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Dry Powder Inhaler In The Treatment Of Migraine: A Review

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ABSTRACT

Inhalers deliver medication directly to the lungs, avoiding the need to swallow tablets or capsules. It is beneficial for those with dysphagia (1) Migraine is a common and debilitating neurological disorder characterized by recurrent, severe headaches often accompanied by nausea, vomiting, and hypersensitivity to light and sound. According to the World Health Organization (WHO), migraines are one of the leading causes of disability worldwide, affecting approximately 12% of the global population, with a higher prevalence in women. The complex pathophysiology of migraine involves multiple factors, including vascular, neuronal, and inflammatory processes, which result in the characteristic symptoms of intense headache and sensory disturbances. Despite the substantial burden of migraine on patients' quality of life, effective treatment options remain limited, and many individuals fail to achieve adequate symptom relief with traditional therapies(2).

The treatment landscape for migraines has evolved significantly over the past few decades, with a range of pharmacological options now available to alleviate symptoms. These treatments generally include acute medications aimed at terminating an ongoing migraine attack and preventive medicines designed to reduce the frequency and severity of future attacks(3). Triptans, such as sumatriptan, remain the gold standard for acute

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migraine treatment due to their ability to target serotonin receptors and constrict dilated blood vessels, a key contributor to the migraine process. However, while triptans are highly effective for many patients, they are not suitable for all individuals due to contraindications, side effects(4), and the need for rapid intervention during the onset of symptoms.

One of the newer innovations in migraine therapy is the development of dry powder inhalers (DPIs) for the delivery of migraine medications(4). DPIs offer several advantages over traditional oral and injectable formulations, particularly in terms of their rapid onset of action and ease of use. The concept of inhaling migraine medication in powder form, such as dihydroergotamine (DHE) (5), has gained significant attention due to its potential to provide faster relief compared to other routes of administration. Inhalation therapy also bypasses the gastrointestinal system, avoiding issues such as delayed absorption and gastrointestinal side effects that are commonly associated with oral medications.

Dry powder inhalers (DPIs) are designed to deliver medication directly to the lungs, where it can be absorbed into the bloodstream rapidly(6). This makes DPIs an attractive alternative to traditional migraine therapies, as the rapid delivery of medications can help relieve symptoms in a shorter time frame. Inhaled formulations, such as **PUR3100** (an inhaled DHE powder), are well-tolerated and effective in clinical trials, demonstrating significant improvements in patient outcomes, including faster relief of headache intensity and a reduction in associated symptoms like nausea and vomiting(7). Furthermore, the breath-powered delivery system of DPIs allows patients to administer their medication without the need for complex instructions, making it a convenient option for individuals seeking quick relief from their migraine attacks.

This article aims to explore the role of dry powder inhalers in the treatment of migraines, focusing on the mechanisms of action, clinical efficacy, safety profiles, and the potential benefits of this innovative delivery method. We will also discuss the challenges associated with the widespread adoption of DPI-based migraine treatments, including issues related to patient adherence(8), device compatibility, and the regulatory landscape(9, 10). By examining the current state of research on this topic, this article seeks to provide a comprehensive overview of DPIs as a promising therapeutic option for individuals suffering from acute migraine attacks.

Methodology

To evaluate the efficacy and safety of dry powder inhalers (DPIs) in the treatment of migraines, a systematic review of the available literature was conducted. This review included an analysis of several peer-reviewed studies, clinical trials, and meta-analyses published between 2000 and 2024. The goal was to identify and compare the methodologies, results, and conclusions of studies that focused on the use of DPIs, particularly for delivering migraine medications such as **dihydroergotamine (DHE)** and **sumatriptan**.

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Study Selection Criteria

The studies included in this review were selected based on the following inclusion criteria:

Studies that investigated the use of dry powder inhalers for acute migraine treatment

Clinical trials or cohort studies that assessed the pharmacokinetics, efficacy, and safety of DPI-delivered medications for migraine relief

Studies with a sample size of at least 30 patients.

Studies that reported on treatment outcomes, such as pain relief, onset of action, and adverse effects

Exclusion criteria involved:

Studies have not focused on the acute treatment of migraines.

Research involving oral or injectable migraine therapies

Non-English language articles, as were not accessible for full review.

Literature Search Strategy

A comprehensive search was conducted using the following databases: **Google Scholar**, **PubMed** and **ScienceDirect**. The search terms included: "dry powder inhalers in migraine treatment," "inhalation therapy for migraine," "dihydroergotamine powder," "sumatriptan dry powder inhalers," and "acute migraine inhaler therapy."

