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AI IN PULMONARY DRUG DELIVERY SYSTEM

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ABSTRACT

Pulmonary drug delivery looks like a solid option for getting meds into the body. It works because of how the lungs are built, with that huge surface area for soaking stuff up, a super thin layer to cross, and all those blood vessels ready to go. Folks have stuck with the usual gear for breathing treatments, you know, like those pressurized metered-dose inhalers, the dry powder versions, and nebulizers that turn liquid into mist. Still, there are hang-ups that won't quit. Things like dosing it just right, figuring out the perfect particle size, making sure the drug doesn't fall apart, and hitting the exact spots it needs to. Tech keeps pushing forward though. Artificial intelligence steps up with fresh ways to tackle those problems. Smart inhalers come into play, along with wearables and these AI biosensors that watch everything. They sharpen up the treatment accuracy, keep tabs on whether patients follow through, and spit out instant tips on breathing technique during use. AI goes further too. It personalizes the whole deal by fine-tuning the drug mixes, forecasting where particles will settle in the lungs, and speeding along the hunt for new medicines. Pretty much, it opens doors that were stuck before. But integrating AI isn't smooth sailing. Costs run high for setting it all up, privacy issues pop up with all that patient data, algorithms can carry biases that skew results, and regulations throw up roadblocks everywhere. Looking down the line, AI in pulmonary delivery could shake up respiratory care big time. It promises safer paths, quicker results, therapies that actually hit harder, and real improvements for folks dealing with chronic lung issues or sudden flare-ups.

KEYWORDS: MDI, Artificial Intelligence, Pulmonary drug delivery system.

INTRODUCTION

The pulmonary route is becoming popular because to its unique qualities, including a wide absorptive surface of up to 100m2, a thin 0.1 µm - 0.2 µm mucosal barrier, and enough blood supply. Devices that administer drugs via the pulmonary route are based on one of three platforms: pressured metered dosage inhalers, nebulizers, and dry powder. The pulmonary route has many advantages over other routes of administration for the treatment of specific disease states, particularly lung-associated large protein molecules that degrade in the gastrointestinal system and are eliminated by first-pass metabolism in the liver, but can be delivered via the pulmonary route if deposited in the respiratory zone of the lung.[1]

The pulmonary route has been utilized to treat a variety of respiratory disorders for ages. Ancient inhalation remedies included the use of plant leaves, fragrant plant vapors, balsams, and myrrh. Adrenaline was developed as a nebulizer solution in the 1920s, nebulizer porcine insulin was used in diabetic experimental investigations in 1925, and pulmonary administration of the newly discovered penicillin was examined in 1945. Steroids were introduced in the mid-1950s to treat asthma, and nebulizers were widely used. The pressurized metered dosage inhaler (pMDI) was launched in 1956, and during the last five decades, because to breakthroughs in molecular design and drug discovery, the pMDI has risen to become the primary method of asthma therapy.

Over the last decade, certain medications have been offered in formulations suited for creating drug dispersion for pulmonary delivery to treat a variety of human illnesses. Such pulmonary drug delivery compositions are intended to be administered to the patient via inhalation of drug dispersion, allowing the active drug within the dispersion to reach the lung. Certain medications administered via the pulmonary route have been discovered to be easily absorbed through the alveolar region and into the bloodstream. The pulmonary route has several benefits over other routes of administration for treating certain disease states, notably lung-associated big protein molecules that breakdown in gastrointestinal conditions and are cleared by the first pass. If the liver's metabolism is deposited in the lungs' respiratory zone, it can be given via the pulmonary pathway. This advanced pulmonary technology provides a unique and innovative delivery alternative for therapies that must currently be administered by injection or oral delivery, which causes adverse effects or is poorly absorbed.[2]

New dispersible formulations and drug aerosol delivery methods for inhalable peptides, proteins, and other small molecules have grown in popularity during the last decade for the treatment of systemic and respiratory disorders. These include, but go well beyond, the standard and long-available (but still neglected) treatments for asthma and chronic obstructive lung disease. Advances in using the lungs as gateways for delivering medication to the bloodstream have substantially extended the possible uses of pulmonary delivery. This innovative technique was first used for the systemic administration of big molecules including insulin, interferon-b, and a1 proteinase inhibitor.[3]

