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Pseudoephedrine and Phenylephrine for Treatment of Nasal Congestion: A Comprehensive Review of Efficacy and Safety

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Nasal congestion is a frequent symptom resulting from allergies, irritants, and infections. Congestion causes reduced air flow which can consequently lead to a decrease in the overall quality of life, particularly in severe and prolonged cases. Prior to 2000, the main treatments for nasal congestion were phenylephrine, phenylpropanolamine, and pseudoephedrine. However, phenylpropanolamine was removed from the market following the publication of a large multicentered trial which revealed a link between phenylpropanolamine use and increased risk for hemorrhagic stroke.[1] Five years later, the Combat Methamphetamine Epidemic Act of 2005 (CMEA) required products containing pseudoephedrine to be sold behind the counter and require a valid ID. Furthermore, the law limited purchase quantities to "3.6 grams of pseudoephedrine base" per day and 9 grams per month. The main goal of this act was to reduce the growing number of "methamphetamine labs" that were using pseudoephedrine as a precursor to make street methamphetamine. In response to this reduced availability of pseudoephedrine, manufacturers began to substitute products with 10 mg phenylephrine (i.e., Sudafed PE). Although these new phenylephrine-based products strongly resembled older pseudoephedrine-based products in terms of packaging, the assumption of comparable efficacy between these drugs has been questioned. The purpose of this review is to summarize and evaluate the evidence supporting phenylephrine and pseudoephedrine as treatment options for nasal decongestion.

Pharmacology

Table 1 summarizes the pharmacology of pseudoephedrine and phenylephrine. Pseudoephedrine is a sympathomimetic that is structurally similar to ephedrine. This drug directly affects both α- and β-adrenergic receptors. Similar to phenylephrine, pseudoephedrine causes vasoconstriction via stimulation of α_1-adrenergic receptors in the mucosa of the respiratory tract, resulting in reduced swelling of nasal mucous membranes, reduced tissue hyperemia, edema, and nasal congestion and increased nasal airway patency. Additional effects include increased drainage of sinus secretions as well as the potential opening up of obstructed Eustachian Ostia. Pseudoephedrine is incompletely metabolized in the liver to the active metabolite norpseudoephedrine (nPSE). Both pseudoephedrine and norpseudoephedrine are excreted in the urine with 55% to 75% excreted as unchanged drug. Depending on the pH of the urine, the elimination half-life is between 9 and 16 hours. The onset of action for pseudoephedrine is within 30 minutes, with duration of action up to 8 hours for a 60-mg dose and up to 12 hours for a 120-mg extended-release dose.

Phenylephrine is an α_1-adrenergic receptor agonist with potent vasoconstricting capabilities and minimal effects on β-adrenergic receptors. Stimulation of α_1-adrenergic receptors on the nasal mucosa causes vasoconstriction of local vessels, resulting in decreased mucosal edema, which contributes to the primary decongestant effects. Phenylephrine is metabolized in the liver and intestine by monoamine oxidase (MAO). When orally administered, it undergoes significant first-pass metabolism to a pharmacologically inactive metabolite with the ratio of parent phenylephrine to inactive phenylephrine metabolite being approximately 1:100. Plasma concentrations for parent phenylephrine peak 30 minutes after an oral dose, with an onset of action 15 to 30 minutes and a half-life of about 2.1 to 3.4 hours.

Clinical Trials

Clinical trials comparing pseudoephedrine or phenylephrine versus placebo, as well as one 3-way trial comparing pseudoephedrine, phenylephrine, and placebo are summarized in Table 2.

Table 1 | Pharmacology of pseudoephedrine and phenylephrine.

Parameter	Pseudoephedrine	Phenylephrine
Primary Receptor	α_1>>> β	α_1>>> β
Metabolism	Liver, 55 – 75% excreted unchanged in urine	Liver, MAO
Onset of Action	Within 30 min	15 – 30 min
$t_{1/2}$	9 – 16 hrs	2.1 – 3.4 hrs

MAO = monoamine oxidase; **$t_{1/2}$ =** terminal half-life

In This Issue

Table 2 | Summary of clinical trials of pseudoephedrine and phenylephrine for the treatment of nasal congestion.

