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REVIEW ON "FAST-DISSOLVING DRUG DELIVERY SYSTEMS: A FOCUS ON AZELNIDIPINE FOR HYPERTENSIVE PATIENTS"

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ABSTRACT

The review focuses on the use of Fast-Dissolving Drug Delivery Systems (FDDs) to administer azelnidipine to patients with hypertension. FDDs are designed to dissolve quickly in the mouth, which improves patient compliance, especially for those who have trouble swallowing. The calcium channel blocker azelnidipine is used to treat hypertension; its formulation dissolves quickly, resulting in better patient results. This paper examines the many aspects of FDDs, including formulation methods, advantages over traditional administration methods, and their role in enhancing the stability and bioavailability of azelnidipine. It also discusses the challenges that FDDs present, such as taste masking and maintaining the effectiveness of the medication. All things considered, FDDs offer a viable way to improve azelnidipine-assisted hypertension treatment.

KEYWORDS: Fast-dissolving drug delivery systems, Azelnidipine, Bioavailability, Formulation Methods, Taste Masking, Antihypertensive Therapy.

INTRODUCTION

Elevated arterial blood pressure is a hallmark of hypertension, also known as high blood pressure, a chronic medical illness. It is a significant risk factor for heart attacks, strokes, and kidney disease, among other cardiovascular conditions. Changes in lifestyle and medication are frequently necessary for the effective management of hypertension. When it comes to

antihypertensive medications like azelnidipine, fast-dissolving drug delivery systems (FDDS) have been a game-changer among the many drug delivery technologies that have come before.[1]

An overview of the definition of hypertension

A persistent rise in arterial blood pressure with a systolic blood pressure (SBP) of 140 mmHg and/or a diastolic blood pressure (DBP) of 90 mmHg is referred to as hypertension. It frequently necessitates lifetime care.

Grouping

1. SBP <120 mmHg and DBP <80 mmHg are considered normal.
2. Increased: DBP <80 mmHg and SBP 120–129 mmHg
3. Stage 1 of hypertension: DBP 80-89 mmHg or SBP 130-139 mmHg
4. Stage 2 hypertension: DBP ≥90 mmHg or SBP ≥140 mmHg.[2, 3]

Causes

1. Primary (Essential) hypertension: influenced by lifestyle, environmental, and hereditary variables; no known underlying cause. represents 90–95% of cases.
2. Secondary hypertension: brought on by particular illnesses like

- Conditions affecting the kidneys, such as chronic kidney disease
- Endocrine conditions, such as hyperaldosteronism
- Obstructive sleep apnea for example: Adverse drug reactions (NSAIDs, corticosteroids, etc.).[4]

Signs and symptoms

The "silent killer" moniker is frequently used to hypertension because of its asymptomatic nature. When present, symptoms could include:

1. Headaches
2. Lightheadedness
3. Blurred eyesight
4. Breathing difficulties
5. Nosebleeds (in extreme situations).[5]

Goals of Treatment

Reducing blood pressure to 130/80 mm Hg is the main objective of treatment in order to lower the risk of renal and cardiovascular problems.[6]

Drug Delivery Systems That Dissolve Quickly (FDDS)

Meaning

Innovative dosage forms known as "fast-dissolving drug delivery systems" dissolve or disintegrate quickly in the mouth without the need for water, making drug administration quick and easy.[7]

Qualities

1. Quick breakdown and dissolving in the mouth.
2. Simplicity in administering without water.
3. Fit for patients who have trouble swallowing, such as young children, elderly people, and bedridden patients.
4. In certain situations, pre-gastric absorption results in increased bioavailability.
5. Fast mechanism of action.[8]

Benefits

1. Patient Compliance: Better adherence, particularly for dysphagic patients.
2. Faster Onset of Action: Rapid therapeutic effects are guaranteed by quick medication release.
3. Convenience: Perfect for communities where access to water is scarce.
4. Improved Stability: FDDS has superior shelf stability than liquid formulations.[9]

Difficulties

1. Formulation Restrictions: Ensuring quick disintegration while preserving mechanical strength.
2. Managing the bitterness of active pharmaceutical ingredients (APIs) is known as taste masking.
3. Hygroscopic formulations need to be packaged with protection due to their moisture sensitivity.[10]