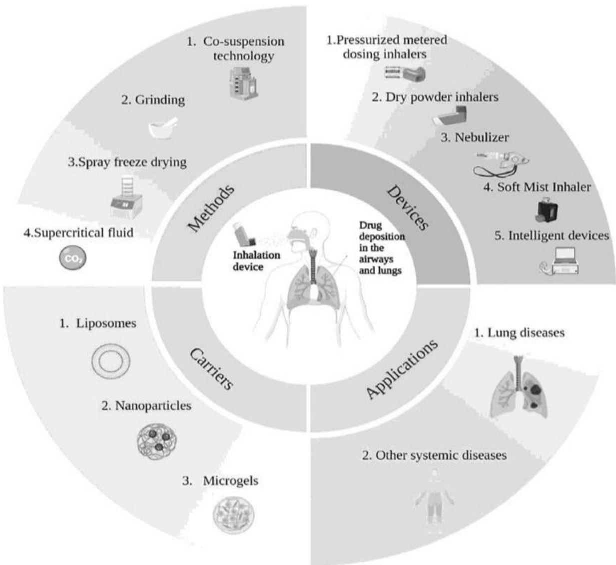

Fig. 1 Pulmonary Drug Delivery.

ADVANTAGES OF PULMONARY DRUG DELIVERY SYSTEM

1. It is needle-free pulmonary delivery.

- Drugs are delivered directly through the lungs, avoiding the need for injections.
- This increases patient comfort and compliance, especially for those afraid of needles.

2. It having a very negligible side effect since the rest of the body not exposed to a drug.

- Since the drug mainly stays localized in the lungs, the rest of the body is less exposed.
- This reduces unwanted side effects compared to oral or injectable drugs.

3. The onset of action is very quick.

- The lungs have a large surface area and a rich blood supply.
- Drugs quickly enter circulation, producing effects within minutes.

4. Degradation of a drug by the liver is avoided.

- Drugs taken orally are broken down by the liver before reaching the bloodstream (first-pass effect).

- Pulmonary delivery bypasses this, preserving drug potency.

5. It requires low and fraction of oral dose.
- Only a fraction of the oral dose is needed since absorption through the lungs is efficient.
- This reduces cost and minimizes drug waste.

6. Avoid the first pass metabolism.
- Drugs are absorbed directly into systemic circulation through the lungs.
- This ensures more predictable and effective blood concentrations.

7. The dose needed to produce a pharmacological effect can be reduced.
- Because delivery is targeted and efficient, smaller doses can achieve the desired effect.

8. Safer for long-term diseases (e.g., asthma, diabetes)
- In asthma and diabetes requires long-term treatment if it is given by pulmonary drug delivery safety is maximum because the rest of the body not exposed to the drug.

9. Avoidance of gastrointestinal upset.
- Drugs that may upset the stomach when taken orally can be safely delivered via the lungs.

10. Bioavailability of smaller drug molecule is very good.
- Small drug molecules are absorbed rapidly and efficiently through the lung membranes.

11. Improved delivery of larger molecules
- Bioavailability of larger drug molecule can be improved by means of the absorption enhancer.

12. Convenient for long-term therapy, compared to parenteral medication.
- Compared to injections, pulmonary delivery is non-invasive and easier for patients to use regularly.
- This improves adherence to treatment plans.[4]

DISADVANTAGES OF PULMONARY DRUG DELIVERY SYSTEM:

1. Improper dosing.
2. Stability of drug in vivo.
3. Some drug may produce irritation and toxicity.
4. Difficulty in producing optimum particle size.
5. Some drugs may be retained in lungs and clearance of the drug may be difficult.
6. Targeting specificity.
7. Difficult to transport.
8. Difficult to use
9. Drug absorption may be limited by the physical barrier of the mucus layer. [5]

IMPORTANCE

This delivery device improves therapy for respiratory disorders by delivering medication directly to the site of action. This offers considerable advantages.