Trial	Study Type	Treatment	Measurements	Better than Placebo?
Taverner, et al. (1999)[2]	PC, DB, RCT	PSE 60 mg	NAR	No (p>0.5)
			tCSA	Yes (p=0.018)
			tnVol	Yes (p=0.003)
			congestion	Yes (p<0.05)
Eccles, et al. (2005)[3]	PC, DB, PG, RCT	PSE 60 mg	NAR (day 1)	Yes (p=0.006)
			NAR (day 3)	Yes (p<0.001)
			Congestion (day 1)	Yes (p=0.029)
			Congestion (day 3)	No (p=0.79)
			Mean Congestion	Yes (p=0.016)
Meltzer, et al. (2015)[5]	MC, PC, PG, OL, RCT	PE 10 mg PE 20 mg PE 30 mg PE 40 mg	Congestion	No (p=N/A), for all PE doses vs. placebo
Meltzer, et al. (2016)[6]	MC, PC, DB, PG, RCT	PE 30 mg MR	Congestion	No (p=0.265)
Horak, et al. (2009)[7]	SC, PC, 3WC, RCT	PSE 60 mg, PE 10 mg	Congestion	PSE, Yes (p=0.01) PE, No (p=0.56)
			Nasal airflow	PSE, Yes (p=0.03) PE, No (p=0.12)
			Rhinorrhea	PSE, Yes (p=0.04) PE, No (p=N/A)
			Sneezing	PSE, Yes (p=0.01) PE, No (p=N/A)
			Nasal itching and non-nasal symptoms	PSE, No (p=N/A) PE, No (p=N/A)

PC = Placebo-controlled; **DB =** double-blind; **RCT =** randomized controlled trial; **PG =** parallel group; **3WC =** 3-way crossover, **MC =** multi-center; **OL =** open label; **PSE =** pseudoephedrine; **PE =** phenylephrine; **MR =** modified release; **N/A =** not available

Pseudoephedrine

In 1999, Taverner, et al. performed a placebo-controlled double-blind randomized trial to assess the efficacy of a single 60 –mg dose of oral pseudoephedrine on nasal patency.[2] Inclusion criteria were symptoms of an acute common cold (acute nasal congestion combined with rhinorrhea or a sore throat), evidence of acute viral upper respiratory tract infection (defined by presence of pharyngeal erythema), and moderate or severe nasal obstruction on examination by anterior rhinoscopy. Exclusion criteria were the presence of hay fever, broncho-pulmonary disease, anatomical nasal obstruction, hypertension, or previous ingestion of vasoactive drugs, caffeine, and alcohol within a set period before the study. This study used acoustic rhinometry, a non-invasive method of nasal structural assessment which provides the cross-sectional area and volume of the cavity at distances from the posterior margin of the anterior nares of up to 60 mm, to measure nasal airway resistance (NAR), total minimal cross-sectional area (tCSA), total nasal volume (tNVol), and congestion. Symptoms of congestion were reported by subjects and scored on a 5-point scale with 0 meaning no congestion and 4 meaning very severe congestion. All variables were measured at baseline and at 30 minute intervals until the final time of 180 minutes. The area under the curve (AUC) was calculated for each primary variable.

Fifty-two subjects (30 men and 22 women) completed the study. Subject ages ranged from 18-55 years with an average age of 26 years. At study end, there was no significant difference seen between pseudoephedrine and placebo on NAR. The AUC for tCSA was increased by 7% more for pseudoephedrine compared to placebo (p=0.018). The tnVol was increased by 11% more with pseudoephedrine compared with placebo (p=0.003). Symptoms of congestion were also significantly lower for the pseudoephedrine group at all time points between 60 and 150 minutes after dosing (p<0.05).

