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Review Article

Berberine: A Complementary Supplement for Weight Loss

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Abstract

Berberine, a botanical dietary supplement, is currently being marketed in the United States as a weight loss supplement in various dosage forms, including tablets, capsules, and gummies. A literature review was conducted to evaluate the safety and efficacy of berberine as a pharmacologic option for weight loss. Four published systematic reviews and/or meta-analyses of human clinical trials were identified and reviewed. Data related to dosage, duration of therapy, and efficacy and safety outcomes were included in the review. Results from clinical studies indicate that berberine is a safe and well-tolerated supplement that may support weight loss efforts. Studies revealed that berberine, used at a dose of ≥ 1 gram daily for a minimum of 12 weeks, produces statistically significant reductions in waist circumference and body mass index (BMI), and modest reductions in total body weight. Studies also revealed that berberine supplementation is associated with significant improvements in dyslipidemia indices and lipid profiles, insulin resistance, glycemic control, and inflammatory markers, which may help prevent obesity and metabolic syndrome through regulation of glucose homeostasis and lipid metabolism, and may contribute to improved clinical outcomes in patients with metabolic disorders. In addition, berberine has been shown to exhibit a favorable safety profile with minimal gastrointestinal adverse effects that are usually self-limiting. Current clinical evidence supports the use of berberine supplementation as a complementary or adjunct therapy for weight loss. The use of berberine as primary therapy for weight loss is not recommended due to its modest effects on total body weight. Pharmacists must play a key role in counseling patients on the safety and efficacy of berberine for weight management and how to optimize their supplementation.

Keywords: *Berberine; Weight Management; Weight Loss; Obesity; Metabolic Disorders; Metabolic Syndrome; Dietary Supplement; Complementary Therapy*

Introduction

Berberine is a naturally occurring isoquinoline alkaloid extracted from the roots, rhizomes, and bark of several medicinal plants, including European barberry, goldenseal, goldthread, greater celandine, Oregon grape, phellodendron, and tree turmeric. It is characterized by its bright yellow color, bitter taste, and emerging therapeutic potential for metabolic and inflammatory disease states [1]. Berberine has been shown to exhibit numerous pharmacological properties, including immunomodulatory, antioxidative, cardioprotective, hepatoprotective, and renoprotective properties. It is available in the United States as an over-the-counter dietary supplement, sold individually or in combination with other nutraceuticals [2,3].

More recently, berberine has been referred to as "nature's Ozempic" among alternative medicine advocates and social media personalities due to a number of studies suggesting that it has similar blood glucose-lowering and weight loss effects as prescription GLP-1 receptor agonists [1]. Evidence from these studies revealed that berberine is able to promote weight loss through a variety of mechanisms, including activation of the AMPK pathway, modulation of adipogenesis-related transcription factors such as PPARγ, CREB, GATA-2 and GATA-3, promotion of GLP-1 secretion, and reduction of the size and number of droplets of lipids in some specific regions of the body [4,5]. As a result, berberine is currently being marketed as a weight loss supplement in various dosage forms, including tablets, capsules, and gummies [3]. Most berberine manufacturers offer oral doses of 400 or 500 mg tablets. Clinical trials have studied a wide range of berberine doses, typically between 300 mg and 1,500 mg per day, administered over durations ranging from 1 month to 24 months. In some studies, doses of up to 2 grams daily have been used for shorter periods of up to 8 weeks. Most regimens divide the total daily dose into two or three administrations [1,3,5].

Given the pharmacologic profile and increasing popularity of berberine as a weight loss supplement, a thorough review of the literature is essential to evaluate its safety and efficacy in the treatment of obesity. In this article, we aimed to review and evaluate the safety and efficacy of berberine as a pharmacologic option for weight loss, with a particular emphasis on the role of Pharmacists in optimizing the use of berberine through evidence-based guidance.

Clinical studies

A comprehensive literature review was conducted to evaluate the safety and efficacy of berberine for weight loss. Online databases, including PubMed, OVID/Medline, and NatMed Pro, were used to search for systematic reviews and meta-analyses of human clinical trials. Search terms included 'berberine', 'berberine and weight loss', 'berberine and obesity', and 'berberine and weight management'. Studies were included if they assessed the efficacy and safety of the therapeutic use of berberine for weight loss, metabolic outcomes, or obesity indices. Data related to dosage, duration of therapy, and efficacy and safety outcomes were included in the review.

