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Review Article

Oral Disintegrating Tablets for Insomnia: A Comprehensive Review

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ABSTRACT

Despite the fact that humans sleep for roughly one-third of their lives, most people don't know much about it. All higher living forms, including humans, require sleep, albeit its exact role is still unknown. Without it, there are major physiological repercussions. The features of REM and NREM sleep and gives a general review of sleep physiology. Circadian-generating mechanisms and sleep. Developed in the early 1980s, the quick dissolving drug delivery systems set a new standard and competed with previous oral drug delivery systems that used diverse dosage forms, such as tablets, suspensions, syrups, and capsules. Since the medicine dissolves in saliva without the need for water and disintegrates quickly, the Fast-Dissolving medicine Delivery System (FDTS) offers a significant advantage over traditional dose forms. These oral dosage forms provide useful functions like self-medication, improved patient compliance, convenience of manufacturing, and pain relief, despite the drawback of having a delayed beginning of action. With a wide range of medications serving numerous functions, Fast Disintegrating Tablets (FDTS) technology has thus been increasing prominence in recent years. Since Fast Disintegrating Tablets (FDTS) dissolve in saliva in less than a minute, their demand has grown over the past ten years, improving compliance in elderly and pediatric patients who have trouble swallowing liquids or tablets.

INTRODUCTION

Insomnia Disorder is characterized by Dissatisfaction with the length or quality of sleep, along with trouble falling or staying asleep, significant distress, or deficits during the day, are the characteristics of insomnia disorder. Although it is frequently left untreated, insomnia is the most common sleep condition in the general population and one of the most common concerns brought up by patients during primary care appointments.15% to 20 % of adults report having occasional symptoms of insomnia, while 10% of adults fit the criteria for insomnia disorder.[1] While a hypnotic induces drowsiness and encourages sleep, an a sedative reduces excitation and soothes the patient who is awake. Depending on the dosage,

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nonbenzodiazepine sedatives typically reduce central nervous system (CNS) activity in a range of ways, starting with calming and progressing to sleep, unconsciousness, coma, surgical aesthesia, and, finally, to fatal cardiovascular and respiratory depression. This range of effects is shared by sedatives and numerous other substances, such as ethyl alcohol, other aliphatic alcohols, and general anaesthetic drugs.[2]

NREM Sleep in Four Stages:

Different brain physiology and activity are linked to each of the four NREM sleep stages.

NREM 1:

In sleep-stage cycling, NREM stage 1 sleep acts as a transitional period. The average person's sleep session starts in NREM stage 1, with the exception of infants, those with narcolepsy, and people with other particular neurological conditions. This stage, which typically lasts 1 to 7 minutes in the first cycle and accounts for 2 to 5% of total sleep, is easily disrupted by a loud disturbance. In stage 1, the EEG shows a shift in brain activity from rhythmic alpha waves, which indicate wakefulness, to low-voltage, mixed-frequency waves. Alpha waves have a frequency of 8 to 13 cycles per second and are linked to a state of wakeful relaxation.[3]

NREM 2:

This stage begins after the NREM1 stage is finished. The brain wave slows down and the eye movement is completely closed. ß wave saw sleepers gradually become more resilient when they woke up. 45 to 55 percent of the human body's entire sleep occurs during this phase. The frequency range of sleep axles is 12–14 Hz. EMG decreases and conscious awareness of the outside world are indicators of muscular movements.[4]

NREM 3:

Delta waves start to show up in the EEG during stage III, but the EOG stays the same. As the sleep progresses from stage II to stages III and IV, the EMG may also stay the same or slightly decrease. Delta waves are quantitatively increasing.[5]

NREM 4:

REM is not seen as a tranquil sleep state and is linked to dreaming. Except for the eyes and diaphragmatic muscles, which are still working, the skeletal muscles are atonic and immobile although the EEG is comparable to that of an awake person. The breathing rate is more unpredictable and irregular, though. With each REM cycle growing during the night, this stage typically begins 90 minutes after the sleep state. Usually, the initial cycle lasts ten minutes, while the last cycle can go up to an hour. Penile/clitoral tumescence, nightmares, and dreaming all happen during REM. [6]

TYPES OF INSOMNIA:

Lifelong insomnia:

- It is with a supposed organic component is known as idiopathic insomnia.
- Poor sleep hygiene insomnia is a type of insomnia that is thought to be largely caused by lifestyle problems.
- In the absence of middle or late insomnia (also known as sleep-onset insomnia), initial insomnia is characterized by difficulty falling asleep.
- NOS, or insomnia not otherwise specified, is a type of insomnia that is thought to be caused by unidentified reasons.