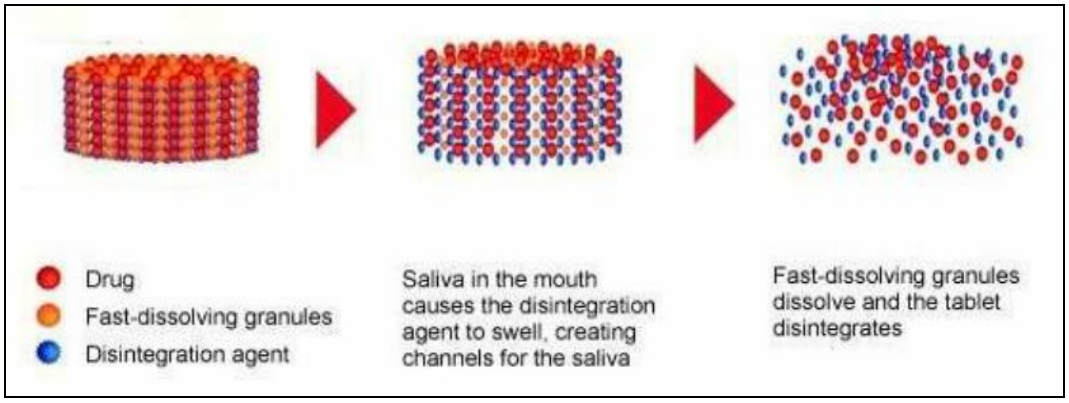

Fig 1: Mechanism of FDDS.[10]

Highlights of Azelnidipine in a Comparative Analysis of Fast-Dissolving Tablets for Hypertension.[11]

Drug Name	Drug Class	Indications	Advantages in FDT form	Challenges
Fosinopril	ACE Inhibitor	Hypertension, Heart Failure	Rapid onset, good bioavailability, enhances patient adherence	Risk of cough, hyperkalemia, renal dysfunction
Valsartan	Angiotensin II Receptor Blocker (ARB)	Hypertension, Heart Failure	No need for water for administration, non-inferior to oral ARBs	Hyperkalemia, renal impairment
Amlodipine	Calcium Channel Blocker (CCB)	Hypertension, Angina	Quick onset, effective for lowering blood pressure in 10-15 minutes	Peripheral edema, headache
Metoprolol	Beta-Adrenergic Blocker	Hypertension, post-MI	Rapidly dissolves for quicker absorption, reduces heart rate	Fatigue, bradycardia, sexual dysfunction
Hydrochlorothiazide	Diuretic	Hypertension, Edema	Fast onset, helps with fluid retention issues	Electrolyte imbalance, hypotension

Benefits of Azelnidipine FDTs Compared to Other Options

1. Extended half-life and continuous release to improve blood pressure regulation.
2. Reflex tachycardia is one of the few adverse effects, which increases tolerability.
3. Patient-centered design for groups that have trouble swallowing.[12, 13]

Azelnidipine as an Antihypertensive Agent

- **Drug profile: Basic Information**

Name of drug: Azelnidipine

Class of Chemical: Derivative of dihydropyridine

Formula for molecules: C33H34N4O6

Weight in molecules: 582.65 g/mol

Physical Characteristics: A crystalline yellow powder

Solubility: Soluble in organic solvents such as ethanol and methanol, but poorly soluble in water.

Antihypertensive medication (Calcium Channel Blocker, CCB) is the therapeutic category.

- **Mechanism of Action:** One dihydropyridine calcium channel blocker that prevents calcium ions from entering vascular smooth muscle cells is azelnidipine. Vasodilation and a decrease in peripheral resistance follow, which lowers blood pressure.