1)Targeted therapy: Inhaling high medication concentrations directly into the lungs minimizes exposure to other organs and dramatically reduces systemic adverse effects. This is especially important when addressing chronic and life-threatening illnesses such as:

• Asthma and Chronic Obstructive Pulmonary Disease (COPD).

•Cystic Fibrosis.

•Pulmonary hypertension.

Reduced dosage: Because the afflicted region is targeted directly, a lower amount is required to produce the desired therapeutic effect than oral medicine, which is disseminated throughout the body.

Fast action: Inhaled medicines have a quick beginning of action, which is critical for treating acute respiratory symptoms like bronchoconstriction during an asthma attack[6]

CONVENTIONAL METHOD

Metered dose inhalers, dry powder inhalers, and nebulisers are the three main devices available for pulmonary medication delivery.

Metered-Dose Inhalers Under Pressure (pMDI)

Moreover, metered dosage inhalers are not ecologically friendly since they emit chlorofluorocarbons (CFCs), which accumulate in the stratosphere of the Earth's atmosphere and destroy the ozone layer. The pMDI was the first widely used multi-dose portable inhalation device. Nearly all patients with COPD and asthma use or have taken a pMDI, often albuterol and/or ipratropium. In a pMDI, each type of inhaled drug for obstructive lung diseases is available as a single or combination product. However, the pMDI is one of the most difficult devices for patients to operate correctly. One of the most significant changes to the pMDI throughout time was the switch from CFC to hydrofluoroalkane (HFA) as the propellant.

Metered-dose inhalers are under pressure from technological improvements. New pMDIs fall into two categories: breath-actuated and coordination devices. The Easy breath and other breath-actuated pMDIs were designed to address the issue of poor coordination between the patient's breath and the inhaler's actuation. When the mechanical device senses the patient's respiration and responds by emitting the dosage, it is activated. The patient has enough time to successfully activate the pMDI during inhalation, and the actuator controls the inhalation flow rate.[7]

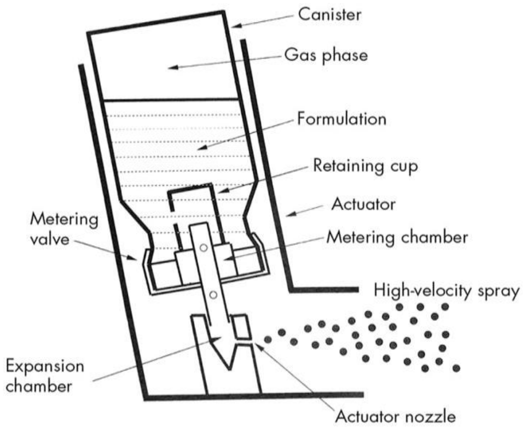

Fig. 2: Pressurized Metered-Dose Inhaler.

Dry Powder Inhaler

It's a flexible system that demands a certain level of skill. The word itself denotes that the formulation is in solid form. It is a bolus medication delivery device that contains the solid medicine in a dry powder mix that becomes fluid when the patient inhales. It includes only the active medicine or combines it with a carrier powder to improve the flow characteristics of the drug. Dry powder inhalers are more stable, easier to use, and less expensive than metered dosage inhalers. There is no need for hazardous propellants such as CFC. They can be constructed for a single or multiple dosage application.

DPIs are breath-actuated and do not require propellants to generate aerosols. The patient inhales the device, which disperses the powder composition and delivers it to their lungs. Patients can make critical errors when using a DPI, such as incorrectly loading a dose or inhaling into the device, causing the dose to be lost. Some patients may not understand the importance of securely sealing their lips around the mouthpiece, leading to an ineffective "open mouth" inhaling technique. The Turbuhaler DPI and other DPIs use metered dosages from bulk powders. When loading a dose for inhalation, keep the reservoir upright (vertical) to allow gravity to fill the dosing chamber. A DPI produces fewer inhaler technique errors than a normal pMDI. Many DPIs must be stored dry to prevent moisture from degrading the drug composition.[8]

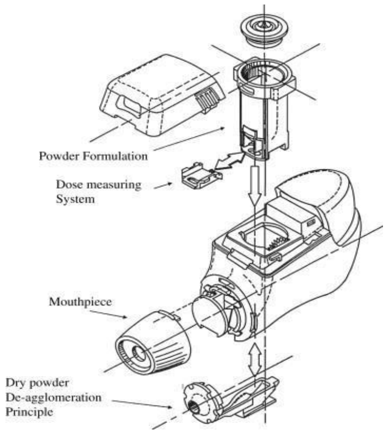

Fig. 3: Dry Powder Inhaler.