Late insomnia:

Having trouble waking up in the morning when there is no final or middle insomnia (also known as terminal insomnia or sleep offset insomnia).

Middle insomnia:

It is also known as sleep maintenance insomnia, is the inability to maintain sleep in the absence of final or late insomnia.

Paradoxical insomnia:

It is a type of insomnia in which the patient's feeling of sleep disturbance and the polysomnography-measured severity of insomnia differ significantly.

Physiological insomnia:

It is a type of insomnia that is thought to be largely caused by organic reasons.

Psychophysiologic insomnia is a type of insomnia that is thought to be caused by both physiological and psychological (behavioural and cognitive) components.

The phrase "sleep continuity" is used in two interconnected ways.

One is to refer to the degree to which sleep is effective in terms of waking after sleep onset (WASO) and/or sleep efficiency as measured by sleep latency (SL).

The alternative application particularly relates to the class of variables (as opposed to sleep architecture) that quantify sleep "performance," such as SLand/or WASO, total sleep time (TST), number of awakenings (NWAK) measurements, and sleep efficiency as a percentage measure of the ratio of TST to total time in bed (SE%).[7]

ORAL DISINTEGRATING TABLETS:

Throughout all age groups, dysphagia, or difficulty swallowing, is common.[8] About 35% of the general population, 30–40% of elderly institutionalized patients, and 18–22% of all individuals in long-term care facilities suffer with dysphagia. The size, shape, flavour, and appearance of pills are the most frequently reported issues about difficulty swallowing, in order of frequency of complaints. Dosage forms that are easy to swallow are especially important for elderly and young patients as well as travellers who might not always have access to water.[9] According to another survey, this issue affects an estimated 50% of the population. According to these findings, a novel dose form that can increase patient compliance is essential.[10] Solid dosage forms that can be dissolved or suspended with water in the mouth for easy swallowing are highly desirable for the paediatric and geriatric population, as well as other patients who prefer the convenience of readily administered dosage forms.[11]

FORMULATION AND MANUFACTURING OF ODTs:

The quick entry of water into the tablet matrix, which causes rapid disintegration, is responsible for the FDTs' speedy dissolving ability.

Therefore, the fundamental methods for creating FDTs are as follows: Optimizing the tablet matrix's porous structure. Adding the proper dissolving agent or agents. Including excipients in the formulation that are extremely soluble in water[12]

NON-PATENTED TECHNOLOGIES:

1. Direct Compression Method:

The simplest method for making tablets is direct compression. The preferred method for producing

tablets containing medications that are moisture-sensitive and thermolabile is direct compression. Direct compression's reduced manufacturing costs are a huge benefit. It makes use of standard tools, widely accessible excipients, and a small number of phases in the process. The dissolution and solubilization of directly compressed tablets are necessary for the single or combined action of disintegrants, water-soluble excipients, and effervescent agents. Inadequate physical resistance protection leads to tablet cracking during blister alveolus opening and tablet edges breaking during handling.[13]

2. Tablet Moulding:

This approach produces tablets that are solid dispersions. Compared to compressed tablets, moulded tablets are less compact and have a porous structure that makes dissolve and quick disintegration easier. The water-soluble carbohydrates in the dispersion matrix give moulded tablets a better taste. There are two sorts of moulding techniques.[14]

A. Solvent Method:

This method creates a wet mass by compressing the powder mixture at low pressure in moulded plates after dampening it with an alcoholic solvent. Tablets made using this method of air drying are less dense than compressed tablets and have a porous structure that speeds up disintegration.[15]

B. The process of heat:

It Involves making a suspension with a medication, agar, and sugar, putting it into blister packing wells, allowing the agar to solidify at room temperature to create a jelly, then

vacuum-drying it at 30ºC. Binding agents are combined to provide strength since the mechanical strength of moulded tablets needs to be known. By spray congealing a molten

mixture of hydrogenated cottonseed oil, sodium carbonate, lecithin, polyethylene glycol, and an active component into a lactose-based tablet triturate form, the taste-masked drug particles were created.[16]

3. Spray Drying:

The spray drying technique is used to create thin, porous powders that dissolve quickly. Hydrolysed and non-hydrolysed gelatins serve as supporting agents, mannitol acts as a bulking agent, sodium starch glycolate or croscarmellose sodium acts as a disintegrating agent, and an acidic (like citric acid) or alkaline (like sodium bicarbonate) substance enhances dissolution and disintegration. This formulation method yields porous powder with a disintegration time of less than 20 seconds [17].