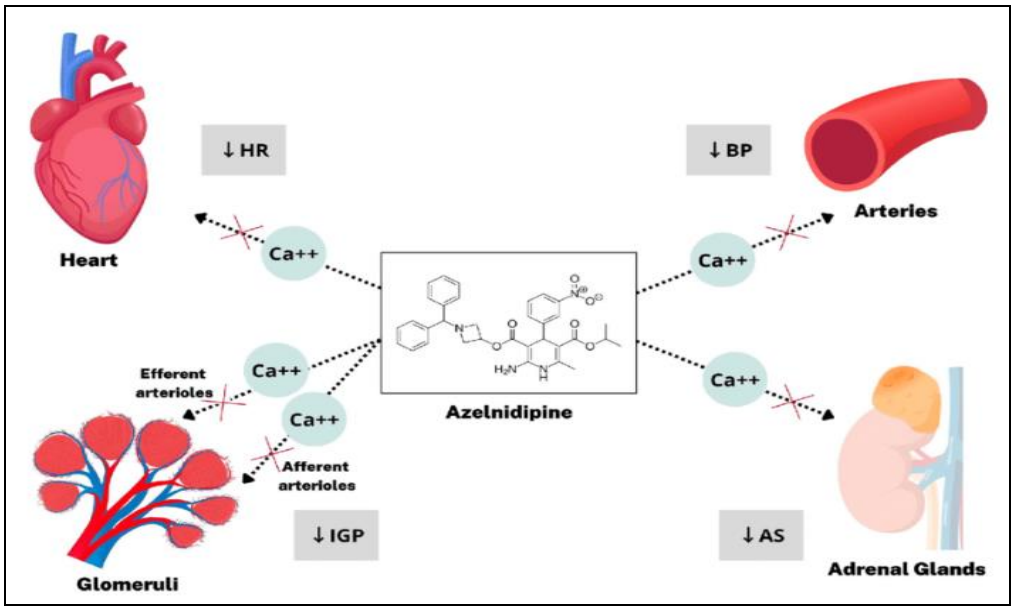

Fig 2: Mechanism of action of Azelnidipine.[14]

- **Pharmacokinetics**

1. Absorption: Azelnidipine exhibits a modest rate of absorption following oral dosing.

2. Half-life: A long half-life (~24 hours) supports a once-daily dosing.

3.Metabolism: It is significantly broken down by the liver using cytochrome P450 enzymes.

4. Excretion: Mainly removed by bile and excrement.

- **Clinical benefits**

1. Prolonged antihypertensive Effect: Maintains blood pressure control throughout the day.
2. Improved Patient Tolerance: One of the rare side effects is reflex tachycardia.
3. Once-Daily Dosage: Facilitates ease of adherence.[15]

- **Drug Interactions with FDDs of Azelnidipine**

Fast Dissolving Dosage Forms (FDDs) of azelnidipine may interact with other medications, reducing their effectiveness or raising the possibility of side effects. The concurrent use of calcium channel blockers, such as nifedipine or amlodipine, for example, can intensify the hypotensive effects, increasing the risk of an excessive drop in blood pressure. Furthermore, the CYP3A4 enzyme pathway is the primary mechanism of azelnidipine metabolism. Inhibitors of this enzyme, like erythromycin or ketoconazole, can slow down this metabolism, increasing drug concentration and possibly increasing toxicity. On the other hand, by speeding up its metabolism, CYP3A4 inducers such as rifampin may lessen its efficacy. Azelnidipine may also raise the risk of severe hypotension when taken with other antihypertensive medications or vasodilators. Consequently, close observation of blood pressure and renal.

Therefore, when azelnidipine is administered with interacting medications, vigilant blood pressure and renal function monitoring is advised.[16]

In nations including China, India, and Japan, azelnidipine, a dihydropyridine calcium channel blocker (CCB), is authorized for the treatment of hypertension. It is sold under a number of brand names, such as Azusa in India and CalBlock in Japan.

Azelnidipine's Clinical Effectiveness in Hypertension

1. **Lowering Blood Pressure:** Azelnidipine successfully reduces both the systolic and diastolic blood pressure in people with essential hypertension, according to clinical research. Azelnidipine was found to significantly lower both systolic blood pressure (SBP) and diastolic blood pressure (DBP) when compared to baseline measures in a comprehensive review and meta-analysis of 11 randomized clinical studies.

2. Heart Rate: Azelnidipine has been associated with a significant drop in heart rate. The same meta-analysis found that azelnidipine had a greater effect on heart rate than amlodipine, lowering heart rate by an average of -3.63 beats per minute (bpm).

3. Comparison with Amlodipine: Amlodipine, another commonly used CCB, has similar antihypertensive effects to azelnidipine in terms of reducing blood pressure. But azelnidipine has a better profile when it comes to decreasing heart rate.

4. Safety Profile: Azelnidipine is generally well tolerated. In a trial comparing the two medications in patients with mild to moderate hypertension, azelnidipine and amlodipine both showed similar safety profiles, with no discernible differences in the frequency of side events.

