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Black elderberry (*Sambucus nigra*) supplementation effectively treats upper respiratory symptoms: A meta-analysis of randomized, controlled clinical trials

Jessie Hawkins*, Colby Baker, Lindsey Cherry, Elizabeth Dunne

Franklin Institute of Wellness, 504 Autumn Springs Court, Franklin, TN, 37067, United States

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ABSTRACT

Upper respiratory symptoms are often treated with over the counter drugs, antibiotics, and antiviral medications. Due to concerns about safety and efficacy, there is a demand for an alternative solution. Black elderberry (*Sambucus nigra*) has been used to treat cold and flu symptoms, but there are no large-scale studies or meta-analyses. This meta-analysis quantifies the effects of elderberry supplementation and evaluates moderators including vaccination status and the underlying pathology.

This analysis included a total of 180 participants and evaluates moderators such as vaccination status and cause of the upper respiratory symptoms.

Supplementation with elderberry was found to substantially reduce upper respiratory symptoms. The quantitative synthesis of the effects yielded a large mean effect size. These findings present an alternative to antibiotic misuse for upper respiratory symptoms due to viral infections, and a potentially safer alternative to prescription drugs for routine cases of the common cold and influenza.

1. Introduction

Cough, nasal congestion, nasal discharge, sore throat, and other upper respiratory symptoms are signs of infection, often from winter viruses such as the common cold (typically due to rhinovirus) and influenza. Each year, Americans experience between 9.2 and 35.6 million cases of influenza, and approximately 2–3 cases of the common cold per adult and 5–7 cases per child.[1,2]

These cold and flu symptoms are often treated with over the counter drugs, though prescription drugs, such as oseltamivir, zanamivir, or peramivir may be prescribed for documented cases of influenza. To achieve efficacy, these drugs should be taken within the first 2 days of illness. However, questions have been posed regarding the safety and efficacy of these drugs, particularly among children due to findings from post market surveillance.[3] Resistance to some of these prescription drugs has also been documented, leading to questions regarding the sustainability of these medications.[4]

Cold and flu symptoms are also be treated with antibiotics. Between 2006–2007, approximately 28.6% of outpatient visits with a diagnosis of the common cold were treated with antibiotics.[5] This practice persists despite warnings from public health agencies that antibiotics are not beneficial for viral infections such as the common cold or influenza.[6] This misuse of antibiotics contributes to the rise of antibiotic resistant bacterial infections.

As a result of both the widespread prevalence of upper respiratory symptoms and a lack of sustainable and effective options to treat these conditions, there is a clearly established need for an easily accessible and effective treatment for upper respiratory symptoms.

The berries of the black elder plant (*Sambucus nigra*) have been traditionally used to address cold and flu symptoms. [7,8] The berries have demonstrated antiviral activity against certain viruses which experience an increase in incidence during the winter months, including the common cold and influenza, in both in-vitro and in-vivo models.[9,10,11]

Elderberries contain many active chemicals, including anthocyanins (primarily cyanidin 3-glucoside and cyanidin 3-sambubioside), which have been shown to boost immune function and exhibit anti-viral effects.[12,13] Oral ingestion of elderberry results in detectable levels of these anthocyanins in blood plasma.[14]

As a result, elderberry supplementation has become a popular home remedy for upper respiratory symptoms, and industry predictions indicate that demand is continuing to rise.[15] Existing clinical research on the effects of elderberry supplementation for upper respiratory symptoms is based on small clinical trials. While reviews of these small

* Corresponding Author.
E-mail address: j.hawkins@franklininstituteofwellness.com (J. Hawkins).

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studies exist, there are no large-scale studies on the impact of elderberry supplementation, and no meta-analyses to quantify effect size or evaluate moderator variables.

This is the first meta-analysis on the effects of elderberry supplementation on upper respiratory symptoms. The purpose of this study is to quantify the effect size for elderberry supplementation for upper respiratory symptoms and to analyze moderator variables of vaccination status and underlying pathology that may influence that total effect size.