Nebulizer

The nebulizer is commonly employed as an aerosolizing medication solution or suspension for drug delivery to the respiratory system, notably in the treatment of hospitalized patients. It is widely used to treat cystic fibrosis, asthma, and other respiratory illnesses. A nebulizer is prepared by,

- The pharmaceutical solution technology- parenteral products
- Formulated in water
- Co-solvents
- pH above 5

There are two types of the nebulizer, namely jet and ultrasonic,

Jet Nebulizer

In a jet nebulizer, the liquid is converted and sprayed into fine droplets by use of compressed gas, for the prevention of exits of a large droplet from the device the baffles are used in a jet nebulizer.

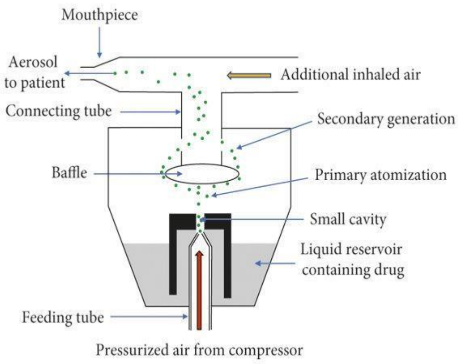

Fig. 4: Jet Nebulizer.

Disadvantage

- Time consumption
- Drug wastage

Ultrasonic Nebulizer

Aerosol droplets are created by high-frequency vibrations of a piezoelectric crystal, resulting in the formation of ultrasound waves. Ultrasonic nebulizers have played an essential role in pulmonary drug administration. Because the process of producing aerosol droplets is independent and does not require breath actuation, ultrasonic nebulizers have the potential to instantly fine-tune the dose administered to the specific needs of a patient, taking into account the patient's breathing pattern, physiological profile, and disease state. Nonetheless, due to the challenges and restrictions involved with traditional designs and technology.[9]

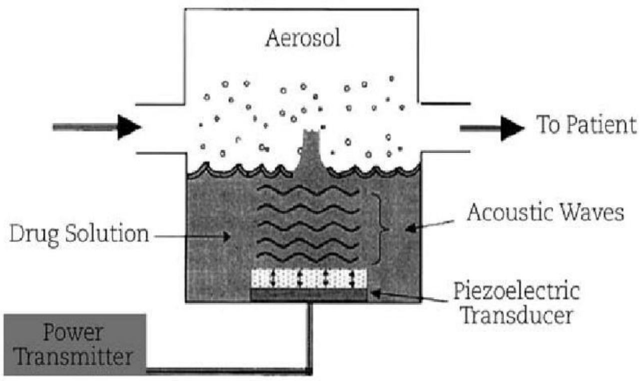

Fig 5: Ultrasonic nebulizer.

Soft Mist Inhaler

The invention of soft mist inhalers (SMIs) has created new potential for inhaled medication administration. SMIs employ liquid formulations similar to those found in nebulizers, but they are often multi-dose devices that might compete with pMDIs and DPIs in the portable inhaler market. While other SMIs are under development, the only one currently on the market is the Respimat Soft Mist Inhaler (Boehringer Ingelheim GmbH & Co. KG, Ingelheim, Germany). This device includes enough doses of a bronchodilator formulation to last one month, which are kept in a fluid reservoir.