5. **Additional Benefits:** Azelnidipine may have protective effects on the kidneys because it has been demonstrated to reduce proteinuria in people with hypertension and concurrent chronic kidney disease.[17,18]

Similar to other antihypertensive drugs, azelnidipine may cause common side effects. These may include the following and range in intensity from mild to moderate:

Typical side effects of azelnidipine include

1. Peripheral Edema: Lower limb swelling brought on by fluid retention is one of the cardiovascular effects.
2. Hypotension: An abrupt decrease in blood pressure, especially in the early phases of therapy.
3. An elevated heart rate, or tachycardia.

Effects on the digestive system

1. Nausea and vomiting.
2. Pain or discomfort in the abdomen.
3. Heartburn or gastroesophageal reflux.

Effects on the Central Nervous System:

1. Headache.
2. Lightheadedness or dizziness.

Lethargy or exhaustion.[19]

Additional Impacts

1. Palpitations: Perception of a strong or erratic heartbeat.
2. Flush: Skin that is heated or red.

3. Nasal congestion is the obstruction or constipation of the nasal passages.
4. Metabolic Effects: Retention of fluids leads to weight increase.

Serious Side Effects: Although they are uncommon, serious side effects can happen, such as
1. Hyperkalemia (high blood potassium levels).
2. Liver Dysfunction: High dosages or extended use may have an impact on liver function.
3. Severe Hypotension: When an excessive dosage or improper use occurs.
Regular follow-ups with medical professionals are crucial for people using azelnidipine in order to monitor for these adverse effects and modify treatment as necessary.

Controlling Adverse Effects

1. The majority of side effects are minor and curable.
2. It could be essential to stop taking the medication or change the dosage if severe adverse effects appear.
3. Throughout treatment, routine blood pressure and kidney function monitoring is advise.[20]

Azelnidipine Fast-Dissolving Tablet Development

- **Excipient Selection**

1. Superdisintegrants: Facilitate quick disintegration (e.g., sodium starch glycolate, crospovidone).
2. Binders (such as hydroxypropyl cellulose): o Guarantee tablet cohesiveness.
3. Taste Masking Agents: Improve palatability (aspartame, sucralose, etc.).
4. Fillers (such as lactose and microcrystalline cellulose): o Offer homogeneity and bulk.[21]

- **Methods of Manufacturing**

1. Direct compression is the simplest and most economical technique, and it works well with APIs that have acceptable flow characteristics.
2. Wet Granulation: Improves compressibility and flow for APIs with subpar handling properties.
3. Lyophilization: creates extremely porous tablets that dissolve incredibly quickly.[22,23]

Evaluation

1. Pre-Compression Evaluation: The goal of pre-compression examination is to evaluate the characteristics of the granules and powders used to create tablets. Prior to real tablet compression, these tests aid in determining the materials' appropriateness.

a) Angle of repose

Goal: Evaluate the granules' or powder blend's flowability.

Method: To determine the angle of repose, let a powder fall in the shape of a cone through a funnel onto a level surface. The following formula is used to determine the angle formed: Repose Angle (θ)=tan−1(h\r)

where "r" is the radius in centimeters, "h" is the height in centimeters, and "θ" is the angle of repose. 25° to 30° is the ideal value for optimal flowability.

b) Bulk Density

Goal: Calculate the mass of powder in each bulk volume unit.

Technique: Without tapping, weigh the powder in a specified volume.

The formula is: Bulk Density (ρb) = Powder Mass (W) The powder's bulk volume (V). 0.4 to 0.6 g/cc is the ideal range for optimal flow characteristics.

c) Density Tapped

Goal: To reduce air spaces, measure the powder's density after tapping.

Method: After tapping the powder into a graduated cylinder, weigh it.

The formula is: Tapped Density (ρt) = Powder Mass (W)\Powder Tapped Volume (V).

Aim for 0.5 to 0.8 g/cc.

d) The Compressibility Index, or Carr's Index

Goal: Determine the granules' compressibility in order to forecast the properties of the powder flow.

Carr's Index is calculated as follows: (Tapped Density−Bulk Density\Tapped Density)×100

10–15% is the ideal range for optimal flowability.[24,25]

2. Post-Compression Evaluation: This stage involves evaluating the finished tablets to make sure their functional, chemical, and physical characteristics satisfy the necessary requirements.

a) Thickness

Goal: Determine how consistently thick the tablet is.

Method: Measure the thickness of many tablets using a digital caliper.

±5% of the nominal thickness is the ideal range.

b) Diameter

Goal: Make sure tablets are of the same size.