4. Sublimation:

The presence of a porous structure in the tablet matrix is essential for the quick disintegration of mouth-dispersing tablets. Due to the low porosity of the matrix, conventional compressed tablets containing highly water-soluble components frequently dissolve quickly. Benzoic acid, menthol, camphor, ammonium bicarbonate, ammonium carbonate, naphthalene, urea, urethane, or phthalic anhydride are examples of highly volatile substances that could be crushed into a tablet together with additional excipients. According to reports, tablets made using this method typically dissolve in 10–20 seconds and have adequate mechanical strength.[18]

5. Freeze drying or lyophilization:

Freeze drying is a method where water is sublimated from the substance after it has frozen. Compared to other solid products on the market, freeze-dried forms offer a faster rate of disintegration. The tablets' high porosity causes them to dissolve rapidly when they come into contact with saliva via the lyophilization process. The carrier, a polymer15, disperses the active medication in an aqueous solution. In order to freeze the medication solution or dispersion, the trays containing the sample are first frozen in blister packs by passing through a liquid nitrogen freezing tunnel. The material is first chilled in order to lower its eutectic point. The goal of this initial drying is to reduce the moisture content to roughly 4% of the dry product. by performing secondary drying again, which lowers the bound moisture to the medicinal product's necessary volume. However, the high expense of processing and equipment limits the usage of freeze-drying. The freeze-drying method has shown increased bioavailability and better absorption. The final dosage form's lack of physical resistance in conventional blister packs is one of its main drawbacks.[19]

6. Melt Granulation:

A meltable binder effectively agglomerates medicinal powders using the melt granulation technique. It is a helpful method for increasing the pace at which medications that are not very soluble in water, such griseofulvin, dissolve. The primary advantage of the melt granulation process is that it eliminates the requirement for drying. One advantage over a traditional granulation is that it doesn't require organic solvents or water. Compared to wet granulation, the method takes less time and energy because there is no drying step.[20]

7. Mass extrusion:

The mass extrusion technique uses a solvent mixture of methanol and water-soluble polyethylene glycol to soften the drug blend. The softened mass is then removed using an extruder or Syringe to obtain cylinder of the product into even segments using heated blade to form tablet. The dried cylinder can also be used to coat granules for bitter drugs and thereby achieving taste masking.[21]

8. Cotton candy process:

This method uses a shear foam process to transform polysaccharides or carbohydrates into an amorphous floss, which forms the matrix. Using a special spinning mechanism, this method creates crystalline structures that resemble floss and like cotton candy. Consequently, this is known as In the cotton candy method, flash melting and spinning are done simultaneously to create a matrix of polysaccharides or saccharides.[22]

PATENTED TECHNOLOGIES:

1. Lyoc Technology:

Pharmalyco has a patent on Lyoc technology. Although Lyoc uses a freeze-drying method, it is not like Zydis in that the product is frozen on the shelves of the freeze dryer. To enhance the viscosity of the in-process suspension and avoid homogeneity through sedimentation during this process, these formulations additionally call for a significant amount of undissolved inert filler, like mannitol. The large filler content lowers the dry dosage form's potential porosity, producing denser tablets with disintegration rates similar to those of the fast-melt, loosely compressed formulations.[23]

2. Wow Tab Technology:

Yamanouchi Pharmaceutical Company is the patent holder of the Wow tab technology. Wow

tab's WOW designates that the tablet should be administered "With Out Water." To create quickly dissolving tablets using standard granulation and tableting methods, it consists of a blend of low-moldability saccharides such as lactose, mannitol, glucose, sucrose, and xylitol and high-moldability saccharides such as maltose, sorbitol, and oligosaccharides. [24,25,26]