Individual dosages are administered by a finely built nozzle system as a slow-moving aerosol cloud (thus the phrase "soft mist"). The spray velocity from the Respimat Soft Mist Inhaler is approximately one-tenth that of a CFC-based pMDI. However, scintigraphical investigations have revealed that lung deposition is many times more than that of a CFC-based pMDI, and clinical trials have proven that medications supplied by the Respimat Soft Mist Inhaler are efficacious in COPD patients in proportionately lower dosages. Respimat Soft Mist Inhaler is a "push and breathe" device, and the proper inhaling method is similar to that employed with a pMDIWhile coordination between firing and inhaling is essential, the moderate spray velocity and lengthy duration of the aerosol cloud (usually 1-1.5 seconds) should allow patients to do so more readily than with a pMDI. Respimat Soft Mist.[9]

MECHANISM OF DRUG DEPOSITION

The deposition of inhaled particles in various parts of the respiratory system is extremely complex and depends on numerous factors. Several factors influence respiratory deposition, including.

- Breathing rate
- Mouth or nose breathing
- Lung volume
- Respiratory volume
- Individual health
- Bifurcations in the airways cause a constantly changing hydrodynamic flow field.

Depending on particle size, airflow, and location in the respiratory system, particle deposition happens by one of the following main mechanisms.

Impaction

When the airflow changes due to a bifurcation in the airways, suspended particles tend to follow their original path due to inertia and may collide with an airway surface. This mechanism is heavily reliant on aerodynamic diameter, as the stopping distance for very small particles is quite short. Impaction is particularly common with larger particles that are extremely close to the airway walls, around the first airway bifurcation. As a result, impaction deposition occurs most frequently in the bronchial area. Impaction is responsible for the vast bulk of particle deposition on a mass basis.

Sedimentation

Sedimentation is the separation of particles in the smaller airways of the bronchioles and alveoli, when the airflow is low and the airway dimensions are small. The rate of sedimentation is proportional to the particle's terminal settling velocity hence sedimentation is more important in the deposition of particles with larger aerodynamic diameters. As hygroscopic particles flow through warm, humid air passageways, their size might increase, increasing the likelihood of sedimentation deposition.

Interception

Interception happens when a particle's physical size or shape causes it to come into touch with an airway surface. Unlike impaction, particles deposited via interception do not stray from their air streamlines. Interception is especially common in tiny airways or when the airstream is close to an airway wall. Interception is more important for fibers, which can easily contact airway surfaces due to their length. Furthermore, fibers have tiny aerodynamic widths relative to their size, allowing them to reach even the smallest airways.

Diffusion

Diffusion is the primary method of deposition for particles less than 0.5 microns in diameter, and it is determined by geometric rather than aerodynamic size. Diffusion is the net movement of particles from a high-concentration region to a low-concentration region via Brownian motion. Brownian motion is the random wiggling motion of a particle caused by the continuous bombardment of air molecules. Diffusional deposition occurs mostly when particles reach the nasopharynx, and it is also more likely to occur in the narrower airways of the pulmonary (alveolar) area, where airflow is low.[10]

CHALLENGES OF PULMONARY DRUG DELIVERY SYSTEM

1) Low Efficiency of Inhalation System

The primary problem in pulmonary medication administration is the poor efficiency of currently available inhalation devices. Ideal aerosol particle size is critical for deep lung distribution (pulmonary medication delivery). Because if the particles are too tiny, the optimal particle size for deep lung deposition is 1-5 mm, they will be readily expelled; if the particle size is too large, they harm the oropharynx and larynx.

2) Less Drug Mass per Puff

Many medications require milligram dosages to provide sufficient effects through the pulmonary drug delivery system, but most present methods transmit too little drug each puff to the lower respiratory tract (less than 1000mcg).

3) Poor Formulations Stability for Drugs

Most classic small-molecule asthma medicines are crystalline and relatively moisture resistant in dry form. In contrast, corticosteroids are unstable in liquid form, amorphous, and very moisture sensitive in the dry state.

4) Improper Dosing Reproducibility

Poor dosage repeatability is caused mostly by illness progression, device issues, and formulation instability.