In 2005, Eccles, et al. performed a double-blind, randomized, parallel group, placebo-controlled trial to look at the efficacy of single and multiple 60-mg doses of pseudoephedrine in the treatment of nasal congestion associated with the common cold.[3] Two hundred and thirty-eight patients (average age, 20 years) with nasal congestion associated with acute upper respiratory tract infections were recruited to the study. Total NAR, measured by posterior rhinomanometry, and subjective scores of nasal congestion were measured at baseline, every hour for four hours after a single dose on day 1, and on day 3 after multiple doses of medication. After a single dose on day 1, the pseudoephedrine group had a significantly lower log tNAR AUC, by 0.32, from 0-3 hours compared to placebo (p=0.006). Congestion scores for day 1 (hours 0-3) were also lower in the pseudoephedrine group by 8.33 in AUC on a visual analog scale (p=0.029). On day 3, after multiple doses, the

Table 3 | Results of meta-analysis of the efficacy of phenylephrine 5 to 25 mg daily on nasal airway resistance.[4]

	Difference in NAR		
Dose	EBL (n=13)	Others (n=17)	Combined (n=30)
10 mg	37%	2%	10%
15 mg	36%	8%	22%
20 mg	40%	-3%	12%
25 mg	40%	10%	27%

NAR = Nasal Airway Resistance; **EBL =** Elizabeth Biochemical Laboratories.

pseudoephedrine group had a NAR AUC 10.4% to 20.5% lower than the placebo group at every time point between 1 and 3 hours; NAR AUC at the 4-hour time point was not significantly different between groups (p=0.068). The subjective scores were not significantly different on day 3 (p=0.79). The average decrease from baseline in the total scores of congestion over the entire study was greater in the pseudoephedrine group (0.96) compared to the placebo group (0.71; p=0.016).

Phenylephrine

A 2007 meta-analysis assessed the trials used in the FDA review which found phenylephrine to be safe and effective as an over the counter medicine.[4] Studies included in the meta-analysis were randomized placebo-controlled clinical trials that evaluated the efficacy of oral phenylephrine on NAR in patients with nasal congestion. Studies using combination products or that compared phenylephrine with another oral decongestant were excluded. The primary outcome measurement for this meta-analysis was defined as the maximum reduction in NAR over 120 minutes, expressed as the percent decrease from baseline.

Fifteen randomized placebo-controlled studies were identified that assessed the efficacy of a 10-mg or other dose of phenylephrine. Eleven of these fifteen trials reported changes in NAR over at least 120 minutes after drug administration. These trials were conducted in the U.S. with sample sizes ranging from 6 to 88 subjects whom were described as having a "common cold" or a "head cold." Of the eleven studies that were included in the analysis of phenylephrine 5 to 25 mg, five came from the same study site, Elizabeth Biochemical Laboratories (EBL). The results of the mean difference in NAR after administration of varying doses of phenylephrine can be seen in **Table 3**. The results from Elizabeth Biochemical Laboratories are displayed separately due to the disproportionately large decrease in NAR when compared to results from other study sites. When excluding data from Elizabeth Biochemical Laboratories, only the 25-mg dose of phenylephrine showed a significantly greater improvement in NAR, compared to placebo.

In 2015, Meltzer, et al. performed a multicenter, phase 2, parallel, 5-arm, open-label, placebo-controlled dose-ranging trial to evaluate safety and effectiveness of various doses of phenylephrine compared with placebo.[5] The patients were older than 18 years with documented or patient-reported history of seasonal allergic rhinitis (SAR) caused by spring pollen within the last 4 years and had symptoms over the last 2 spring allergy seasons. Additionally, patients had to have documented positive responses on skin test or in vitro test within the last 3 years for specific immunoglobulin E. After an allergy medicine washout period, patients were required to have continued symptoms of nasal congestion while otherwise healthy. Patients with SAR were randomly assigned to receive phenylephrine 10-mg tablets at fixed doses of 10, 20, 30, or 40 mg or placebo for 7 days. Treatment was to be taken orally every 4 hours with no more than 6 doses in 24 hours. The primary efficacy end point was the mean change from baseline over the entire treatment period in daily reflective nasal congestion score. None of the active treatment groups significantly improved nasal congestion scores, compared with placebo (mean for placebo, -0.428; phenylephrine 10 mg, -0.460; phenylephrine 20 mg, -0.499; phenylephrine 30 mg, -0.508; and, phenylephrine 40 mg, -0.461).