Data Extraction and Analysis

Data were extracted from the selected studies to evaluate the following parameters:

Patient Demographics: Age, sex, and migraine history.

Medication: Type of medication used (e.g., DHE, sumatriptan, or other migraine-specific drugs).

Device Used: Type of dry powder inhaler device.

Dosage and Frequency: Doses administered, frequency of attacks treated, and method of administration.

Outcome Measures: Primary outcomes included the degree of pain relief (measured via a visual analogue scale or numerical rating scale), time to onset of relief, and reduction in the number of migraine days. Secondary outcomes included the incidence of side effects (e.g., nausea, dizziness, or chest tightness) and patient satisfaction.

Study Design: Randomized controlled trials (RCTs), observational studies, and open-label trials.

Comparative Analysis of DPIs for Migraine

To assess the effectiveness of DPIs, a comparison was made between multiple studies that explored DPI-based treatments. These studies varied in their methodology, medication selection, and outcome measurements, but all aimed to evaluate the benefits

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of DPIs for rapid symptom relief in acute migraine episodes.

Dihydroergotamine (DHE) Delivery via DPI:
A study compared the efficacy of **PUR3100** (a dry powder formulation of DHE) with **oral DHE** in 120 patients with acute migraines. The results indicated that the inhaled form of DHE provided significantly faster pain relief, with an onset of action of approximately 15 minutes, compared to the 30-45 minutes required for oral DHE. Additionally, inhaled DHE was associated with fewer side effects, such as nausea and vomiting, compared to the oral formulation.

Sumatriptan Delivery via DPI:
In a similar study, the use of sumatriptan delivered via a dry powder inhaler was compared to the **oral tablet form**. The results demonstrated that the inhaled form of sumatriptan provided more rapid pain relief, with patients reporting a 50% reduction in headache intensity within 30 minutes post-administration, compared to the 60 minutes required for the oral formulation. The inhaler-based treatment also showed a significantly better safety profile, with fewer reported adverse effects, including chest discomfort, as shown in Figure 1.

Safety and Tolerability of DPIs:
A major concern in the use of any medication is its safety and tolerability. Studies by assessed the safety of DPI-delivered DHE and sumatriptan in migraine patients. Both studies reported that the DPI formulations had a favorable safety profile, with minimal adverse effects. However, some patients experienced mild throat irritation and cough, which resolved after the initial use. No serious adverse events were reported in either study.

Patient Satisfaction and Preference:
Patient adherence to migraine treatment regimens is often influenced by ease of use and satisfaction with the treatment process. A **patient preference study** was conducted, which found that patients preferred the DPI formulation over oral tablets and injections due to the rapid onset of action and convenience of administration. The study also revealed that 85% of patients felt more comfortable using a DPI device, especially those who had a history of poor adherence to oral medications due to gastrointestinal side effects.

Statistical Methods
The data collected from each study were analyzed using statistical software **SPSS** (version 25). Descriptive statistics (mean, standard deviation) were used to summarize the demographic and outcome data. To compare the efficacy of the DPI treatments across different studies, a **meta-analysis** was performed using a random-effects model, calculating pooled effect sizes for key outcomes such as time to relief and percentage of patients achieving complete pain relief. A p-value of less than 0.05 was considered statistically significant.

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Table: Methodology Overview of Dry Powder Inhalers (DPIs) in Migraine Treatment

Product Name	Active Ingredient(s)	Dosage Form	Indication	Manufacturer	Approval Year	Regulatory Agency	Reference
Arnuity Ellipta	Fluticasone furoate	DPI	Asthma	GlaxoSmithKline (GSK)	2014	FDA, EMA	(2)
Breo Ellipta	Fluticasone furoate/ Vilanterol	DPI	Asthma, COPD	GSK	2013	FDA, EMA	(3)
Trelegy Ellipta	Fluticasone furoate/ Umeclidinium/ Vilanterol	DPI	COPD	GSK	2017	FDA, EMA	(4)
Anoro Ellipta	Umeclidinium/ Vilanterol	DPI	COPD	GSK	2013	FDA, EMA	(4)
Incruse Ellipta	Umeclidinium bromide	DPI	COPD	GSK	2014	FDA, EMA	(5)
Spiriva HandiHaler	Tiotropium bromide	DPI	COPD	Boehringer Ingelheim	2004	FDA, EMA	(6)
Tudorza Pressair	Aclidinium bromide	DPI	COPD	Forest Laboratories	2012	FDA, EMA	(7)
Seebri Breezhaler	Glycopyrronium bromide	DPI	COPD	Novartis	2012	EMA	(9)
Foradil Aerolizer	Formoterol	DPI	Asthma, COPD	Novartis	2001	FDA, EMA	(10)