Patient education is critical for achieving optimal dosage repeatability.[11]

INNOVATIVE APPLICATION/OPPORTUNITIES OF AI IN THE PULMONARY DRUG DELIVERY SYSTEM

Smart Inhaler

The term "smart inhaler" lacks a widely accepted definition. We define them as electronic monitoring devices that use inhalers to track drug. Use the equipment with or without assessing its technique. This practical classification excludes nebulizers and software systems that rely solely on a separate electronic device, such as image recognition on smartphones or tablets. Over the past decade, the majority of smart inhalers have been regular inhalers with an added electronic component. For almost 30 years, electronic monitoring of inhaler adherence has been available. The Nebulizer Chronolog was the first device widely used in academic settings. In recent years, electronics have gotten compact, dependable, and affordable, allowing for widespread deployment. Wireless technologies and mobile computers have made it possible to quickly send information from an inhaler to a personal device, analyze it remotely, and provide it to the user in a meaningful and visually appealing fashion.[12]

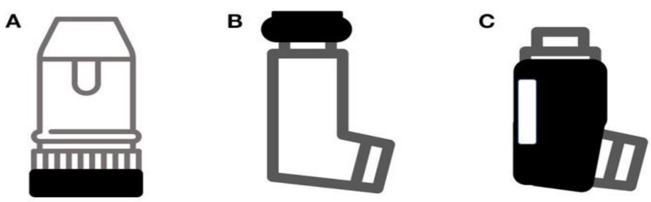

Fig. 6: Smart Inhaler.

Common types of add-on devices to create smart inhalers. (A) Detection of device priming; (B) Detection of patient actuating device; (C) Jacket to detect airflow. Not shown are devices such as Inhaler Compliance

Assessment (INCA) that detect actuation and technique purely acoustically

Current technological capabilities include tracking inhaler use, reminding patients of their next dose, analyzing technique through inhalation flow rate, and providing feedback on technique and time. These gadgets can securely communicate data to healthcare professionals, providing a "real world" view on patients' medication adherence and competency. This can improve adherence by making users aware that their activities are being recorded and allowing healthcare practitioners to tailor consultations to individual patients, promoting consistent use and recognizing and rewarding concordance. Additionally, each clinician or team's patient concordance is tracked.[13]

Wearable Devices and Biosensors

Wearable biomedical sensors are devices that can assess physiological and environmental data while allowing the patient to move freely and go about their everyday activities. These gadgets can monitor the following.

• Monitor physiological parameters, including respiratory rate, heart rate, SpO_2, lung sounds, movements, and electrocardiogram

• Environmental parameters include air temperature, humidity, allergy and pollutant concentrations, and ozone levels.[14]

Wearable sensors can monitor patients' physical activity, which impacts health outcomes like disease morbidity, hospitalization, and mortality. lists examples of technology. Recent advancements in the field of AI and wearable technology have enabled Real-time monitoring of patients' health can detect stress, COVID-19-related respiratory difficulties, and other medical disorders. Previous studies have successfully used AI algorithms to analyze biosignals from wearable sensors and accurately identify stress levels. The study found that using machine learning approaches allowed for the successful identification of stress based on biosignals, with a high level of accuracy. These findings promote the development of noninvasive wearable technologies to detect and manage stress at an early stage. In a similar manner have developed a wearable stethoscope that utilizes an AI system to provide instantaneous monitoring of lung sounds and automated Identification of wheezing.[15] The lung sound monitoring patch employed in this study can detect normal and abnormal breathing patterns. The AI-based counter has achieved over 80% accuracy in identifying abnormal breathing episodes, including wheezing, in clinical settings. Wearable technology has been studied for monitoring respiratory rates and SpO_2 levels in COVID-19.

patients. A thorough review found that wearable technologies are effective for continuous monitoring.[16]

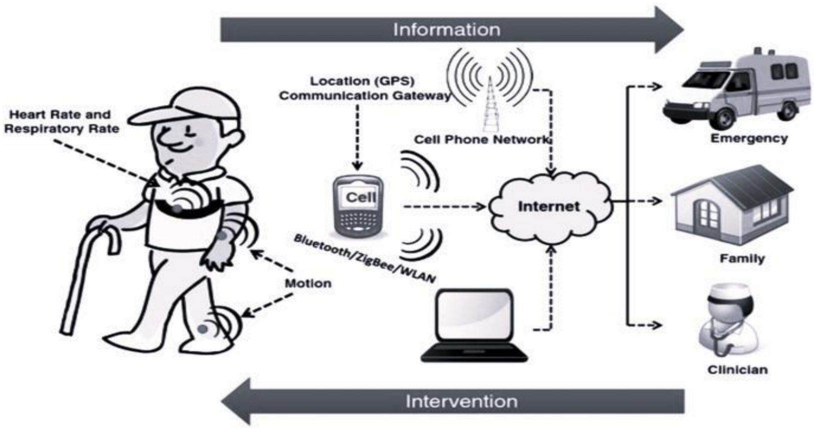

Fig. 7: AI Devices.