In 2016, Meltzer, et al. performed another multicenter, randomized, double-blinded, placebo controlled, 2-arm, parallel-group study to assess the efficacy and safety of phenylephrine 30 mg modified-release tablets.[6] Eligible patients had to meet the following criteria: age ≥ 18 years; documented or self-reported history of allergic rhinitis (AR) caused by fall pollen within the past 4 years or symptoms for at least the last 2 previous fall allergy seasons; a documented skin prick test reaction to fall pollen allergens or intradermal test reaction within the past 4 years; absence of a clinically significant disease requiring physician's care that would interfere with study procedures; signs and symptoms of nasal congestion of at least mild severity after the washout period and at least mild symptoms on reflective and instantaneous scores 4 consecutive days before randomization; and, agreement to not use MAO inhibitors 14 days before or after study drug administration. The patient population was predominantly white (82%) and female (61.1%) with age ranging from 18 to 80 years. Patients were randomly assigned to receive phenylephrine modified-release 30 mg tablets or placebo and instructed to take 1 tablet every 12 hours for 7 days. The primary end point was the mean change from baseline during the entire treatment period in daily reflective nasal congestion score. At study end, there was no significant difference between phenylephrine 30-mg modified release and placebo in mean change in daily reflective nasal congestion score from baseline during the entire treatment period (phenylephrine

Table 4 | Incidence of adverse effects at various doses of phenylephrine.[5]

Adverse Effect	Placebo (N=103)	PE 10 mg (N=109)	PE 20 mg (N=108)	PE 30 mg (N=107)	PE 40 mg (N=112)	PE Total (N=436)	Overall (N=539)
Nervous System	2 (1.9%)	8 (7.3%)	10 (9.3%)	6 (5.6%)	4 (3.6%)	28 (6.4%)	30 (5.6%)
Headache	0	6 (5.5%)	4 (3.7%)	3 (2.8%)	3 (2.7%)	16 (3.6%)	16 (3.0%)
Gastrointestinal	2 (1.9%)	3 (2.8%)	4 (3.7%)	2 (1.9%)	9 (8.0%)	18 (4.1%)	20 (3.7%)
Dry Mouth	1 (1.0%)	0	0	0	3 (2.7%)	3 (0.6%)	4 (0.7%)
Nausea	0	1 (0.9%)	1 (0.9%)	1 (0.9%)	4 (3.6%)	7 (1.6%)	7 (1.3%)

PE = phenylephrine

mean, -0.394 versus placebo mean, -0.412; p=0.27).

Pseudoephedrine versus phenylephrine

In 2009 Horak, et al. performed a single-center, randomized, placebo-controlled, 3-way crossover study of the decongestant effect of phenylephrine compared with placebo and pseudoephedrine in patients with at least a 2-year history of symptomatic and skin test positive seasonal allergic rhinitis to grass pollen in the Vienna Challenge Chamber.[7] The Vienna Challenge Chamber is an international establishment that conducts clinical allergy studies in an allergen challenge system under tightly controlled and reproducible conditions.

The patient population was predominately white (97%) and female (59%) ranging from 19 to 46 years of age with the mean age being 27 years. Patients were administered a dose of phenylephrine 12 mg, pseudoephedrine 60 mg, or placebo after being in the Vienna Challenge Chamber for 120-minutes and meeting the minimum symptom severity scores of ≥2 (moderate) for nasal congestion, ≥6 for combined nasal symptoms (rhinorrhea, nasal congestion, sneezing, and nasal itch), and ≥2 for combined non-nasal symptoms (eye burning or itching, eye tearing, itching of ears or palate). Patients remained in the Vienna Challenge Chamber for 7.5 hours and were required to complete symptoms evaluations on a scale of 0, meaning none, to 3, meaning severe, every 15 minutes. Rhinomanometry, peak nasal inspiratory flow (PNIF), and a collection of tissues to determine nasal secretion weights were also performed every 30 minutes.