2. Methods

The search for literature concluded in September 2018, and included PubMed, Google Scholar, and Science Direct. In an attempt to identify any unpublished papers, including dissertations and rejected papers, the authors also manually searched the citation section of published studies, related papers and presentations, and herbal medicine databases.

Terms for the search included various combinations of these words: elderberry, sambucus, influenza, flu, respiratory, cough, and cold. While the general search included combinations of those terms, the terms elderberry and sambucus were also searched individually. To ensure that all potential studies were included, no search limitations or publication date limitations were applied to the search.

2.1. Study selection and eligibility

Inclusion criteria were applied to the search results to identify which studies would be suitable for this analysis. Studies to be included must be randomized controlled clinical trials with human subjects. Studies conducted on primates or other animals were excluded.

This analysis was restricted to studies that used elderberry supplementation as the primary intervention with upper respiratory symptoms as the primary outcome. There was no restriction on the cause of these symptoms or a requirement for a diagnosis from the symptoms. Studies on elderberry supplementation with outcomes including cytokines, anti-inflammatory activity, or its effects on lipid profiles are available in the literature but were not included in this analysis.[16–19] Additionally, a study which evaluated the effects of an elderberry and echinacea hot drink was excluded because the treatment was a combination.[20]

The search produced 137 total studies. After evaluation for inclusion criteria, 131 studies were excluded. After evaluating the remaining studies, a total of four articles were included in this analysis.[22–25] (See Fig. 1: PRISMA Flow Chart) After potential studies were identified, studies were coded according to the inclusion characteristics, patient demographics, and research methodology. Each study was coded by two authors, then results were compared for inter-coder reliability. Reliability was found to be 100%.

2.2. Measurement

All four studies utilized a self-reporting instrument to measure upper respiratory symptoms ranging from fever to sinus congestion. Three of the studies utilized a visual analog scale (VAS). The Tiralongo study used the Jackson scale, which differentiates between symptoms which are consistent with the common cold and symptoms from other causes.[21] Symptoms were measured at baseline and at least once per day while symptoms were present.

Tiralongo evaluated the preventive effects of elderberry supplementation on 312 total participants. Twenty-nine of these patients developed upper respiratory symptoms which were classified by the Jackson scale as a cold. Because the purpose of this analysis is to evaluate the treatment effects of elderberry supplementation and symptom severity or duration does not exist for the participants who did not become sick, only the 29 patients with upper respiratory symptoms were included in this analysis.

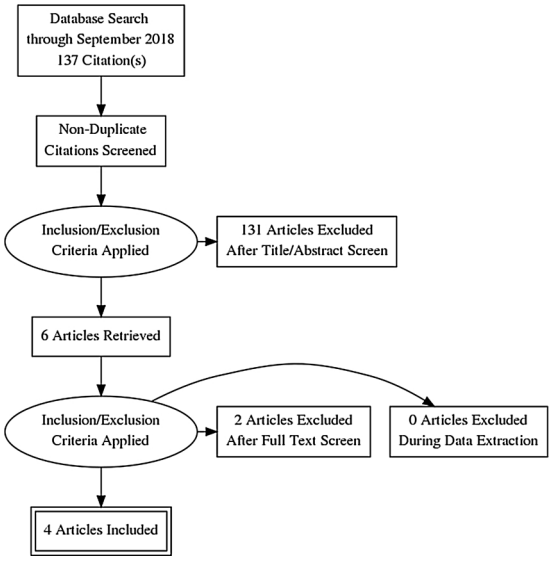


Fig. 1. PRISMA Flow Chart.

Three of the studies (Zakay-Rones 1995, 2004; Tiralongo, 2016) evaluated total duration of upper respiratory symptoms. Kong (2009) measured symptoms throughout a 48 h intervention across 6 symptom scales which were converted into a single score for the purposes of this analysis. Effect sizes were calculated from the symptom duration and the severity post-test scores to conduct the analysis.

2.3. Summary measures and effect size calculation

Two of the studies included in the analysis only provided a mean duration for the presence of symptoms. However, data for these studies was available through other forms in the article and these data were used to calculate the mean and standard deviation for the total period of upper respiratory symptoms.