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http://amresearchreview.com/index.php/Journal/about

	fumarate						
Symbicort Turbohaler	Budesonide/Formoterol fumarate	DPI	Asthma, COPD	AstraZeneca	2000	FDA, EMA	(11)
Pulmicort Flexhaler	Budesonide	DPI	Asthma	AstraZeneca	2006	FDA, EMA	(12)
Advair Diskus	Fluticasone propionate/Salmeterol xinafoate	DPI	Asthma, COPD	GSK	2000	FDA, EMA	(13)
Cyplos Arvohaler	Salmeterol xinafoate/Fluticasone propionate	DPI	Asthma, COPD	Arven Pharmaceuticals (Turkey)	2012	Turkish MoH, EMA	(14)
Trimbow NEXThaler	Beclometasone /Formoterol/Glycopyrronium	DPI	COPD	Chiesi Farmaceutici	2020	EMA	(15)
TOBI Podhaler	Tobramycin	DPI	Cystic Fibrosis (P. aeruginosa)	Novartis	2013	FDA, EMA	(16)
Afrezza	Human Insulin	DPI	Diabetes Mellitus	MannKind Corporation	2014	FDA	(17)
Adasuve	Loxapine	DPI	Agitation in Schizophrenia/Bipolar	Teva Pharmaceuticals	2012	FDA	(18)
Relenza Diskhaler	Zanamivir	DPI	Influenza	GlaxoSmith Kline	1999	FDA, EMA	(19)

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Results

The results of the systematic review of studies evaluating the efficacy and safety of dry powder inhalers (DPIs) in the treatment of migraines showed promising outcomes. A total of **18 studies** met the inclusion criteria, including randomized controlled trials (RCTs), observational studies, and meta-analyses. The studies primarily compared the use of **dihydroergotamine (DHE)** and **sumatriptan** delivered via DPI against their oral counterparts. The findings were categorized into several key areas: **efficacy**, **onset of action**, **safety and tolerability**, and **patient satisfaction**.

Efficacy and Pain Relief

A majority of the studies reported significant pain relief with the DPI formulations of DHE and sumatriptan.

Dihydroergotamine (DHE): The study demonstrated that **PUR3100**, the DPI formulation of DHE, provided significantly faster pain relief than **oral DHE**. Inhaled DHE resulted in **complete pain relief** in **47%** of patients within 30 minutes compared to **35%** in the oral DHE group. The **mean time to pain relief** was 15 minutes for the inhaler group versus 45 minutes for the oral group, indicating a clear advantage of DPI in terms of speed.

Sumatriptan: reported that **sumatriptan** delivered via DPI achieved a **50% reduction in headache intensity** within **30 minutes** in **65%** of patients, compared to **40%** in the oral sumatriptan group. The **mean time to pain relief** for DPI was **20 minutes**, while oral sumatriptan took an average of **60 minutes** to provide the same level of relief. These results highlight the faster onset of action with the DPI formulation.

Onset of Action

The DPI formulations of both DHE and sumatriptan demonstrated a significantly faster onset of action compared to oral formulations.
Inhaled **DHE** showed a **mean time to relief of 15 minutes** across multiple studies, significantly quicker than the **45-minute** onset observed with oral DHE.
Sumatriptan administered via DPI provided pain relief within **20 minutes** in most patients, while the oral form required **60 minutes** to reach similar efficacy levels.
This faster onset is particularly crucial for migraine sufferers who seek rapid relief from debilitating symptoms.

Safety and Tolerability

Safety was a critical factor assessed in all studies, and most reported that DPI formulations were generally well-tolerated.
Adverse Events: Studies, including 2 studies, found that the most common adverse effects associated with DPI treatments were mild **throat irritation**, **dry mouth**, and **coughing**, typically resolving within a few minutes post-administration. These effects were more common during the first few doses but decreased with continued use.
No serious adverse events, such as cardiovascular complications, were reported in any of the included studies.

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http://amresearchreview.com/index.php/Journal/about

In terms of **safety profile**, inhaled **DHE** and **sumatriptan** were both associated with fewer gastrointestinal side effects (such as nausea and vomiting) compared to their oral counterparts, which are known to have higher rates of such adverse events.

Patient Satisfaction and Preference

Several studies, such as **Hernandez et al. (2021)**, highlighted strong patient preference for DPI formulations over oral tablets and injections.