3. Flash Dose Technology:

Fuisz Technologies Ltd. is the patent holder of the flash dosage technique. It creates a crystalline structure that resembles floss using a special spinning motor, much like cotton candy. The self-binding shear form matrix known as "floss" makes up the Flash dosage tablets. The medication can then be incorporated into this crystalline sugar and crushed into a tablet. The created final product has a very large surface area that can dissolve it. Once on the tongue, it dissolves and spreads rapidly.[27]

4. DuraSolv R Technology:

Ciba created DuraSolv R technology to produce stronger tablets that could be packaged in bottles or blisters. Because DuraSolv is so resilient, it can be sold in vials or conventional blister packaging. Filler and lubricant are the main components of this formulation. About 2% of the tablets are friable. Less than 60 seconds have passed since the disintegration. This process can create tablets utilizing standard packaging equipment, traditional tableting techniques, and the direct compression approach. As a result, the cost of production is greatly decreased.[28]

5. Quicksolv Technology:

Quick Solv technology is patented by Beese, Belgium's Janssen Pharmaceuticals. This technique claimed to have homogeneous porosity, sufficient handling strength, and the ability to minimize or lessen the incidence of cracking during final preparation.

This approach involves dissolving the matrix components in a solvent, often water, and then freezing the resulting solution [29,30]. The first solvent will stay solid, and the frozen solution will then come into contact with the second solvent, which is typically acetone, ethanol, or menthol. In order to produce a useable matrix, the first solvent is thus eliminated after a few hours of coming into contact with the second solvent. The finished product breaks down practically immediately.[31]

6. Advatab/Ziplets:

Italy's Passano with Barnago is the patent holder of this invention. This method creates ODT with enhanced mechanical strength and the ideal disintegration time at low compression force by combining water-insoluble ingredients with one or more efficient disintegrants.[32]

7. Nanocrystals Technology:

Elan, King of Prussia, is the patent holder of this. Using this method, water-soluble components are mixed with crystal colloidal dispersions of the medicinal compounds, which are then filled into blisters and lyophilized. This method circumvents production procedures including blending, tableting, and granulation, which is better for extremely dangerous and potent products.[33]

8. OraSolv Technology:

OraSolv was Cima's first fast-dissolving/disintegrating dosage form. This includes the use of effervescent disintegrating agents which is compressed with low pressure to produce the fast-dissolving tablets. Tablets are made by direct compression technique at low compression force in order to minimize oral dissolution time. The evolution of carbon dioxide

from the tablet produces a fizzing sensation, which is a positive organoleptic property. The limitation associated is that the tablets produced are soft and friable.[34]

9. Pharmaburst Technique:

SPI Pharma is the patent holder of the Pharmaburst technology. Tablets made using this technique are strong enough to be packaged in bottles and blister packs.

A dry mixture comprising a medication, tastes, and lubricant is used to create the tablet, which is then compressed into tablets that dissolve in 30 to 40 seconds.[35]

10. Zydis Technology:

The Zydis technology is patented by Scherer. The medication is made in this way by lyophilizing it in a gelatin matrix or freeze drying it. The resulting product comes in blister packets and weighs relatively little. Patients should be instructed to peel back the foil layer to release the tablet rather than pushing it through. This method uses specific polymers and resins to microencapsulate the medication and hide its harsh taste. This method is highly costly. Use the Zydis formulation within six months of opening. Compared to other traditional tablets, this technology promises higher bioavailability. This technology's primary benefit is its ease; its drawback is that the production process of freeze drying is highly costly.[36]

11. Rapid-dis technology:

This technology is exclusive to Lavipharm Laboratories and is patented. The film dissolves quickly and is thin and flexible. The film is positioned on the tongue's floor or top. It quickly releases the active ingredient for local and/or systemic absorption while remaining at the application location.