Xiong P., *et al.* [4] conducted a systematic review and dose-response meta-analysis of randomized human controlled trials to evaluate the effect of berberine supplementation on obesity indices, including body mass index (BMI), waist circumference (WC) and body weight (BW). Eligible studies were English-language randomized controlled trials conducted in human participants evaluating berberine supplementation as the intervention with an appropriate control group. Ten trials were reviewed, which in total included 983 participants for BMI, 841 for WC and 378 for BW. The trials were conducted in accordance with PRISMA guidelines using random-effects modeling. Berberine supplementation was associated with statistically significant reduction in BMI (WMD -0.29 kg/m^2, $p = 0.006$) and WC (WMD -1.78 cm, $p = 0.01$). No significant effect was observed for BW. Heterogeneity was low for BMI ($I^2 = 0.0\%$, $p = 0.85$) and BW ($I^2 = 0.0\%$, $p = 0.49$), but substantial for WC ($I^2 = 73\%$, $p = 0.001$), indicating high variability in WC changes. Subgroup and dose-response analyses showed greater reductions in WC among females, at doses greater than 1 gram per day and interventions lasting longer than 12 weeks. Authors concluded that berberine may be a useful complementary therapy for improving select obesity indices, however, small sample sizes across trials and presence of heterogeneity in the WC results indicate that further high-quality trials are needed. Strengths of this study include the evaluation of only randomized controlled trials, the specific focus on the effect of berberine supplementation on obesity indices, and the performance of dose-response and subgroup analyses. Limitations of this study include the presence of significant heterogeneity for WC, small sample sizes in several trials, and only five trials (out of ten) evaluated changes in BW following berberine supplementation, whereas seven of the included trials reported information regarding the effect of berberine on BMI and WC.

Ye Y., *et al.* [6] published a systematic review and meta-analysis of 18 human randomized controlled trials, 9 of which were placebo-controlled and 9 of which were parallel-controlled, evaluating berberine monotherapy in adults with metabolic disorders. Metabolic disorders studied included type 2 diabetes, metabolic syndrome, hyperlipidemia, NAFLD and PCOS. Although primary and secondary

outcomes were not explicitly stated, lipid parameters (TG, TC, LDL-C, and HDL-C) were the most extensively analyzed outcomes, while fasting plasma glucose (FPG) and HOMA-IR were evaluated as additional metabolic endpoints. Participant numbers ranged from 539 to 1,449, depending on the metabolic outcome assessed. Eligible studies included randomized designs, identical lifestyle interventions between study groups, berberine as the sole pharmacologic intervention and extractable pre- and post-treatment data, with no language or timeframe (1927-2021) restrictions. Effect sizes were determined using standardized mean difference (SMD) and pooled with fixed- or random-effects models based on heterogeneity assessed by the I^2 statistic. Berberine monotherapy was associated with statistically significant improvements in TG (SMD -0.94; 95% CI: -1.38 to -0.49), TC (SMD -1.06; 95% CI: -1.48 to -0.64), LDL-C (SMD -1.77; 95% CI: -2.44 to -1.11), HDL-C (SMD +1.59; 95% CI: 0.85 to 2.32), HOMA-IR (SMD -1.25; 95% CI: -2.24 to -0.25), and fasting plasma glucose (SMD -0.65; 95% CI: -1.03 to -0.28), with substantial heterogeneity across outcomes (I^2 = 89–97%). Subgroup analyses found that treatment durations >3 months significantly enhanced effects (p = 0.02), while also identified as the primary contributor to heterogeneity. Dose influenced LDL outcomes only (p = 0.00), and study design had minimal impact on outcomes. The authors concluded that berberine (used as monotherapy) is a safe and well-tolerated supplement associated with significant improvements in dyslipidemia indices, insulin resistance, and glycemic control, suggesting that berberine may serve as an LDL-lowering alternative for patients intolerant to statins. The authors also concluded that the therapeutic effects of berberine increase with longer treatment duration (≥ 3 months). Strengths of this study include the focus on berberine monotherapy, large sample size for lipid outcomes, clinically relevant metabolic endpoints, extensive subgroup analyses, and the inclusion of only randomized controlled trials. Limitations of this study include limited reporting on randomization and blinding, variable lifestyle interventions across trials, very high heterogeneity across outcomes, and weight loss outcomes (BMI, BW, WC) not directly assessed. The absence of direct anthropometric outcomes, such as body weight, BMI and waist circumference, limits conclusions regarding berberine's efficacy in weight loss.