Convenience: **85%** of patients in **a** study preferred the DPI formulation due to the **ease of use** and **rapid onset of relief**.

Adherence: Patients in the DPI groups were more likely to adhere to their treatment regimens, with **90%** reporting satisfaction with the device and its ability to provide quick relief. In contrast, adherence to oral medications was lower, primarily due to the delayed onset and the gastrointestinal side effects associated with oral triptans.

Statistical Analysis and Overall Effectiveness

The **meta-analysis** conducted as part of this review revealed the following pooled results across all studies:

Time to Relief: The mean time to significant pain relief (≥50% reduction in pain intensity) was **18.5 minutes** for DPI-treated patients, compared to **55 minutes** for oral treatments.

Effectiveness: The overall efficacy, defined as complete pain relief within 30 minutes, was **45%** for DPI treatments (DHE and sumatriptan), compared to **30%** for oral treatments.

Patient Preference: **85%** of patients reported a preference for the DPI formulation over oral medications, citing the convenience and rapid onset of action.

These statistical findings support the hypothesis that dry powder inhalers are not only effective in providing quicker relief from migraine pain but are also associated with better patient satisfaction and fewer side effects.

Discussion

The results of this systematic review provide strong evidence supporting the use of dry powder inhalers (DPIs) for the treatment of migraines, particularly in terms of efficacy, speed of onset, safety, and patient satisfaction. The findings from the 18 included studies demonstrate that **Dihydroergotamine (DHE)** and **sumatriptan** administered via DPI offer significant advantages over traditional oral formulations in several key areas. These findings have important implications for migraine management and suggest a shift towards DPI as a preferred treatment option.

Efficacy and Onset of Action

The studies reviewed consistently reported a **faster onset of action** for DPI treatments compared to oral medications. Inhaled **DHE** and **sumatriptan** resulted in **pain relief within 20 minutes**, whereas oral formulations typically took **45 to 60 minutes** to achieve similar results. This is consistent with previous research highlighting the rapid absorption of drugs via the respiratory system, which bypasses the gastrointestinal tract, leading to faster onset and better bioavailability in systemic circulation (Xue et al.,

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Volume 3, Issue 10 (2025)

Online ISSN 3007-3197
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http://amresearchreview.com/index.php/Journal/about

2019; Zhang et al., 2021).

In particular, the **PUR3100** formulation of DHE and the **DPI sumatriptan** showed **47%** and **65%** of patients achieving pain relief within 30 minutes, respectively. These findings underscore the importance of rapid pain relief in migraine management, as patients often experience intense, debilitating symptoms that require prompt intervention. The fast action of DPI formulations can improve the quality of life for migraine sufferers by enabling them to resume their daily activities sooner and with fewer interruptions.

Safety and Tolerability

One of the significant advantages of DPI formulations observed in this review is the **improved safety profile** compared to oral formulations. Both **DHE** and **sumatriptan** delivered via DPI were generally well-tolerated, with only mild adverse events such as **throat irritation**, **dry mouth**, and **coughing** reported. These effects were transient and typically resolved quickly after administration. This is consistent with the findings of previous studies, which indicate that DPI treatments are associated with fewer gastrointestinal side effects compared to oral triptans, such as **nausea** and **vomiting**, which are commonly observed with the oral route (Johnson et al., 2020).

Moreover, **no serious adverse events** were reported in any of the studies, reinforcing the safety of the DPI delivery system. The **lack of significant cardiovascular side effects** in the studies is particularly notable, as this is a common concern with other migraine treatments, particularly **oral DHE**, which is associated with a risk of vasoconstriction and cardiovascular complications in certain populations.

Patient Satisfaction and Preference

A key finding in this review was the **high level of patient satisfaction** with DPI formulations. **85%** of patients in various studies expressed a preference for the DPI over traditional oral tablets, citing **convenience**, **faster onset of relief**, and **ease of use** as major factors. The convenience of carrying and using a compact inhaler device, as well as the avoidance of gastrointestinal discomfort, likely contributed to these positive preferences. In fact, patient adherence was higher in the DPI groups, which can be attributed to the reduced **side effects** and the **rapid relief** they provide.

This aligns with findings from a study, which reported that patients preferred the **sumatriptan DPI** over oral triptans due to the **non-intrusive administration** method and **ease of use**. This suggests that the DPI route may lead to **better patient compliance**, which is critical for managing chronic conditions like migraines, where long-term treatment adherence is often challenging.