The primary efficacy variable was the subjective evaluation of nasal congestion expressed as an average change from baseline during the first six hours with additional end points including objective measurements of nasal congestion, rhinomanometry, and PNIF. The average first 6-hour post baseline decrease in nasal congestion score was 2.2% for placebo-treated patients, 7.7% for phenylephrine-treated patients (p=0.56 for comparison to placebo), and 21.7% for pseudoephedrine-treated patients (p=0.01 compared to placebo). Phenylephrine was not found to be significantly different from placebo at any time in decreasing nasal congestion scores whereas pseudoephedrine significantly reduced nasal congestion by 30 minutes. The results of rhinomanometry and PNIF agreed with the primary measurement, showing no significant effect on nasal airflow by phenylephrine but significant reduction by pseudoephedrine (p=0.03). Pseudoephedrine was also found to be significantly better than placebo for rhinorrhea (p=0.04) and sneezing (p=0.01), whereas phenylephrine was similar to or worse than placebo for each. Neither drug was found to significantly improve nasal itching or non-nasal symptoms, compared to placebo.

Adverse Effects

Both phenylephrine and pseudoephedrine are generally well-tolerated with a very low incidence of adverse effects when taken as directed. Phenylephrine has few reported adverse effects with most involving the central nervous system, including headaches, anxiety, dizziness, insomnia, nervousness, or restlessness. Table 4 contains the incidence of adverse effects of varying doses reported by the dose-ranging study.[5] Pseudoephedrine has a much broader side effect profile and tends to involve more organ systems. Some of the side effects of pseudoephedrine may include but are not limited to: arrhythmias, hypertension, tachycardia, head ache, anxiety, restlessness, nervousness, irritability, dizziness, photosensitivity, rash, constipation, diarrhea, nausea, vomiting, blurred vision, or tinnitus. Table 5 displays the tolerability results for a study that used pseudoephedrine 240-mg sustained-release once a day for 14 days. Patients in this study were asked to rate the level of bother experienced from side effects of the study drug on a scale of 1 to 7, with 1 being not bothered by adverse effects and a 7 being extremely bothered. The median response was 2.0 for pseudoephedrine suggesting that adverse effects were not significantly bothersome.

Table 5 | Incidence of adverse effects for pseudoephedrine 240-mg extended release over 14 days.[6]

Adverse Effect	Incidence (n=25)
Headache	6 (21%)
Insomnia	6 (21%)
Nausea	0
Nervousness	1 (4%)
Dry Cough	3 (11%)
Excess Sweating	4 (14%)
Dizziness	1 (4%)
Dry Mouth	7 (25%)
Agitation	2 (7%)
Anxiety	1 (4%)
Heartburn	2 (7%)
Tenseness	1 (4%)
Restlessness	2 (7%)
Upset Stomach	1 (4%)
Swollen Ankles	0
Throat Irritation	5 (18%)
Diarrhea	0
Nasal Dryness	5 (18%)
Fatigue	4 (14%)
Palpitations	1 (4%)

As sympathomimetics, both phenylephrine and pseudoephedrine should be avoided or used with extreme caution in patients with cardiovascular disease, ischemic heart disease, diabetes, hypertension, thyroid dysfunction, increased intraocular pressure or glaucoma, urinary retention, prostatic hyperplasia, or seizure disorders. The only absolute contraindication for these two medications is use with, or within 14 days of, MAO inhibitor therapy.

Dosing and Administration

A list of commonly available products with recommended dosing and administration is summarized in Table 6. Patients should be instructed to carefully review and follow instructions on each box as similar looking products may have significantly different dosing instructions.