ADVANTAGES OF AI IN PULMONARY DRUG DELIVERY SYSTEM

For personalized therapy, AI pulls in patient data like lung function or illness severity and even genetics. It tweaks the dosage, particle size, and inhaler type to make everything work better for that person. Targeting gets improved too with AI models. They simulate how air flows and where particles land in the lungs. So medications hit the sick areas more directly. Side effects drop because AI predicts drug interactions and adjusts doses. It keeps systemic absorption low, you know. Not as many problems overall. Then there's smart inhalers with AI built in. They track if patients are sticking to the routine, how they inhale, and their technique. All that helps outcomes improve. Drug discovery speeds up a lot. Machine learning sifts through huge chemical databases to spot new candidates for lung delivery. Pretty straightforward. Predictive analytics is another thing. AI forecasts how the disease might progress and how meds will respond. Clinicians can switch treatments sooner if needed. Costs and time save big here. Less guessing in research means optimized clinical trials. Development happens faster without wasting as much.[17]

DISADVANTAGES OF AI IN PULMONARY DRUG DELIVERY SYSTEM

High implementation costs: Creating AI models, smart inhalers, and complex simulations needs a large investment.

Data privacy risks - AI-enabled systems that collect patient health data may pose security and confidentiality concerns.AI requires big, high-quality clinical datasets for accuracy, which are not usually available in pulmonary research.

Technical difficulties - Integrating AI techniques into drug development and medical device design necessitates significant skills and infrastructure.[18]

Risk of algorithm bias - If training data is incomplete or biased, AI predictions may not be as effective for all patient categories.

Regulatory constraints - Strict medical restrictions make obtaining permission for AI-assisted pulmonary medication delivery techniques difficult.

Overreliance on technology - Using AI may impair healthcare practitioners' clinical intuition and judgment.

Maintenance and updates - To remain effective, AI systems must be continuously monitored, upgraded, and validated.[19]

FUTURE SCOPE OF AI IN THE PULMONARY DRUG DELIVERY

Artificial intelligence has the potential to drastically change the way that drugs are delivered to the lungs in the future. AI has the potential to completely transform the development and delivery of respiratory medicines by facilitating individualised treatment programs catered to the requirements of each patient. AI can improve medication compositions and delivery systems to increase effectiveness and decrease negative effects through sophisticated data analysis. By anticipating aerosol behaviour and patient usage habits, it can also enhance the design of inhalation devices, guaranteeing more accurate drug deposition in the lungs. Additionally, real-time feedback on inhaling technique and adherence might be provided via AI-powered inhalers with sensors, which would improve treatment results. Beyond delivery, AI can speed up medication discovery and development, analyse patient responses, and combine with telemedicine to provide remote monitoring and management of respiratory disorders, resulting in more effective and accessible pulmonary care.

CONCLUSION

Artificial intelligence's incorporation into pulmonary drug delivery systems, in our opinion, is a significant step toward revolutionizing healthcare as well as a technical breakthrough. AI improves patient compliance, improves formulation precision, and aids in overcoming obstacles like drug targeting and dosage accuracy. Learning about this area excites us since it relates what we studying to practical innovation, demonstrating how technology can improve the efficacy and accessibility of treatments. AI increases the potential of pulmonary drug delivery, which already has benefits like quick drug action and needle-free administration. In addition to helping patients, we believe this advancement will motivate aspiring pharmacists like us to help develop more intelligent, patient entered treatments.

CONFLICT OF INTREST: Authors have no any conflict of interest**.**

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