These data were entered into Comprehensive Meta Analysis version 3 for the final analysis. Unbiased standardized difference in means was calculated using the duration of symptoms and the symptom severity score. A random effects model was used due to clear heterogeneity of the studies ($I^2 = 83.12$). Publication bias was analyzed using an Eggar's analysis, a funnel plot, and Tweedie's Trim and Fill.

2.4. Moderator analyses

Two of the most common causes of upper respiratory symptoms include the common cold and influenza viruses. The Zakay-Rones studies identified laboratory-confirmed influenza as the cause of upper respiratory symptoms in the their patients. Kong evaluated upper respiratory symptoms which are consistent with an influenza diagnosis. The Tiralongo study evaluated upper respiratory symptoms which are consistent with the common cold. To evaluate a potential difference in effect size due to the cause of the upper respiratory symptoms, a moderator analysis comparing the underlying condition was conducted.

Those who receive the flu vaccine have been found to experience a reduction in the duration and severity of influenza symptoms as compared to those who do not receive the flu vaccine.[26,27,28] Two of the studies excluded patients who had received the flu vaccine. The other two only excluded patients who had received the vaccine just before the start of the study. To evaluate the potential for vaccination status to influence the duration of upper respiratory symptoms, the moderator of vaccine status was used to conduct an additional analysis.

Table 1
Study Results.

Study Name	Flu Vaccine?	*n* (Treatment /Control)	Cause of Symptoms	Cohen's d	SE
Zakay-Rones, 2004	no	30/30	influenza	2.008	0.317
Kong, 2009	unknown	30/30	influenza	2.767	0.350
Zakay-Rones, 1995	no	15/12	influenza	1.360	0.429
Tiralongo, 2016	unknown	12/17	common cold	0.662	0.387

3. Results

Results from the four studies included in this analysis are summarized in Table 1. This analysis included 89 participants in the elderberry group and 91 participants in the control group for a total of 180 participants. Moderator variables, including flu vaccination status and type of underlying illness are also reflected in Table 1.

All four studies included a balanced distribution of both males and females, but none of them analyzed the outcomes by sex. The 1995 Zakay-Rones study included children, with a total age distribution of 5 years to 56 years, while the other three studies only included adults with a total age distribution of 18 years to 59 years. None of the studies analyzed outcomes by age. As a result, moderator analysis by age and sex could not be conducted.

Overall, 4 effect sizes were calculated from the studies. The effect sizes and Forest Plot are reflected in Table 2. The quantitative synthesis of the effects yielded a large mean effect size of 1.717 (*SE = 0.447; 95% CI: 0.840-2.593*), p = < .001, using a random effects model. This indicates that supplementation with elderberry substantially reduces the duration of upper respiratory symptoms.

Significant heterogeneity was identified (I^2 *= 83.12; P = < .001*) among the four studies included in the analysis. Therefore, a random effects model was used to evaluate the effect of elderberry supplementation on upper respiratory symptoms, and moderator variables were analyzed.

3.1. Cause of upper respiratory symptoms

Three of the studies evaluated the effects of elderberry supplementation on either verified cases of influenza or cases with symptoms consistent with influenza infection. The other study evaluated the effects of elderberry on symptoms consistent with the common cold. The criterion for categorization for this analysis was the type of underlying viral infection.

The moderator analysis revealed that elderberry supplementation reduces upper respiratory symptoms from both viral infections, but is more effective at reducing duration and severity of upper respiratory symptoms from influenza with a weighted effect size of 2.074 (*SE: 0.383; 95% CI: 1.323–2.824; P = < .001*) than for symptoms caused by the common cold, which has a weighted effect size of 0.662 (*SE: 0.387; 95% CI:* -0.096 - *1.421; P = .087*).

A test of heterogeneity revealed an I^2 of 70.085 (*P = .035*). This reflects a reduction from the whole group analysis, but remains within the classification of moderate heterogeneity. Random effects were used for both groups in this moderator analysis. The type of underlying condition (common cold vs influenza) does appear to affect the efficacy of elderberry supplementation.