12. Flash Tab Technology:

The Flash tab technology is patented by Prographarm Laboratories. With the use of this technology, tablets with an active component in the form of microcrystals are prepared that dissolve quickly. All of the procedures used traditional tableting technologies, such as coacervation, extrusion-spheronization, basic pan coating techniques, and microencapsulation, to create drug microgranules. It takes little than a minute for these tablets to dissolve.[37]

13. Frosta technology:

Akina is the patent holder of this technology. Strong tablets with a high porosity are created by preparing and compressing plastic granules under low pressure. After combining the porous plastic material with a water penetration enhancer, the mixture is granulated using a binder. Depending on tablet size, the resulting tablets have a quick disintegration period of 15 to 30 seconds and exceptional hardness.[38]

EVALUATION OF FAST DISSOLVING TABLETS:

1. Weight Variation Tests:

To check for weight variance, 20 tablets were chosen at random from the lot and weighed separately.A variance of ±10% is permitted for tablets containing less than or equal to 80 mg, while a departure of ±7.5% is permitted for tablets containing 80–250 mg. A variation of ±5% is permitted for tablets containing more than 250 mg.[39]

2. Hardness Tests:

A tablet hardness tester is used to determine tensile strength, which is the amount of force needed to shatter a tablet when compressed radially. The

hardness of the tablets34 is measured by driving the hardness tester's plunger down at a rate of 20 mm/min.[40]

3. Friability Tests:

Using a tablet friability device, the friability test is conducted at 25 rpm for 4 minutes (100 rotations), with a limit of no more than 1%. The main difficulty for a formulator is to obtain friability within this range for FDT products while maintaining the lowest level of hardness to achieve the shortest disintegration time. This test is always advised for tablets made using direct compression and molding techniques11,15 but is not appropriate for lyophilized or flash-dose tablets.[41,42]

4. Moisture Absorption:

Because mouth dissolving tablets have a high concentration of hydrophilic excipients with the least amount of hardness, they are more susceptible to absorbing moisture. As a result, more care must be taken when storing and packaging these dosage forms. To conduct the test, ten pills and calcium chloride can be kept in a desiccator set at 37°C for twenty-four hours to guarantee that the tablets are completely dried. After that, the tablets are weighed and left at room temperature for two weeks with a 75% relative humidity. Keep a saturated sodium chloride solution in the desiccator for 24 hours to reach the desired humidity. After reweighing the tablets, the weight gain as a percentage is noted.[43]

5. Tablet Porosity:

The tablet porosity, a relative measure of the amount of water penetration in the formulation that causes its rapid disintegration, can be measured with a mercury penetration porosimeter.[44,45]

6. Water Absorption Ratio and Wetting Time:

A piece of double-folded tissue paper is used in this investigation, and it is put in a petri dish with six milliliters of water. A single tablet was put on this paper, and the amount of time it took for the tablet to completely wet was recorded as the "wetting time." After weighing the wet pill, the water absorption ratio R,was calculated using an equation. where Wb and Wa are the tablet's weights prior to and following water absorption, respectively. where R is the ratio of water absorption.[46]

7. In vivo Disintegration Time:

Orally disintegrating tablets disintegrate in less than a minute; in fact, the disintegration process takes only five to thirty seconds.[47,48]

8. Dissolution Tests:

The development of dissolve techniques for conventional and oral tablets is comparable. Scouting runs for bioequivalent oral dissolving tablets can begin with the dissolution conditions for medications described in a pharmacopoeia monograph. Similar to regular tablets, other media like 0.1N HCl and buffers (pH 4.5 and 6.8) should be assessed for oral dissolving tablets.

For this investigation, USP dissolving apparatuses 1 and 2 can be utilized. Although the USP 1 Basket device may have some uses, occasionally tablet fragments or masses of broken tablets may get stuck on the inside top of the basket at the spindle, where there is little to no efficient stirring, producing irreproducible dissolution profiles. The most popular and appropriate option for ODTs is the USP 2 Paddle equipment, which typically has a paddle speed of 50 rpm. Slower paddle speeds may be used to generate a profile because, under USP standard circumstances, tablet dissolving is

typically quite rapid. Taste-masked drug dissolution testing can also be done with the USP 2 Paddle equipment at 50 to 100 rpm.[49,50]

