastrointestinal system cancer in the postoperative period, was determined to improve intestinal dysfunction.³⁷ In a study conducted with 22 patients with chronic constipation, daikenchuto reduced constipation-related bloating and abdominal pain.³⁸ The results of another study conducted with 34 patients with stroke suffering from constipation problems revealed that daikenchuto could treat functional constipation, improved clinical constipation scores and decreased the intestinal gas volume.³⁹

While there are no domestic (Turkish) studies on the use of CAM methods to reduce the symptoms of pregnancy-related constipation, there are many studies conducted abroad, but these studies included small sample sizes. In order for the applications to

have evidence-based value, randomized controlled experimental studies to be conducted in the future should have larger samples.

Glucomannan is one of the medicinal herbs widely used in the treatment of various diseases. This plant prevents stool from hardening, prevents the retention of feces in the rectum, and thus increases bowel movements.^{33,40} In the literature, although there are several studies indicating the effect of glucomannan on the symptoms of constipation especially in children,^{41,42,44} there is only one study investigating its effect on pregnant women.³³ In Staiano et al.'s randomized controlled study conducted with 20 pediatric patients with a brain injury (2004), glucomannan increased the frequency of defecation (stool frequency), but had no effect on the colon motility.⁴² In their experimental study conducted with 31 children suffering from chronic constipation (2004), Loening-Baucke et al. found that glucomannan was effective in the treatment of constipation.⁴¹ In their systematic review including 8 studies conducted with children (2017), Han et al. reported that glucomannan moderately increased the frequency of defecation in children with constipation, but did not decrease stool consistency or did not lead to a general improvement in the treatment success.⁴⁴ Although the results of these studies indicate that glucomannan had positive effects, side effects of glucomannan remain unknown due to the small sizes of the samples. Therefore, given the small sample size and the risk status of the side effects, the results of these studies should be interpreted more carefully. The third study included in our review was a study of foot reflexology. Reflexology is a massage technique applied to the hands, soles of the feet and ears under certain rules.⁴⁵ Reflexology is a non-invasive and safe intervention method. The review of the literature demonstrated that reflexology reduced pain, anxiety, depression, fatigue, symptoms related to gastrointestinal tract and constipation, and improved immune functions, and quality of sleep and life.^{46,47} In Sajadi et al.'s randomized controlled study conducted with 63 patients with multiple sclerosis (MS) who underwent foot reflexology (2020), this method was found to reduce the symptoms of constipation.⁴⁷ Similarly, in another study performed with 40 children with cerebral palsy suffering from constipation, foot reflexology helped relieve constipation.⁴⁵ In their study (2017), Canbulat and Demirgoz reported that foot reflexology did not make a statistically significant difference in stool consistency and the number of defecation in 37 children with functional constipation.⁴⁶ The number

of studies investigating the effect of foot reflexology on constipation is rather limited, and what is more, these studies included small sample sizes. In addition, in the literature, there is no systematic review or meta-analysis investigating the effect of foot reflexology on constipation

Limitations

The main problem encountered during our review was that the studies were very few. There was no study conducted on each CAM therapy. The studies available differed from each other in terms of the method investigated and sample sizes. In addition, due to language limitation, not all studies were reached. Therefore, the review was completed with 3 clinical studies.

Strengths

This study evaluating CAM methods for reducing the symptoms of pregnancy-related constipation is the first high-degree systematic review in terms of the period in which the articles were published, the number of studies examined and the number of databases. The most noteworthy strength of the study was that it revealed that the number of studies on the effects of CAM on the reduction of the symptoms of pregnancy-related constipation was very few, and that in the future, on this issue, more studies with larger samples should be conducted.

CONCLUSION

Diagnosis and treatment in CAM is often complicated. Although the duration of interventions for each CAM method was determined in some studies, this cannot be generalized to all CAM treatments. Today, in the medical literature, more studies should be carried out to provide evidence of molecular biology for the use of CAM methods in individual diagnosis and intervention within the framework of the concept of "Individualized Medicine".⁷ CAM methods used in reducing the symptoms of pregnancy-related constipation differ from one study to another, in terms of the type of the study, and the application method, measurement tools and assessment methods used in the study. This systematic review of 3 studies (2 on the use of herbal medicine and 1 on the use of foot reflexology) demonstrated that the methods used in these 3 studies were effective in reducing the symptoms of pregnancy-related constipation. In order to provide valid evidence on the long-term safety of CAM applications, a large number of well-designed randomized controlled trials with larger samples should be performed in the future.

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