3.2. Vaccination status

For the moderator analysis of flu vaccination status, studies were classified according to known flu vaccination status. Two of the studies excluded patients who had received a flu vaccine. The other two studies only excluded patients who had been recently vaccinated, with the flu-vaccine status of the patient population unknown.

This moderator analysis did not find that flu vaccination status was related to the overall effect of elderberry supplementation on upper respiratory symptoms. The effect size among patients who did not have the flu vaccine was 1.749 (*SE:0.317; 95% CI: 1.127–2.370; P = < .001*). The effect size in studies which combined patients who did and did not have the flu vaccine was 1.721 (*SE:1.053; 95% CI: -0.342 - 3.786; P = < .102*) using a random effects model.

This increased homogeneity (I^2 = 32.129 P = .225) among the unvaccinated group with a more precise confidence interval, but the group with unknown vaccination status still had considerable heterogeneity (I^2 *93.861; P < .001*). Elderberry supplementation appears to be equally effective among patients who did and who did not receive the flu vaccination.

3.3. Bias across studies

Publication bias is a known problem in scientific research. The authors have attempted to address this concern by searching for unpublished and rejected works. Because all of the included studies were published works, analysis of publication bias and modified point estimates were conducted.

An Eggers analysis did not find publication bias. This is shown in Fig. 2, which includes a funnel plot with Duval and Tweedie's Trim and Fill. The modified point estimate was 1.717, which matches the original analysis.

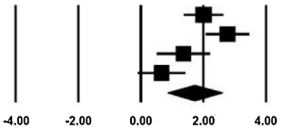
3.4. Bias within studies

The full 27-item Downs and Black checklist was used to assess bias within each of the four studies. The mean score was 21, indicating a low risk of bias within studies. The most common finding was failure to report power or justification for sample sizes. Studies in this analysis also failed to identify whether the analysis was intent to treat or actual treatment.

Funding sources were disclosed for three of the four studies. Each of these three studies were funded by elderberry supplement manufacturing companies. The fourth study (Zakay-Rones, 1995) did not

Table 2
Effect Sizes and Forest Plot.

Study Name	Std diff in means	Standard error	Variance	Lower limit	Upper limit	z-value	p-value	Standard Difference in Means and 95% Confidence Interval
Zakay-Rones, 2004	2.008	0.317	0.100	1.387	2.628	6.340	< 0.001	
Kong, 2009	2.767	0.350	0.122	2.082	3.453	7.912	< 0.001	
Zakay-Rones, 1995	1.360	0.429	0.184	0.519	2.201	3.169	0.002	
Tiralongo, 2016	0.662	0.387	0.150	−0.096	1.421	1.712	0.087	
	1.717	**0.447**	**0.200**	**0.840**	**2.593**	**3.839**	**< 0.001**	



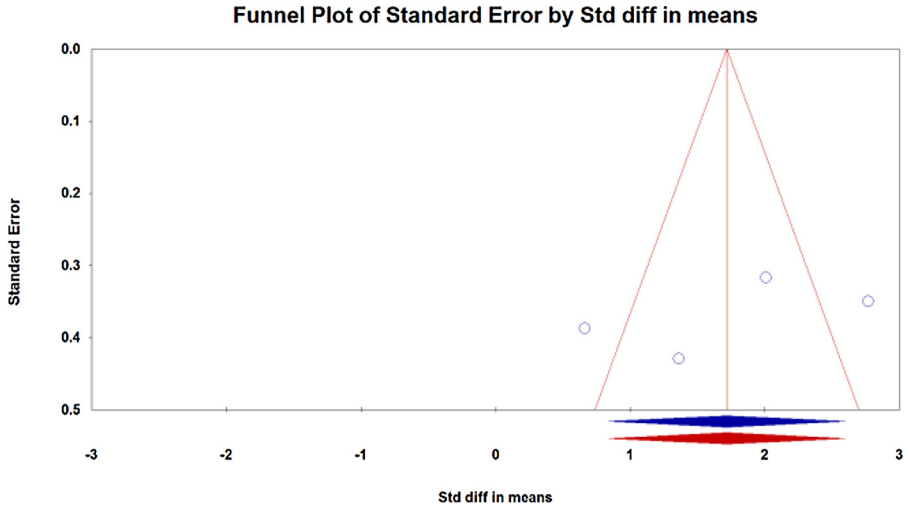


Fig. 2. Funnel Plot with Trim and Fill.

disclose funding sources, but used the same commercial product that funded a later study by the same lead author.