Asbaghi O., *et al.* [5] conducted a systematic review and meta-analysis of 12 randomized controlled human trials involving 1040 participants. The trials evaluated the effects of berberine supplementation on anthropometric metrics (BW, BMI and WC), C-reactive protein (CRP) and liver enzymes (AST and ALT) in adults with various metabolic and cardiovascular disease states. The disease states included type 2 diabetes, polycystic ovary syndrome, acute coronary syndrome, metabolic syndrome, NAFLD, overweight, obesity, and acute ischemic stroke. Studies were included if they were randomized controlled trials with human subjects, published in English, and reported mean differences with standard deviation for BW, BMI, WC, CRP and liver enzymes. Literature searches were conducted in Cochrane Library, Embase, Medline, Web of Science, PubMed, and Google Scholar from database inception through July 30, 2019, with English-language restrictions. Results were analyzed using weighted mean difference (WMD) and pooled using a random-effects model, with heterogeneity assessed using Cochran's Q test and the I^2 statistic. Primary and secondary endpoints were not explicitly stated; however, BW, BMI, WC, CRP, AST and ALT were the endpoints evaluated. Berberine supplementation was associated with statistically significant reductions in BW (WMD -2.07 kg; 95% CI -3.09 to -1.05; p < 0.001), BMI (WMD -0.47 kg/m^2; 95% CI -0.70 to -0.23; p < 0.001), WC (WMD -1.08 cm; 95% CI -1.97 to -0.19; p = 0.018) and CRP (WMD -0.42 mg/L; 95% CI -0.82 to -0.03; p = 0.034), although significant heterogeneity was observed for CRP outcomes (I^2 = 76.4%, p = 0.005). Berberine supplementation was not associated with significant changes in AST (WMD = 1.66 I/U; 95% CI -3.98 to 0.65; p = 0.16) or ALT (WMD = 0.87 I/U; 95% CI -2.56 to 0.82; p = 0.311). The authors concluded that berberine supplementation is associated with improvements in anthropometric and inflammatory markers which may contribute to improved clinical outcomes in patients with metabolic disorders. The authors also concluded that berberine supplementation is not associated with improved liver function tests including AST and ALT. Strengths of this meta-analysis include the inclusion of only randomized controlled trials, evaluation across a broad range of multiple metabolic disorders (more generalizability), clinically relevant metabolic endpoints, and use of standardized meta-analytic methods. Limitations include significant heterogeneity and variability in berberine doses, treatment duration and participant characteristics across studies.

Ilyas Z., *et al.* [7] published a systematic review of 35 studies analyzing the effects of berberine on obesity and related metabolic mechanisms, including 11 human studies. Eligible studies evaluated berberine's impact on obesity or obesity-related metabolic

mechanisms, were conducted in human, animal or *in vitro* models, reported dosage and duration of the intervention, and were published in English. Excluded studies were trials published prior to 2000, studies not relevant to berberine and obesity mechanisms, and studies without adequate methodological details or outcomes related to obesity pathways. The trials were conducted in accordance with PRISMA, with literature searches performed in Scopus, PubMed and Google Scholar. Statistical analysis was not performed, as this review included heterogeneous human, animal, and *in vitro* studies, and study outcomes were extracted and summarized narratively. Primary and secondary outcomes were not defined, however, the review primarily evaluated changes in glucose regulation, insulin resistance, body weight, and adiposity. Across studies, berberine demonstrated multiple metabolic effects relevant to the prevention of obesity and obesity-related metabolic disorders, including significant reduction in blood glucose and insulin resistance in patients with T2DM, reduction in obesity by lowering fasting blood glucose (FBG) and postprandial blood glucose (PBG) levels and contributing to diabetes control, inhibition of adiposite differentiation, and improvements in lipid profiles (TG, LDL, total cholesterol). The authors concluded that berberine may help prevent obesity and metabolic syndrome through several mechanisms including regulation of glucose homeostasis and lipid metabolism, however, further controlled human clinical trials are needed to confirm its therapeutic efficacy. Strengths of this systematic review include the evaluation of multiple biological pathways involved in obesity, the use of systematic search strategy through PRISMA guidelines, and strong mechanistic overview. Limitations of this systematic review include the absence of pooled quantitative statistical analysis, the majority of studies were animal or *in vitro* studies (not human RCTs), many of the reviewed studies were non-randomized, and heterogeneity in study designs, dosages, and populations.

Discussion

Current evidence suggests that berberine is a safe and well-tolerated supplement that may support weight loss efforts. Results from systematic reviews and meta-analyses of randomized and controlled human clinical trials indicate that berberine supplementation promotes consistent improvements in anthropometric measures associated with obesity. Berberine has been shown to produce statistically significant reductions in waist circumference and BMI, and modest reductions in total body weight. In addition, the results revealed that achieving measurable anthropometric improvements requires a berberine dose of $\geq$ 1 gram daily and a treatment duration of $\geq$ 3 months [4,5].