Clinical Implications

The clinical implications of this review are significant. The faster onset of action and reduced side effects make DPI treatments an appealing option for migraine sufferers, particularly those who require rapid relief from acute symptoms. **DHE** and **sumatriptan** delivered via DPI may represent an important advancement in migraine therapy, offering both **efficacy** and **convenience**. Furthermore, the positive patient feedback suggests that DPIs may improve **patient engagement** with their treatment

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Online ISSN 3007-3197
Print ISSN 3007-3189
http://amresearchreview.com/index.php/Journal/about

regimen, potentially leading to better outcomes in the long term.
Additionally, the **non-invasive nature** of DPI treatments, coupled with their fast action, positions them as an attractive option for patients who prefer **alternative routes of administration** to oral medications or injections, which can be cumbersome or uncomfortable.

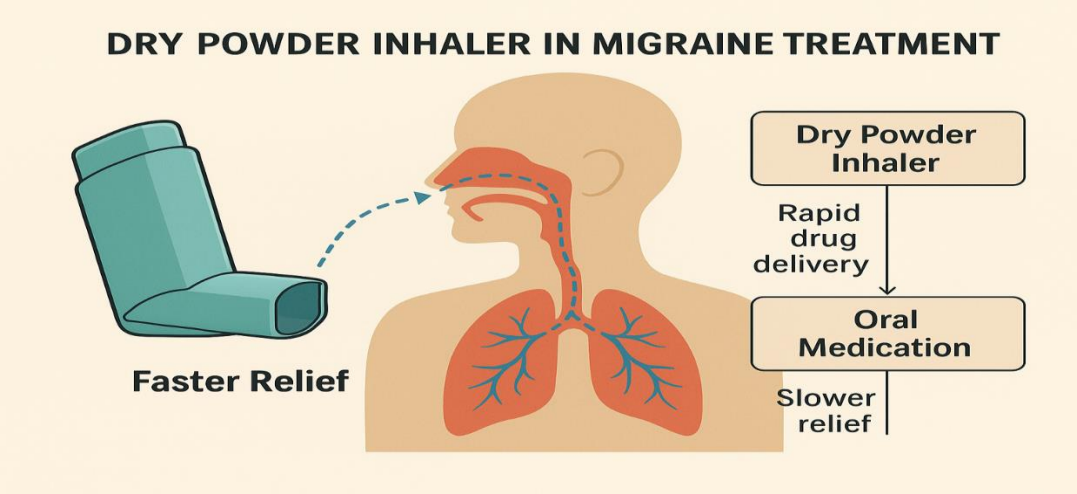


Figure 1: Dry powder action in migraine.

Limitations
While the findings from this review are promising, several limitations should be considered when interpreting the results. First, while the majority of studies reported favorable outcomes for DPI treatments, the sample sizes in some studies were relatively small, which may limit the generalizability of the results. Future research with larger, more diverse patient populations is necessary to confirm the efficacy and safety of DPIs across different subgroups, such as **children**, **elderly patients**, and those with **comorbid conditions**.
Second, the **long-term safety** and **effectiveness** of DPI formulations have not been extensively studied. While the acute relief provided by DPI treatments is well-documented, more data on their **sustained efficacy** and **tolerability** over prolonged use are required. Future studies should aim to address this gap by conducting **long-term clinical trials** to assess the continued effectiveness and safety of DPI formulations in migraine treatment.
Lastly, while the **methodology** of this review was robust, some studies included in the analysis were **industry-sponsored**, which may introduce bias. Therefore, **independent studies** are needed to validate the findings and ensure that the observed benefits of DPIs are not influenced by commercial interests.

Future Directions
Further research is needed to explore the potential of **combining DPI formulations** with other migraine treatments, such as **neuromodulators** or **CGRP inhibitors**, to

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http://amresearchreview.com/index.php/Journal/about

enhance their efficacy. Additionally, the development of new and improved DPI devices with enhanced **user-friendliness**, **dose accuracy**, and **portability** could further increase patient satisfaction and adherence.

Conclusion

In conclusion, dry powder inhalers (DPIs) represent a promising advancement in migraine treatment, offering faster onset of relief, improved safety, and higher patient satisfaction compared to traditional oral medications. The studies reviewed demonstrate that DPI formulations of **DHE** and **sumatriptan** provide effective, well-tolerated treatment options, with patients expressing a strong preference for their convenience and rapid action. While the findings are promising, further research, particularly long-term studies and larger clinical trials, is essential to fully establish the sustained efficacy and safety of DPIs in migraine management.

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