4. Discussion

This meta-analysis provides evidence that elderberry supplementation at the onset of upper respiratory symptoms substantially reduces overall symptom duration as compared to a control group, with an effect size of 1.717. Flu vaccination status does not significantly alter the effects of elderberry supplementation (*ES: 1.721; ES: 1.749*). Elderberry supplementation appears to reduce symptoms caused by influenza virus (*ES: 2.074*) substantially more effectively than upper respiratory symptoms caused by the common cold (*ES: 0.662*).

The results on varying underlying pathology should be interpreted cautiously as this analysis only includes one study on elderberry supplementation for the common cold. Additionally, while the effect on influenza symptoms (2.074) far exceeds the standard for a large effect, the effect on cold symptoms (0.662) is still within the standard for a medium effect. This indicates that elderberry supplementation produces a medium to large reduction in upper respiratory symptoms regardless of pathology.

Elderberry supplementation is available as a commercially prepared standardized product that does not require a prescription. It provides an effective treatment option when advanced or more invasive care is not warranted.

4.1. Safety

Elderberries contain cyanogenic glycosides (i.e. sambunigrin) which are hydrolyzed to hydrogen cyanide (HCN) in the gastrointestinal tract.[29] Ingestion of uncooked products from elderberry species in the United States have resulted in poisoning and hospitalization.[30] Smaller doses of these glycosides do not typically result in hospitalization, but can produce gastric complaints, such as nausea, vomiting, and diarrhea, particularly in children.[31]

The berries of the fruit contain the lowest levels of cyanogenic glycosides as compared to other parts of the plant, and the total concentration of cyanogenic glycosides in the berries can vary depending on growing conditions.[32] The unknown quantity of cyanogenic glycosides in elderberry fruit may pose a risk when medicinal elderberry preparations are produced at home. HCN is volatile, so the risk of toxicity is eliminated when the berries are cooked or otherwise exposed to heat, making sufficiently cooked elderberry products safe to consume.[33] To prepare a product that is safe for consumption, heat must be applied to the berries with sufficient evaporation to release the compounds from the elderberry product.

A review of popular elderberry recipes indicates that many homemade products do not include the heat and evaporation required to alleviate this risk. The authors caution that an increase in the use of homemade products could result in increased prevalence of gastric complaints that accompany upper respiratory conditions among the general population.

The studies in this analysis used commercially prepared products. Researchers monitored for adverse effects, and nausea and vomiting were not reported during the study period for any of the participants in these trials.

4.2. Limitations

The total number of randomized controlled studies for this analysis was small, representing only 180 total patients. Additional research should be conducted on the effects of elderberry supplementation on upper respiratory symptoms, particularly with symptoms specific to the common cold.

While study authors did provide total sex distribution among the two groups, sex-specific analysis was not available. Future research should provide sex-specific results so that the influence of sex on supplementation outcomes can be evaluated.

4.3. Conclusion

Supplementation with a standardized elderberry extract is significantly effective at reducing the total duration and severity of upper respiratory symptoms, as compared to a placebo group. The effect of elderberry supplementation is larger among cases of the flu than the common cold, but supplementation successfully reduces the symptoms regardless of underlying cause. These findings present an alternative to antibiotic misuse for upper respiratory symptoms due to viral infections, and a potentially safer alternative to prescription drugs for routine cases of the common cold and influenza.

5. Declarations of interest

The authors confirm that they do not have any financial interest in the subject matter researched in this manuscript.

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