Method: Use a digital caliper or micrometer to measure the diameter of tablets.

Consistent within ±5% is the ideal range.

c) Hardness

Goal: Evaluate the tablets' mechanical strength.

Method: Use a hardness tester to determine how much force is needed to shatter the tablet.

The optimal range is 3–5 kg/cm².

d) Friability

Goal: Assess the robustness of tablets during handling and transit.

Method: Measure the weight loss by subjecting tablets to mechanical stress using a friability tester.

Less than 1% weight loss is the acceptable limit.

e) Disintegration Time

Goal: Calculate how long it takes for the tablet to break up into smaller pieces in media such as simulated saliva.

Method: Use a buffer solution or water in a disintegration equipment.

≤3 minutes is the ideal limit for FDTs.

f) Rate of Dissolution

Goal: Track how much azelnidipine is released from the pill over time.

Method: Measure the amount of drug released at various time intervals using a dissolution equipment (USP Type II) in a dissolution media. Over 85% medication release in 30 minutes is the ideal limit.

g) Uniformity of Content

Goal: Make sure the active component in every pill is consistent.

Method: Take samples of several pills and use UV spectrophotometry or HPLC to determine the drug concentration.

Acceptance Criteria: 5% of the content that has been tagged.

h) Wetting time

Six milliliters of 6.8 phosphate buffer were placed in a petri dish. A tablet was set on a piece

of tissue paper that had been folded twice and kept in the dish. A tiny bit of amaranth red was applied to the tablet's top surface. The soaking time of the tablet was defined as the amount of time needed for its upper surface to turn red. Three readings were averaged, and the standard deviation was calculated.[26]

Stability Research

Goal: Make sure that throughout time, azelnidipine FDTs retain their characteristics, such as drug content, rate of disintegration, and look.

Method: In accordance with ICH requirements, store samples at various humidity and temperature levels. Then, periodically assess the drug's content, rate of dissolution, and physical stability. [27,28]

Azelnidipine The following are some clinical advantages of FDDS for hypertension

1. Greater bioavailability: It can sometimes evade first-pass metabolism.
2. Rapid Relief: Faster absorption and breakdown speed up the therapeutic action.
3. Convenience: Perfect for those who have trouble swallowing or complying, Reduced Side Effects: There are fewer systemic fluctuations due to controlled medication release.[29,30]

Use in specific populations (hypertensive patients with azelinidipine fdds)

Elderly: More susceptible to dizziness and hypotension. Titrate carefully and start with lesser doses.

Minimal renal excretion, however in extreme cases (CrCl <30 mL/min), watch for drug buildup.

Use with caution and modify dosages according to liver function if you have hepatic impairment.

Use Category C during pregnancy only if the advantages outweigh the hazards.

Breastfeeding: Expelled in breast milk; use carefully, considering the dangers and advantages.

Pediatrics: Because of the paucity of clinical data, it is not advised.[31,32]

CONCLUSION

Fast-Dissolving Drug Delivery Systems (FDDs) have been a major breakthrough in pharmaceutical technology, providing better therapeutic results and patient compliance for a range of drugs, including azelnidipine, which is used to treat hypertension. These systems are

made to dissolve quickly in the mouth, improving drug absorption and delivering a quicker commencement of action. This is particularly advantageous for hypertensive patients who need steady blood pressure control and prompt symptom relief.

The problems with traditional oral dose forms, like delayed onset of action and difficulties swallowing, are addressed by the addition of azelnidipine to FDDs. FDDs' quick disintegration properties make them more convenient for patients, especially those who are elderly or have swallowing difficulties. Furthermore, FDDs have the potential to increase bioavailability, which could result in improved medication efficacy and fewer doses.

Despite these advantages, a number of problems still need to be fixed. These include ensuring consistent medication release throughout the product's shelf life, maintaining drug stability during manufacture, and concealing flavor to ensure patient acceptability. Additionally, studies are still being conducted to enhance the formulation of FDDs in order to strike a compromise between therapeutic efficacy and safety and the fast dissolution properties.

To sum up, azelnidipine's introduction into fast-dissolving drug delivery systems offers a lot of potential to better the treatment of hypertension. By overcoming the limitations of traditional dose forms, FDDs offer a patient-centered approach with enhanced therapeutic benefits. However, further advancements in formulation science and technology are needed to effectively exploit FDDs in clinical practice.

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