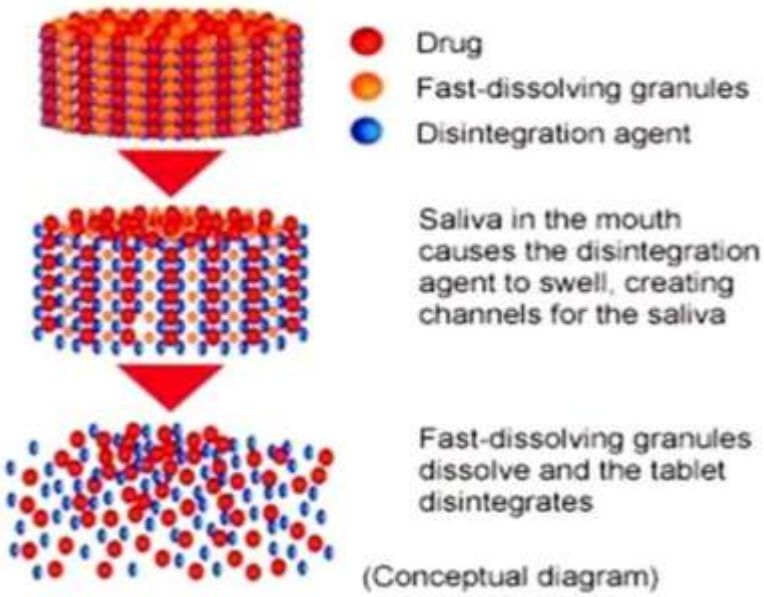

Figure:1 Conceptual Diagram of Rapid - Disintegrating Tablets

Table:1 Commercially Available Rapid – Disintegrating Tablets:

BRAND NAME	ACTIVE INGREDIENT	COMPANY
Benadryl Fastmelt®	Diphenhydramine Citrate	Pfizer
Childrens Dimetapp®ND	Loratidine	Wyeth Consumer Healthcare
Claritin® RediTabs®	Loratadine	Scherig Corporation
Domray MD	Domperidone	Ray remedies
Dolib MD	Rofecoxib	Panacea
Excedrin® QuickTabs	Acetaminophen	Bristol-Myers Squibb
Felden FM	Piroxicam	Pfizer
Gadster D	Famotidine	Yamanouchi
Imodium Instant Melts	Loperamide HCL	Janssen
Klonopin® Wafer	Clonazepam	Roche
Kozicold	Nimeselide	Kaizen Drugs
Lonazep MD	Olanzapine	Sun Pharma
Maxalt-MLT	Rizatriptan Benzoate	Merck
Mosid MT	Mosapride	Torrent Pharma
Nasea OD	Ramosetoron HCL	Yamanouchi
Nimulid MD	Nimesulide	Panacea
Olanex Instab	Olanzapine	Ranbaxy Labs Ltd
Ondem MD	Ondensetron	Alkem Pharma
Pepcid RPD	Famotidine	Merck Pharma
Propulsid® Quicksolv®	Cisapride Monohydrate	Janssen
Remeron® Soltab®	Mirtazapine	Organon Inc.
Resperdal® MTabTM	Resperidone	Janssen
Rofixx MD	Rofecoxib	Cipla Ltd.
Romilast	Montelukast	Ranbaxy
Tempra Quicksolv	Acetaminophen	Bristol-Mters Squibb
Torrox MT	Rofecoxib	Torrent
Triaminic® Softchews®	Various Combination	Novartis Consumer Health
Valus	Valdecoxib	Galen Mark
Vomidon MD	Domperidone	Olcare Lab
Zelapar TM	Selegiline	Elanl Amarin Corporation
Zofer MD	Ondansetron	Sun Pharma

Zofer-25 MD	Rofecoxib	Zota Pharma
Zontacet MD	Cetrizine	Zosta Pharma India
Zubrin TM (Pet Drug)	Canine Tepoxelion	Scherig Corporation
Zyperxa®	Olanzapine	Elli Lilly

CONCLUSIONS:

Since many elderly patients report that it is difficult for them to take some commonly used dose forms, including tablets, capsules, or powders, due to a decline in their capacity to swallow as they age, fast-dissolving tablets are the best substitute for these dosage forms.

Some of these technologies provide formulations of fast-dissolving tablets that dissolve or disintegrate quickly in the mouth and have enough mechanical strength. An expansion of the market monopoly, which can be offered via oral, fast-dissolving tablets, films, or disintegrating dosage forms, increases the pharmaceutical company's revenue and enables it to target patient communities that are underserved and undertreated. Their incomparable features such as administration without water, wherever, anytime contribute to their applicability to geriatric and pediatric patients.

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