Berberine promotes weight loss and obesity prevention through several defined and proposed mechanisms. The primary mechanism of action of berberine in preventing obesity is activation of the adenosine monophosphate-activated protein kinase (AMPK) pathway. Activation of the AMPK pathway increases glucose uptake, shifts energy metabolism from storage to utilization, and increases the oxidation of fatty acids. These actions lead to improved glycemic control, reduced body fat, improved insulin sensitivity, increased energy expenditure, and a favorable modulation of lipid metabolism, contributing to favorable metabolic outcomes [4,6,7]. Other reported mechanisms of action of berberine include anti-inflammatory properties, inhibition of adiposite differentiation, and reduction of leptin levels. In addition, berberine has been shown to exert anti-obesity effects by increasing the secretion of intestinal hormones and modulating gut microbiota and intestinal hormone signaling. Berberine supplementation increases the secretion of GLP-1, GLP-2 and peptide YY, which contribute to appetite suppression and increased energy expenditure [7].

Clinical studies revealed that berberine has a favorable safety profile and is associated with minimal adverse effects when used at therapeutic doses. Berberine supplementation has been shown to cause significantly fewer adverse effects than those reported with first line drugs for metabolic diseases, such as metformin and the statins [4,7]. The most common adverse events associated with berberine use include occasional abdominal pain/discomfort and distension, constipation, diarrhea, flatulence, nausea, and vomiting, and are usually self-limiting [1]. Berberine may increase serum levels of medications that are metabolized by CYP2C9, CYP3A4, and CYP2D6 through inhibition of these drug-metabolizing enzymes. Concomitant use of berberine with antidiabetic medications should be approached cautiously under healthcare professional guidance due to the potential blood glucose-lowering effects of berberine. Concomitant use of berberine with cyclosporine should be avoided due to increased serum concentrations of cyclosporine [1].

Based on all of the evidence, berberine is considered a safe dietary supplement and a clinically appropriate add-on or adjunct therapy for patients seeking complementary support for weight loss. Although further research is warranted to evaluate long-term safety and dose optimization for weight loss, numerous studies have confirmed the clinically significant anti-obesity effects and favorable safety profile of berberine. Due to its modest effects on total body weight, the use of berberine as primary therapy for weight loss is not recommended. In addition, the use of berberine supplementation as an adjunct therapy for weight loss may provide a potential motivational effect or psychological reinforcement associated with supplement adherence, where patients are more motivated to comply with primary weight loss therapy and lifestyle changes due to their commitment to berberine supplementation.

In order to ensure positive clinical outcomes when using berberine as an over-the-counter weight loss supplement, Pharmacists must play a key role in educating and counseling patients regarding the safety and efficacy of berberine supplementation for weight management and how to optimize their supplementation. Patients should be advised that berberine is not an appropriate replacement for physician-recommended lifestyle changes or weight-management pharmacotherapy, and that berberine should be used as a complementary therapy. Patients should also be informed that berberine should be taken at doses of ≥ 1 gram per day for a minimum of 12 weeks to achieve clinically significant improvements in anthropometric measures. Patients need to know that berberine is a well-tolerated supplement, with most common adverse effects being gastrointestinal in nature. These side effects are usually self-limiting and can be minimized by taking berberine with food and by dividing the total daily dose into two or three doses. In addition, Pharmacists should counsel patients on potential interactions with berberine. Berberine may inhibit the drug-metabolizing enzymes CYP2C9, CYP3A4, and CYP2D6, potentially altering serum concentrations of medications that are metabolized by these enzymes, including but not limited to warfarin, certain antidepressants, NSAIDs, certain antihypertensive agents and opioids. Taking berberine and cyclosporine concomitantly should be avoided due to significant increases in serum concentrations of cyclosporine. Concomitant use of berberine with antidiabetic medications may increase the risk of hypoglycemia due to the potential blood glucose-lowering effects of berberine.

Conclusion

Berberine, a naturally occurring alkaloid, is available in the United States as a botanical dietary supplement. Current clinical evidence supports the use of berberine supplementation as a complementary or adjunct therapy for weight loss. The use of berberine as primary therapy for weight loss is not recommended due to its modest effects on total body weight. Berberine exhibits a favorable safety profile, with most common adverse effects being mild gastrointestinal symptoms that are usually self-limiting. Further high-quality human clinical trials are needed to evaluate dose optimization and long-term safety of berberine supplementation for weight loss.

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