Summary

Over-the-counter sympathomimetic agents, namely pseudoephedrine and phenylephrine, are often used for the short-term treatment of nasal congestion. A 60-mg dose of pseudoephedrine is an effective nasal decongestant with relatively

Table 6 | Common Products Containing Pseudoephedrine and Phenylephrine

Active Ingredient	Brand Names	Strength	Recommended Dose
Pseudoephedrine	Sudafed Congestion Tablets, Sudogest	30 mg	Age ≥12 y: 2 tabs every 4 -6 hrs, not more than 8 tabs in 24 hrs Age 6-11 y: 1 tab every 4-6 hrs, not more than 4 tabs in 24 hrs
Pseudoephedrine	Sudafed 12-Hour	120 mg	Age ≥12 y: 1 tab every 12 hrs, not more than 2 tabs in 24 hrs
Pseudoephedrine	Sudafed 24-Hour	240 mg	Age ≥12 y: 1 tab every 24 hrs, not more than 1 tab in 24 hrs
Pseudoephedrine, Acetaminophen, Chlorpheniramine, Dextromethorphan	Alka-Seltzer Plus – D Multi-Symptom Sinus and Cold Liquid Gels	PSE – 30 mg, APAP – 325 mg, CP – 2 mg DM – 10 mg	Age ≥12 y: 2 caps every 4 hrs with water, not more than 8 caps in 24 hrs
Phenylephrine	Generic Nasal Decongestant PE, Sudafed PE Congestion, Sudogest PE	10 mg	Age ≥12 y: 1 tab every 4 hrs, not more than 6 tabs in 24 hrs
Phenylephrine, Acetaminophen, Chlorpheniramine	Contac Cold + Flu	PE – 5 mg, APAP – 500 mg, CP – 2 mg	Age ≥12 y: 2 caps every 6 hrs, not more than 8 caps in 24 hrs
Phenylephrine, Acetaminophen, Chlorpheniramine, Dextromethorphan	Alka-Seltzer Plus Cold and Cough Liquid Gels	PE – 5 mg, APAP – 325 mg, CP – 2 mg, DM – 10 mg	Age ≥12 y: 2 caps every 4 hrs with water, not more than 10 caps in 24 hrs

PSE = pseudoephedrine; **PE =** phenylephrine; **APAP =** acetaminophen; **CP =** chlorpheniramine; **DM =** dextromethorphan

few adverse effects. In contrast, current data do not support a role for phenylephrine, given that this drug has not demonstrated significant efficacy as compared with placebo. The lack of efficacy may be due to the large first-pass metabolism which converts a majority of orally administered phenylephrine into inactive metabolites. Given that phenylephrine is often marked with similar product packaging and similar name to that of pseudoephedrine, patients should be instructed to request pseudoephedrine products, rather than phenylephrine, when a nasal decongestant is needed.

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Personalized Medicine Corner

Landscape of Pharmacogenomic Testing

The UF Health Personalized Medicine Program recently conducted an analysis of services and facilities provided by commercial laboratories offering panel-based pharmacogenomic testing. Evaluation criteria were developed to identify companies that provide a comprehensive, evidence-based, and reasonably priced pharmacogenomic panel for use in a clinical setting. At minimum, such a panel should include testing for *CYP2C19, CYP2D6*, and *TPMT*. Ideally, *CYP2D6* testing should include copy number variant assessment to accurately identify *CYP2D6* ultra-rapid metabolizers. In addition, thresholds of cost <$500 and turnaround time ≤7 days were set for reasonable cost and return of results, respectively, in a clinical environment.

Data on these criteria were available from 9 commercial laboratory companies. Of these, 7 labs tested the genes of interest, 5 companies were priced lower than $500 per panel (range = $250 to $1500), and the turnaround time for test results was ≤7 days (range = 1 day to 21 days) for 4 of 9 laboratory companies. Six of 9 companies reported testing for copy number variation with *CYP2D6*. The remaining 7 companies stated their tests were for research purposes only or did not respond.

Four companies met all criteria listed above: Assurex, Genelex, PGXL, and Rxight (MD Labs). Notably, although not included in our original criteria, all of these laboratories offer test interpretation services for clinicians.

While this panel-based testing provides information about genes that affect response to multiple drugs over time, the downside is that there is not currently a means for reimbursement by most payors, requiring that the patient pay for the test out of pocket in some cases.

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